As filed with the U.S. Securities and Exchange Commission on June 1, 2023

Registration No. 333-269483

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 4 to
FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

60 DEGREES PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**45-2406880**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

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Approximate date of commencement of proposed sale to the public: **As soon as practicable after the effective date of this Registration Statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

EXPLANATORY NOTE

This registration statement contains two prospectuses, as set forth below.

- *Public Offering Prospectus*. A prospectus to be used for the initial public offering (the "Public Offering Prospectus") of up to 1,415,095[(1)] units ("Units"), each Unit consisting of one share of common stock of 60 Degrees Pharmaceuticals, Inc. (the "Company"), one tradeable warrant to purchase one share of common stock of the Company, and one non-tradeable warrant to purchase one share of common stock of the Company, with such Units to be sold in a firm commitment underwritten offering through the underwriters named on the cover page of the Public Offering Prospectus. The Public Offering Prospectus also relates to the issuance of warrants, including the shares issuable upon the exercise of the warrants, by the Company to the representative of the initial public offering as underwriting compensation.

- *Resale Prospectus*. A prospectus to be used for the resale by the selling stockholders (the "Selling Stockholders" set forth in the section of the resale prospectus (the "Resale Prospectus") entitled "Selling Stockholders" of an aggregate of 2,224,763 shares of common stock, consisting of (i) 10,482 shares of common stock to be issued upon conversion of a convertible note immediately prior to the consummation of the initial public offering, (ii) 373,426 shares of common stock to be issued in conjunction with the conversion or extinguishment of interim financing notes on the date of effectiveness of this registration statement, (iii) 1,608,938 shares of common stock and (iv) 231,917 shares of common stock issuable upon the exercise of warrants that are to be issued on the date of effectiveness of this registration statement.

The Resale Prospectus is substantively identical to the Public Offering Prospectus, except for the following principal points:

- they contain different outside and inside front covers and back covers;

- they contain different "*Offering*" sections in the "*Prospectus Summary*" section beginning on page Alt-1;

- they contain different "*Use of Proceeds*" sections on page Alt-16;

- the "*Capitalization*" and "*Dilution*" sections from the Public Offering Prospectus are deleted from the Resale Prospectus;

- a "*Selling Stockholders*" section is included in the Resale Prospectus;

- the "*Underwriting*" section from the Public Offering Prospectus is deleted from the Resale Prospectus and a "*Selling Stockholder Plan of Distribution*" is inserted in its place in the Resale Prospectus; and

- the "*Legal Matters*" section in the Resale Prospectus on page Alt-19 deletes the reference to counsel for the underwriters.

The Company has included in this registration statement a set of alternate pages after the back cover page of the Public Offering Prospectus (the "Alternate Pages") to reflect the foregoing differences in the Resale Prospectus as compared to the Public Offering Prospectus. The Public Offering Prospectus will exclude the Alternate Pages and will be used for the initial public offering by the Company. The Resale Prospectus will be substantively identical to the Public Offering Prospectus except for the addition or substitution of the Alternate Pages, and such other changes as may be necessary to clarify references to the initial public offering or the resale offering and will be used for the resale offering by the Selling Stockholders.

(1) Assumes the underwriters' 45-day option to purchase up to 15% additional Units to cover over-allotments if any, has not been exercised.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 1, 2023

PRELIMINARY PROSPECTUS

1,415,095 Units
Each Unit Consisting of
One Share of Common Stock,
One Warrant to Purchase One share of Common Stock, and
One Non-tradeable Warrant to Purchase One Share of Common Stock
and the 2,830,190 Shares of Common Stock underlying such Warrants

60 Degrees Pharmaceuticals, Inc.

This is a firm commitment initial public offering of 1,415,095 units (each, a "Unit," collectively, the "Units") of 60 Degrees Pharmaceuticals, Inc. (the "Company," "we," "us" or "our"). The initial public offering price of our Units is $ per Unit. Each Unit consists of one share of our common stock, one tradeable warrant (each, a "Tradeable Warrant," collectively, the "Tradeable Warrants") to purchase one share of common stock at an exercise price of $ per share, and one non-tradeable warrant (each, a "Non-tradeable Warrant," collectively, the "Non-tradeable Warrants"; together with the Tradeable Warrants, each, a "Warrant," collectively, the "Warrants") to purchase one share of our common stock at an exercise price of $. The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of common stock and the Warrants underlying the Units are immediately separable and will be issued separately in this offering. Each Warrant offered as part of this offering is immediately exercisable on the date of issuance and will expire five years from the date of issuance.

The Warrants will be issued in book-entry form pursuant to a warrant agent agreement (the "Warrant Agent Agreement") between us and Equity Stock Transfer, LLC, who will be acting as the warrant agent (the "Warrant Agent").

We currently estimate that the offering price will be between $4.30 and $6.30 per Unit and the exercise price per Tradeable Warrant will be between $4.945 and $7.245 (115% of the offering price per Unit) and between $5.16 and $7.56 (120% of the offering price per Unit) per Non-tradeable Warrant.

Prior to this offering, there has been no public market for our common stock or Tradeable Warrants. We have applied to have our common stock and Tradeable Warrants listed on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively. This offering is contingent upon final approval of our listing application with The Nasdaq Stock Market LLC ("Nasdaq"). There can be no assurance that we will be successful in listing our common stock and Tradeable Warrants on The Nasdaq Capital Market. We have not and do not intend to apply for listing of the Non-tradeable warrants on any exchange or market.

We intend to use the proceeds from this offering for general corporate purposes, including working capital. See "*Use of Proceeds*."

In addition, the selling stockholders (the "Selling Stockholders") are offering an aggregate of 2,224,763 shares of common stock to be sold pursuant to a separate resale prospectus (the "Resale Prospectus"), consisting of (i) 10,482 shares of common stock to be issued upon conversion of a convertible note immediately prior to the consummation of the initial public offering, (ii) 373,426 shares of common stock to be issued in conjunction with the conversion or extinguishment of interim financing notes on the date of the effectiveness of the registration statement of which this prospectus forms a part, (iii) 1,608,938 shares of common stock held by certain of the Selling Stockholders and (iv) 231,917 shares of common stock issuable upon the exercise of warrants that are to be issued on the date of effectiveness of the registration statement of which the Resale Prospectus forms a part. We will not receive any proceeds from the sale or other disposition of shares by the Selling Stockholders. The Selling Stockholders will bear all commissions and discounts, if any, attributable to the sale or other disposition of the shares. We will bear all costs, expenses and fees in connection with the registration of the Selling Stockholders' shares. The Selling Stockholders may not offer or sell shares prior to the closing of the initial public offering.

Investing in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 20 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission ("SEC") nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We are an "emerging growth company" and a "smaller reporting company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and have elected to comply with certain reduced public company reporting requirements. See "*Summary—Implications of Being an Emerging Growth Company and Smaller Reporting Company*."

	Per Unit	Total

Initial public offering price	$	$
Underwriting discounts and commissions[1][2]	$	$
Proceeds, before expenses, to us	$	$

(1) Represents underwriting discount and commissions equal to $ per Unit.

(2) Does not include a non-accountable expense allowance equal to 1.5% of the gross proceeds of this offering, payable to WallachBeth Capital LLC, as representative of the underwriters (the "Representative"), or the reimbursement of certain expenses of the underwriters. See "*Underwriting*" beginning on page 120 of this prospectus for additional information regarding underwriting compensation.

In addition to the underwriting discounts listed above and the non-accountable expense allowance described in the footnote, we have agreed to issue upon the closing of this offering to the Representative, warrants that will expire on the fifth anniversary of the effective date of the registration statement of which this prospectus is a part, entitling the Representative to purchase 6% of the number of shares of common stock sold in this offering (excluding shares of common stock sold to cover over-allotments, if any) (the "Representative Warrants"). The registration statement of which this prospectus is a part also covers the Representative Warrants and the shares of common stock issuable upon the exercise thereof. For additional information regarding our arrangement with the underwriters, please see "*Underwriting*" beginning on page 120.

We have also granted the Representative an option to purchase from us, at the public offering price, up to 212,265 additional shares of common stock and/or 212,265 Tradeable Warrants and/or 212,265 Non-tradeable Warrants, less the underwriting discounts and commissions, within 45 days from the date of this prospectus to cover over-allotments, if any. If the Representative exercises the option in full, the total underwriting discounts and commissions payable will be $, and the total proceeds to us, before expenses, will be $.

The underwriters expect to deliver the securities against payment on or about _____, 2023.

Sole Book-Running Manager

WallachBeth Capital LLC

Prospectus dated _____, 2023

TABLE OF CONTENTS

Through and including _____, 2023 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriter and with respect to their unsold allotments or subscriptions.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment. Neither we, nor the underwriters, have authorized any other person to provide you with information that is different from, or adds to, that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. Neither we nor the underwriters take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. You should assume that the information contained in this prospectus or any free writing prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not making an offer of any securities in any jurisdiction in which such offer is unlawful.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our securities or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this public offering and the distribution of this prospectus applicable to that jurisdiction.

ABOUT THIS PROSPECTUS

Throughout this prospectus, unless otherwise designated or the context suggests otherwise,

- all references to the "Company," "60P," the "registrant," "we," "our," or "us" in this prospectus mean 60 Degrees Pharmaceuticals, Inc., a Delaware corporation, and 60P Australia Pty Ltd, an Australian proprietary company limited by shares, our subsidiary;
- assumes an initial public offering price of our Units of $5.30 per Unit, the midpoint of the estimated range of $4.30 and $6.30;
- "year" or "fiscal year" means the year ending December 31; and
- all dollar or $ references, when used in this prospectus, refer to United States dollars.

Except as otherwise indicated, all information in this prospectus assumes that:

- no shares of common stock have been issued pursuant to (i) the conversion of certain of our outstanding debt and (ii) certain consultant agreements;
- no shares of common stock have been issued pursuant to any warrants;
- no shares of common stock have been issued pursuant to the Representative's over-allotment option; and
- no shares of common stock have been issued pursuant to the Representative Warrants.

TRADEMARKS

Solely for convenience, our trademarks and tradenames referred to in this prospectus, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames. All other trademarks, service marks and trade names included or incorporated by reference into this prospectus or the accompanying prospectus are the property of their respective owners.

GLOSSARY OF SELECTED TERMS

The following are definitions of certain terms that are commonly used in the medical industry and in this prospectus:

"8-aminoquinoline" refers to the structural class of antimalarials to which Tafenoquine and Primaquine belong. 8-aminoquinolines are characterized by the presence of an 8-amino substitution on their core quinoline ring, which confers their unique properties including an oxidative Mode of Action and activity against the relapsing liver forms of *Plasmodium vivax*.

"API" means active pharmaceutical ingredient, the active molecule contained in a pharmaceutical product.

"Arakoda" means ARAKODA®, the 60P-owned and FDA-approved product to prevent malaria in travelers, which contains as its active pharmaceutical ingredient, Tafenoquine succinate.

"Broad Spectrum of Activity" refers to a molecule or drug that is active against a range of different pathogens.

"CAR-T" means chimeric antigen receptor therapy.

"CLIA" means The Clinical Laboratory Improvements Amendment of 1988.

"Dengue" means a mosquito-borne viral disease occurring in tropical and subtropical areas.

"Ethics Committee" a stand-alone or institutional committee responsible for ensuring clinical trials are conducted ethically, and from whom permission is required for a clinical trial to proceed.

"EUA" means Emergency Use Authorization.

"FDA" refers to the U.S. Food and Drug Administration.

"G6PD" means glucose-6-phosphate dehydrogenase.

"GMP" means Good Manufacturing Practices.

"IND" means investigational new drug application.

"Kodatef" is the brand name of Arakoda outside the United States. Kodatef has been approved for use in Australia by the Therapeutic Goods Administration.

"Legacy Studies" is a reference to the collection of clinical and non-clinical studies involving Tafenoquine, which were conducted by the U.S. Army prior to 2014, and which were included in the new drug application submitted by 60P to the FDA in 2018. Some of those Legacy Studies are described in the account of the Army development program published by Zottig et. al.

"Mode of Action" is the process by which an anti-infective or other pharmaceutical product is known or suspected to affect a disease process. This process is different for each drug and may or may not be known at the time of FDA approval.

"Named-patient" use of a drug refers to the prescription by a physician of a drug to one of their patients in a jurisdiction in which the prescribed drug has not received marketing authorization, but is believed by said physician to be safe and medically necessary. Also, sometimes referred to as "compassionate use."

"NIH" means the National Institutes of Health.

"PDUFA" means The Prescription Drug User Fee Act.

"PMA" means Premarket Approval by the FDA.

"Primaquine" is the FDA-approved antimalarial from which Tafenoquine is chemically derived.

"*P. vivax*" is an abbreviation for Plasmodium vivax, one of the two most important malaria parasites, characterized by its ability to relapse utilizing a dormant life cycle stage that persists in the human liver following a bite from an infected mosquito.

"RSV" means respiratory syncytial virus, which is a common respiratory virus that usually causes cold-like symptoms.

"Repositioned Molecule" is one which was approved by the FDA or other regulatory authorities to treat one disease, and is being developed for a new disease.

"Tafenoquine" is the shortened name of the active ingredient of Arakoda and Kodatef, tafenoquine succinate.

"TGA" is the Therapeutic Goods Administration, the Australian equivalent of the FDA.

"TMPRSS2" means transmembrane protease, serine 2, which is an enzyme that in humans is encoded by the TMPRSS2 gene, and belongs to the TMPRSS family of proteins, whose members are transmembrane proteins which have a serine protease activity.

In connection with presentation of scientific data, this prospectus references "*P*-values" at various points. These values are provided to convey the likelihood of a particular set of data occurring by chance. For example, a *P*-value of 0.12 associated with a stand-alone, pre-conceived hypothesis is generally understood to mean that the likelihood of that particular outcome occurring purely by chance is 12%. It is scientific convention that a particular observation is "proven" if its associated *P* value is lower than 0.05 (i.e., associated with a likelihood of occurring by chance of < 5%). However, clinical observations of interest are routinely reported in the peer-reviewed scientific literature even if their associated *P*-values are > 0.05, because they may represent important therapeutic signals, and motivate additional research. With the exception of the data reported in Figure B, the efficacy data described herein related to our COVID-19 program and Arakoda have been published in a peer-reviewed scientific journal.[1] *P*-values presented herein are not corrected for multiple comparison error, and represent the outcomes of both pre-conceived, and post-hoc, analyses.

USE OF PRODUCT VERSUS GENERIC NAMES

This prospectus makes reference to two commercial products owned/manufactured by 60P, Arakoda and Kodatef, which are approved by regulators in the United States and Australia, respectively, for the prevention of malaria. The active molecule in those products is tafenoquine succinate (Tafenoquine for short), which we are repositioning for other indications using either (i) the same dosing regimen employed in the commercial Arakoda product (in which case reference is made to the "Arakoda regimen of tafenoquine" or (ii) different dosing regimens (in which case reference is made to "Tafenoquine"). We also utilize the molecular name (Tafenoquine), where the active ingredient of Arakoda and Kodatef was tested in cell culture or animal models. These different usages have been employed both for convenience and to avoid any assertions that Arakoda or Kodatef have been granted marketing authorization by regulators for uses other than the prevention of malaria.

MARKET DATA

Market data and certain industry data and forecasts used throughout this prospectus were obtained from internal company surveys, market research, consultant surveys, publicly available information, reports of governmental agencies and industry publications and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. To our knowledge, certain third-party industry data that includes projections for future periods does not take into account the effects of the worldwide coronavirus (COVID-19) pandemic. Accordingly, those third-party projections may be overstated and should not be given undue weight. Forecasts are particularly likely to be inaccurate, especially over long periods of time. In addition, we do not necessarily know what assumptions regarding general economic growth were used in preparing the forecasts we cite. Statements regarding our market position are based on the most currently available data. While we are not aware of any misstatements regarding the industry data presented in this prospectus, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "*Risk Factors*" in this prospectus.

[1] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

PROSPECTUS SUMMARY

This summary provides a brief overview of the key aspects of our business and our securities. The reader should read the entire prospectus carefully, especially the risks of investing in our securities discussed under "Risk Factors." Some of the statements contained in this prospectus, including statements under "Summary" and "Risk Factors" as well as those noted in the documents incorporated herein by reference, are forward-looking statements and may involve a number of risks and uncertainties. Our actual results and future events may differ significantly based upon a number of factors. The reader should not put undue reliance on the forward-looking statements in this document, which speak only as of the date on the cover of this prospectus.

Unless the context otherwise requires, references in this prospectus to "60P," the "Company," "we," "us" and "our" refer to 60 Degrees Pharmaceuticals, Inc., a Delaware corporation, and 60P Australia Pty Ltd, an Australian proprietary company limited by shares, our majority-owned subsidiary.

Overview

We are a growth-oriented specialty pharmaceutical company with a goal of using cutting-edge biological science and applied research to further develop and commercialize new therapies for the prevention and treatment of infectious diseases. We have successfully achieved regulatory approval of Arakoda, a malaria preventative treatment that has been on the market since late 2019. Currently, 60P's pipeline under development covers development programs for COVID-19, fungal, tick-borne, and other viral diseases utilizing three of the Company's future products: (i) new products that contain the Arakoda regimen of Tafenoquine; (ii) new products that contain Tafenoquine; and (iii) Celgosivir.

Mission

Our mission is to address the unmet medical need associated with infectious diseases, through the development and commercialization of new small molecule therapeutics, focusing on synthetic drugs (made by chemists in labs, excluding biologics) with good safety profiles based on prior clinical studies, in order to reduce cost, risk, and capitalize on existing research. We are seeking to expand Arakoda's use for malaria prevention and to demonstrate clinical benefit for other disease indications. We are further testing the viability of another product (Celgosivir) to determine whether to advance it into further clinical development, and may seek to develop and license other molecules in the future. Celgosivir is being developed for COVID-19, RSV and Dengue.

Market Opportunity

In 2018, the FDA approved Arakoda for malaria prevention in individuals 18 years and older, an indication for which there has historically been approximately 550,000 prescriptions (one prescription per three weeks of travel) in the United States each year for the current market-leading product (atovaquone-proguanil). Arakoda entered the U.S. supply chain in the third quarter of 2019, just prior to the COVID-19 pandemic. As the approved indication is for travel medicine, and international travel was substantially impacted by the pandemic, we did not undertake any active marketing efforts for Arakoda. Targeted marketing efforts will commence in the second half of 2023 to promote the malaria indication as resources permit, although we expect our primary efforts to be developing Arakoda for other applications.

We are repositioning the Arakoda regimen of Tafenoquine for new indications to address several therapeutic indications that have substantial U.S. caseloads, as further described below:

- Treatment of COVID-19. According to *The New York Times*, the lowest daily case rate for the COVID-19 virus since March 2020 based on a seven-day average has not typically been below 11,000 cases. Assuming this trend continues, this dynamic translates into a potential market size of at least 4,000,000 cases per year in 2023 and future years. Paxlovid and molnupiravir have received emergency use authorization for the prevention of death and hospitalization in individuals with high risk of disease progression and their use for those purposes continues to be recommended by public health experts. However, to our knowledge, there is not published evidence from randomized controlled clinical trials that either drug reduces the time to sustained clinical recovery for four or more days in standard risk patients infected with contemporary viral strains, and Pfizer has formally abandoned efforts related to this endpoint for paxlovid.[2] Additionally molnupiravir and paxlovid are not approved by FDA for use in patients without risk factors for disease progression, and that excluded lower risk population comprises about 25% of the U.S. population.[3] The economic value of that unsatisfied market may be a multi-billion-dollar opportunity, given that the value of paxlovid and molnupiravir in the 75% of the population in which they can be used was ~ $12 billion in 2022.[4] If proven effective for early relief of COVID-19 symptoms in standard risk COVID-19 patients, Tafenoquine (Arakoda regimen) could fulfill a patient's need unmet by the approved antivirals.

[2] Press release: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reports-additional-data-paxlovidtm-supporting.

[3] See the Paxlovid (www.paxlovid.com) and Lagevrio (www.lagevrio.com) prescribing information and epidemiology data described by Ajufo et al Am J Preventive Cardiol 2021;6:101156.

[4] See 2022 revenue data for Paxlovid in Pfizer (https://investors.pfizer.com/Investors/Financials/SEC-Filings/SEC-Filings-Details/default.aspx?FilingId=16428097) and Lagevrio (https://d18rn0p25nwr6d.cloudfront.net/CIK-0000064978/b390be48-92bf-4595-96da-ac5cd7c3d92e.pdf) in Merck financial reports.

- Treatment and Post-Exposure Prevention of Tick-Borne Diseases. There are at least 47,000 cases of babesiosis (red blood cell infections caused by deer tick bites) in the United States each year. This estimate is based on the observations of Krugeler who reported that 476,000 cases of Lyme disease occur in U.S. states where babesiosis is endemic and Krause et. al. who reported that 10% of Lyme disease patients are co-infected with babesiosis (thus 476,000*10% = 47,600 cases of babesiosis per year).[5] Furthermore, post-exposure prophylaxis following a tick-bite is a recognized indication to prevent Lyme disease, and it is likely that a drug proven to be effective for this indication for babesiosis would also be used in conjunction with Lyme prophylaxis. There may be more than 400,000 tick bites in the United States requiring medical treatment each year. This estimate is based on the observation that approximately 50,000 tick bites are treated in U.S. hospital emergency rooms each year but this calculation represents only about 12% of actual treated tick bites based on observations from comparable ex-U.S health systems.[6] Arakoda has the potential to be added to the existing standard of care for treatment of babesiosis, and to be a market leading product for pre- and post-exposure prophylaxis of babesiosis.

- Prevention of fungal pneumonias. There are up to ~ 91-92,000 new medical conditions each year in the United States including acute lymphoblastic leukemia (up to 6.540 cases) and large B-cell lymphoma (up to 18,000 cases) patients receiving CAR-T therapy, solid organ transplant patients (up to 42,887 cases), allogeneic (~ 9,000 cases) and autologous (~ 15,000 cases) hematopoietic stem cell transplant patients for whom the use of antifungal prophylaxis is recommended.[7] Despite the availability and use of antifungal prophylaxis, the risk of some patient groups contracting fungal pneumonia exceeds the risk of contracting malaria during travel to West Africa.[6] Arakoda has the potential to be added to existing standard of care regimens for the prevention of fungal pneumonias.

- Treatment of *Candida* infections. According to the Centers for Diseases Control (CDC), there are 50,000 cases of candidiasis (a type of fungal infection) each year in the United States and up to 1,900 clinical cases of *C. auris*, for which there are few available treatments, have been reported to date[9] Arakoda has the potential to be a market leading therapy for treatment/prevention of *C. auris*, and to be added to the standard of care regimens for other *Candida* infections.

Dengue and RSV, both afflictions against which 60P's early clinical candidates (e.g., Celgosivir) show potential in non-clinical studies, are associated with at least 4.1 million cases globally according to the European CDC (Dengue) [10] and up to 240,000 hospitalizations (RSV) in children less than five years of age and adults greater than 65 years of age in the United States each year according to the CDC.[11]

More information about our products is provided in the next section, and the status of various development efforts for the above-mentioned diseases is outlined in Figure A, below.

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[5] Krause et al JAMA 1996;275:1657-16602. Krugeler et al *Emerg Infect Dis* 2021;27:616-619

[6] Marx et. al., MMWR 2021;70:612-616.

[7] See statistics for solid organ transplants at the Organ Transplant and Procurement Network at: National data - OPTN (hrsa.gov); See statistics for hematopoietic stem cell transplant in Dsouza et al Biology of Blood and Bone Marrow Transplantation 202;26: e177-e182; See statistics for acute lymphoblastic leukemia at: Key Statistics for Acute Lymphocytic Leukemia (ALL) (cancer.org); See statistics for large cell large B-cell lymphoma at; Diffuse Large B-Cell Lymphoma - Lymphoma Research Foundation; Treatment guidelines recommending antifungal prophylaxis for these diseases can be reviewed in (i) Fishman et al Clinical Transplantation. 2019;33:e13587, (ii) Hematopoietic Cell Transplantation (cancernetwork.com), (iii) Cooper et al Journal of the National Comprehensive Cancer Network 2016;14:882-913 and (iv) Los Arcos et al Infection (2021) 49:215–231.

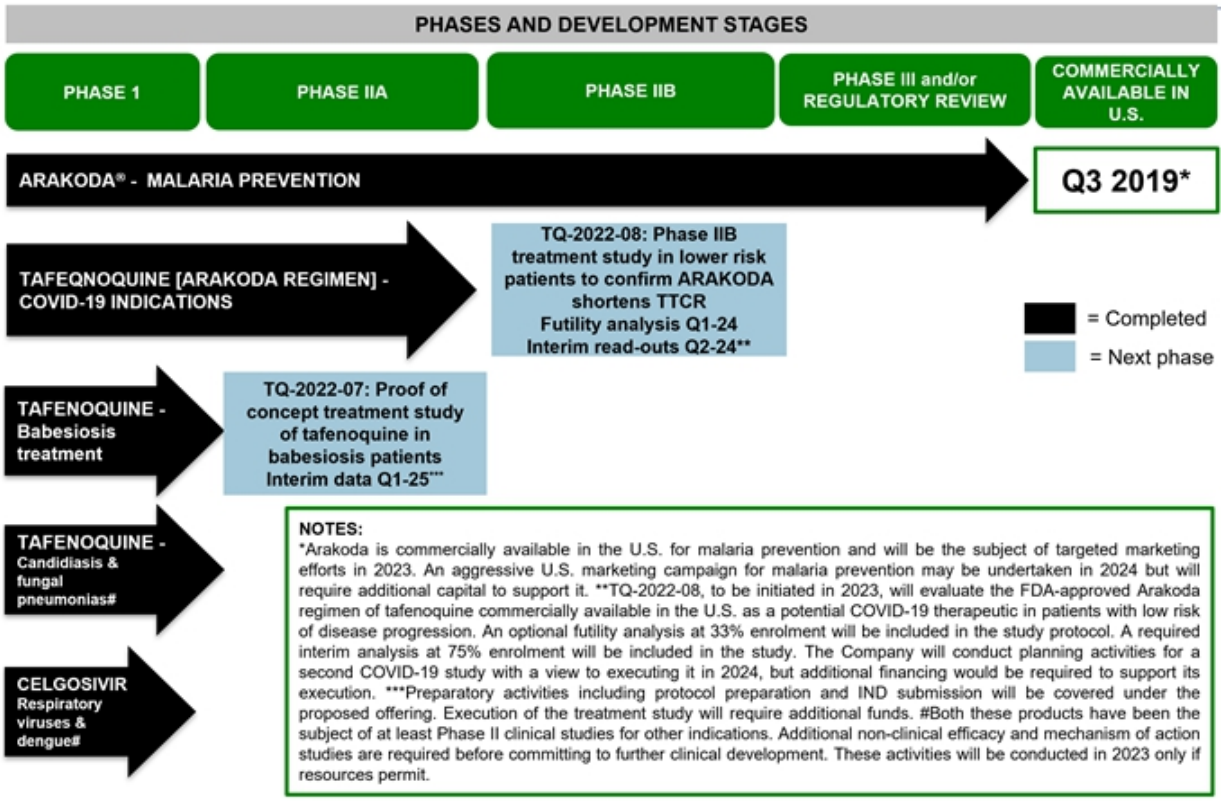
[8] Aguilar-Guisado et al Clin Transplant 2011;25:E629–38; Mace et al MMWR 202;70:1–35

[9] https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html.; https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html.

[10] https://www.ecdc.europa.eu/en/dengue-monthly#:~:text=This%20is%20an%20increase%20of%2032%20653%20cases%20and%2032,853%20deaths%20have%20been%20reported.

[11] https://www.cdc.gov/rsv/research/index.html#:~:text=Each%20year%20in%20the%20United,younger%20than%205%20years%20old.&text=58%2C000-80%2C000%20hospitalizations%20among%20children%20younger%20than%205%20years%20old.&text=60%2C000-120%2C000%20hospitalizations%20among%20adults%2065%20years%20and%20older.

Figure A


PHASES AND DEVELOPMENT STAGES
PHASE 1
PHASE IIA
PHASE IIB
PHASE III and/or REGULATORY REVIEW
COMMERCIALLY AVAILABLE IN U.S.
ARAKODA® - MALARIA PREVENTION
Q3 2019*
TAFEQNOQUINE [ARAKODA REGIMEN] - COVID-19 INDICATIONS
TQ-2022-08: Phase IIB treatment study in lower risk patients to confirm ARAKODA shortens TTCR
Futility analysis Q1-24
Interim read-outs Q2-24**
= Completed
= Next phase
TAFENOQUINE - Babesiosis treatment
TQ-2022-07: Proof of concept treatment study of tafenoquine in babesiosis patients
Interim data Q1-25***
TAFENOQUINE - Candidiasis & fungal pneumonias#
CELGOSIVIR Respiratory viruses & dengue#
NOTES:
*Arakoda is commercially available in the U.S. for malaria prevention and will be the subject of targeted marketing efforts in 2023. An aggressive U.S. marketing campaign for malaria prevention may be undertaken in 2024 but will require additional capital to support it. **TQ-2022-08, to be initiated in 2023, will evaluate the FDA-approved Arakoda regimen of tafenoquine commercially available in the U.S. as a potential COVID-19 therapeutic in patients with low risk of disease progression. An optional futility analysis at 33% enrolment will be included in the study protocol. A required interim analysis at 75% enrolment will be included in the study. The Company will conduct planning activities for a second COVID-19 study with a view to executing it in 2024, but additional financing would be required to support its execution. ***Preparatory activities including protocol preparation and IND submission will be covered under the proposed offering. Execution of the treatment study will require additional funds. #Both these products have been the subject of at least Phase II clinical studies for other indications. Additional non-clinical efficacy and mechanism of action studies are required before committing to further clinical development. These activities will be conducted in 2023 only if resources permit.

Products

Arakoda (Tafenoquine) for malaria prevention

We entered into a cooperative research and development agreement with the United States Army in 2014 to complete development of Arakoda for prevention of malaria.[12] With the U.S. Army, and other private sector entities as partners, we coordinated the execution of two clinical trials, development of a full manufacturing package, gap-filling non-clinical studies, compilation of a full regulatory dossier, successful defense of our program at an FDA advisory committee meeting, and submitted a new drug application ("NDA") to the FDA in 2018. The history of that collaboration has been publicly communicated by the U.S. Army.[13]

The FDA and Australia's medicinal regulatory agency, Therapeutic Goods Administration, subsequently approved Arakoda and Kodatef (brand name in Australia), respectively, for prevention of malaria in travelers in 2018. Prescribing information and guidance for patients can be found at *www.arakoda.com*. The features and benefits of Tafenoquine for malaria prophylaxis (marketed as Arakoda in the United States), some of which have been noted by third-party experts, include: convenient once weekly dosing following a three day load; the absence of reports of drug resistance during malaria prophylaxis; activity against liver and blood stages of malaria as well as both the major malaria species (*Plasmodium vivax* and *Plasmodium falciparum);* absence of any black-box safety warnings; good tolerability including in women and individuals with prior psychiatric medical history, and a comparable adverse event rate to placebo with up to 12 months continuous dosing.[14] Tafenoquine entered the commercial supply chains in the U.S. (as Arakoda) and Australia (as Kodatef) in the third quarter of 2019.

The only limitation of Arakoda is the requirement for a G6PD test prior to administration.[15] The G6PD test must be administered to a prospective patient prior to administration of Arakoda in order to prevent the potential occurrence of hemolytic anemia in individuals with G6PD deficiency.[16] G6PD is one of the most common enzyme deficiencies and is implicated in hemolysis following administration/ingestion of a variety of oxidant drugs/food. G6PD must also be ruled out as a possible cause when diagnosing neonatal jaundice. As a consequence, G6PD testing is widely available in the United States through commercial pathology service providers (e.g., Labcorp, Quest Diagnostics, etc.). Although these tests have a turn-around time of up to 72 hours, the test needs only to be administered once. Thus, existing U.S. testing infrastructure is sufficient to support the FDA-approved use of the product (malaria prevention) by members of the armed forces (who automatically have a G6PD test when they enlist), civilian travelers with a long planning horizon or repeat travelers.

Tafenoquine (Arakoda regimen) for COVID-19

During the COVID-19 pandemic, since our commercial opportunities were limited, we embarked upon an exploratory research and development campaign to identify new indications for the Arakoda dosing regimen of Tafenoquine. In the second quarter and third quarter of 2020, we commissioned cell culture studies that showed that Tafenoquine, the active ingredient in Arakoda, inhibited replication of SARS-CoV-2 (the virus that causes COVID-19).[17] Then, we commissioned computer simulations, which showed that the predicted concentration of Tafenoquine in the lungs of COVID-19 patients following administration of the first four doses of the approved antimalarial prophylactic regimen of Arakoda exceeded those inhibiting the virus in cell culture. The foregoing provided the rationale for seeking approval from the FDA to conduct a Phase II clinical trial in patients with the COVID-19 disease, for which the FDA granted clearance to proceed in October 2020.

In 2021, with financial support from the U.S. Army[16], we conducted a Phase II clinical investigation of the safety and efficacy of Tafenoquine using the Arakoda regimen in outpatients with mild-moderate COVID-19 disease (assumed to be mostly caused by the delta variant of SARS-COV-2). In summary, safety and efficacy of Tafenoquine administered at the approved dose for malaria prevention (200 mg dose once per day on days 1, 2, 3, and 10) was evaluated over a 28-day period in mild-moderate COVID-19 patients. The primary endpoint was day 14 clinical recovery from COVID-19 symptoms, defined as cough mild or absent, respiratory rate < 24 bpm, and no shortness of breath or fever. From March 2021 through September 2021, this study enrolled 87 of the originally planned 275 patients. In October 2021, a data safety monitoring board, after conducting a futility analysis for the primary endpoint and reviewing adverse event data, recommended that the study be continued as planned. However, at the time of the unblinding of this study, topline results from Phase III studies for three oral COVID-19 therapeutics in at risk patients with mild-moderate COVID-19 disease had been announced: Fluvoxamine, molnupiravir, and paxlovid reduced the risk of hospitalization by approximately 30%, 50% (in the first public announcement) and 90%, respectively.[19] As reported in our publication[18], an informal survey of potential funding/commercialization partners for a follow-on program suggested it would be important to know the magnitude of possible benefit prior to initiating such an effort. Primarily for the above reasons, the study was terminated and unblinded early.

The results of the study were accepted for peer-reviewed publication in May 2022.[21] For the primary endpoint, the proportion of patients not recovered on Day 14 was numerically decreased by 27% in the intent to treat population (8/45 v 10/42 not recovered in the Tafenoquine and placebo arms, $P = 0.60$) and 47% in the per protocol population (5/42 v 9/41, $P = 0.25$). Amongst individuals who recorded responses in an electronic diary on day 28, all Tafenoquine patients were recovered, whereas up to 12% of placebo patients exhibited lingering shortness of breath. Analysis of secondary/exploratory endpoints suggested Arakoda reduced time to clinical recovery from shortness of breath, cough and fever ($P < 0.02$) and numerically improved aggregate symptom scores five days after treatment ($P < 0.1$).[22] The risk of COVID-19-related hospitalization was numerically reduced in the Arakoda arm (by approximately 50%; two instances for placebo versus one for Arakoda). Mild, drug related adverse events occurred in 8.4% of individuals in the Tafenoquine arm (v 2.4% in the placebo). We plan to confirm that Arakoda accelerates sustained recovery from COVID-19 symptoms in our next study (described in "*Prospectus Summary—Strategy*" beginning on page 4).

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[12] In 2014, we signed a cooperative research and development agreement with the United States Army Medical and Materiel Development Activity (Agreement W81XWH-14-0313). Under this agreement, we agreed to submit an NDA for Tafenoquine to the FDA (as Arakoda), while the US Army agreed to finance the bulk of the necessary development activities in support of that goal.

[13] Zottig et al Military Medicine 2020; 185 (S1): 687.

[14] Tan and Hwang Journal of Travel Medicine, 2018, 1–2; Baird Journal of Travel Medicine 2018:, 1–13; Schlagenhauf et al Travel Medicine and Infectious Disease 2022; 46:102268; See Arakoda prescribing information at www.arakoda.com; McCarthy et al CID 2019:69:480-486; Dow et al. Malar J (2015) 14:473; Dow et al. Malaria Journal 2014, 13:49; Novitt-Moreno et al Travel Med Infect Dis 2022 Jan-Feb;45:102211.

[15] See prescribing information at www.arakoda.com.

[16] See prescribing information at www.arakoda.com.

[17] U.S. Patent application # 17/189,544, Dow et. al. bioRxiv 2020.07.12.199059; doi: https://doi.org/10.1101/2020.07.12.199059.

[18] Financial support was obtained from Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (which may be referred to as “JPEO”) or JPEO via other transactional authority agreement #W911QY-21-9-0011.

[19] Reis et al Lancet Global Health 2022;10:e42-51, Bernal et al New Eng J Med 2021; https://doi.org/10.1056/NEJMoa2116044; Pfizer Inc. Press release (November 5, 2021) – Pfizer’s novel COVID 19 oral antiviral treatment candidate reduced risk of hospitalization or death by 89% in interim analysis of Phase 2/3 EPIC-HR study. Accessible at: Pfizer’s Novel COVID-19 Oral Antiviral Treatment Candidate Reduced Risk of Hospitalization or Death by 89% in Interim Analysis of Phase 2/3 EPIC-HR Study | Pfizer.

[20] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

[21] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

[22] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

In 2022, we conducted additional analyses of laboratory endpoint data from the clinical study described above and are preparing a manuscript for publication. That analysis and the scientific literature suggest two possible modes of action for Arakoda: (i) down-regulation of cytokines (immune system inflammatory proteins) associated with severe COVID-19 and a greater risk of hospitalization or death and/or (ii) inhibition of viral entry in the lung or elsewhere in the body, perhaps through inhibition of a host enzyme called TMPRSS2 (which facilitates entry of the virus that causes COVID-19, SARS-CoV-2, into human cells).

Assuming the efficacy of Tafenoquine in COVID-19 disease is proven in our next study, some of the features of the Arakoda regimen that make it ideal for malaria prophylaxis might also make it very useful for COVID-19 related indications. Tafenoquine is slowly metabolized and has few important drug-drug interactions, so it might be an ideal partner for standard of care oral COVID-19 therapeutics that reduce hospitalization but have no demonstrated effect on the time to clinical recovery in non-hospitalized patients. The Arakoda regimen requires fewer tablets (8 in the first ten days versus 30 or 40 for paxlovid and molnupiravir) which should make compliance with medication easier for patients. This is an important consideration in the attractiveness of a regimen in standard risk patients at lower risk of hospitalization, and who may be interested in taking a COVID-19 therapeutic primarily to treat early symptoms and accelerate recovery. The potential for better compliance may also suggest suitability for outbreak control in some settings (including, for example, nursing homes).

Tafenoquine for other infectious diseases

During the pandemic, we also worked with NIH to evaluate the utility of Tafenoquine as an antifungal. We, and the NIH, found that Tafenoquine exhibits a Broad Spectrum of Activity in cell culture against *Candida* and other yeast strains via a different Mode of Action than traditional antifungals and also exhibits antifungal activity against some fungal strains at clinically relevant doses in animal models.[23] Our work followed Legacy Studies that show Tafenoquine is effective for treatment and prevention of *Pneumocystis* pneumonia in animal models.[24] We believe that if added to the standard of care for anti-fungal and yeast infection treatments for general use, Tafenoquine has the potential to improve patient outcomes in terms of recovery from yeast infections, and prevention of fungal pneumonias in immunosuppressed patients. There are limited treatment options available for these indications, and Tafenoquine's novel mechanism of action might also mitigate problems of resistance. Clinical trial(s) to prove safety and efficacy, and approval by the FDA and other regulators, would be required before Tafenoquine could be marketed for these indications.

Tafenoquine is effective in animal models of babesiosis (tick borne red blood cell infections). In two of three recent clinical case studies, Tafenoquine administered after failure of conventional antibiotics in immunosuppressed babesiosis patients resulted in cures.[25] Consequently, we believe that (i) if combined with standard of care products, Tafenoquine has the potential to reduce the duration of treatment with antibiotic therapy in immunosuppressed patients and the time to parasite clearance in non-immunosuppressed patients and (ii) that once appropriate clinical studies have been conducted, it is likely that Tafenoquine would be quickly embraced for post-exposure prophylaxis of babesiosis in patients with tick bites and suspected of being co-infected with Lyme disease. Clinical trial(s) to prove safety and efficacy, and approval by FDA and other regulators, would be required before Tafenoquine could be marketed for these indications.

Celgosivir

Celgosivir is a host targeted glucosidase inhibitor that was developed separately by other sponsors for HIV then for hepatitis C.[26] The sponsors abandoned Celgosivir after completion of Phase II clinical trials involving 700+ patients, because other antivirals in development at the time had superior activity. The National University of Singapore initiated development of Celgosivir independently for Dengue fever. A clinical study, conducted in Singapore, and the results of which were accepted for publication in the peer-reviewed journal Lancet Infectious Diseases, confirmed its safety but the observed reduction in viral load was lower than what the study was powered to detect.[27] Celgosivir (as with other Dengue antivirals) exhibits greater capacity to cure Dengue infections in animal models when administered prior to symptom onset compared to post-symptom onset. In animal models, this problem can be addressed for Celgosivir, by administering the same dose of drug split into four doses per day rather than two doses per day (as was the case in the Singaporean clinical trial).[28] This observation led to the filing and approval of a patent related to Dengue, which we licensed from the National University of Singapore.

[23] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

[24] Queener et al Journal of Infectious Diseases 1992;165:764-8).

[25] Liu et al. Antimicrobial Agents Chemo 2021;65:e00204-21, Marcos et al. IDCases 2022;27:e01460; Rogers et al. Clin Infect Dis. 2022 Jun 10:ciac473, Prasad and Wormsner. Pathogens 2022;11:1015.

[26] Sorbera et al, Drugs of the Future 2005; 30:545-552.

[27] Low et. al., Lancet ID 2014; 14:706-715.

[28] Watanabe et al, Antiviral Research 2016; 10:e19.

Additional clinical studies would be required to prove that such a 4x daily dosing regimen would be safe and effective in Dengue patients to regulators' satisfaction. To that end, earlier in our history, we, in partnership with the National University of Singapore, and Singapore General Hospital, successfully secured a grant from the government of Singapore for a follow-on clinical trial, but were unable at that time to raise matching private sector funding. We concluded as a result that development of Repositioned Molecules for Dengue, solely and without simultaneous development for other therapeutic use, despite substantial morbidity and mortality in tropical countries, was an effort best suited for philanthropic entities. Accordingly, during the pandemic, we undertook an effort (in partnership with NIH's Division of Microbiology and Infectious Diseases program and Florida State University) to determine whether Celgosivir might be more broadly useful for respiratory diseases that have impact in both tropical and temperate countries. Preliminary data suggest Celgosivir inhibits the replication of the virus that causes COVID-19 (SARS-CoV-2) in cell culture, and the RSV virus in cell culture and provides benefits in animals. We have filed and/or licensed patents in relation to Celgosivir for these other viruses as we believe there is potential applications to fight respiratory diseases that might have more commercial viability than historical development of Celgosivir to combat Dengue fever.

Competitive Strengths

Our main competitive strength has been our ability to achieve important clinical milestones inexpensively in therapeutic areas that other entities have found extremely challenging. With a small virtual management team, we have successfully built productive research partnerships with public and academic entities, and licensed products with well characterized safety profiles in prior clinical studies, thereby reducing the cost and risk of clinical development. This business and product model enabled Arakoda to be approved in 2018, with a total operating expense of < $10 million. We plan to focus in the future on generating proof of concept clinical data sets for the approved Arakoda regimen of Tafenoquine in other therapeutic areas, all of which is expected to foster and continue our existing tradition of inexpensive product development.

Strategy

Our general strategy is to demonstrate clinical proof of concept that the FDA-approved Arakoda regimen of Tafenoquine provides clinical benefits in non-malaria therapeutic areas. Our initial focus is on COVID-19, but additional indications have been identified for development, namely babesiosis and fungal infections, pending further data generation. Upon demonstration of clinical proof of concept, we plan to enter into a strategic partnership with a larger entity with commercialization capacity, or raise additional capital to facilitate commercialization of Arakoda, and any additional clinical studies that may be required by regulators, for both travel medicine and broad infectious disease indications. We will continue to develop our portfolio products as resources permit.

Beginning in the second half of 2023, we plan to execute a Phase IIB, randomized, placebo-controlled double blind clinical study powered (at 80%) to prove that the Arakoda regimen of Tafenoquine accelerates time to sustained clinical recovery in patients with mild-moderate disease with low risk for disease progression. This trial will utilize the bulk of proceeds raised in this offering. Based on an analysis of unpublished data from our earlier COVID-19 clinical trial,[29] we believe that the Arakoda regimen of Tafenoquine has the potential to reduce the time to sustained clinical recovery by about three days (see Figure B, below). The study will be conducted in out-patient clinics in the United States. The study will utilize the majority of the proceeds of the offering reserved for research and development activities for this purpose. As of the date of this prospectus, we have completed a clinical study synopsis. Submission of the full protocol to the Ethics Committees and to U.S. regulators, and posting of the trial at *clinicaltrials.gov* will follow this initial public offering.

Figure B

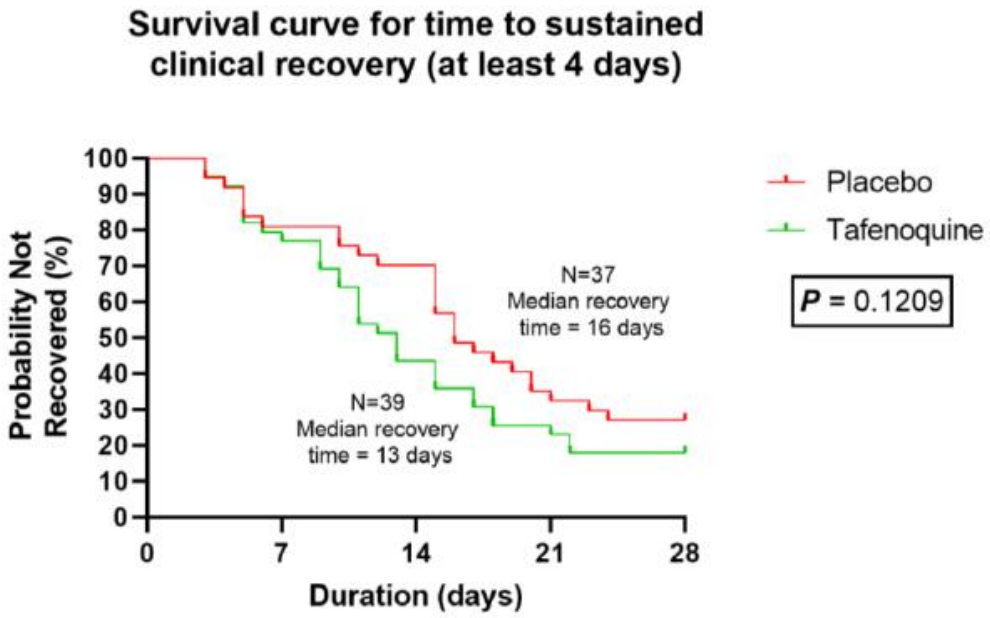

Figure B: Survival curve for sustained clinical recovery in outpatients with mild-moderate COVID-19 disease randomized to receive Tafenoquine (Arakoda regimen) or placebo. Sustained clinical recovery was defined as the first instance of patient reported symptoms scores being < 3 for four or more days, with symptoms scores assessed according to FDA guidance.[30] This analysis utilized unpublished data from our earlier Phase II clinical trial.[31] The analysis excludes individuals hospitalized or loss to follow-up and with a symptom score on the days of dosing < 3. This analysis represents a post-hoc analysis of our Phase II clinical trial data. If this were a formal, pre-conceived primary study endpoint, the *P* value of 0.1209 would imply the associated difference between Tafenoquine (Arakoda regimen) and placebo has a 12.09% chance of occurring by chance.

We intend to design the study, subject to approval by the FDA and Ethics Committee(s) as appropriate, to include two interim endpoints to manage risk. The first will be an optional futility analysis at the earlier of 33% enrollment or six months following the first patient enrolled, which would allow early termination of the study if the conditional power of proving the intended hypothesis is < 20%. The second, mandatory interim analysis will occur at 75% enrollment and follow a step-wise (sponsor-blinded) process involving testing for futility, statistical significance, and sample-size reassessment if required. The test for statistical significance would allow early termination of the study if results are unexpectedly positive and the sample size reassessment would allow the study to enroll more patients within pre-specified limits if variability is more, and/or the magnitude of the expected treatment effect is less, than expected.

We plan to conduct additional non-clinical studies to clarify the process by which Tafenoquine alters the course of COVID-19 illness. Specifically, such studies will attempt to determine whether Tafenoquine acts as an immunomodulator (by decreasing the production of immune system molecules that cause inflammation) and/or exhibits an antiviral effect via inhibition of the host protease TMPRSS2. Antivirals are generally utilized earlier, and immunomodulators later, in treating patients with COVID-19 disease. However, the clinical hypothesis of our planned study will be that Arakoda accelerates clinical recovery by three days in individuals who have experienced symptoms for fewer than seven days, thereby confirming observations from our earlier clinical study (see Figure B). Since the potential clinical benefit is already known, the primary purpose of clarifying the manner in which Arakoda works is to (i) address anticipated regulatory questions and (ii) ascertain whether other indications, such as relief of COVID-19 symptoms during vaccination, treatment of long COVID-19 patients, or use during hospitalization, might be plausible.

Following completion of our planned COVID-19 clinical study, if warranted based on the data generated, we intend to request a change in prescribing information to facilitate an expansion of use of Arakoda for malaria prevention from six to twelve months (mirroring our recently published post-marketing safety study) and to include reference to the recently generated COVID-19 treatment data. Prior to doing so, we plan to discuss with the FDA additional labeling related to COVID-19 which might be acceptable.

We intend to design and conduct feasibility assessments for one or more additional studies in the same type of patients as the planned study and/or for a COVID 19-related indication different from that targeted by our clinical study in 2023. One of these additional studies would be conducted in Australia, and would be a requirement to secure tax rebates for the overall COVID-19 program (see next paragraph). A second study is likely to be required by regulators which may or may not be the same as the study conducted in Australia. The value of conducting additional studies, in addition to securing tax credits or for regulatory approvals, would be (i) independently confirming the therapeutic modality/clinical mode of action of Arakoda (i.e. that it accelerates clinical recovery from COVID-19 symptoms and/or acts as an antiviral or disease modulator) and (ii) broadening the COVID-19 indication beyond treatment of lower risk patients (i.e. potentially increasing the volume of annual prescriptions). Thus, possible study designs could be (i) a simple repetition of the planned study with a larger sample size, (ii) a treatment study in higher risk patients or (iii) a pre-treatment loading study in individuals known to be exposed to the virus that causes COVID-19, and/or (iv) amelioration of COVID-19 disease-like symptoms in individuals receiving mRNA COVID-19 vaccines (if it turns out Arakoda is an immunomodulator).

We plan to license ex-U.S. rights to COVID-19 indications to our Australian subsidiary, 60P Australia Pty Ltd. This will facilitate claiming the Australian government's research tax credit for any of our COVID-19-related research activities conducted in Australia. 60P Australia has been successful in securing research tax credits for malaria and Dengue-related research since 2013. Since conducting our planned COVID-19 study in Australia is likely to be unfeasible and must be conducted in the U.S., we plan to apply for an overseas finding to the Australian Tax Office in the second quarter of 2023 to request an overseas finding for the U.S. study. Should such a finding be awarded, it would allow a tax rebate of 43.5% on research and development costs associated with the planned U.S. COVID-19 study to be claimed, but commit the Company to conduct COVID-19 research activities in Australia of a value at least as much as the cost of the planned U.S. clinical study.

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[29] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

[30] *FDA 2020 Guidance on Assessing COVID-19 Symptoms*-14 Common COVID-19 Symptoms Severity Scale.

[31] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

We are planning several commercial initiatives for the malaria market in parallel with further clinical development activities. Three routes exist for commercialization of Arakoda for the malaria prevention market are: (i) U.S. civilian travel clinics, travel prescribing centers, and large private sector entities with employees deployed overseas (e.g., mining companies), (ii) the prospect of additional U.S. Department of Defense ("DoD") and government agency procurement in the future (noting that as described on page 60 our existing contract with DoD has been fulfilled and has not been extended or modified) and (iii) ex U.S. sales strategy where we currently (or in the future) have exclusive distribution arrangements in overseas markets.

As of the date of this prospectus, we did not have plans to hire a U.S. field sales force, but are exploring possible commercial arrangements with contract sales organizations to target U.S. travel clinics for malaria prophylaxis. We may consummate a contract with a lobbying firm/contract sales organization to attempt to improve the position of Arakoda in the DoD formulary and to raise awareness of Arakoda amongst other U.S. government agencies. For such agencies, the product is expected to meet many of the requirements for occupational malaria prevention identified by the independent parties that have endorsed the product. We have been successful in securing procurement contracts with U.S. government agencies for Arakoda, and anticipate continued success in the future. In the third quarter of 2022, we made our first sale to our European distributor, and made additional sales to our Australian distributor in the second quarter of 2022. We are actively exploring the possibility of named-patient sales in jurisdictions outside Australia, Europe, and the United States. We plan to undertake a focused marketing campaign for Arakoda for malaria prevention in the second half of 2023. This will consist of promotion at relevant conferences, email promotion to prescribers, and target print and electronic advertisements.

It is expected that a point of care G6PD test might be required to maximize the economic potential of a COVID-19 indication for Tafenoquine (regardless of regimen). We do not intend to pursue independent development of such a test as there are well resourced development efforts already underway (see "*Risk Factors—Any future clinical trial for Arakoda will require screening for G6PD deficiency in order to safely administer the product. In the United States, G6PD testing can obtained through commercial pathology services which is associated with delays. The use of a third-party diagnostic provider of point of care testing may be required and we may not directly control the timing, conduct and expense of such testing*" beginning on page 18). However, we will continue to monitor the progress of development and U.S. commercialization of G6PD tests. We will seek to pursue collaborative commercial partnerships with the companies involved in commercialization efforts, if such activities can be conducted through resource sharing efforts.

We plan to generate additional validation data for our portfolio products if resources permit. Specifically, we will evaluate whether Celgosivir provides therapeutic benefit in a COVID-19 animal model, and complete critical activities related to confirming GMP process feasibility.

We may elect, as resources permit, to undertake a clinical study of Tafenoquine in combination with standard of care for hospitalized patients with babesiosis. We have developed such a protocol concept in partnership with academic collaborators and are planning to submit an investigational new drug application ("IND") to the FDA and pursue public and philanthropic funding to support our execution. We plan to seek public funding to support additional non-clinical studies to validate the mechanism of action of Tafenoquine against *Candida spp*. and further assess our utility in combination with standard of care agents in cell culture and animal studies.

Most new antimalarial treatment products are developed as drug combinations to proactively combat drug resistance. Tafenoquine, due to its long half-life and activity against all parasite species and strains, would be ideal partner in a drug combination. In the second half of 2023, we will actively seek out a potential partner antimalarial drug for Arakoda, with the goal of pursuing licensure of a new drug combination. We will only enter into a partnership to develop such a drug combination, if clear legal guidance can be obtained that such a combination if developed would have a high probability of securing a priority review voucher upon FDA approval.

There are currently efforts underway, in malaria-endemic countries outside the U.S., to generate datasets supporting the use of Tafenoquine for mass drug administration in asymptomatic individuals to prevent malaria transmission. We believe that such efforts are important to promote community acceptance of Tafenoquine and may eventually support World Health Organization pre-qualification of Tafenoquine for malaria eradication efforts. To that end, we intend to support, on a case-by-case basis, clinical studies sponsored by others, by providing commercial Arakoda and/or Kodatef for research use (provided such product would not otherwise have been commercially salable, and the study sponsor covers shipping costs). We have previously provided Tafenoquine for such efforts on a limited basis.

We have a post-marketing requirement to conduct a malaria prophylaxis study of Arakoda in pediatric and adolescent subjects. We proposed to the FDA, in late 2021, that this might not be safe to execute given that malaria prevention is administered to asymptomatic individuals and that methemoglobinemia (damage to the hemoglobin in blood that carries oxygen) occurred in 5% of patients, and exceeded a level of 10% in 3% of individuals in a study conducted by another sponsor in pediatric subjects with symptomatic vivax malaria.[32] The FDA has asked us to propose an alternate design, for which we submitted a concept protocol in the fourth quarter of 2022, and plan to submit a full protocol by the end of the second quarter of 2023. We estimate the cost of conducting the study proposed by the FDA, if conducted in the manner suggested by the FDA, would be $2 million, and, due to the time periods required to secure protocol approvals from the FDA and Ethics Committees, could not be initiated any earlier than the third quarter of 2024. The funds from this offering to be expended on such a pediatric study will be limited to the minimum required to support protocol preparation and regulatory interactions with the FDA.

[32] Velez et al 2021 - Lancet Child Adolesc Health 2022; 6: 86–95.

Intellectual Property

We are co-owners, with the U.S. Army, of patents in the United States and certain foreign jurisdictions directed toward use of Tafenoquine for malaria and have obtained an exclusive worldwide license from the U.S. Army to practice these inventions. We also have an exclusive worldwide license to use manufacturing information and non-clinical and clinical data that the U.S. Army possesses relating to use of Tafenoquine for all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. We have submitted patent applications in the United States and certain foreign jurisdictions for use of Tafenoquine for COVID-19, fungal lung infections, tick-borne diseases, and other infectious and non-infectious diseases in which induction of host cytokines/inflammation is a component of the disease process. The United States Patent and Trademark Office ("USPTO") recently allowed our first COVID-19 patent for Tafenoquine. We have optioned or licensed patents involving Celgosivir for the treatment and prevention of Dengue (from the National University of Singapore), COVID-19 & Zika (Florida State University), and have submitted provisional patent applications related to Celgosivir for RSV. We have optioned or own manufacturing methods related to Celgosivir. A detailed list of our intellectual property is as follows:

Patents

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Dosing Regimen For Use Of Celgosivir As An Antiviral Therapeutic For Dengue Virus Infections	2013203400	Australia			2013203400+	10-April-2033*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	2014228035	Australia			2014228035	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	MY-170991-A	Malaysia			PI2015002372	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	378015	Mexico			MX/a/2015/013115	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11201507254V	Singapore			11201507254V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	Pending	Singapore	Pending		10201908089V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	9763921	US		9/19/2017	14/772,873	14-Mar-2034^
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	10517854	US		12/31/2019	15/706,845	14-Mar-2034^
Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11219616	US		1/11/2022	16/725,387	14-Mar-2034^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	2015358566	Australia			2015358566	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Canada	Pending		2968694	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	10342791	US		7/9/2019	15/532,280	02-Dec-2035^
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	10888558	US		1/12/2021	16/504,533	02-Dec-2035^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Singapore	Pending		10201904908Q	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	EP	Pending		15865264.4	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Hong Kong	Pending		18103081.4	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	Pending	US	Pending		17/145,530	02-Dec-2035^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	New Zealand	Pending		731813	02-Dec-2035*
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	2016368580	Australia			2016368580	09-Dec-2036*
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	Pending	Singapore	Pending		10201912141Y	09-Dec-2036*
Dosing Regimens Of Celgosivir For The Prevention Of Dengue	11000516	US		5/11/2011	16/060,945	09-Dec-2036^
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	EP	Pending		21764438.4	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	China	Pending		202180029643.7	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	Australia	Pending		2021231743	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	Pending	US	Pending		17/189,544	02-Mar-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Fungus By Administration Of Tafenoquine	Pending	US	Pending		17/683,679	02-Mar-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Sars-Cov-2 Virus By Administration Of Tafenoquine	Pending	US	Pending		17/683,718	02-Mar-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	11369592	US		6/28/2022	17/180,140#	19-Feb-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	US	Pending		17/664,693#	19-Feb-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	EP	Pending		2021757552#	19-Feb-2041*
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof	*Provisional*	US	*Provisional*		63/461,060	~21-Apr-2044&
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	*Provisional*	US	*Provisional*		63/358,341	~05-Jul-2043&
Methods For The Treatment And Prevention Of Diseases Or Infections With Mcp-1 Involvement By Administration Of Tafenoquine	*Provisional*	US	*Provisional*		63/411,654	~30-Sep-2043&
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,328,061+	US		6-25-2019	15/584,952+	2-May-37
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,561,642+	US		2-18-2020	15/856,377+	2-May-37

* = For foreign patents and applications, the estimated and/or anticipated patent expiration is the date that is twenty years from the PCT filing date. For all issued Australian patents, this estimated date was also confirmed through the Australian patent office web database.

^ = For issued U.S. patents, the estimated patent expiration was calculated using information from the front cover of the patent, *i.e.*, 20 years from the date of the nonprovisional filing plus any listed Patent Term Adjustment less any time disclaimed through a Terminal Disclaimer. For pending U.S. applications, the anticipated patent expiration is the date twenty years from the earliest nonprovisional filing date and does not account for possible Patent Term Adjustment (PTA), Patent Term Extension (PTE), or Terminal Disclaimers.

& = For U.S. provisional applications that are not yet the subject of a nonprovisional or PCT application, the anticipated patent expiration was determined using the assumption that a nonprovisional application or PCT will be filed one year after filing the provisional application with a term lasting twenty years from the date of that nonprovisional or PCT filing. This does not account for possible Patent Term Adjustment (PTA), Patent Term Extension (PTE), or Terminal Disclaimers.

+ = 60 Degrees Pharmaceuticals, Inc. is not a listed Applicant and Geoffrey S. Dow, Ph.D. is not a listed inventor.

= 60 Degrees Pharmaceuticals, Inc. is not a listed Applicant, but Geoffrey S. Dow, Ph.D. is a listed inventor.

All patents not designated with a "+" list Geoffrey S. Dow, Ph.D. as an inventor.
All patents not designated with a "+" or a "#" list 60 Degrees Pharmaceuticals, Inc. as an applicant.
All estimated patent expiration dates and anticipated patent expiration assume payment of any maintenance/annuity fees during the patent term.

Trademarks

Country	Mark	Status	Application Number	Date Filed	Registration Date	Registration Number	BIR Ref Number	Due Date	Due Date Description
Australia	KODATEF	Registered	1774631	2-Jun-16	6/2/2016	1774631	0081716-000029	2-Jun-26	Renewal Due
Canada	KODATEF	Registered	1785098	1-Jun-16	11/26/2019	TMA1,064,371	0081716-000028	26-Nov-29	Renewal Due
Canada	ARAKODA	Registered	1899317	15-May-18	8/20/2020	TMA1,081,180	0081716-000053	20-Aug-30	Renewal Due
China	KODATEF	Registered	20842242	2-Aug-16	9/28/2017	20842242	0081716-000035	27-Sep-27	Renewal Due
European Union	KODATEF	Registered	15508872	3-Jun-16	9/21/2016	15508872	0081716-000034	3-Jun-26	Renewal Due
European Union	ARAKODA	Registered	17900852	16-May-18	9/20/2018	17900852	0081716-000054	16-May-28	Renewal Due
Israel	KODATEF	Registered	285476	6-Jun-16	6/6/2016	285476	0081716-000033	6-Jun-26	Renewal Due
New Zealand	KODATEF	Registered	1044407	7-Jun-16	12/8/2016	1044407	0081716-000031	6-May-26	Renewal Due
Russian Federation	KODATEF	Registered	2016720181	6-Jun-16	7/10/2017	623174	0081716-000032	6-Jun-26	Renewal Due
Singapore	KODATEF	Registered	40201707950V	2-May-17	11/8/2017	40201707950V	0081716-000040	2-May-27	Renewal Due
United Kingdom	ARAKODA	Registered	17900852	16-May-18	9/20/2018	UK00917900852	0081716-000054	16-May-28	Renewal Due
United Kingdom	KODATEF	Registered	15508872	3-Jun-16	9/21/2016	UK009015508872	0081716-000072	3-Jun-26	Renewal Due
United States of America	TQ 100 & TABLET DESIGN	Registered	87608493	14-Sep-17	9/11/2018	5562900	0081716-000037	11-Sep-24	Section 8 & 15 Due
United States of America	ARAKODA	Registered	87688137	16-Nov-17	12/31/2019	5950691	0081716-000050	31-Dec-25	Section 8 & 15 Due
United States of America	KODATEF	Allowed - 02/16/2021	90072885	24-Jul-20			0081716-000069	16-Aug-23	Statement of Use/3rd Extension of Time Due

Key Relationships & Licenses

On May 30, 2014, we entered into the Exclusive License Agreement (the “2014 NUS-SHS Agreement”) with National University of Singapore (“NUS”) and Singapore Health Services Pte Ltd (“SHS”) in which we were granted a license from NUS and SHS with respect to their share of patent rights regarding “Dosing Regimen for Use of Celgosivir as an Antiviral Therapeutic for Dengue Virus Infection” to develop, market and sell licensed products. The 2014 NUS-SHS Agreement continues in force until the expiration of the last to expire of any patents under the patent rights unless terminated earlier in accordance with the 2014 NUS-SHS Agreement. We are obligated to pay at the rate of 1.5% of gross sales.

On July 15, 2015, we entered into the Exclusive License Agreement with the U.S. Army Medical Materiel Development Activity (the "U.S. Army"), which was subsequently amended (the "U.S. Army Agreement"), in which we obtained a license to develop and commercialize the licensed technology with respect to all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. This exclusion does not impact our ability to market Arakoda for the FDA-approved use, which is the prevention of malaria utilizing the indicated dose in asymptomatic individuals traveling to high-malaria or malaria-prone regions (whereas the license exclusion relates to its use to treat symptomatic vivax malaria in a patient already presenting with that disease). The term of the U.S. Army Agreement will continue until the expiration of the last to expire of the patent application or valid claim of the licensed technology, or 20 years from the start date of the U.S. Army Agreement, unless terminated earlier by the parties. We will be required to make a minimum annual royalty payment of 3% of net sales for net sales < $35 million, and 5% of net sales greater than $35 million, with US government sales excluded from the definition of net sales. In addition, we must pay a milestone fee of $75,000 once cumulative net sales from all sources exceeds $6 million, $100,000 if we are acquired or merge, and regulatory approval milestone payments once marketing authorizations are achieved in Canada ($5,000) and Europe ($5,000). Also, we will be required to obtain the U.S. Army Medical Materiel Development Activity's consent prior to a change of control of the Company, which consent was obtained on September 2, 2022.

On September 15, 2016, we entered into the Exclusive License Agreement (the "2016 NUS-SHS Agreement") with National University of Singapore and Singapore Health Services Pte Ltd ("SHS") in which we were granted a license from NUS and SHS with respect to their share of patent rights regarding "Novel Dosing Regimens of Celgosivir for The Prevention of Dengue" to develop, market and sell licensed products. The 2016 NUS-SHS Agreement continues in force until the expiration of the last to expire of any patents under the patent rights unless terminated earlier in accordance with the 2016 NUS-SHS Agreement. We are obligated to pay at the rate of 1.5% of gross sales or minimum annual royalty ($5,000 in 2022 and $15,000 in 2023). In July 2022, we renegotiated the timing of a license fee of $85,000 Singapore Dollars, payable to NUS, such that payment would be due at the earlier of (i) enrollment of a patient in a Phase II clinical trial involving Celgosivir, (ii) two years from the agreement date and (iii) an initial public offering.

On December 4, 2020, we entered into the Other Transaction Authority for Prototype Agreement ("OTAP Agreement") with the Natick Contracting Division of the U.S. government in which we will, among other things, conduct activities for a Phase II clinical trial to assess the safety and efficacy of Tafenoquine for the treatment of mild to moderate COVID-19 disease, with the goal of delivering Tafenoquine with an FDA Emergency Use Authorization ("EUA") approved as a countermeasure against COVID-19. The total amount of the OTAP Agreement is $4,999,814. The term of the OTAP Agreement commences on December 4, 2020 and was completed in the third quarter of 2022. Pursuant to the OTAP Agreement, we will not offer, sell or otherwise provide the EUA or licensed version of the prototype (Tafenoquine) that is FDA approved for COVID-19 or any like product to any entity at a price lower than that offered to the DoD, which applies only to products sold in the U.S., European Union and Canada related to COVID-19.

On February 15, 2021, we entered into the Inter-Institutional Agreement (the "FSURF Agreement") with the Florida State University Research Foundation ("FSURF") in which FUSRF granted us the right to manage the licensing of intellectual property created at FSURF. The term of the FSURF Agreement expires five years from February 15, 2021. After deduction of a 5% administrative fee by FSURF, capped at $15,000 annually, and reimbursement of patent prosecution expenses, we will receive 20% of license income and FSURF will receive 80% of license income. Payments of license income shall be paid in U.S. dollars quarterly each year. On February 19, 2021, we entered into an agreement with FSURF, subsequently amended on February 15, 2023, that collectively granted an option, effective through August 19, 2023, to us to license methods for purifying castanospermine and its use for the treatment of COVID-19. On August 19, 2021, we entered into an agreement with FSURF, subsequently amended on February 15, 2023, that collectively granted an option, effective through August 19, 2023, to us to license a patent relating to the use of alpha glucosidase inhibitors (including castanospermine and Celgosivir) for treatment of Zika infections.

Pursuant to the Knight Debt Conversion Agreement, for a period commencing on January 1, 2022 and ending upon the earlier of ten years after the closing date of this offering or the conversion or redemption in full of all of the shares of Series A Preferred Stock owned by Knight, we will pay Knight a royalty equal to 3.5% of our net sales, where "net sales" has the same meaning as in our license agreement with the U.S. Army for Tafenoquine. Upon closing the qualified initial public offering ("IPO"), at the end of the first quarter (or portion thereof) and each subsequent quarter thereafter the royalty will be calculated, and payment will be made within fifteen days.

Corporate Structure

60 Degrees Pharmaceuticals, Inc. is a Delaware corporation that was incorporated on June 1, 2022.

On June 1, 2022, 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company ("60P LLC"), entered into the Agreement and Plan of Merger with 60 Degrees Pharmaceuticals, Inc., pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. The value of each outstanding member's membership interest in 60P LLC was correspondingly converted into common stock of 60 Degrees Pharmaceuticals, Inc., par value $0.0001 per share, with a cost-basis equal to $5.00 per share.

Our majority-owned subsidiary, 60P Australia Pty Ltd, an Australian proprietary company limited by shares ("60P Australia"), was formed and registered in Queensland on December 3, 2013, and conducts operations in Australia.

60P Australia previously solely owned a Singaporean subsidiary company, 60P Singapore Pte. Ltd., which dissolved at our election in the second quarter of 2022.

Going Concern

Our independent auditors have issued a report raising substantial doubt of our ability to continue as a going concern. We anticipate that we will require additional capital to continue as a going concern and expand our operations in accordance with our current business plan.

Suppliers

We have quality and contract manufacturing agreements relating to Arakoda in place with Piramal Enterprises Limited (API, tablets) and PCI Pharma Services (secondary packaging) ("PCI") and supply/quality/pharmacovigilance agreements in place with Biocelect Pty Ltd, Scandinavian Biopharma, and Knight Therapeutics Inc. (to allow supply of Arakoda/Kodatef to Australia, Europe and Canada/Israel/Latin America and Russia, respectively). As of the date of this prospectus, we have not supplied any of our products to Russia nor do we anticipate supplying any of our products to Russia in the near future.

Recent Developments

Effects of COVID-19 Outbreak. In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China, which has and is continuing to spread throughout China and other parts of the world, including the United States. On January 30, 2020, the World Health Organization declared the outbreak of COVID-19 a "Public Health Emergency of International Concern." On January 31, 2020, U.S. Health and Human Services Secretary Alex M. Azar II declared a public health emergency for the United States to aid the U.S. healthcare community in responding to COVID-19, and on March 11, 2020, the World Health Organization characterized the outbreak as a "pandemic." A significant outbreak of COVID-19 and other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide.

We are monitoring the global outbreak and spread of COVID-19 and taking steps in an effort to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and the governmental and community reactions thereto. The current outbreak of COVID-19 has globally resulted in loss of life, business closures, restrictions on travel, and widespread cancellation of social gatherings. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted at this time, including:

- new information which may emerge concerning the severity of the disease;
- the duration and spread of the outbreak;
- the severity of travel restrictions imposed by geographic areas in which we operate, mandatory or voluntary business closures;
- regulatory actions taken in response to the pandemic, which may impact our product offerings;
- other business disruptions that affect our workforce and supply chain;
- the impact on capital and financial markets; and
- actions taken throughout the world, including in markets in which we operate, to contain the COVID-19 outbreak or treat its impact.

In addition, the current outbreak of COVID-19 has resulted in a widespread global health crisis and adversely affected global economies and financial markets, and similar public health threats could do so in the future. Such events have impacted, and could in the future impact, demand for our products, which in turn could adversely affect our revenue and results of operations.

The spread of COVID-19 has caused us to modify our business practices, including employee travel, employee work locations in certain cases, and cancellation of physical participation in certain meetings, events and conferences and further actions may be taken as required or recommended by government authorities or as we determine are in the best interests of our employees, customers and other business partners. We are monitoring the global outbreak of the pandemic and are taking steps in an effort to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and the governmental and community reactions thereto. See "*Risk Factors—Our financial condition and results of operations may be adversely affected by the COVID-19 pandemic*."

2023 Financings

On May 8, 2023, we issued a note in the amount of $111,111.10 to Cyberbahn Federal Solutions, LLC with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Cyberbahn Federal Solutions, LLC shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Ariana Bakery Inc with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Ariana Bakery Inc shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $333,333.30 to Sabby Volatility Warrant Master Fund, Ltd. with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Sabby Volatility Warrant Master Fund, Ltd. shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $55,555.55 to Steel Anderson with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Steel Anderson shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Bixi Gao & Ling Ling Wang with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Bixi Gao & Ling Ling Wang shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

Our Resale Offering

Certain of our stockholders will be selling through the Resale Prospectus a total of 2,224,763 shares of common stock, consisting of (i) 10,482 shares of common stock to be issued upon conversion of a convertible note immediately prior to the consummation of the initial public offering, (ii) 373,426 shares of common stock to be issued in conjunction with the conversion or extinguishment of interim financing notes on the date of the effectiveness of the registration statement of which this prospectus forms a part, (iii) 1,608,938 shares of common stock held by certain of the Selling Stockholders and (iv) 231,917 shares of common stock issuable upon the exercise of warrants that are to be issued on the date of effectiveness of the registration statement of which the Resale Prospectus forms a part. We will not receive any proceeds from the sales by the Selling Stockholders of the securities set forth in the Resale Prospectus.

The Resale Prospectus is substantively identical to the Public Offering Prospectus, except for the following principal points:

- they contain different outside and inside front covers and back covers;
- they contain different "*Offering*" sections in the "*Prospectus Summary*" section beginning on page Alt-1;
- they contain different "*Use of Proceeds*" sections on page Alt-16;
- the "*Capitalization*" and "*Dilution*" sections from the Public Offering Prospectus are deleted from the Resale Prospectus;

- a "*Selling Stockholders*" section is included in the Resale Prospectus;
- the "*Underwriting*" section from the Public Offering Prospectus is deleted from the Resale Prospectus and a "*Selling Stockholder Plan of Distribution*" is inserted in its place in the Resale Prospectus; and
- the "*Legal Matters*" section in the Resale Prospectus on page Alt-19 deletes the reference to counsel for the underwriters.

Summary Risk Factors

Our business is subject to a number of risks. You should be aware of these risks before making an investment decision. These risks are discussed more fully in the section of this prospectus titled "*Risk Factors*," which begins on page 18 of this prospectus. These risks include, among others, that:

- Our financial statements have been prepared on a going-concern basis and our continued operations are in doubt;
- We have incurred net losses since our inception and if we continue to incur net losses in the foreseeable future, the market price of our common stock may decline;
- There is no assurance that we will be profitable;
- There is no assurance that we will be eligible for Australian government research and development tax rebates;
- Our financial condition and results of operations may be adversely affected by the COVID-19 pandemic;
- If we are not able to successfully develop, obtain FDA approval for, and provide for the commercialization of non-malaria prevention indications for Tafenoquine (Arakoda or other regimen) or Celgosivir in a timely manner, we may not be able to expand our business operations;
- Our clinical trials for our product candidates may not yield results that will enable us to further develop our products and obtain regulatory approvals necessary to sell them;
- The mechanisms of actions of some of our products, and interactions with other antiviral products are not known, which may restrict regulatory label claims;
- We expect to depend on existing and future collaborations with third parties for the development of some of our product candidates. If those collaborations are not successful, we may not be able to complete the development of these product candidates;
- Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable;
- Any future clinical trial for Arakoda will require screening for G6PD deficiency in order to safely administer the product. In the United States, G6PD testing can obtained through commercial pathology services which is associated with delays. The use of a third-party diagnostic provider of point of care testing may be required and we do not directly control the timing, conduct, expense of such testing or the timing of market entry into the US;
- Our product candidates are subject to extensive regulation, which can be costly and time-consuming, and unsuccessful or delayed regulatory approvals could increase our future development costs or impair our future revenue;
- If our product candidates receive regulatory approval, we would be subject to ongoing regulatory obligations and restrictions, which will continue to change, and which may result in significant expenses and limit our ability to develop and commercialize other potential products;
- We have no manufacturing capacity which puts us at risk of lengthy and costly delays of bringing our products to market;
- We rely on relationships with third-party contract manufacturers and raw material suppliers, which limits our ability to control the availability of, and manufacturing costs for, our product candidates;
- Our future growth depends on our ability to successfully commercialize Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir and our other product candidates, and we can provide no assurance that we will successfully commercialize Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir and other product candidates;
- Health care reform measures could materially and adversely affect our business;
- Our competitors may be better positioned in the marketplace and thereby may be more successful than us at developing, manufacturing and marketing approved products;
- We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive;
- We would be subject to applicable regulatory approval requirements of the foreign countries in which we market our products, which are costly and may prevent or delay us from marketing our products in those countries;
- Defending against claims relating to improper handling, storage or disposal of hazardous chemicals, radioactive or biological materials could be time consuming and expensive;
- Geopolitical conditions, including direct or indirect acts of war or terrorism could have an adverse effect on our operations and financial results;
- If product liability lawsuits are successfully brought against us, then we will incur substantial liabilities and may be required to limit commercialization of Arakoda, Celgosivir or other product candidates;

- Our intellectual property rights may not preclude competitors from developing competing products and our business may suffer;
- If the manufacture, use or sale of our products infringe on the intellectual property rights of others, we could face costly litigation, which could cause us to pay substantial damages or licensing fees and limit our ability to sell some or all of our products;
- We may not be able to protect our intellectual property rights throughout the world;
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- The earliest Paragraph IV certification date for Arakoda has passed. Generic companies may file an ANDA at any time, and successful challenge of our malaria use patents would negatively impact our business;
- There has been no public market for our common stock prior to this offering, and we cannot assure you that an active trading market will develop in the near future. An active market in which investors can resell their shares may not develop. If there is no viable public market for our common stock, you may be unable to sell your shares at or above the initial public offering price;
- We may not be able to satisfy listing requirements of Nasdaq to maintain a listing of our common stock or Tradeable Warrants;
- There is no public market for the Non-tradeable Warrants being offered in this offering;
- The warrants may have an adverse effect on the market price of our common stock and make it more difficult to effect a business combination;
- Any failure to maintain effective internal controls over financial reporting could have an adverse impact on us; and
- We are an "emerging growth company" and a "smaller reporting company" under the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

Information Regarding our Capitalization

As of June 1, 2023, we had 2,378,009 shares of common stock issued and outstanding. Additional information regarding our issued and outstanding securities may be found under "*Market for Common Equity and Related Stockholder Matters*" and "*Description of Securities*."

Unless otherwise specifically stated, information throughout this prospectus does not assume the exercise of outstanding options or warrants to purchase shares of our common stock.

Corporate Information

Our principal executive offices are located at 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036. Our corporate website address is *60degreespharma.com*. Our telephone number is (202) 327-5422. The information included on our website is not part of this prospectus.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act; (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure requirements that are applicable to other public companies that are not emerging growth companies.

These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" disclosure;
- not being required to comply with the requirement of auditor attestation of our internal controls over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

An emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act to comply with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the dates on which adoption of such standards is required for other public reporting companies.

We are also a "smaller reporting company" as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and have elected to take advantage of certain of the scaled disclosure available for smaller reporting companies. We will remain a smaller reporting company until the end of the fiscal year in which (1) we have a public common equity float of more than $250 million, or (2) we have annual revenues for the most recently completed fiscal year of more than $100 million and a public common equity float or public float of more than $700 million. We also would not be eligible for status as a smaller reporting company if we become an investment company, an asset-backed issuer or a majority-owned subsidiary of a parent company that is not a smaller reporting company.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

SUMMARY OF THE OFFERING

Issuer	60 Degrees Pharmaceuticals, Inc.
Units offered by us	1,415,095 Units, each Unit consisting of one share of common stock, one Tradeable Warrant to purchase one share of common stock and one Non-tradeable Warrant to purchase one share of common stock. The Units will not be certificated or issued in stand-alone form. The shares of our common stock and the warrants comprising the Units are immediately separable upon issuance and will be issued separately in this offering.
Common stock outstanding prior to the offering[(1)]	2,378,009 shares
Common stock to be outstanding after the offering[(2)(3)]	5,569,528 shares (5,781,793 shares if the underwriters exercise their option to purchase additional shares in full).
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to an aggregate of 212,265 additional shares of common stock and/or 212,265 Tradeable Warrants and/or 212,265 Non-tradeable Warrants at the public offering price per share of common stock and per warrant, respectively, less, in each case, underwriting discounts and commissions, on the same terms as set forth in this prospectus, solely to cover over-allotments, if any.
Description of the Warrants	The Tradeable Warrants will be exercisable from the date of issuance until the fifth anniversary date of issuance date for $4.945 and $7.245 per share (115% of the public offering price of one Unit), subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock as described herein. The Non-tradeable Warrants will be exercisable from the date of issuance until the fifth anniversary date of issuance date for $5.16 and $7.56 per share (120% of the public offering price of one Unit), subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock as described herein. A holder may not exercise any portion of a warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of the outstanding common stock after exercise, as such percentage ownership is determined in accordance with the terms of the warrants, except that upon notice from the holder to us, the holder may waive such limitation up to a percentage, not in excess of 9.99%. The terms of the warrants will be governed by the Warrant Agent Agreement. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants. See "*Description of Securities–Warrants*."
Use of Proceeds	The principal purposes of this offering are to fund the development of new indications for our products with a focus on executing a COVID-19 clinical trial involving Arakoda, to repay debt associated with prior financing, increase our capitalization and financial flexibility, increase our visibility in the marketplace and create a public market for our common stock. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. However, we currently intend to use the net proceeds to us from this offering for debt repayment and research and general corporate purposes, including working capital. See "*Use of Proceeds*" beginning on page 54.
Proposed Listing	We have applied to have our common stock and Tradeable Warrants listed on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively, which listing is a condition to this offering. We do not intend to apply for listing of the Non-tradeable Warrants on any exchange or market.
Representative Warrants	Upon the closing of this offering, we have agreed to issue to the Representative, warrants that will expire on the fifth anniversary of the commencement date of sales in this offering, entitling the Representative to purchase 6% of the number of shares of common stock sold in this offering. The registration statement of which this prospectus is a part also covers the

	Representative Warrants and the shares of common stock issuable upon the exercise thereof. For additional information regarding our arrangement with the underwriters, please see "*Underwriting*."
Lock-up agreements	Our executive officers and directors have agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for six months following the effective date of the registration statement for this offering without the prior written consent of WallachBeth Capital LLC. Any other holders of more than 5% of the outstanding shares of our common stock have also agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for six months following the effective date of the registration statement for this offering without the prior written consent of the underwriters. For additional information regarding our arrangement with the underwriters, please see "*Underwriting*."
Knight Therapeutics Preferred Stock	Knight will be granted 80,965 preferred shares (share price of $100, total value $8,096,500) in consideration for extinguishment of accumulated interest associated with their loans. The preferred shares are nonvoting, have a 6% cumulative dividend accumulating annually on March 31st, are not redeemable and are convertible into shares of common stock solely at the discretion of the Company, determined by (A) multiplying the number of shares of Series A Preferred Stock to be converted by $100, (B) adding to the result all accrued and accumulated and unpaid dividends on such shares to be converted, if any, and then (C) dividing the result by a price equal to the lower of (1) $100, (2) the price paid for the shares of common stock in this offering and (3) the 10-day volume weighted average share price immediately preceding our election to convert the shares of Series A Preferred Stock; provided that the conversion of the shares of Series A Preferred Stock does not result in the holder's ownership of common stock exceeding 19.9%.
Transfer Agent	Equity Stock Transfer, LLC.
Risk Factors	You should carefully consider the information set forth in this prospectus and, in particular, the specific factors set forth in the "*Risk Factors*" section beginning on page 20 of this prospectus before deciding whether or not to invest in shares of our common stock.

(1) As of June 1, 2023 and excludes 238,601 shares of common stock reserved for issuance under our 2022 Equity Incentive Plan.

(2) Includes (i) 29,245 shares of our common stock issued to BioIntelect Pty Ltd ("BioIntelect") pursuant to the Master Consultancy Agreement dated as of May 29, 2013 (the "BioIntelect Agreement"), which provides that in connection with our initial public offering, BioIntelect will be entitled to receive deferred equity compensation in the amount equal to $155,000 (or $245,000 if Australian VC Horizon Biotech participates in the offering), (ii) 1,108,337 shares of our common stock that are to be issued to Knight Therapeutics International S.A. (formerly known as Knight Therapeutics (Barbados) Inc.) ("Knight") determined by dividing the outstanding principal amount as of March 31, 2022 of $10,770,037 by the public offering price discounted by 15%, up to 19.9% of our outstanding common stock after giving effect to the initial public offering, for a total value of common shares to be issued of $5,874,186 pursuant to the Debt Conversion Agreement dated as of January 9, 2023, as amended on January 19, 2023 and January 27, 2023 (the "Knight Debt Conversion Agreement"), (iii) 383,908 shares of our common stock that are to be issued prior to the closing of this offering as a result of either the conversion or extinguishment of our interim financing notes totaling $1,949,991 excluding the Xu Yu Equity Conversion Note, (iv) 214,934 shares of our common stock that are to be issued prior to the closing of this offering as a result of the conversion of certain debt totaling $1,164,190 pursuant to the Equity Conversion Note dated as of October 11, 2017, as amended on December 23, 2017 and December 11, 2022 (the "Xu Yu Equity Conversion Note") entered into with Xu Yu and (v) 40,000 shares of our common stock valued at $5.00 per share that are to be issued to four of our directors on the date of effectiveness of the registration statement of which this prospectus forms a part.

(3) Does not include (i) 31,447 shares of our common stock underlying a warrant issued to Bigger Capital Fund, LP with an exercise price equal to 110% of the initial public offering price of the Units, (ii) 26,205 shares of our common stock underlying a warrant issued to Cavalry Investment Fund, LP with an exercise price equal to 110% of the initial public offering price of the Units, (iii) 26,205 shares of our common stock underlying a warrant issued to Walleye Opportunities Master Fund Ltd with an exercise price equal to 110% of the initial public offering price of the Units, (iv) 10,482 shares of our common stock underlying a warrant issued to Geoffrey Dow (in the form of his revocable grantor trust, the Geoffrey S. Dow Revocable Trust for which Mr. Dow is the sole trustee) with an exercise price equal to 110% of the initial public offering price of the Units, (v) 69,444 shares of our common stock underlying a warrant issued to Mountjoy Trust with an exercise price equal to 110% of the initial public offering price of the Units, (vi) 10,482 shares of our common stock underlying a warrant issued to Cyberbahn Federal Solutions, LLC with an exercise price equal to 110% of the initial public offering price of the Units, (vii) 10,482 shares of our common stock underlying a warrant issued to Ariana Bakery Inc with an exercise price equal to 110% of the initial public offering price of the Units, (viii) 31,447 shares of our common stock underlying a warrant issued to Sabby Volatility Warrant Master Fund, Ltd. with an exercise price equal to 110% of the initial public offering price of the Units, (ix) 5,241 shares of our common stock underlying a warrant issued to Steel Anderson with an exercise price equal to 110% of the initial public offering price of the Units, (x) 10,482 shares of our common stock underlying a warrant issued to Bixi Gao & Ling Ling Wang with an exercise price equal to 110% of the initial public offering price of the Units, (xi) 84,906 shares of our common stock issuable upon the exercise of the Representative Warrants with an exercise price equal to 110% of the initial public offering price of the Units, (xii) 238,601 shares of common stock reserved for issuance under our 2022 Equity Incentive Plan and (xiii) $40,000 in value of shares of our common stock, based on the 30 day average after the IPO, to be issued pursuant to the Red Chip services agreement.

Except as otherwise indicated, all information in this prospectus assumes that:

- a public offering price of $5.30 per Unit, which is the midpoint of the range of the offering price per Unit;
- no shares of common stock have been issued pursuant to the (i) conversion of certain of our outstanding debt owed to Knight, (ii) BioIntelect Agreement, (iii) conversion and extinguishment of our interim financing notes and (iv) Xu Yu Equity Conversion Note;
- no shares of common stock have been issued pursuant to any warrants or options; and
- no shares of common stock have been issued pursuant to the Representative's over-allotment option;
- no shares of common stock have been issued pursuant to the Representative Warrants.

SUMMARY FINANCIAL DATA

The following tables summarize our financial data. We derived the summary financial statement data for the years ended December 31, 2022 and 2021 set forth below from our audited financial statements and related notes contained in this prospectus, and the summary financial statement data for the three months ended March 31, 2023 and March 31, 2022 set forth below from our unaudited financial statements and related notes contained in this prospectus. The unaudited interim financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the information presented below together with "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," our financial statements, the notes to those statements and the other financial information contained in this prospectus.

Summary of Operations in U.S. Dollars

	Year Ended December 31,		Three Months Ended March 31,	
	2022	2021	2023 (unaudited)	2022 (unaudited)
Product revenues – net of discounts and rebates	$ 192,913	$ 1,078,440	$ 17,172	$ 47,024
Service revenues	30,295	81,900	-	-
Product and service revenues	223,208	1,160,340	17,172	47,024
Cost of revenues	432,370	850,742	73,120	90,134
Gross profit (loss)	(209,162)	309,598	(55,948)	(43,110)
Research revenues	288,002	5,192,516	4,292	117,147
Net revenue	78,840	5,502,114	(51,656)	74,037
Operating expenses:				
Research & development	525,563	5,510,866	123,994	63,057

General and administrative expenses	1,303,722	1,115,350	775,014	174,692
Total operating expenses	1,829,285	6,626,216	899,008	237,749
Loss from operations	(1,750,445)	(1,124,102)	(950,664)	(163,712)
Interest and other income (expense), net:				
Interest expense	(3,989,359)	(3,172,712)	(1,141,429)	(762,217)
Derivative expense	(504,613)	-	-	-
Change in fair value of derivative liabilities	(10,312)	-	(5,134)	-
Gain (loss) on debt extinguishment	120,683	-	(839,887)	-
Change in fair value of promissory note	-	-	339,052	-
Other income (expense)	(43,238)	37,515	591	18,732
Total interest and other income (expense), net	(4,426,839)	(3,135,197)	(1,646,807)	(743,485)
Loss from operations before provision for income taxes	(6,177,284)	(4,259,299)	(2,597,471)	(907,197)
Provision for income taxes	500	1,000	63	250
Net loss including noncontrolling interest	$ (6,177,784)	$ (4,260,299)	$ (2,597,534)	$ (907,447)

	As of December 31,		As of March 31,
	2022	2021	2023 (unaudited)
Consolidated Balance Sheet Data:			
Total assets	$ 1,297,206	$ 1,393,527	$ 7,586,974
Total liabilities	25,446,266	19,548,011	27,119,858
Total liabilities and members' equity (deficit)	-	1,393,527	-
Total liabilities and stockholders' equity (deficit)	$ 1,297,206	$ -	$ 7,586,974

RISK FACTORS

Our business is subject to many risks and uncertainties, which may affect our future financial performance. If any of the events or circumstances described below occur, our business and financial performance could be adversely affected, our actual results could differ materially from our expectations, and the price of our stock could decline. The risks and uncertainties discussed below are not the only ones we face. There may be additional risks and uncertainties not currently known to us or that we currently do not believe are material that may adversely affect our business and financial performance. You should carefully consider the risks described below, together with all other information included in this prospectus, including our financial statements and related notes, before making an investment decision. The statements contained in this prospectus that are not historic facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those set forth in or implied by forward-looking statements. If any of the following risks actually occurs, our business, financial condition or results of operations could be harmed. In that case, the trading price of our common stock could decline, and investors in our securities may lose all or part of their investment.

Risks Related to Our Business

Our financial statements have been prepared on a going-concern basis and our continued operations are in doubt.

The financial statements have been prepared on a going concern basis under which an entity is considered to be able to realize its assets and satisfy its liabilities in the ordinary course of business. Our future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that we will be successful in completing an equity or debt financing or in achieving profitability.

We have incurred net losses since our inception and if we continue to incur net losses in the foreseeable future, the market price of our common stock may decline.

To date, we have financed our operations primarily through the issuance of equity, promissory notes and convertible notes. We incurred annual net losses of $6,177,784 in 2022 and $4,260,299 in 2021, respectively and operating losses were $1,750,445 in 2022 and $1,124,102 in 2021. We had an accumulated deficit of $28,815,148 as of December 31, 2022 ($22,633,428 as of December 31, 2021). For the quarterly period ending March 31, 2023, we incurred a net loss of $2,600,061 and an operating loss of $950,664 and now have accumulated losses of $31,415,209.

We may not achieve or maintain profitability in the future. In particular, we expect that our expenses relating to sales and marketing and product development and support, as well as our general and administrative costs, will increase, requiring us to increase sales in order to achieve and maintain profitability. If we do not achieve and maintain profitability, our financial condition will be materially and adversely affected. We would eventually be unable to continue our operations unless we were able to raise additional capital. We may not be able to raise any necessary capital on commercially reasonable terms or at all. If we fail to achieve or maintain profitability on a quarterly or annual basis within the timeframe expected by investors, the market price of our common stock may decline.

There is no assurance that we will be profitable.

There is no assurance that we will earn profits in the future, or that profitability will be sustained. There is no assurance that future revenues will be sufficient to generate the funds required to continue our business and product development and marketing activities. If we do not have sufficient capital to fund our operations, we may be required to reduce our sales and marketing efforts or forego certain business opportunities.

There is no assurance we will be eligible for Australian Government research and development tax credits and eligibility rules might change in a manner that jeopardizes our business.

There is no assurance that the Australian government will pay research and development rebates on our research activities conducted by our subsidiary, 60P Australia Pty Ltd, in Australia. There is no assurance that we will be able to demonstrate that our subsidiary will have < $20 million AUD in aggregate turnover amongst beneficial owners with > 40% beneficial interest. If any of these risks materialize, we might not be able to complete our planned COVID-19 clinical study, which would negatively impair our business.

Even if Australian government grants an overseas finding, if we could not raise additional financing to fund the linked Australian research and development activities. Also, it is possible depending on evolving interpretations by the Australian Tax Office of the legislation, that matching Australian core research might not be eligible for consideration when a determination of an overseas finding is made. Either of these scenarios if realized might require us to refund any rebates on the COVID-19 clinical study to the Australian government or result in us not being to obtain rebates, thereby negatively impairing our business.

We have limited revenues to date, and any potential revenues from commercial use may not materialize in the future.

We have earned limited revenues to date from Arakoda. Any potential revenues from the sale of current approved commercial use may not materialize in the future. There is no guarantee that we will be able to generate revenue in the future. No assurance can be given that our efforts from sale of current approved products for commercial use will be successful in the future.

Our financial condition and results of operations may be adversely affected by the COVID-19 pandemic.

A significant outbreak, epidemic or pandemic of contagious diseases in any geographic area in which we operate or plan to operate could result in a health crisis adversely affecting the economies, financial markets and overall demand for our services in such areas. In addition, any preventative or protective actions that governments implement or that we take in response to a health crisis, such as travel restrictions, quarantines, or site closures, may interfere with the ability of our employees, suppliers and customers to perform their responsibilities. Such results could have a material adverse effect on our business.

The continued global COVID-19 pandemic has created significant volatility, uncertainty and economic disruption. To date, this pandemic has affected nearly all regions around the world. In the United States, businesses as well as federal, state and local governments implemented significant actions to mitigate this public health crisis. While we cannot predict the duration or scope of the COVID-19 pandemic, it may negatively impact our business and such impact could be material to our financial results, condition and outlook related to:

- disruption to our operations or the operations of our suppliers, through the effects of business and facilities closures, worker sickness and COVID-19 related inability to work, social, economic, political or labor instability in affected areas, transportation delays, difficulty in enrolling patients, travel restrictions and changes in operating procedures, including for additional cleaning and safety protocols;

- increased volatility or significant disruption of global financial markets due in part to the COVID-19 pandemic, which could have a negative impact on our ability to access capital markets and other funding sources, on acceptable terms or at all and impede our ability to comply with debt covenants; and

- the further spread of COVID-19, and the requirements to take action to mitigate the spread of the pandemic (e.g., vaccination requirements that have been and continue to be taken in response to the pandemic and enhanced health and hygiene requirements or social distancing or other measures), will impact our ability to carry out our business as usual and may materially adversely impact global economic conditions, our business, results of operations, cash flows and financial condition.

To the extent the COVID-19 pandemic or a similar public health threat has an impact on our business, it is likely to also have the effect of heightening many of the other risks described in this "*Risk Factors*" section.

If COVID-19 cases decline, it could jeopardize our business and make us less profitable.

Although the number of U.S. cases of COVID-19 remains high, it is possible that this may not be the case in the future. Since our major business objective is to conduct clinical trials to evaluate the use of the Arakoda regimen of Tafenoquine for treatment of COVID-19, a future decline in U.S cases would reduce our sales and profitability, and therefore harm our business.

U.S. public sector procurement of Arakoda might not materialize in the future, which could jeopardize our business.

Sales to the U.S. DoD were important to our revenue stream in the recent past. Although, as of the date of this prospectus, we were not in discussions with the DoD about additional/future procurement, we anticipate that this will be feasible in the future if one or more of the conditions/events described in this paragraph occur. First, the position of Arakoda in the DoD formulary (Tricare, deployed personnel) needs to be improved from second/third tier to at least equivalency with competing products (as is the case for civilian use as recommended by the CDC). Second, the shelf-life of the existing product requires extension, which is known to be technically possible as the shelf-life of Kodatef in Australia is 48 months, but appropriate data must be generated to meet FDA requirements. Finally, a change in the operational footprint of DoD deployments to areas with higher malaria attack rates (e.g., the Liberia deployment to manage the Ebola outbreak in 2014) may lead to a rapid reassessment by DoD of the position of Arakoda in the formulary (advancement of the last approved prophylactic antimalarial to co-equal standard of care took thirteen years). It is possible that none of these events would transpire, which would reduce our revenues and jeopardize our business.

Supply chain disruptions across the globe, including in the U.S., could jeopardize our business and harm our operations.

Global business interruptions may adversely impact our third-party relationships whom we rely upon in our business as well as manufacturers, suppliers, and makers of raw materials. If any such parties are adversely impacted by supply chain restrictions, or if they cannot obtain the necessary supplies, or if such third parties need to prioritize other products or customers over us, we may experience delays or disruptions in our supply chain, which could have a material and adverse impact on our business. Third-party manufacturers may also need to implement measures and changes, or deviate from typical requirements because of the COVID-19 pandemic that may otherwise adversely impact our supply chain or the quality of the resulting products or supplies. Depending on the change, we may need to obtain FDA approval or otherwise provide the FDA with a notification of the change. As a result, we may not be able to obtain sufficient quantities of certain items, which could impair our ability to commercialize our products and conduct the post-marketing studies requested by the FDA, in connection with the approval of our goods. In addition, if there are continued or future disruptions, our third-party manufacturers may not be able to supply our other potential product candidates, which would adversely affect our research and development activities.

We may lose the services of key management personnel and may not be able to attract and retain other necessary personnel.

Changes in our management could have an adverse effect on our business. This is especially an issue while our staff is small. We are dependent upon the active participation of several key management personnel, including Geoffrey Dow, our President and Chief Executive Officer. We also do not carry key person life insurance on any of our senior management or other key personnel. Hence, we may suffer if the services of our management were to become unavailable to us in the future.

We must hire highly skilled technical personnel as employees and as independent contractors in order to develop our products. As of the date of this prospectus, we have two full-time employees, and we rely on two independent contractors to provide us with skilled technical support. The competition for highly skilled technical, managerial and other personnel is intense and we may not be able to retain or recruit such personnel. Our recruiting and retention success is substantially dependent on our ability to offer competitive salaries and benefits to our employees and competitive compensation to contractors. We must compete with companies that possess greater financial and other resources than we do and that may be more attractive to potential employees and contractors. To be competitive, we may have to increase the compensation, bonuses, stock options and other fringe benefits offered to employees in order to attract and retain such personnel. The costs of retaining or attracting new personnel may have a material adverse effect on our business and operating results. If we fail to attract and retain the technical and managerial personnel needed to be successful, our business, operating results and financial condition could be materially adversely affected.

Cybersecurity risks could adversely affect our business and disrupt our operations.

The threats to network and data security are increasingly diverse and sophisticated. Despite our efforts and processes to prevent breaches, our devices, as well as our servers, computer systems, and those of third parties that we use in our operations are vulnerable to cybersecurity risks, including cyber-attacks such as viruses and worms, phishing attacks, denial-of-service attacks, physical or electronic break-ins, employee theft or misuse, and similar disruptions from unauthorized tampering with our servers and computer systems or those of third parties that we use in our operations, which could lead to interruptions, delays, loss of critical data, and unauthorized access to user data. In addition, we may be the target of email scams that attempt to acquire personal information or our assets. Despite our efforts to create security barriers to such threats, we may not be able to entirely mitigate these risks. Any cyber-attack that attempts to obtain our or our users' data and assets, disrupt our service, or otherwise access our systems, or those of third parties we use, if successful, could adversely affect our business, operating results, and financial condition, be expensive to remedy, and damage our reputation. In addition, any such breaches may result in negative publicity, adversely affect our brand, decrease demand for our products and services, and adversely affect our operating results and financial condition.

The illegal sale or distribution by third parties of counterfeit versions of our products could have a negative impact on our business.

Pharmaceutical products are vulnerable to counterfeiting. Third parties may illegally produce and distribute counterfeit versions of our products that are below the various manufacturing and testing standards that our products undergo. Counterfeit products are often unsafe, ineffective and potentially life-threatening. As many counterfeit products may be visually indistinguishable from their authentic versions, the presence of counterfeit products could affect overall consumer confidence in the authentic product. A public loss of confidence in the integrity of pharmaceutical products in general or in any of our products in particular due to counterfeiting could have a material adverse effect on our business, prospects, financial condition and results of operations.

If we encounter difficulties enrolling patients in any future clinical trials, our future trials could be delayed or otherwise adversely affected. Furthermore, our current COVID-19 trials may not necessarily yield sufficient results or patient participants.

If we have difficulty enrolling a sufficient number of patients in any future clinical trial, including for COVID-19 studies for which the number of cases is unpredictable, we may need to delay or terminate our trial, which would impair our ability to develop marketable products, and have a negative impact on our business. Delays in enrolling patients in any future clinical trials would also adversely affect our ability to generate any product, milestone and royalty revenues under collaboration agreements, if any, and could impose significant additional costs on us or on any future collaborators.

Our clinical trials for our product candidates may not yield results that will enable us to further develop our products and obtain regulatory approvals necessary to sell them.

We will receive regulatory approval for our product candidates only if we can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. We do not know whether any current or future clinical trials for Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or Celgosivir or any other product candidate will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products.

Clinical trials are lengthy, complex and expensive processes with uncertain results. We have spent, and expect to continue to spend, significant amounts of time and money on the clinical development of our product candidates. The three clinical trials we conducted in the past were managed directly by us, but executed contract research organizations ("CROs"). While certain of our employees have experience in designing and administering clinical trials, our experience is limited to three clinical trials conducted by the management team.

The results we obtain in preclinical testing and early clinical trials may not be predictive of results that are obtained in later studies. We may suffer significant setbacks in advanced clinical trials, even after seeing promising results in earlier studies. Based on results at any stage of clinical trials, we may decide to repeat or redesign a trial or discontinue development of one or more of our product candidates. If we fail to adequately demonstrate the safety and efficacy of our products under development, we will not be able to obtain the required regulatory approvals to commercialize our product candidates, and our business, results of operations and financial condition would be materially adversely affected.

Administering our product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications.

If clinical trials for a product candidate are unsuccessful, we will be unable to commercialize the product candidate. If one or more of our clinical trials are delayed, we will be unable to meet our anticipated development timelines. Either circumstance could cause the market price of our common stock to decline.

In planning for, and executing, clinical trials, the targeted standard of care in the United States or other jurisdictions for the therapeutic indication may change, necessitating changes to the design of such trials. Changes to such design trials will cause delays, and increase costs, thereby rendering us unable to meet development timelines or complete development programs. The clinical data generated from clinical trials may not be acceptable to regulatory agencies if changes to the standard of care occurred during trial execution, which may prevent regulatory approval, thereby damaging our business prospects.

Because patients with COVID-19 disease enrolled in our Phase II clinical study of Tafenoquine (Arakoda regimen) were presumed to be mostly infected with the SARS-CoV-2 delta variant, it is possible that the results of the study might not be representative of those of future studies of Tafenoquine (Arakoda regimen) that utilize patients infected with newer viral strains. If this risk materialized, our planned clinical trial might fail, thereby damaging our business prospects. It should be stated that, due to the changing nature of the pandemic, this risk is common to all COVID-19 therapeutics. It is possible this risk may be less likely to occur if the mechanism of Tafenoquine turns out not to be mediated via a direct antiviral effect.

Because our 2021 Phase II clinical study of Tafenoquine (Arakoda regimen) in COVID-19 patients was small, it is possible that the magnitude of clinical benefit implied in Figure B listed in "*Prospectus Summary—Strategy*" (a three-day acceleration of recovery in the Tafenoquine arm) may be an overestimate of the true therapeutic effect of Tafenoquine (Arakoda regimen). We have attempted to mitigate this risk in our planned Phase IIB clinical trial design by providing for an interim analysis at 75% patient enrollment which will include a sample size reanalysis, which would allow additional enrollment of patients if required without study termination. If additional patients did need to be enrolled, it would increase the overall cost of the study. This risk mitigation strategy would not work if the true therapeutic benefit of Tafenoquine (Arakoda regimen) is minimal or non-existent, or actual patient to patient variability is larger than assumed. Any of those outcomes might result in failure of the study.

We believe that the inclusion of a placebo arm in our planned Phase IIB study is ethical because there are not any FDA-approved orally administered medications available for patients with low risk of disease progression. However, because the standard of care for COVID-19 is evolving, it is possible that FDA or an Ethics Committee may not agree with our assessment that inclusion of a placebo arm in our Phase IIB study is ethical. If this risk was realized, it might result in (i) wasted expenditure on development of clinical sites if this was done aggressively in parallel with seeking FDA feedback (a typical approach in the industry), and/or (ii) necessitate conducting our trial outside the United States in jurisdictions without approved oral antivirals and accepting a greater risk of failing an FDA audit of the study in the future and/or (iii) replacement of the placebo control with an active control arm and accepting the greater cost associated with such a study design (because they require a higher number of patients). To mitigate against the first risk, we are planning to initiate preparations for the clinical trial at only a small number of sites in parallel with seeking FDA and Ethics Committee feedback. If either of the second or third risks materialized, our business might be irreparably harmed.

Because the number of COVID-19 cases is episodic, and the severity of the COVID-19 disease is generally perceived as being milder than it was earlier in the pandemic meaning patients seek out medical treatment less often, it is possible that that there may be fewer COVID-19 patients available to be enrolled than expected in our study. If this risk materialized, it would result in slower recruitment in our study than planned, forcing either a delay in the timeline for data being available, or increasing the overall cost in order to increase the number of study sites, or both. Either eventuality would harm our business.

The mechanisms of actions of some of our products, and interactions with other antiviral products are not known, which may restrict regulatory label claims.

The FDA has granted full or limited marketing authority for COVID-19 products based on the clinical benefit demonstrated in clinical trials, for products that have both antiviral and non-antiviral modes of action. However, the FDA may require specific additional evidence to grant a labeling claim of antiviral activity. We are planning to further develop Tafenoquine (Arakoda regimen) for treatment of COVID-19 based on the observation of trends towards accelerated recovery observed in the exploratory endpoints of a Phase II clinical trial we recently completed. We plan to undertake limited research activities to confirm whether Tafenoquine provides clinical benefit via an antiviral or other mechanism. However, we cannot guarantee such efforts will confirm a direct antiviral mechanism to the satisfaction of the FDA, or that any data generated will support regulatory claims of antiviral activity in additional to whatever claims related to clinical benefit in COVID-19 treatment that the FDA may allow. Relatedly, the FDA required warning language to be placed on the remdesivir label related to a theoretical drug-drug interaction with other antimalarials based on in vitro (not clinical) data. Although we have conducted in vitro drug interactions studies of Tafenoquine versus molnupiravir, remdesivir, and paxlovid, which do not suggest the possibility of

clinically meaningful antagonism, we cannot guarantee these studies will discharge any theoretical risks or concerns regulators may have (including the need for disclaimers or warning labels).

We will rely on contract research organizations to conduct substantial portions of our clinical trials, including any future clinical trial of Arakoda Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or Celgosivir, and as a result, we will be unable to directly control the timing, conduct and expense of all aspects of our clinical trials.

We do not currently have sufficient staff to conduct our clinical trials ourselves, and therefore, we will rely on third parties to conduct certain aspects of any future clinical trials. We previously contracted with a CRO to conduct components of our clinical trials and anticipate contracting with a CRO to conduct components of any future clinical trial for Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or Celgosivir or any future clinical trials for our other product candidates. As a result, we will have less control over many details and steps of any clinical trial, the timing and completion of any clinical trial, the required reporting of adverse events and the management of data developed through any clinical trial than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties, such as CROs, may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our clinical trial. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternative service provider. However, making any change may be costly and may delay ongoing trials, if any, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct clinical trials in an acceptable manner and at an acceptable cost.

Even though we anticipate relying on CROs in the future, we will likely have to devote substantial resources and rely on the expertise of our employees to manage the work being done by the CROs. We and our management team have experience in managing clinical trials being executed on our behalf by CROs based on three clinical studies. Therefore, we cannot guarantee that our employees will manage such studies effectively in the future.

We expect to depend on existing and future collaborations with third parties for the development of some of our product candidates. If those collaborations are not successful, we may not be able to complete the development of these product candidates.

Collaborations involving our product candidates pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator’s strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- collaborators may not comply with regulatory requirements and as a result their operations may be disrupted or ended until they resolve their regulatory issues with government officials;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- collaborators may elect to take over manufacturing rather than retain us as manufacturers and may encounter problems in starting up or gaining approval for their manufacturing facility and so be unable to continue development of product candidates;

- we may be required to undertake the expenditure of substantial operational, financial and management resources in connection with any collaboration;

- we may be required to issue equity securities to collaborators that would dilute our existing stockholders' percentage ownership;

- we may be required to assume substantial actual or contingent liabilities;

- collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products; and

- collaborators may experience financial difficulties.

We face a number of challenges in seeking additional collaborations. Collaborations are complex and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors, such as the design or results of our clinical trials, the potential market for our product candidates, the costs and complexities of manufacturing and delivering our product candidates to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our intellectual property, and industry and market conditions generally. If we were to determine that additional collaborations for our Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or Celgosivir development program are necessary and were unable to enter into such collaborations on acceptable terms, we might elect to delay or scale back the development or commercialization of Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or Celgosivir in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

Collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

Any future clinical trial for Tafenoquine (all regimens) will require screening for G6PD deficiency in order to safely administer the product. In the United States, G6PD testing can obtained through commercial pathology services which is associated with delays. The use of a third-party diagnostic provider of point of care testing may be required and we do not directly control the timing, conduct and expense of such testing.

According to prescribing information for Arakoda, administration of a test for G6PD deficiency is required before administration in order prevent the occurrence of hemolytic anemia that has been observed in some patients who have G6PD deficiency and were inadvertently administered Arakoda in clinical trials. Therefore, G6PD deficiency is an exclusion criteria in clinical trials involving Tafenoquine (all regimens).

For clinical trials administered in the United States, G6PD testing is provided through commercial pathology companies including Labcorp and Quest Diagnostics. Such testing, while usually available with 72-hour turnaround time, may sometimes take much longer. There is a single FDA-approved point of care test (Abbott's Binax Now) but this requires administration in a CLIA-certified laboratory, which not all clinical trial sites have access to.

For many clinical trials, and in particular those involving viral diseases, rapid administration of the investigational agent is required to maximize efficacy. Therefore, we will attempt to import and utilize hand-held point of care tests approved elsewhere in the world in our clinical trials involving Tafenoquine (any regimen). We may not be successful in this process, which would compromise our ability to recruit patients or result in a lower-than-expected effect of Tafenoquine (any regimen) in such a trial.

Tafenoquine (all regimens) requires administration of a G6PD test. The lack of point of care tests may negatively impair sales of Arakoda or other drug regimens containing Tafenoquine.

A G6PD test need only be administered once and can be recorded in electronic health records for future reference. The commercial providers of G6PD testing in the United States will usually only commit to at best a 72-hour turn-around time for G6PD testing. Thus, while this does not present a problem in principle for the existing malaria indication for individuals who travel frequently, or for organizations with organized occupational health and safety programs where G6PD testing results are held on file, it may be a barrier to use of Arakoda by first time travelers or those planning to travel and hence be a barrier to use of Arakoda if prospective patients are unwilling or unable to take the G6PD test.

If it is confirmed that the Mode of Action of Tafenoquine in COVID-19 is via a direct antiviral mechanism, it is likely that, as with other antivirals, rapid administration of the product is important to maximize efficacy. Therefore, it is possible that the current lack of an FDA-approved, widely available point of care G6PD test will negatively impact sales of Tafenoquine (any regimen) for COVID-19, under the assumption that the FDA eventually approves Arakoda (or other) regimen of Tafenoquine for this indication and appropriate G6PD tests are never approved by FDA.

Several third-party diagnostic test companies are developing point of care G6PD tests (or platforms that would accommodate them) that utilize finger stick blood samples and which may be appropriate for use in the United States. One of these tests is approved in Brazil and Australia.[33] Another is available for use in Europe and was recently approved by the FDA in the United States.[34] A third test is being developed with the NIH grant support for the U.S. and ex U.S. markets and is in clinical development.[35] There is no guarantee that tests will succeed in clinical development or ever become commercially available to the public. Having to take a test at all, or to go to a third-party lab in order to take the test, may be a hindrance to the use of Arakoda, which would negatively impact our sales.

Our product candidates are subject to extensive regulation, which can be costly and time-consuming, and unsuccessful or delayed regulatory approvals could increase our future development costs or impair our future revenue.

The preclinical and clinical development, testing, manufacture, safety, efficacy, labeling, storage, recordkeeping, and subsequent advertising, promotion, sale, marketing, and distribution, if approved, of our product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and elsewhere. These regulations also vary in important, meaningful ways from country to country. We are not permitted to market a potential new drug in the United States until we receive approval of an NDA from the FDA for such drug. We have received an NDA approval for Arakoda for malaria prevention, but have not received approval from the FDA for any non-malaria prevention indications for Tafenoquine (Arakoda regimen), Tafenoquine or any NDA approval from the FDA for Celgosivir or any of our other product candidates. There can be no guarantees with respect to our product candidates that clinical studies will adequately support an NDA, that the products will receive necessary regulatory approvals, or that they will prove to be commercially successful.

[33] https://www.sdbiosensor.com/product/product_view?product_no=183.

[34] Baebies Receives FDA 510(k) Clearance for G6PD Test on FINDER Platform | Baebies.

[35] https://ivd.solutions/grant/.

To receive regulatory approval for the commercial sale of any product candidates, we must demonstrate safety and efficacy in humans to the satisfaction of regulatory authorities through preclinical studies and adequate and well-controlled clinical trials of the product candidates. This process is expensive and can take many years, and failure can occur at any stage of the testing. Our failure to adequately demonstrate the safety and efficacy of our product candidates will prevent regulatory approval and commercialization of such products.

In the event that we or our collaborators conduct preclinical studies that do not comply with Good Laboratory Practices ("GLP"), or incorrectly design or carry out human clinical trials in accordance with Good Clinical Practices ("GCP"), or those clinical trials fail to demonstrate clinical significance, it is unlikely that we will be able to obtain FDA approval for product development candidates. Our inability to successfully initiate and effectively complete clinical trials for any product candidate on schedule, or at all, will severely harm our business. Significant delays in clinical development could materially increase product development costs or allow our competitors to bring products to market before we do, impairing our ability to effectively commercialize any future product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidates for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an Institutional Review Board ("IRB") to conduct a clinical trial at a prospective study site;
- delays in recruiting patients to participate in a clinical trial, which may be due to the size of the patient population, eligibility criteria, protocol design, perceived risks and benefits of the drug, availability of other approved and standard of care therapies or, availability of clinical trial sites;
- other clinical trials seeking to enroll subjects with similar profile;
- failure of our clinical trials and clinical investigators to be in compliance with GCP;
- unforeseen safety issues, including negative results from ongoing preclinical studies;
- inability to monitor patients adequately during or after treatment;
- difficulty recruiting and monitoring multiple study sites; and
- failure of our third-party contract research organizations, clinical site organizations and other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines; and

- an insufficient number of patients who have, or are willing to have, a device implanted for monitoring and recording data.

In addition, any approvals we may obtain may not cover all of the clinical indications for which we seek approval or permit us to make claims of superiority over currently marketed competitive products. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use. If the FDA determines that a risk evaluation and mitigation strategy ("REMS") is necessary to ensure that the benefits of the drug outweigh the risks, we may be required to include as part of the NDA a proposed REMS that may include a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide better information to consumers about the drug's risks and benefits. Finally, approval could be conditioned on our commitment to conduct further clinical trials, which we may not have the resources to conduct or which may negatively impact our financial situation.

The manufacture and tableting of Arakoda, Tafenoquine (all regimens) or Celgosivir is, or will be done, by third-party suppliers, who must also meet current Good Manufacturing Practices ("cGMP") requirements and pass a pre-approval inspection of their facilities before we obtain marketing approval (now or in the future). All of our product candidates are prone to the risks of failure inherent in drug development. The results from preclinical animal testing and early human clinical trials may not be predictive of results obtained in later human clinical trials. Further, although a new product may show promising results in preclinical or early human clinical trials, it may subsequently prove unfeasible or impossible to generate sufficient safety and efficacy data to obtain necessary regulatory approvals. The data obtained from preclinical and clinical studies are susceptible to varying interpretations that may delay, limit or prevent regulatory approval, and the FDA and other regulatory authorities in the United States and elsewhere exercise substantial discretion in the drug approval process. The numbers, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the product candidate, the disease or condition for which the product candidate is intended to be used and the regulations and guidance documents applicable to any particular product candidate. The FDA or other regulators can delay, limit or deny approval of any product candidate for many reasons, including, but not limited to:

- side effects;
- safety and efficacy;
- defects in the design of clinical trials;
- new understanding related to the pharmacology of other related drug products and their side effects;
- the fact that the FDA or other regulatory officials may not approve our or our third-party manufacturer's processes or facilities; or
- the fact that new regulations may be enacted by the FDA or other regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a product candidate.

In light of widely publicized events concerning the safety of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of certain drug products, revisions to certain drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and approval. Data from clinical trials may receive greater scrutiny with respect to safety and the product's risk/benefit profile, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense, and a delay or failure in obtaining approval or approval for a more limited indication than originally sought. Aside from issues concerning the quality and sufficiency of submitted preclinical and clinical data, the FDA may be constrained by limited resources from reviewing and determining the approvability of an NDA or regulatory supplement for Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications or of a Celgosivir NDA in a timely manner.

In pursuing clinical development of Tafenoquine (Arakoda or other regimen) for a non-malaria prevention indication or Celgosivir for other indications, we will be required to amend existing prescribing information, or prepare a new NDA as appropriate. The FDA could approve Tafenoquine (Arakoda or other regimen) or Celgosivir, but without including some or all of the prescribing information that we have requested. For instance, the FDA could approve Tafenoquine (Arakoda or other regimen) or Celgosivir in a more limited patient population or include additional warnings in the drug's label. This, in turn, could substantially and detrimentally impact our ability to successfully commercialize Tafenoquine (Arakoda or other regimen) or Celgosivir and effectively protect our intellectual property rights in Tafenoquine (Arakoda or other regimen) or Celgosivir.

If we are not able to successfully develop, obtain FDA approval for, and provide for the commercialization of non-malaria prevention indications for Tafenoquine (Arakoda or other regimen) or Celgosivir in a timely manner, we may not be able to expand our business operations.

We currently have only a single product (Arakoda for malaria prevention) that has received regulatory approval for commercial sale. The process to develop, obtain regulatory approval for and commercialize potential product candidates is long, complex and costly. Any future development of Tafenoquine (Arakoda or other regimen for a non-malaria prevention indication) or Celgosivir, including initiating clinical trials, is dependent on obtaining additional financing, even if we enter into a strategic collaboration.

Failure to demonstrate that a product candidate, including Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or, in the future, Celgosivir, is safe and effective, or significant delays in demonstrating such safety and efficacy, would adversely affect our business. Failure to obtain marketing approval of Tafenoquine (Arakoda or other regimen for non-malaria prevention indications) or Celgosivir from appropriate regulatory authorities, or significant delays in obtaining such approval, would also adversely affect our business and could, among other things, preclude us from completing a strategic transaction or obtaining additional financing necessary to continue as a going concern.

Even if approved for sale, a product candidate must be successfully commercialized to generate value. Although we plan to undertake limited efforts through a contracts sales organization to begin commercialization activities for Arakoda for malaria prevention, we do not currently have the capital resources or management expertise to commercialize Tafenoquine (Arakoda other regimen for non-malaria prevention indications), or Celgosivir or any of our other product candidates and, as a result, will need to complete a strategic transaction, or, alternatively, raise substantial additional funds to enable commercialization of Arakoda, Tafenoquine (Arakoda or other regimen for non-malaria prevention indications) or Celgosivir or any of our other product candidates, if approved. Failure to successfully provide for the commercialization of Arakoda for its current malaria prevention application, or Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications or Celgosivir or any other product candidate, would damage our business.

If our product candidates receive regulatory approval, we would be subject to ongoing regulatory obligations and restrictions, and possible litigation exposure, which may result in significant expenses and limit our ability to develop and commercialize other potential products.

If a product candidate of ours is approved by the FDA or by another regulatory authority, we would be held to extensive regulatory requirements over product manufacturing, testing, distribution, labeling, packaging, adverse event reporting and other reporting to regulatory authorities, storage, advertising, marketing, promotion, distribution, and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the product candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in additional regulatory controls or restrictions on the marketing or use of the product or the need for post marketing studies, and could include suspension or withdrawal of the products from the market.

Furthermore, our third-party manufacturers and the manufacturing facilities that they use to make our product candidates are regulated by the FDA. Quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug manufacturers and their subcontractors are required to register their facilities and products manufactured annually with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA, state and/or other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our collaborators, may result in restrictions on the product, or on the manufacturing or laboratory facility, including a withdrawal of the drug from the market or suspension of manufacturing. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our third-party manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information.

The marketing and advertising of our drug products by our collaborators or us will be regulated by the FDA, certain state agencies or foreign regulatory authorities including the Federal Trade Commission ("FTC"). Violations of these laws and regulations, including promotion of our products for unapproved "off-label" uses or failing to disclose risk information, are punishable by criminal and civil sanctions and may result in the issuance of enforcement letters or other enforcement action by the FDA, U.S. Department of Justice, state agencies, or foreign regulatory authorities that could jeopardize our ability to market the product.

In addition to the FDA, state or foreign regulations, the marketing of our drug products by us or our collaborators will be regulated by federal, state or foreign laws pertaining to health care "fraud and abuse," such as the federal anti-kickback law prohibiting bribes, kickbacks or other remuneration for the order or recommendation of items or services reimbursed by federal health care programs. Many states have similar laws applicable to items or services reimbursed by commercial insurers. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including the Medicare, Medicaid and Veterans Affairs healthcare programs. Because of the far-reaching nature of these laws, we may be required to discontinue one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Any violations of these laws, or any action against us for violations of these laws, even if we successfully defend against it, could have a material adverse effect on our business, financial condition and results of operations.

If we, our collaborators or our third-party manufacturers fail to comply with applicable continuing regulatory requirements, our business could be seriously harmed because a regulatory agency may:

- issue untitled or warning letters;
- suspend or withdraw our regulatory approval for approved products;
- seize or detain products or recommend a product recall of a drug or medical device, or issue a mandatory recall of a medical device;
- refuse import or export of any of our drug products;
- refuse to approve pending applications or supplements to approved applications filed by us;
- suspend our ongoing clinical trials;
- restrict our operations, including costly new manufacturing requirements, or restrict the sale, marketing and/or distribution of our products;
- seek an injunction;
- pursue criminal prosecutions;
- close the facilities of our contract manufacturers; or
- impose civil or criminal penalties.

We could become subject to false claims litigation under federal statutes, which can lead to civil money penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state health care programs.

False claims statutes include the False Claims Act, which allows any person to bring a suit on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. These suits against pharmaceutical companies have increased significantly in volume and breadth in recent years. Some of these suits have been brought on the basis of certain sales practices promoting drug products for unapproved uses. This new growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay fines or restitution, or be excluded from the Medicare, Medicaid, Veterans Affairs and other federal and state healthcare programs as a result of an investigation arising out of such action. We may become subject to such litigation and, if we are not successful in defending against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

We could also become subject to false claims litigation and consumer protection claims under state statutes, which also could lead to civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in state health care programs. Of note, over the past few years there has been an increased focus on the sales and marketing practices of the pharmaceutical industry at both the federal and state level. Additionally, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be adopted that could prevent or delay regulatory approval of our product candidates or limit our ability to commercialize our products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere.

Failure to be included in formularies developed by MCOs and other organizations may impact the use of our products.

Managed Care Organizations (“MCOs”) and other third-party payers try to negotiate the pricing of medical services and products to control their costs. MCOs and pharmacy benefit managers typically develop formularies to reduce their cost for medications. These formularies can be based on the prices and therapeutic benefits of the available products. The breadth of the products covered by formularies varies considerably from one MCO to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the use of our products. If our products are not included within an adequate number of formularies, additional coverage criteria are required or if the patient’s cost-sharing obligations are high, our market share and gross margins could be adversely impacted, which could have a material adverse effect on our business.

Even if we obtain regulatory approvals and market our products as planned, there is no guarantee of widespread market acceptance and the results of our efforts to commercialize our products are uncertain.

Even if we are able to obtain and maintain regulatory approvals for our products, the success of our products depends upon achieving and maintaining market acceptance. Commercializing products is time-consuming, expensive and unpredictable. Furthermore, the market for products that address unmet medical needs is highly speculative. If we overestimate the market opportunity for any of our products or candidates, or if we are unsuccessful in gaining market share, these factors could have a material adverse effect on our business. There can be no assurance that we will be able to successfully commercialize our products or gain market acceptance for such products, including in new markets. New product candidates that appear promising in development may fail to reach the market or may have only limited or no commercial success. If any of our products fail to gain, or lose, market acceptance, our revenues could be adversely impacted, which in turn could have a material adverse effect on our business.

Levels of market acceptance for our products could be impacted by several factors, some of which are not within our control, including, among others:

- safety, efficacy, convenience and cost-effectiveness of our products as compared to products of our competitors;
- scope of approved uses and marketing approval;
- availability of patent or regulatory exclusivity;
- timing of market approvals and market entry;
- availability of alternative products from our competitors;
- acceptance of the price of our products;
- the shelf life of our products;
- effectiveness of our sales forces and promotional efforts;
- the level of reimbursement of our products;
- acceptance of our products on government and private formularies;
- ability to market our products effectively at the retail level or in the appropriate setting of care; and
- reputation of our products.

Unexpected safety, efficacy or other concerns, whether actual or perceived, about our products may arise which could have a material adverse effect on our business and operations.

Unexpected safety or efficacy concerns can arise with respect to our products, whether or not scientifically justified. These concerns are especially more likely to arise as our products are used or studied over longer periods of time or used by a wider group of patients, some of whom may be taking other medicines or have additional underlying health problems. Such developments can potentially result in product recalls, withdrawals and/or declining sales, as well as product liability, consumer fraud and/or other claims, any of which could have a material adverse effect on our business.

Any negative publicity about any of our products, such as the discovery of safety or efficacy issues, adverse events involving our products or even public rumors about such events, could have a material adverse effect on our business. In addition, the discovery of one or more significant problems with a product similar to one of our products that implicates (or are perceived to implicate) an entire class of products, or the withdrawal or recall of such similar products, could have an adverse effect on the sales of our products. New data about our products, or products similar to our products, could also cause us reputational harm and could negatively impact demand for our products (or result in product withdrawal), due to real or perceived side effects or uncertainty regarding safety or efficacy.

Reliance on third parties to commercialize Arakoda, Tafenoquine (Arakoda or other regimen) Celgosivir or our other product candidates could negatively impact our business. If we are required to establish a direct sales force in the United States and are unable to do so, our business may be harmed.

We have received FDA approval of Arakoda for malaria prevention. Arakoda entered the U.S. commercial supply chain in the third quarter of 2019. Sales have been limited due to the impact of the COVID-19 pandemic, and we accordingly suspended our efforts to build internal sales and marketing capability. Re-establishing such sales and marketing capability for the malaria indication would require substantial additional resources.

Future commercialization of Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or Celgosivir or any other product candidate, if approved, particularly the establishment of a sales organization, will require substantial additional capital resources. We currently intend to pursue a strategic partnership alternative for the commercialization of Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or Celgosivir, if it is approved, and we have suspended our efforts to build internal sales, marketing and distribution capabilities. If we elect to rely on third parties to sell Arakoda, Tafenoquine (Arakoda or other regimen), or Celgosivir and any other products, then we may receive less revenue than if we sold such products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to complete a strategic transaction, we would be unable to commercialize Arakoda, Tafenoquine (Arakoda or other regimen) or Celgosivir or any other product candidate without substantial additional capital. Even if such capital were secured, we would be required to rely on our existing distribution network in place through prime vendors for sales and marketing and capabilities, since we lack our own internal resources to directly sell and market Arakoda, Tafenoquine (Arakoda or other regimen) or Celgosivir in the United States. None of our current employees have experience in establishing and managing a sales force.

In the event we are unable to establish an effective sales channel for Arakoda, Tafenoquine (Arakoda or other regimen) or Celgosivir and other selected product candidates, either directly or through third parties via a strategic transaction, the commercialization of Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, or Celgosivir, if approved, may be delayed indefinitely and our revenues will be impaired.

We may explore new strategic collaborations that may never materialize or may fail.

We may, in the future, periodically explore a variety of new strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and these strategic collaborations can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing strategic collaborations.

We have no manufacturing capacity, which puts us at risk of lengthy and costly delays of bringing our products to market.

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates, including their API. We have no experience in drug formulation or manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We do not intend to develop Company-owned facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future. We have contracted with Piramal to manufacture the API for Arakoda. For drug product, we previously contracted with Piramal to manufacture the Arakoda tablets (and placebos) for commercial and clinical use and with PCI in the United States for secondary packaging. In addition, we contracted with a separate service provider for packaging and distribution of our clinical trial materials. We may also need to contract with similar manufacturers for similar services in connection with any planned or future clinical trials of Arakoda and Celgosivir.

Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products. In addition, these manufacturers may have staffing difficulties, may not be able to manufacture our products on a timely basis or may become financially distressed. In the event of errors in forecasting production quantities required to meet demand, natural disaster, equipment malfunctions or failures, technology malfunctions, strikes, lock-outs or work stoppages, regional power outages, product tampering, war or terrorist activities, actions of regulatory authorities, business failure, strike or other difficulty, we may be unable to find an alternative third-party manufacturer in a timely manner and the production of our product candidates would be interrupted, resulting in delays and additional costs, which could impact our ability to commercialize and sell our product candidates. We or our contract manufacturers may also fail to achieve and maintain required manufacturing standards, which could result in patient injury or death, product recalls or withdrawals, an order by governmental authorities to halt production, delays or failures in product testing or delivery, stability testing failures, cost overruns or other problems that could seriously hurt our business.

Contract manufacturers also often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. In addition, our contract manufacturers are subject to ongoing inspections and regulation by the FDA, the U.S. Drug Enforcement Agency and corresponding foreign and state agencies and they may fail to meet these agencies' acceptable standards of compliance. If our contract manufacturers fail to comply with applicable governmental regulations, such as quality control, quality assurance and the maintenance of records and documentation, we may not be able to continue production of the API or finished product. If the safety of any API or product supplied is compromised due to failure to adhere to applicable laws or for other reasons, this may jeopardize our regulatory approval for Arakoda, or Celgosivir and other product candidates, and we may be held liable for any injuries sustained as a result. Upon the occurrence of one of the aforementioned events, the ability to switch manufacturers may be difficult for a number of reasons, including:

- the number of potential manufacturers is limited and we may not be able to negotiate agreements with alternative manufacturers on commercially reasonable terms, if at all;
- long lead times are often needed to manufacture drugs;
- the manufacturing process is complex and may require a significant learning curve; and
- the FDA must approve any replacement prior to manufacturing, which requires new testing and compliance inspections.

Our contract manufacturers are subject to significant regulation with respect to the manufacturing of our products.

All entities involved in the preparation of a product candidate for clinical trials or commercial sale, including our contract manufacturing organizations used for bulk product manufacturing and filling and finishing of our bulk product, are subject to extensive regulation. Components of a finished product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of any regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors or raw material suppliers. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, the relevant regulatory authority may require remedial measures that may be costly and time-consuming to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Our third-party contractors or raw material suppliers may refuse to implement remedial measures required by regulatory authorities. Any failure to comply with applicable manufacturing regulations or failure to implement required remedial measures imposed upon third parties with whom we contract could materially harm our business.

We rely on relationships with third-party contract manufacturers and raw material suppliers, which limits our ability to control the availability of, and manufacturing costs for, our product candidates.

Problems with any of our contract manufacturers' or raw material suppliers' facilities or processes, could prevent or delay the production of adequate supplies of finished products. This could delay clinical trials or delay and reduce commercial sales and materially harm our business. Any prolonged delay or interruption in the operations of our collaborators' facilities or contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in availability of a product candidate or products. A number of factors could cause interruptions, including, but not limited to:

- the inability of a supplier to provide raw materials;
- equipment malfunctions or failures at the facilities of our collaborators or suppliers;
- high process failure rates;
- damage to facilities due to natural or man-made disasters;
- changes in regulatory requirements or standards that require modifications to our or our collaborators' and suppliers' manufacturing processes;
- action by regulatory authorities or by us that results in the halting or slowdown of production of components or finished product at our facilities or the facilities of our collaborators or suppliers;
- problems that delay or prevent manufacturing technology transfer to another facility, contract manufacturer or collaborator with subsequent delay or inability to start up a commercial facility;
- a contract manufacturer or supplier going out of business, undergoing a capacity shortfall or otherwise failing to produce product as contractually required;
- employee or contractor misconduct or negligence; and
- shipping delays, losses or interruptions; and other similar factors.

Because manufacturing processes are complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of drug substances could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to timely meet market demand for any products that are approved for sale.

The manufacturing process for our product candidates has several components that are sourced from a single manufacturer. If we utilize an alternative manufacturer or alternative component, we may be required to demonstrate comparability of the drug product before releasing the product for clinical use and we may not be to find an alternative supplier.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Our future growth depends on our ability to successfully commercialize Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir and our other product candidates, and we can provide no assurance that we will successfully commercialize Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir and other product candidates.

Our future growth depends on our ability to successfully commercialize Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir and our other product candidates, including our ability to:

- conduct additional clinical trials and develop and obtain regulatory approval for Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir or other product candidates;
- successfully partner a companion genetic test (if required by the FDA) with the commercialization of Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications and Celgosivir;
- pursue additional indications for Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications and Celgosivir and develop other product candidates, including other therapies; and
- obtain commercial quantities of Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications and Celgosivir or other product candidates at acceptable cost levels.

Any one of these or other factors could affect our ability to successfully commercialize products.

If approved by the FDA, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, and Celgosivir, will be entering a competitive marketplace and may not succeed.

Our commercial opportunity may be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications and Celgosivir. If products with any of these properties are developed, or any of the existing products are better marketed, then Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications and Celgosivir could be rendered obsolete and noncompetitive. Further, public announcements regarding the development of any such competing drugs could adversely affect the market price of our common stock and the value of our assets.

State-specific regulatory activities may negatively affect our business.

In the United States, individual state governments regulate certain aspects of the pharmaceutical industry including price transparency, requirements in some cases to obtain state licenses, compliance with cGMPs, and for environmental stewardship/take-back programs. For distribution of Arakoda, we have employed a "title model" approach to distribution which limits the extent of state licenses required, and we have contracted with third-party organizations to ensure we are participating in appropriate stewardship/take programs, and have complied (or have a process in place to comply) with state licensing/price transparency requirements that we are aware of. However, we cannot guarantee that we will be compliant with all state regulations, or that we will become aware of and act on any new requirements (which are constantly changing) in time to ensure 100% compliance at all times. State compliance is expensive and new requirements may impose new costs we were not previously aware of.

Health care reform measures could materially and adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. The U.S. Congress has enacted legislation to reform the health care system. While we anticipate that this legislation may, over time, increase the number of patients who have insurance coverage for pharmaceutical products, it also imposes cost containment measures that may adversely affect the amount of reimbursement for pharmaceutical products. These measures include increasing the minimum rebates for products covered by Medicaid programs and extending such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations as well as expansion of the 340(B) Public Health Services drug discount program. In addition, such legislation contains a number of provisions designed to generate the revenues necessary to fund the coverage expansion, including new fees or taxes on certain health-related industries, including medical device manufacturers. Each medical device manufacturer has to pay an excise tax (or sales tax) in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. Such excise taxes may impact any potential sales of the genetic test if it is approved for marketing. On January 22, 2018, legislation was enacted suspending the medical device tax in 2018 and 2019. In December 2019, a permanent repeal of the medical device tax was enacted. The Celgosivir test is likely to be subject to this tax if this tax is reinstated in the future. In foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control and we expect to see continued efforts to reduce healthcare costs in international markets.

In August 2022, the Inflation Reduction Act of 2022 was signed into law. This law requires the federal government to negotiate prices for a small number of high-cost drugs covered under Medicare, requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries, and caps Medicare beneficiaries' out-of-pocket spending under the Medicare Part D benefit. This legislation could create more demand for negotiated drug prices and further government control of prescription drug pricing. Future legal restrictions regarding our ability to price our drugs could affect our revenues and our business going forward.

Additionally, federal, state and local governments continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. Since 2017, several states and local governments have either implemented or are considering implementation of price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. If adequate reimbursement levels are not maintained by government and other third-party payers for our products, our ability to sell our products may be limited and our ability to establish acceptable pricing levels may be impaired, thereby reducing anticipated revenues and profitability. Further, the pace of change and varying demands of state requirements may render it very difficult to comply with these various laws, and failure to comply with these regulations could expose us to substantial financial penalties and the potential for adverse publicity.

Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for drugs. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future although we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business. We or any strategic partner's ability to commercialize Celgosivir, or any other product candidates that we may seek to commercialize, is highly dependent on the extent to which coverage and reimbursement for these product candidates will be available from government payors, such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-party payors, and any change in reimbursement levels could materially and adversely affect our business. Further, the pendency or approval of future proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws.

Our competitors may be better positioned in the marketplace and thereby may be more successful than us at developing, manufacturing and marketing approved products.

Many of our competitors currently have significantly greater financial resources and expertise in conducting clinical trials, obtaining regulatory approvals, and managing manufacturing and marketing approved products than us. Other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. In addition, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring therapies and therapy licenses complementary to our programs or advantageous to our business. We expect that our ability to compete effectively will depend upon our ability to:

- successfully and rapidly complete clinical trials for any product candidates and obtain all requisite regulatory approvals in a cost-effective manner;
- build an adequate sales and marketing infrastructure, raise additional funding, or enter into strategic transactions enabling the commercialization of our products;
- develop competitive formulations of our product candidates;
- attract and retain key personnel; and
- identify and obtain other product candidates on commercially reasonable terms.

We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.

New developments occur and are expected to continue to occur at a rapid pace in our industry, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive, which could have a material adverse effect on our business, financial condition and results of operations. New data from commercial and clinical-stage products continue to emerge and it is possible that these data may alter current standards of care, completely precluding us from further developing our product candidates or preventing us from getting them approved by regulatory agencies. Further, it is possible that we may initiate a clinical trial or trials for our product candidates, only to find that data from competing products make it impossible for us to complete enrollment in these trials, resulting in our inability to file for marketing approval with regulatory agencies. Even if these products are approved for marketing in a particular indication or indications, they may have limited sales due to particularly intense competition in these markets.

We expect to compete with fully integrated and well-established pharmaceutical and biotechnology companies in the near- and long-term. Most of these companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective or less costly than any that we may develop. Such companies also may be more successful than we are in manufacturing, sales and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of product candidates.

We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

There can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us with proprietary protection or a competitive advantage.

We would be subject to applicable regulatory approval requirements of the foreign countries in which we market our products, which are costly and may prevent or delay us from marketing our products in those countries.

In addition to regulatory requirements in the United States, we would be subject to the regulatory approval requirements in each foreign country where we market our products. Also, we might be required to identify one or more collaborators in these foreign countries to develop, seek approval for and manufacture our products and any companion genetic test that may be required for Arakoda or Celgosivir. If we decide to pursue regulatory approvals and commercialization of our product candidates internationally, we may not be able to obtain the required foreign regulatory approvals on a timely basis, if at all, and any failure to do so may cause us to incur additional costs or prevent us from marketing our products in foreign countries, which may have a material adverse effect on our business, financial condition and results of operations.

Failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act of 1914), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"). Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, the California Consumer Privacy Act, as amended ("CCPA"), became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information (subject to certain exceptions), opt out of certain personal information sharing, correct inaccurate personal information that a business has about them and limit the use and disclosure of sensitive personal information collected about them and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information and the right not to be discriminated against for exercising these rights. The CCPA also gives consumers the right to request disclosure of information collected about them and whether that information has been sold or shared with others.

The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for clinical trial data and the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, the CCPA may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

Foreign data protection laws, including, without limitation, the European Union Directive 95/46/EC, or the Directive, and the European Union's General Data Protection Regulation ("GDPR"), that became effective in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the European Union and the United Kingdom, including in relation to use, collection, analysis, and transfer (including cross-border transfer) of such personal information. These laws include several requirements relating to the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The Directive and the GDPR prohibit, without an appropriate legal basis, the transfer of personal data to countries outside of the European Economic Area ("EEA"), such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with European Union data protection laws remains. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR increases our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Because we have multiple product candidates in our clinical pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus our research and development efforts on those product candidates and specific indications that we believe are the most promising. As a result, we may forego or delay our pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. We may in the future spend our resources on other research programs and product candidates for specific indications that ultimately do not yield any commercially viable products. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

We must meet post-marketing requirements associated with the Arakoda NDA imposed by the FDA. Failure to complete such requirements, or delays due to lack of resources or other factors, may negatively impact our business.

When the FDA approved the Arakoda NDA in August 2018, it imposed post-marketing requirements on us, including associated timelines. We have made substantial progress in meeting all such requirements and recently published data from a clinical trial related to one of them. However, we have experienced delays in our ability to execute our observational and pediatric study requirements and are in discussion with the FDA regarding future plans relating to our pediatric program. We may experience new or additional delays in the future on one or more of its post-marketing requirements in the future. As of the date of this prospectus, we have not received acknowledgement from the FDA that any of the post-marketing requirements are completed nor been referred for enforcement action due to delays in our post-marketing studies. If we fail to meet FDA requirements, experiences additional delays or is referred for enforcement action, we might require diversion of managerial and capital resources from planned research and development to completion of post-marketing requirements, or the FDA might revoke the NDA for Arakoda, and therefore harm the business. In the future, regulators may impose additional post-marketing requirements for Arakoda for malaria or other indications, or in relation to our products. This situation would require expensive clinical or non-clinical studies that might damage our financial position.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Continued uncertain economic conditions, including inflation and the risk of a global recession could impair our ability to forecast and may harm our business, operating results, including our revenue growth and profitability, financial condition and cash flows.

The U.S. economy is experiencing the highest rates of inflation since the 1980s. Historically, we have not experienced significant inflation risk in our business. However, our ability to raise our product prices depends on market conditions and there may be periods during which we are unable to fully recover increases in our costs. In addition, the global economy suffers from slowing growth and rising interest rates, and many economists believe that a global recession may begin in the near future. If the global economy slows, our business would likely be adversely affected.

Also, the global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions.

Geopolitical conditions, including direct or indirect acts of war or terrorism, could have an adverse effect on our operations and financial results.

Our operations could be disrupted by geopolitical conditions, political and social instability, acts of war, terrorist activity or other similar events. In February 2022, Russia initiated significant military action against Ukraine. In response, the U.S. and certain other countries imposed significant sanctions and export controls against Russia, Belarus and certain individuals and entities connected to Russian or Belarusian political, business, and financial organizations, and the U.S. and certain other countries could impose further sanctions, trade restrictions, and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U.S. and other countries in respect thereof as well as any counter measures or retaliatory actions by Russia or Belarus in response, including, for example, potential cyberattacks or the disruption of energy exports, is likely to cause regional instability, geopolitical shifts, and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. The situation remains uncertain, and while it is difficult to predict the impact of any of the foregoing, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

We could be subject to lawsuits.

We may be party to lawsuits, settlement discussions, mediations, arbitrations and other disputes, including patent and product liability claims, whether brought by companies, individuals or governmental authorities. These matters may result in a loss of patent protection, reduced revenue, incurrence of significant liabilities and diversion of our management's time, attention and resources. Our insurance coverage may not provide adequate protection against actual losses. In addition, we are subject to the risk that one or more of our insurers may become insolvent and become unable to pay claims that may be made in the future. Even if we maintain adequate insurance, claims could have a material adverse effect on our financial condition, liquidity and results of operations and on our ability to obtain suitable, adequate or cost-effective insurance in the future. Litigation and other disputes, including any adverse outcomes, may have an adverse impact on our business, operations or financial condition. Even claims without merit could subject us to adverse publicity and require us to incur significant legal fees.

We currently, and may in the future, have assets held at financial institutions that may exceed the insurance coverage offered by the Federal Deposit Insurance Corporation, the loss of such assets would have a severe negative affect on our operations and liquidity.

We may maintain our cash assets at certain financial institutions in the U.S. in amounts that may be in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance limit of $250,000. In the event of a failure of any financial institutions where we maintain our deposits or other assets, we may incur a loss to the extent such loss exceeds the FDIC insurance limitation, which could have a material adverse effect upon our liquidity, financial condition and our results of operations.

Risks Related to Intellectual Property and Other Legal Matters

If product liability lawsuits are successfully brought against us, then we will incur substantial liabilities and may be required to limit commercialization of Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir or other product candidates.

We may face product liability exposure related to the testing of our product candidates in human clinical trials, and may face exposure to claims by an even greater number of persons once we begin marketing and distributing our products commercially. If we cannot successfully defend against product liability claims, then we will incur substantial liabilities.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products and product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenues; and
- the inability to commercialize our products and product candidates.

We have obtained limited product liability insurance coverage. Such coverage, however, may not be adequate or may not continue to be available to us in sufficient amounts or at an acceptable cost, or at all. We may not be able to obtain commercially reasonable product liability insurance for any product candidate.

Defending against claims relating to improper handling, storage or disposal of hazardous chemicals, radioactive or biological materials could be time consuming and expensive.

Our research and development of product candidates may involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from the materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued or be required to pay fines for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

Third parties may own or control patents or patent applications that we may be required to license to commercialize our product candidates or that could result in litigation that would be costly and time consuming.

Our or any strategic partner’s ability to commercialize Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir and other product candidates depends upon our ability to develop, manufacture, market and sell these drugs without infringing the proprietary rights of third parties. A number of pharmaceutical and biotechnology companies, universities and research institutions have or may be granted patents that cover technologies similar to the technologies owned by or licensed to us. We may choose to seek, or be required to seek, licenses under third-party patents, which would likely require the payment of license fees or royalties or both. We may also be unaware of existing patents that may be infringed by Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications or Celgosivir, the genetic testing we intend to use in connection with Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir or our other product candidates. Because patent applications can take many years to issue, there may be other currently pending applications that may later result in issued patents that are infringed by Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir or our other product candidates. Moreover, a license may not be available to us on commercially reasonable terms, or at all.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third-party claims that we are infringing on its technology, then our business and results of operations could be harmed by a number of factors, including:

- infringement and other intellectual property claims, even if without merit, are expensive and time-consuming to litigate and can divert management's attention from our core business;
- monetary damage awards for past infringement can be substantial;
- a court may prohibit us from selling or licensing product candidates unless the patent holder chooses to license the patent to us; and
- if a license is available from a patent holder, we may have to pay substantial royalties.

We may also be forced to bring an infringement action if we believe that a competitor is infringing our protected intellectual property. Any such litigation will be costly, time-consuming and divert management's attention, and the outcome of any such litigation may not be favorable to us.

Our intellectual property rights may not preclude competitors from developing competing products and our business may suffer.

Our competitive success will depend, in part, on our ability to obtain and maintain patent protection for our inventions, technologies and discoveries, including intellectual property that we license. The patent positions of biotechnology companies involve complex legal and factual questions, and we cannot be certain that our patents and licenses will successfully preclude others from using our technology. Consequently, we cannot be certain that any of our patents will provide significant market protection or will not be circumvented or challenged and found to be unenforceable or invalid. In some cases, patent applications in the United States and certain other jurisdictions are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology. Regardless of merit, the listing of patents in the FDA Orange Book for Arakoda, Celgosivir may be challenged as being improperly listed. We may have to defend against such claims and possible associated antitrust issues. We could also incur substantial costs in seeking to enforce our proprietary rights against infringement.

We may not be able to effectively protect our intellectual property rights in some foreign countries, as our patents are limited by jurisdiction and many countries do not offer the same level of legal protection for intellectual property as the United States.

We require our employees, consultants, business partners and members of our scientific advisory board to execute confidentiality agreements upon the commencement of employment, consulting or business relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for us, utilizing the property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law.

Third parties may breach these and other agreements with us regarding our intellectual property and we may not have adequate remedies for the breach. Third parties could also fail to take necessary steps to protect our licensed intellectual property, which could seriously harm our intellectual property position.

If we are not able to protect our proprietary technology, trade secrets and know-how, then our competitors may develop competing products. Any issued patent may not be sufficient to prevent others from competing with us. Further, we have trade secrets relating to Arakoda, Celgosivir, and such trade secrets may become known or independently discovered. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, opposed, invalidated or circumvented, which could allow competitors to market similar products or limit the patent protection term of our product candidates. All of these factors may affect our competitive position.

If the manufacture, use or sale of our products infringe on the intellectual property rights of others, we could face costly litigation, which could cause us to pay substantial damages or licensing fees and limit our ability to sell some or all of our products.

Extensive litigation regarding patents and other intellectual property rights has been common in the biopharmaceutical industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. Litigation may even be necessary to defend disputes of inventorship or ownership of proprietary rights. The defense and prosecution of intellectual property lawsuits, U.S. Patent and Trademark Office interference proceedings, and related legal and administrative proceedings (e.g., a re-examination, *inter partes* review, or post-grant review) in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue, and their outcome is uncertain.

Regardless of merit or outcome, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our stock price to decline. Adverse outcomes in patent litigation may potentially subject us to antitrust litigation which, regardless of the outcome, would adversely affect our business. An adverse determination may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our products, if any. These outcomes could materially harm our business, financial condition and results of operations.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and Ex-US could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), signed into law in the United States on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The patent protection and patent prosecution for some of our product candidates is dependent or may be dependent in the future on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when platform technology patents or product-specific patents that relate to our product candidates are controlled by our licensors. In addition, our licensors and/or licensees may have back-up rights to prosecute patent applications in the event that we do not do so or choose not to do so, and our licensees may have the right to assume patent prosecution rights after certain milestones are reached. If any of our licensing collaborators fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

We may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patent rights are of limited duration. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the U.S. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

The earliest Paragraph IV certification date for Arakoda has passed. Generic companies may file an ANDA at any time, and successful challenge of our malaria use patents would negatively impact our business.

The PDUFA date for Arakoda is August 8, 2018, and the beginning date for exclusivity associated with the product's API is July 20, 2018. The five-year data exclusivity ending date for Arakoda is July 20, 2023. Therefore, the earliest date a generic company could file an ANDA, claiming such an application does not infringe our Orange Book listed patents was July 20, 2022. Any generic company filing such an abbreviated new drug application ("ANDA") with FDA, must notify us within 20 calendar days of receiving acknowledgement from the FDA or receipt of such an ANDA. Thus, the earliest date we could receive such a notification was August 9, 2022.

As of the date of this prospectus, to the best of our knowledge, no such notice has been received by us. However, such a notice might be received at any time. Such a notice might require us to undertake expensive litigation to defend our patents related to Arakoda's malaria indication, thereby diverting funds away from critical research and development efforts for Tafenoquine (Arakoda or other regimen) for other indications. This potential litigation and the related expenditure may harm our business. Additionally, the approval of any ANDA would increase competition and most likely drive down prices for Arakoda.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

Risks Related to this Offering

Our management will have broad discretion over the use of any net proceeds from this offering and you may not agree with how we use the proceeds, and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of any net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering and in ways that do not necessarily improve our results of operations or enhance the value of our common stock. Accordingly, you will be relying on the judgment of our management with regard to the use of any proceeds from this offering and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for you.

Investors in this offering may experience future dilution as a result of this and future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. Investors purchasing our shares or other securities in the future could have rights superior to existing common stockholders, and the price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per Unit in this offering.

If we issue shares of preferred stock your rights as a holder of our common stock or warrants may be materially adversely affected.

As of the date of this prospectus, we are authorized to issue up to 1,000,000 shares of “blank check” preferred stock. Upon the consummation of this offering, we will have authorized shares of 80,965 Series A Preferred Stock, of which 80,965 shares of Series A Preferred Stock will be issued and outstanding. The designations, rights and preferences of our other preferred stock may be determined from time-to-time by our Board. Accordingly, our Board is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of the holders of our common stock. For example, an issuance of shares of preferred stock could:

- adversely affect the voting power of the holders of our common stock;
- make it more difficult for a third-party to gain control of us;
- discourage bids for our common stock;

- limit or eliminate any payments that the holders of our common stock could expect to receive upon our liquidation; or
- adversely affect the market price of our common stock.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common stock would have on the market price of our common stock.

Existing stockholders may sell significant quantities of common stock.

The existing shareholders will own 74.6% of our common stock following the successful completion of this offering. Notwithstanding that certain of our officers and directors who are shareholders will be locked up for a period of six months, and any greater than 5% holders of our common stock will also be locked up for a period of six months, following the completion of this offering, our existing stockholders may have acquired their shares at a lower price than that of this offering. Accordingly, they may be incentivized to sell all or part of their holdings as soon as any applicable transfer restrictions have ended and such sales could have a negative impact on the market price of our common stock. In addition, large number of sales of our common stock by the selling stockholders named in the Resale Prospectus could depress the market price of our common stock and make it more difficult to sell your shares of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Several analysts may cover our stock. If one or more of those analysts downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

The requirements of being a public company.

As a public company, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, (the "Dodd-Frank Act") and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. We may need to hire more employees in the future to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We also expect that being a public company and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors ("Board") and qualified executive officers.

As a result of disclosure of information in this prospectus and in filings required of a public company, our business and financial condition will become more visible, which we believe may result in increased threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

Risks Relating to Ownership of Our Securities

There has been no public market for our common stock or Tradeable Warrants prior to this offering, and we cannot assure you that an active trading market will develop in the near future.

Prior to this offering, there has been no public market for our common stock or Tradable Warrants. All investments in securities involve the risk of loss of capital. No guarantee or representation is made that an investor will receive a return of its capital. The value of our common stock or Tradeable Warrants can be adversely affected by a variety of factors, including development problems, regulatory issues, technical issues, commercial challenges, competition, legislation, government intervention, industry developments and trends, and general business and economic conditions. We cannot predict the extent to which an active market for our common stock or Tradeable Warrants will develop or be sustained after this offering, or how the development of such a market might affect the market price of our common stock.

The public price of our common stock may be volatile, and could, following a sale decline significantly and rapidly.

The initial public offering price for the Units will be determined by negotiations between us and the underwriters and may not be indicative of prices that will prevail in the open market following this offering. The market price of our common stock may decline below the initial offering price, and you may not be able to sell your shares of our common stock at or above the price you paid in the offering, or at all. Following this offering, the public price of our common stock in the secondary market will be determined by private buy and sell transaction orders collected from broker-dealers.

In addition, the stock market in general has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to operating performance of individual companies, particularly following an initial public offering of a company with a small public float. There is the potential for rapid and substantial price volatility of our common stock following this offering. These broad market factors may seriously harm the market price of our common stock, regardless of our actual or expected operating performance and financial condition or prospects, which may make it difficult for investors to assess the rapidly changing value of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A class action suit against us could result in significant liabilities and, regardless of the outcome, could result in substantial costs and the diversion of our management's resources and attention.

Stock price run-ups followed by rapid price declines and stock price volatility may also be completely unrelated to company performance. Such volatility, including any stock-run up, may be unrelated to our actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our stock.

A possible "short squeeze" due to a sudden increase in demand of our common stock that largely exceeds supply may lead to price volatility in our common stock.

Following this offering, investors may purchase our common stock to hedge existing exposure in our common stock or to speculate on the price of our common stock. Speculation on the price of our common stock may involve long and short exposures. To the extent aggregate short exposure exceeds the number of shares of our common stock available for purchase in the open market, investors with short exposure may have to pay a premium to repurchase our common stock for delivery to lenders of our common stock. Those repurchases may in turn dramatically increase the price of our common stock until investors with short exposure are able to purchase additional shares of common stock to cover their short position. This is often referred to as a "short squeeze." A short squeeze could lead to volatile price movements in our common stock that are not directly correlated to the performance or prospects of our Company and once investors purchase the shares of common stock necessary to cover their short position, the price of our common stock may decline.

We may not be able to satisfy listing requirements of Nasdaq to maintain a listing of our common stock or Tradeable Warrants.

If our common stock and Tradeable Warrants are listed on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate the maintenance requirements for continued listing of our common stock and Tradeable Warrants, our common stock and Tradeable Warrants may be delisted. In addition, our Board may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock or Tradeable Warrants from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock or Tradeable Warrants and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock and Tradeable Warrants. In addition, the delisting of our common stock or Tradeable Warrants could significantly impair our ability to raise capital. Although we expect our common stock and Tradeable Warrants will be approved for listing on Nasdaq, an active trading market for our shares or Tradeable Warrants may never develop or be sustained following this offering.

There is no public market for the Non-tradeable Warrants being offered in this offering.

There is no public trading market for the Non-tradeable Warrants offered by this prospectus, and we do not expect a market to develop. In addition, we do not intend to apply to list the Non-tradeable Warrants on any exchange or market. Without an active market, the liquidity of the Non-tradeable Warrants will be limited.

Warrants are speculative in nature.

The warrants offered in this offering do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the Tradeable Warrants may exercise their right to acquire the common stock and pay an exercise price of $6.095 per share (115% of the offering price per Unit), from time to time, until the fifth anniversary from the date of issuance, after which date any unexercised Tradeable Warrants will expire and have no further value. Also, commencing on the date of issuance, holders of the Non-tradeable Warrants may exercise their right to acquire the common stock and pay an exercise price of $6.36 per share (120% of the offering price per Unit), from time to time, until the fifth anniversary from the date of issuance, after which date any unexercised Non-tradeable Warrants will expire and have no further value. In addition, there is no established trading market for the Non-tradeable Warrants.

Since the warrants are executory contracts, they may have no value in a bankruptcy or reorganization proceeding.

In the event a bankruptcy or reorganization proceeding is commenced by or against us, a bankruptcy court may hold that any unexercised warrants are executory contracts that are subject to rejection by us with the approval of the bankruptcy court. As a result, holders of the warrants may, even if we have sufficient funds, not be entitled to receive any consideration for their warrants or may receive an amount less than they would be entitled to if they had exercised their warrants prior to the commencement of any such bankruptcy or reorganization proceeding.

Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.

Until investors acquire shares of our common stock upon exercise of the warrants being offered in this offering, they will have no rights with respect to our common stock such as voting rights or the right to receive dividends. Upon exercise of such warrants, holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Provisions of the warrants offered by this prospectus could discourage an acquisition of us by a third-party.

Certain provisions of the warrants offered by this prospectus could make it more difficult or expensive for a third-party to acquire us. The warrants prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the warrants. These and other provisions of the warrants offered by this prospectus could prevent or deter a third-party from acquiring us even where the acquisition could be beneficial to you.

If we do not file and maintain a current and effective prospectus relating to the common stock issuable upon exercise of the warrants, holders will only be able to exercise such warrants on a "cashless basis."

If we do not file and maintain a current and effective registration statement relating to the common stock issuable upon exercise of the warrants at the time that holders wish to exercise such warrants, they will only be able to exercise them on a "cashless basis" provided that an exemption from registration is available. As a result, the number of shares of common stock that holders will receive upon exercise of the warrants will be fewer than it would have been had such holder exercised his, her or its warrants for cash. Further, if an exemption from registration is not available, holders would not be able to exercise on a cashless basis and would only be able to exercise their warrants for cash if a current and effective registration statement relating to the common stock issuable upon exercise of the warrants is available. Under the terms of the underwriting agreement, we have agreed to use our best efforts to meet these conditions and to file and maintain a current and effective registration statement relating to the common stock issuable upon exercise of the warrants until the expiration of the warrants. However, we cannot assure you that we will be able to do so. If we are unable to do so, the potential "upside" of the holder's investment in our Company may be reduced or the warrants may expire worthless.

We may amend the terms of the warrants in a way that may be adverse to holders with the approval by the holders of a majority of the then outstanding warrants.

The Warrant Agent Agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision. All other modifications or amendments, including any amendment to increase the exercise price of the warrants or shorten the exercise period of the warrants, shall require the written consent of the registered holders of a majority of the then outstanding warrants which may be contrary to your interests.

The warrants may have an adverse effect on the market price of our common stock and make it more difficult to effect a business combination.

We will be issuing warrants to purchase shares of common stock as part of this offering. To the extent we issue shares of common stock to effect a future business combination, the potential for the issuance of a substantial number of additional shares upon exercise of the warrants could make us a less attractive acquisition vehicle in the eyes of a target business. Such warrants, when exercised, will increase the number of issued and outstanding shares of common stock and reduce the value of the shares issued to complete the business combination. Accordingly, the warrants may make it more difficult to effectuate a business combination or increase the cost of acquiring a target business. Additionally, the sale, or even the possibility of a sale, of the shares of common stock underlying the warrants could have an adverse effect on the market price for our securities or on our ability to obtain future financing. If and to the extent the warrants are exercised, you may experience dilution to your holdings.

Our Warrant Agent Agreement designate the courts of the State of New York or the United States District Court for the Southern District of New York as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by holders of our warrants, which could limit the ability of warrant holders to obtain a favorable judicial forum for disputes with our Company.

Our Warrant Agent Agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the Warrant Agent Agreement, including under the Securities Act, will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and (ii) that we irrevocably submit to such jurisdiction, which jurisdiction shall be the exclusive forum for any such action, proceeding or claim. We will waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

Notwithstanding the foregoing, these provisions of the Warrant Agent Agreement do not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum. Any person or entity purchasing or otherwise acquiring any interest in any of our warrants shall be deemed to have notice of and to have consented to the forum provisions in our Warrant Agent Agreement.

If any action, the subject matter of which is within the scope of the forum provisions of the Warrant Agent Agreement, is filed in a court other than courts of the State of New York or the United States District Court for the Southern District of New York (a "foreign action") in the name of any holder of our warrants, such holder shall be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions (an "enforcement action"), and (y) having service of process made upon such warrant holder in any such enforcement action by service upon such warrant holder's counsel in the foreign action as an agent for such warrant holder.

This choice-of-forum provision may limit a warrant holder's ability to bring a claim in a judicial forum that it finds favorable for disputes with our Company, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our Warrant Agent Agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and Board.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

The market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns.

Our failure to maintain effective internal controls over financial reporting could have an adverse impact on us.

We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely impact our public disclosures regarding our business, financial condition or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting, disclosure of management's assessment of our internal controls over financial reporting or disclosure of our public accounting firm's attestation to or report on management's assessment of our internal controls over financial reporting may have an adverse impact on the price of our common stock.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no system of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

At present, we are executing a plan to improve existing internal controls by segregating accounting functions through outsourcing. For over 10 years, our Chief Executive Officer and Chief Financial Officer have worked together in a collaborative relationship using budgets to track finances with limited resources. Our management, including our President and Chief Executive Officer, cannot guarantee that our internal controls and disclosure controls that we have in place will prevent all possible errors, mistakes or fraud. If we fail to have effective controls and procedures for financial reporting in place, we could be unable to provide timely and accurate financial information and be subject to investigation by the SEC and civil or criminal sanctions.

Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which, as a public company, could materially harm our stock price.

We require significant financial resources to maintain our public reporting status. We cannot assure you we will be able to maintain adequate resources to ensure that we will not have any future material weakness in our system of internal controls. The effectiveness of our controls and procedures may in the future be limited by a variety of factors including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Despite these controls, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. Furthermore, smaller reporting companies like us face additional limitations. Smaller reporting companies employ fewer individuals and can find it difficult to employ resources for complicated transactions and effective risk management. Additionally, smaller reporting companies tend to utilize general accounting software packages that lack a rigorous set of software controls.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an "emerging growth company" and because we will have an extended transition period for complying with new or revised financial accounting standards, we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

The elimination of personal liability against our directors and officers under Delaware law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our certificate of incorporation, as corrected ("Certificate of Incorporation"), and our amended and restated bylaws ("Bylaws") eliminate the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Delaware law. Further, our Certificate of Incorporation provides that we are obligated to indemnify each of our directors or officers to the fullest extent authorized by Delaware law. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, even if such actions might otherwise benefit our stockholders. Note that for liabilities arising under the Securities Act, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

You should consult your own independent tax advisor regarding any tax matters arising with respect to the securities offered in connection with this offering.

Participation in this offering could result in various tax-related consequences for investors. All prospective purchasers of the resold securities are advised to consult their own independent tax advisors regarding the U.S. federal, state, local and non-U.S. tax consequences relevant to the purchase, ownership and disposition of the resold securities in their particular situations.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never declared or paid cash dividends on our common stock since inception as this is not how an LLC returns capital to its members and do not anticipate paying any cash dividends on our common stock as a C-Corporation in the foreseeable future. Instead, we currently intend to retain any future earnings for working capital and to support the growth and development of our business. Our payment of any future dividends will be at the discretion of our Board after taking into account various factors, including, but not limited to, our earnings, capital requirements, financial condition, prospects, operating results, cash needs, growth plans, applicable Delaware law and any other factors which our Board may deem relevant. Our ability to pay dividends on our common stock may be limited by Delaware state law. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize a return on their investment. Investors seeking cash dividends should not purchase our common stock.

We are an "emerging growth company" and a "smaller reporting company" under the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" and a "smaller reporting company" as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" and "smaller reporting companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards.

We will remain an "emerging growth company" until the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act, although we will lose that status sooner if our revenues exceed $1.235 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last day of our most recently completed second fiscal quarter.

We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of our common stock held by non-affiliates is equal to or less than $250 million as of the last business day of the most recently completed second fiscal quarter, and (ii) our annual revenues is equal to or less than $100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is equal to or less than $700 million as of the last business day of the most recently completed second fiscal quarter.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, taking advantage of reduced disclosure obligations may make comparison of our financial statements with other public companies difficult or impossible. If investors are unable to compare our business with other companies in our industry, we may not be able to raise additional capital as and when we need it, which may materially and adversely affect our financial condition and results of operations.

Our Certificate of Incorporation designates the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our Certificate of Incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or Bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. However, our Certificate of Incorporation states that this exclusive forum provision does not apply to claims arising under federal securities laws. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Certificate of Incorporation as described above.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. As such, stockholders of the Company seeking to bring a claim regarding the internal affairs of the Company may be subject to increased costs associated with litigating in Delaware as opposed to their home state or other forum, precluded from bringing such a claim in a forum they otherwise consider to be more favorable, and discouraged from bringing such claims as a result of the foregoing or other factors related to forum selection. Alternatively, if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

IN ADDITION TO THE ABOVE RISKS, BUSINESSES ARE OFTEN SUBJECT TO RISKS NOT FORESEEN OR FULLY APPRECIATED BY MANAGEMENT. IN REVIEWING THIS FILING, POTENTIAL INVESTORS SHOULD KEEP IN MIND THAT OTHER POSSIBLE RISKS MAY ADVERSELY IMPACT OUR BUSINESS OPERATIONS AND THE VALUE OF OUR SECURITIES.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements." Forward-looking statements reflect the current view about future events. When used in this prospectus, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions, as they relate to us or our management, identify forward-looking statements. Such statements include, but are not limited to, statements contained in this prospectus relating to our business strategy, our future operating results and liquidity and capital resources outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward–looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation:

- Our ability to effectively operate our business segments;
- Our ability to manage our research, development, expansion, growth and operating expenses;
- Our ability to evaluate and measure our business, prospects and performance metrics;
- Our ability to compete, directly and indirectly, and succeed in a highly competitive and evolving industry;
- Our ability to respond and adapt to changes in technology and customer behavior;
- Our ability to protect our intellectual property and to develop, maintain and enhance a strong brand; and

- other factors (including the risks contained in the section of this prospectus entitled "*Risk Factors*") relating to our industry, our operations and results of operations.

Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $6,336,726 (or approximately $7,354,855 if the underwriters' option to purchase additional shares is exercised in full) from the sale of the Units offered by us in this offering, based on an assumed public offering price of $5.30 per Unit (the midpoint of the price range set forth on the front cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $5.30 per Unit (the midpoint of the price range set forth on the front cover page of this prospectus) would increase or decrease, as applicable, the net proceeds that we receive from this offering by approximately $1,280,660 and ($829,888), respectively, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1,000,000 Units offered by us would increase or decrease, as applicable, the net proceeds that we receive from this offering by approximately $5,247,273 and $(4,345,727), respectively, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, increase our visibility in the marketplace and create a public market for our common stock. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. However, we currently intend to use the majority of the net proceeds to us from this offering for executing clinical studies and trials.

Our strategic priority is to further develop, through clinical studies and related activities, additional/new indications for our products. Assuming the indicated amount of funds are raised, we anticipate up to $3.2 million ($2.0 million net after giving effect to anticipated research and development tax credits) will be dedicated to financing such efforts. If market conditions permit, the majority of the available funds will be utilized for the execution of a clinical trial to confirm that Arakoda accelerates recovery from COVID-19 symptoms. Other research activities may include new product research, trial design and opening of an IND for the babesiosis indication, protocol preparation for the pediatric post-marketing requirement, study feasibility for a second COVID-19 trial and mechanism of action studies. If market conditions are not conducive clinical trial activities may be postponed, but the activities mentioned in the aforementioned sentence will continue.

We plan, as resources permit, to conduct additional research and development activities including execution of animal studies to further evaluate the activities of Tafenoquine against *Candida* and Celgosivir against COVID-19. We may also conduct a targeted promotional campaign for Arakoda for the malaria indication in the United States.

We may also retire the following cash commitments to other parties associated with the public offering: $85,000 Singapore Dollars to the National University of Singapore as a license agreement milestone payment and $100,000 to Biointelect. Both payments are due upon the consummation of this offering and are non-interest bearing.

The table below sets forth the manner in which we expect to use the net proceeds we receive from this offering. All amounts included in the table below are estimates.

Description	**Amount**
Working Capital and General Corporate Purposes	$ 2,436,726
Debt Repayment	$ 1,900,000
Research and Development (clinical trials and related activities)	$ 3,400,000
Anticipated Research and Development Costs	$ 1,400,000
Total	$ 6,336,726

The foregoing information is an estimate based on our current business plan. We may find it necessary or advisable to re-allocate portions of the net proceeds reserved for one category to another, and we will have broad discretion in doing so. Pending these uses, we intend to invest the net proceeds of this offering in a money market or other interest-bearing account.

DIVIDEND POLICY

We have not declared any cash dividends since inception and we do not anticipate paying any dividends in the foreseeable future. Instead, we anticipate that all of our earnings will be used to provide working capital, to support our operations, and to finance the growth and development of our business. The payment of dividends is within the discretion of the Board and will depend on our earnings, capital requirements, financial condition, prospects, operating results, cash needs, growth plans, applicable Delaware law, which provides that dividends are only payable out of surplus or current net profits, and other factors our board might deem relevant. There are no restrictions that currently limit our ability to pay dividends on our common stock other than those generally imposed by applicable state law.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Prior to this offering, our common stock and warrants have not been listed on any stock exchange or quoted on any over-the-counter market or quotation system and there has been no public market for our common stock or warrants. We have applied to have our common stock and Tradeable Warrants listed on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively, which listing is a condition to this offering. There can be no assurance that our listing application will be approved. We do not intend to apply for listing of the Non-tradeable Warrants on any exchange or market. For more information see the section "*Risk Factors*."

As of June 1, 2023, 2,378,009 shares of our common stock were issued and outstanding and were held by fifteen stockholders of record.

CAPITALIZATION

The following table sets forth our consolidated cash and capitalization, as of March 31, 2023. Such information is set forth on the following basis:

- on an actual basis;
- on a pro forma basis to reflect the (i) receipt of short-term advances from related parties totaling $50,000 after March 31, 2023 but prior to the date of this prospectus, (ii) repayment of the (A) $200,000 short-term advance from the Geoffrey S. Dow Revocable Trust contributed in March 2023, (B) $23,000 short term advance from the Geoffrey S. Dow Revocable Trust contributed in April 2023 and (C) $27,000 from Tyrone Miller contributed in May 2023, (iii) issuance of promissory notes in May 2023 for a total principal of $722,222 and a net carrying value of $555,000, (iv) issuance of 29,245 shares of our common stock and payment of $100,000 in cash to BioIntelect pursuant to the BioIntelect Agreement, (v) issuance of 1,108,337 shares of our common stock and 80,965 shares of our preferred stock to Knight as a result of the conversion of our outstanding debt owed to Knight pursuant to the Knight Debt Conversion Agreement, (vi) issuance of 383,908 shares of our common stock as a result of either the conversion or extinguishment of our interim financing notes excluding the Xu Yu Equity Conversion Note, (vii) issuance of 214,934 shares of our common stock pursuant to the Xu Yu Equity Conversion Note and (viii) issuance of 40,000 shares of our common stock that are to be issued to four of our directors on the date of effectiveness of the registration statement of which this prospectus forms a part; and
- on a pro forma as adjusted basis to reflect the pro forma adjustments discussed in the prior bullet and our receipt of the net proceeds our sale and issuance of 1,415,095 Units in this offering at an assumed initial public offering price of $5.30 per Unit (the midpoint of the price range set forth on the front cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and after the use of net proceeds therefrom.

You should read the following table in conjunction with "*Use of Proceeds*," "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our financial statements and related notes included in this prospectus.

The pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

	Actual[1]	Pro Forma[2]	Pro forma, as adjusted[3][4]
Cash	$ 29,993	$ 284,993	$ 6,221,723
Total Assets	$ 7,586,974	$ 7,841,974	$ 14,178,704
Total Current Liabilities	25,542,263	4,403,447	4,403,447
Total Long-Term Liabilities	$ 1,577,595	$ 158,405	$ 158,405
Stockholders' equity:			
Common stock, $0.0001 par value, 150,000,000 shares authorized, 2,378,009 shares issued and outstanding, actual; 150,000,000 shares authorized, 4,154,433 shares issued and outstanding, pro forma; and 150,000,000 shares authorized, 5,569,528 shares issued and outstanding, pro forma as adjusted.	238	415	557
Preferred stock, $0.0001 par value, 1,000,000 shares authorized, 0 shares issued and outstanding, actual; 1,000,000 shares authorized, 80,965 shares issued and outstanding, pro forma; and 1,000,000 shares authorized, 80,965 shares issued and outstanding, pro forma as adjusted.	-	8,096,500	8,096,500
Additional paid-in capital	12,379,462	21,697,612	28,034,200
Retained earnings (deficit)	(31,415,209)	(26,017,030)	(26,017,030)
Total stockholders' equity	(19,532,884)	3,280,122	9,616,852
Total capitalization	$ 7,586,974	$ 7,841,974	$ 14,178,704

(1) As of March 31, 2023.

(2) The number of issued and outstanding shares as of March 31, 2023 on a pro forma basis includes (i) receipt of short-term advances from related parties totaling $50,000 after March 31, 2023 but prior to the date of this prospectus, (ii) repayment of the (A) $200,000 short-term advance from the Geoffrey S. Dow Revocable Trust contributed in March 2023, (B) $23,000 short term advance from the Geoffrey S. Dow Revocable Trust contributed in April 2023 and (C) $27,000 from Tyrone Miller contributed in May 2023, (iii) issuance of promissory notes in May 2023 for a total principal of $722,222 for a net carrying value of $555,000, (iv) 29,245 shares of our common stock to be issued to BioIntelect and payment of $100,000 in cash pursuant to the BioIntelect Agreement, which provides that in connection with our initial public offering, BioIntelect will be entitled to receive deferred equity compensation for a number of shares determined by dividing $155,000 by the public offering price (or $245,000 if Australian VC Horizon Biotech participates in the offering), (v) pursuant to the Knight Debt Conversion Agreement, (a) 1,108,337 shares of our common stock that are to be issued to Knight, determined by dividing the outstanding principal amount as of March 31, 2022 of $10,770,037 by the public offering price discounted by 15%, up to 19.9% of our outstanding common stock after giving effect to the initial public offering, for a total value of common shares to be issued of $5,874,186, (b) 80,965 shares of our preferred stock that are to be issued to Knight, determined by dividing the accumulated interest balance as of March 31, 2022 of $8,096,500 by $100.00, rounding up for fractional shares, for a total value of preferred stock to be issued of $8,096,486, (c) recognition of derivative liability in the amount of $1,964,658, relating to the fair value of the milestone payment to be due to Knight if, after the date of the initial public offering, we sell Arakoda or if a Change of Control occurs, (d) recognition of $8,927 of royalty liability due to Knight after the date of the initial public offering in the amount of 3.5% of net sales, and (e) recognition of a gain on the conversion of debt in the amount of $5,871,570, determined by the fair value of our cumulative outstanding Knight debt as of March 31, 2023 of $21,815,841 less the value of (a) through (d) herein, (vi) 383,908 shares of our common stock that are to be issued prior to the closing of this offering as a result of either the conversion or extinguishment of our interim financing notes, excluding the Xu Yu Equity Conversion Note, and a net loss on conversion of $298,431, which is determined based on the aggregate net carrying value of the convertible promissory notes as of June 1, 2023 of $1,651,560, less the total value of common shares to be issued of $1,949,991, (vii) 214,934 shares of our common stock that are to be issued pursuant to the Xu Yu Equity Conversion Note, and a net gain on conversion of $25,040, which is determined based on the aggregate net carrying value of the Xu Yu Equity Conversion Note as of March 31, 2023 of $1,164,190, less the total value of common shares to be issued of $1,139,150 and (viii) 40,000 shares of our common stock valued at $5.00 per share that are to be issued to four of our directors on the date of effectiveness of the registration statement of which this prospectus forms a part, and an offsetting charge of $200,000 recognized in compensation expense; and excludes 31,447 shares of our common stock underlying a warrant issued to Bigger Capital Fund, LP with an exercise price equal to 110% of the initial public offering price of the Units, 26,205 shares of our common stock underlying a warrant issued to Cavalry Investment Fund, LP with an exercise price equal to 110% of the initial public offering price of the Units, 26,205 shares of our common stock underlying a warrant issued to Walleye Opportunities Master Fund Ltd. with an exercise price equal to 110% of the initial public offering price of the Units, 10,482 shares of our common stock underlying a warrant issued to Geoffrey Dow with an exercise price equal to 110% of the initial public offering price of the Units, 69,444 shares of our common stock underlying a warrant issued to Mountjoy Trust with an exercise price equal to 110% of the initial public offering price of the Units, 10,482 shares of our common stock underlying a warrant issued to Cyberbahn Federal Solutions, LLC with an exercise price equal to 110% of the initial public offering price of the Units, 10,482 shares of our common stock underlying a warrant issued to Ariana Bakery Inc with an exercise price equal to 110% of the initial public offering price of the Units, 31,447 shares of our common stock underlying a warrant issued to Sabby Volatility Warrant Master Fund, Ltd. with an exercise price equal to 110% of the initial public offering price of the Units, 5,241 shares of our common stock underlying a warrant issued to Steel Anderson with an exercise price equal to 110% of the initial public offering price of the Units, 10,482 shares of our common stock underlying a warrant issued to Bixi Gao & Ling Ling Wang, 84,906 shares of our common stock issuable upon the exercise of the Representative Warrants with an exercise price equal to 110% of the initial public offering price of the Units and 238,601 shares of common stock reserved for issuance under our 2022 Equity Incentive Plan.

(3) The number of issued and outstanding shares as of March 31, 2023 on a pro forma as adjusted basis reflects the pro forma adjustments discussed in footnote (2) above and our receipt of the net proceeds of approximately $6,336,726 resulting from our sale and issuance of 1,415,095 Units in this offering at an assumed initial public offering price of $5.30 per Unit (the midpoint of the price range set forth on the front cover page of this prospectus) for total gross proceeds of $7,500,000, after deducting $1,163,274 of estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Each $1.00 increase or decrease in the assumed initial public offering price of $5.30 per Unit (the midpoint of the price range set forth on the front cover page of this prospectus) would increase or decrease, as applicable, the amount of our cash, additional paid-in capital and total stockholders' equity by $1,280,660 and ($829,888), respectively, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus,

remains the same, after deducting estimated underwriting discounts and commissions payable by us. An increase or decrease of 1,000,000 Units of our common stock offered by us would increase or decrease, as applicable, the amount of our cash, additional paid-in capital and total stockholders' equity by $5,247,273 and $(4,345,727), respectively, assuming an initial public offering price of $5.30 per Unit (the midpoint of the price range set forth on the front cover page of this prospectus) after deducting estimated underwriting discounts and commissions payable by us.

DILUTION

Purchasers of our common stock in this offering will experience an immediate and substantial dilution in the adjusted net tangible book value of their shares of common stock. Dilution in as adjusted net tangible book value represents the difference between the public offering price per share that is part of the Unit and the as adjusted net tangible book value per share of our common stock immediately after the offering.

The historical net tangible book value (deficit) of our common stock as of March 31, 2023, was ($19,727,151) or ($8.30) per share. Historical net tangible book value per share of our common stock represents our total tangible assets (total assets less intangible assets) less total liabilities divided by the number of shares of common stock outstanding as of that date. After giving effect to the (i) receipt of short-term advances from related parties totaling $50,000 after March 31, 2023 but prior to the date of this prospectus, (ii) repayment of the (A) $200,000 short-term advance from the Geoffrey S. Dow Revocable Trust contributed in March 2023, (B) $23,000 short term advance from the Geoffrey S. Dow Revocable Trust contributed in April 2023 and (C) $27,000 from Tyrone Miller contributed in May 2023, (iii) issuance of promissory notes in May 2023 for a total principal of $722,222 and a net carrying value of $555,000, (iv) issuance of 29,245 shares of our common stock and payment of $100,000 in cash to BioIntelect pursuant to the BioIntelect Agreement, (v) issuance of 1,108,337 shares of our common stock and 80,965 shares of our preferred stock to Knight as a result of the conversion of our outstanding debt owed to Knight pursuant to the Knight Debt Conversion Agreement, (vi) issuance of 383,908 shares of our common stock as a result of either the conversion or extinguishment of our interim financing notes excluding the Xu Yu Equity Conversion Note, (vii) issuance of 214,934 shares of our common stock pursuant to the Xu Yu Equity Conversion Note and (viii) issuance of 40,000 shares of our common stock that are to be issued to four of our directors on the date of effectiveness of the registration statement of which this prospectus forms a part, our pro forma net tangible book value as of March 31, 2023 would have been $3,085,855 or approximately $0.74 per share of our common stock.

After giving effect to the pro forma adjustments set forth above and the issuance of 1,415,095 shares that are part of the Units in this offering at an assumed initial public offering price of $5.30 per Unit (the midpoint of the price range set forth on the front cover page of this prospectus) for net proceeds of approximately $6,336,726, our pro forma as adjusted net tangible book value as of March 31, 2023 would have been $9,422,585 or approximately $1.69 per share of our common stock. This represents an immediate increase in pro forma net tangible book value per share of $0.95 to the existing stockholders and an immediate dilution in pro forma net tangible book value per share of $3.61. The following table illustrates this per share dilution to new investors:

Public offering price per share		$ 5.30
Historical net tangible book value (deficit) per share as of March 31, 2023	$ (8.30)	
Pro forma increase in net tangible book value per share attributable to the adjustments	9.04	
Pro forma net tangible book value per share as of March 31, 2023	0.74	
Increase in pro forma net tangible book value per share after giving effect to the offering	0.95	
Pro forma as adjusted net tangible book value (deficit) per share as of March 31, 2023 after the offering		1.69
Dilution in pro forma net tangible book value per share to new investors after giving effect to the offering		$ 3.61

Each $1.00 increase or decrease in the assumed initial public offering price of $5.30 per Unit (the midpoint of the price range set forth on the front cover page of this prospectus) would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share to existing investors by approximately $0.23 and ($0.15), respectively, and would increase or decrease, as applicable, dilution per share to new investors in this offering by ($0.23) and $0.15, respectively, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1,000,000 Units offered by us would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share to existing investors by approximately $0.54 and ($0.58), respectively, and increase or decrease, as applicable, the dilution to new investors by ($0.54) and $0.58 per share, respectively, assuming the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

After completion of this offering, our existing stockholders would own approximately 74.6% and our new investors would own approximately 25.4% of the total number of shares of our common stock outstanding after this offering.

To the extent that outstanding options or warrants, if any, are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the information presented in "Selected Historical Consolidated Financial Data" and our historical consolidated financial statements and the related notes included elsewhere in this prospectus. In addition to historical information, the following discussion contains forward-looking statements, such as statements regarding our expectation for future performance, liquidity and capital resources, that involve risks, uncertainties and assumptions that could cause actual results to differ materially from our expectations. Our actual results may differ materially from those contained in or implied by any forward-looking statements. Factors that could cause such differences include those identified below and those described in "Cautionary Note Regarding Forward-Looking Statements," "Risk Factors" and "Audited Consolidated Financial Information." We assume no obligation to update any of these forward-looking statements.

Overview

We specialize in the cost-effective development and commercialization of small molecule therapeutics for infectious diseases. We have a single FDA-approved product Arakoda, for malaria prevention in travelers. This product is revenue-generating in the United States and foreign markets, but not yet profitable, primarily due to the lack of an active marketing campaign following its introduction into the U.S. supply chain in late 2019. The COVID-19 pandemic curtailed foreign travel and therefore any ability to raise financing to support an active marketing effort.

We believe that the pathway to profitability lies through future investment in an active marketing program and recruitment of a direct sales force to support Arakoda. However, the return on investment for such an effort is likely to be much greater if it can be shown that the pool of potential prescriptions/patients is larger than that for malaria prevention alone. To that end, our primary operational goal is to demonstrate the clinical effectiveness of the already approved dosing regimen of Arakoda in other disease states. Thus, in the second half of 2023, our focus will be on executing a Phase II B clinical investigation of the efficacy of Arakoda in COVID-19 outpatients. Other supporting activities referenced below and elsewhere in this prospectus, such as improving technical specifications, limited marketing efforts, portfolio development, and observing the progress of foreign market growth, will be conducted as resources permit.

Key Factors Affecting our Performance

As a result of a number of factors, our historical results of operations may not be comparable to our results of operations in future periods, and our results of operations may not be directly comparable from period to period. Set forth below is a brief discussion of the key factors impacting our results of operations.

Known Trends and Uncertainties

Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Supply Chain

Our approved product, Arakoda, is manufactured in India. During the audited period, our contract manufacturer experienced reduced capacity due to the COVID-19 pandemic, which in theory, but not in practice, could have disrupted continuity of U.S. supply of Arakoda.

Geopolitical Conditions

In February 2022, Russia initiated significant military action against Ukraine. In response, the U.S. and certain other countries imposed significant sanctions and export controls against Russia, Belarus and certain individuals and entities connected to Russian or Belarusian political, business, and financial organizations, and the U.S. and certain other countries could impose further sanctions, trade restrictions, and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U.S. and other countries in respect thereof as well as any counter measures or retaliatory actions by Russia or Belarus in response, including, for example, potential cyberattacks or the disruption of energy exports, is likely to cause regional instability, geopolitical shifts, and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. The situation remains uncertain, and while it is difficult to predict the impact of any of the foregoing, the conflict and actions taken in response to the conflict could increase our costs, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

Effects of the COVID-19 Pandemic

The current pandemic of COVID-19 has globally resulted in loss of life, business closures, restrictions on travel, and widespread cancellation of social gatherings. While the disruption is currently expected to be temporary, there is considerable uncertainty around the duration. Therefore, we expect this matter to negatively impact our operating results.

The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted at this time, including:

- new information which may emerge concerning the severity of the disease;
- the duration and spread of the outbreak;
- the severity of travel restrictions imposed by geographic areas in which we operate, mandatory or voluntary business closures;
- our ability to enroll patients;
- regulatory actions taken in response to the pandemic, which may impact merchant operations, consumer and merchant pricing, and our product offerings;
- other business disruptions that affect our workforce and supply chain;
- the impact on capital and financial markets; and
- actions taken throughout the world, including in markets in which we operate, to contain the COVID-19 outbreak or treat its impact.

In addition, the current pandemic of COVID-19 has resulted in a widespread global health crisis and adversely affected global economies and financial markets, and similar public health threats could do so in the future. Any potential impact to our results will depend on, to a large extent, future developments and new information that may emerge regarding the duration and severity of the COVID-19 pandemic and the actions taken by government authorities and other entities to contain the COVID-19 pandemic or treat its impact, almost all of which are beyond our control. If the disruptions posed by the COVID-19 pandemic or other matters of global concern continue for an extensive period of time, the operations of our business may be materially adversely affected.

To the extent the COVID-19 pandemic or a similar public health threat has an impact on our business, it is likely to also have the effect of heightening many of the other risks described in the "*Risk Factors*" section.

Seasonality

Our business could be affected by seasonal variations. For instance, we expect to experience higher sales in the second and third quarters of the fiscal year. However, taken as a whole, seasonality does not have a material impact on our financial results.

Foreign Currency

Our reporting currency is the U.S. dollar and our operations in Australia and Singapore use their local currency as their functional currencies. We are subject to the effects of exchange rate fluctuations with respect to any of such currency. The income statements of some of our operations are translated into U.S. dollars at the average exchange rates in each applicable period. To the extent the U.S. dollar strengthens against foreign currencies, the translation of these foreign currencies denominated transactions results in reduced revenue, operating expenses and net income for our international operations. We are also exposed to foreign exchange rate fluctuations as we convert the financial statements of our foreign subsidiaries into U.S. dollars in consolidation.

Concentration of Revenues

We received the majority of our revenues from sales of our Arakoda product to the DoD. The DoD has historically been our largest customer. Upon fulfilment of the final purchase of product under the contract, which expired on August 31, 2022, the DoD has not issued any further contracts nor contract modifications to allow additional procurement. Further information is provided in the "*Revenue*" section below. Revenues remain concentrated. The following tables set forth our concentrations of revenues for the three months ended March 31, 2023 and 2022 and the twelve months ended December 31, 2022 and 2021.

Three Months Ended March 31, 2023, and 2022

Customers (Market)	**3/31/2023**	**3/31/2022**	**$ Change**	**% Change**
Biocelect (Australia)	$ 36,438	$ -	$ 36,438	100%
ICS AmerisourceBergen (US Commercial)	(19,266)	47,024	(66,290)	(141)
Net Sales Revenue	$ 17,172	$ 47,024	$ (29,852)	(63)%

Twelve Months Ended December 31, 2022, and 2021

Customers (Market)	**12/31/2022**	**12/31/2021**	**$ Change**	**% Change**
Biocelect (Australia)	$ 86,763	$ 37,046	$ 49,717	134%
DoD (US Military)	30,295	1,150,650	(1,120,355)	(97)%
ICS AmerisourceBergen (US Commercial)	88,150	(27,356)	115,506	(422)%
Scandinavian Biopharma Distribution AB (European Union)	18,000	-	18,000	NA%
Net Sales Revenue	$ 223,208	$ 1,160,340	$ (937,132)	(81)%

Results of Operations

Three Months Ended March 31, 2023, and 2022

The following table sets forth our results of operations for the periods presented:

	Three Months Ended March 31,	
Consolidated Statements of Operations Data:	**2023**	**2022**
Product revenues – net of discounts and rebates	$ 17,172	$ 47,024
Cost of revenues	73,120	90,134
Gross loss	(55,948)	(43,110)
Research revenues	4,292	117,147
Net revenue	(51,656)	74,037
Operating expenses:		
Research and development	123,994	63,057
General and administrative expenses	775,014	174,692
Total operating expenses	899,008	237,749
Loss from operations	(950,664)	(163,712)
Interest and other income (expense), net:		
Interest expense	(1,141,429)	(762,217)
Change in fair value of derivative liabilities	(5,134)	-
Loss on debt extinguishment	(839,887)	-
Change in fair value of promissory note	339,052	-
Other income	591	18,732
Total interest and other income (expense), net	(1,646,807)	(743,485)
Loss from operations before provision for income taxes	(2,597,471)	(907,197)
Provision for income taxes	63	250
Net loss including noncontrolling interest	(2,597,534)	(907,447)
Net gain (loss) noncontrolling interest	2,527	4,835
Net loss - attributed to 60 Degrees Pharmaceuticals Inc	(2,600,061)	(912,282)
Comprehensive loss:		
Net loss	(2,597,534)	(907,447)
Unrealized foreign currency translation gain (loss)	(1,290)	96,556
Total comprehensive loss	(2,598,824)	(810,891)
Net gain (loss) – noncontrolling interest	2,527	4,835
Unrealized foreign currency translation gain from noncontrolling interest	-	-
Comprehensive loss - attributed to 60 Degrees Pharmaceuticals, Inc.	$ (2,601,351)	$ (815,726)

The following table sets forth our results of operations as a percentage of revenue:

	Three Months Ended March 31,	
Consolidated Statements of Operations Data:	**2023**	**2022**
Product revenues – net of discounts and rebates	100.00%	100.00%
Cost of revenues	425.81	191.68
Gross loss	(325.81)	(91.68)
Research revenues	24.99	249.12
Net revenue	(300.82)	157.44
Operating expenses:		
Research and development	722.07	134.10
General and administrative expenses	4,513.24	371.50
Total operating expenses	5,235.31	505.60
Loss from operations	(5,536.13)	(348.16)
Interest and other income (expense), net:		
Interest expense	(6,647.04)	(1,620.91)
Change in fair value of derivative liabilities	(29.90)	-
Loss on debt extinguishment	(4,891.03)	-
Change in fair value of promissory note	1,947.45	-
Other income	3.44	39.83
Total interest and other income (expense), net	(9,590.08)	(1,581.08)
Loss from operations before provision for income taxes	(15,126.21)	(1,929.24)
Provision for income taxes	0.37	0.53
Net loss including noncontrolling interest	(15,126.58)	(1,929.77)
Net gain (loss) noncontrolling interest	14.72	10.28
Net loss - attributed to 60 Degrees Pharmaceuticals Inc	(15,141.30)	(1,940.05)
Comprehensive loss:		

Net loss	(15,126.58)	(1,929.77)
Unrealized foreign currency translation gain (loss)	(7.51)	205.34
Total comprehensive loss	(15,134.09)	(1,724.43)
Net gain (loss) – noncontrolling interest	14.72	10.28
Unrealized foreign currency translation gain from noncontrolling interest	0.00	0.00
Comprehensive loss - attributed to 60 Degrees Pharmaceuticals, Inc.	(15,148.81)	(1,734.71)

Comparison of the Three Months Ended March 31, 2023, and 2022

Product and Service Revenue, Discounts and Rebates, Net Sales Revenue, Cost of Goods Sold, Gross Profit, and Gross Margin

	Three Months Ended March 31,			
	2023	2022	$ Change	% Change
Product revenues – net of discounts and rebates	$ 17,172	$ 47,024	$ (29,852)	(63.48)%
Cost of revenues	73,120	90,134	(17,014)	(18.88)
Gross loss	$ (55,948)	$ (43,110)	$ (12,838)	(29.78)%
Gross margin	(325.81)%	(91.68)%		

Product Revenues – Net of Discounts and Rebates, Service Revenue and Net Product and Service Revenues

Our product revenues were $17,172 for the three months ended March 31, 2023, as compared to $47,024 for the three months ended March 31, 2022. As of March 31, 2023, our Australian distributor accounted for 212% (0% as of March 31, 2022), and our U.S. distributor accounted for (112%) of our total net product sales (100% as of March 31, 2022). While our sales volume increased over the same periods, the decrease in net product sales was impacted by the reduction of our wholesale acquisition cost of Arakoda™ (16 x 100 mg tablets) from $285 to $235 per box in January 2023, in addition to expiring inventory returns.

We offer discounts and rebates to the civilian U.S. supply chain distribution channel. We record sales when our third-party logistics (“3PL”) partner transfers boxes into their title model. Discounts and rebates are offered to our 3PL partner amounting to 2%. Then product is transferred normally to one of the three large U.S. pharmaceutical distributors where rebates range form 10-12%. Lastly, we have relationships with several large pharmacy benefit managers (“PBMs”) that allows patients to purchase Arakoda at a discount. The rebate associated with PBMs ranges from 15% to 30% depending on the amount of coverage provided. For the three months ending March 31, 2023, discounts and rebates were $25,499 compared to 13,396 for the three months ending March 31, 2022.

Although, as of the date of this prospectus, we were not in discussions with the DoD about additional/future procurement, we anticipate that this will be feasible in the future if one or more of the conditions/events described in this paragraph occur. First, the position of Arakoda in the DoD formulary (Tricare, deployed personnel) needs to be improved from second/third tier to at least equivalency with competing products (as is the case for civilian use as recommended by the CDC). Second, the shelf-life of the existing product requires extension, which is known to be technically possible as the shelf-life of Kodatef in Australia is 48 months, but appropriate data must be generated to meet FDA requirements. Finally, a change in the operational footprint of DoD deployments to areas with higher malaria attack rates (e.g., the Liberia deployment to manage the Ebola outbreak in 2014) may lead to a rapid reassessment by DoD of the position of Arakoda in the formulary (advancement of the last approved prophylactic antimalarial to co-equal standard of care took thirteen years).

Arakoda entered the U.S. civilian supply chain in the third quarter of 2019. For the three months ended March 31, 2022, 91 boxes were sold to pharmacies and dispensaries. Sales increased by 101% to 183 boxes to patients for the three months ended March 31, 2023. The increase in commercial sales volume reflects the response to the reduction of our wholesale acquisition cost effective January 2023.

Kodatef sales to our distributor Biocelect in Australia for the three months ended March 31, 2023 were $36,438 ($0 for the three months ended March 31, 2022). Sales to Biocelect are currently subject to a profit share distribution once the original transfer price has been recouped. As of March 31, 2023, no profit share has been due to us, though we did settle the historical profit share through March 31, 2022 for $24,486 (AUD$35,000) on January 16, 2023.

During the first three months of 2023, we recorded our first sale of Arakoda/Kodatef to our European distributor Scandinavian Biopharma Distribution AB. Product will be distributed there on a named patient basis. As in Australia a profit distribution share is possible depending on the retail price established.

Cost of Revenues, Gross (Loss) Profit, and Gross Margin

The cost of goods sold was $73,120 for the three months ended March 31, 2023, as compared to $90,134 for the three months ended March 31, 2022. The decrease in cost of goods sold is primarily due to lower commercial sales. The Gross Margin % fell to (325.81)% for the three months ended March 31, 2023 from (91.68)% for the three months ended March 31, 2022. This is due to the current low sales volume and the fixed part of cost of goods. As the sales volume continues to grow the gross margin will improve as the variable cost of goods of each Unit sold is substantially less than the sales price.

Other Operating Revenues

	Three Months Ended March 31,			
	2023	2022	$ Change	% Change
Research revenues	$ 4,292	$ 117,147	$ (112,855)	(96.34)%

The research revenues earned by us were $4,292 for the three months ended March 31, 2023, as compared to $117,147 for the three months ended March 31, 2022. Our research revenues have historically been derived mostly from a single, awarded research grant in the amount of $4,999,814 at the beginning of December 2020 (with an additional $720,000 awarded February 26, 2021) from the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (which may be referred to as "JPEO") to study Arakoda in mild-to-moderate COVID-19 patients. A majority of the study was completed in 2021 with the planned lab data analysis and the submission of the final study report completed during the first nine months of 2022. During the three months ended March 31, 2022, we recognized $94,908 in revenue from the JPEO, compared to $0 during the three months ended March 31, 2023. We also earn research revenues from the Australian Tax Authority for research activities conducted in Australia. The revenue was $4,292 at the end of three months ended March 31, 2023 compared to $22,239 during the three months ended March 31, 2022.

Operating Expenses

	Three Months Ended March 31,			
	2023	2022	$ Change	% Change
Research and development	$ 123,994	$ 63,057	$ 60,937	96.64%
General and administrative	775,014	174,692	600,322	343.65
Total operating expenses	$ 899,008	$ 237,749	$ 661,259	278.13%

Research and Development Expenses

Research and development costs increased during the three months ended March 31, 2023 when compared to the three months ended March 31, 2022 as we incurred initiation costs related to our Phase IIB COVID-19 clinical trial, which is expected to commence in the second half of 2023. Direct COVID-19-related trial costs are 85% of the costs through the three months ended March 31, 2023 at $105,257 and 29% of the costs for the three months ended March 31, 2022 at $18,514.

General and Administrative Expenses

For the three months ended March 31, 2023, our general and administrative expenses increased by 344% or $600,322. During the three months ended March 31, 2023 we spent substantially more for accounting and auditing at $370,605 (up from $8,634 for the three months ended March 31, 2022). Additionally, during the three months ended March 31, 2023, we incurred $164,539 of investor outreach expenses, $29,333 of advertising and promotion expenses, and $90,000 of pharmacovigilance monitoring costs (up from $0, $0, and $12,000 for the three months ended March 31, 2022, respectively).

Interest and Other Income (Expense), Net

	Three Months Ended March 31,			
	2023	2022	$ Change	% Change
Interest expense	$ (1,141,429)	$ (762,217)	$ (379,212)	49.75%
Change in fair value of derivative liabilities	(5,134)	-	(5,134)	NA
Loss on debt extinguishment	(839,887)	-	(839,887)	NA
Change in fair value of promissory note	339,052	-	339,052	NA
Other income	591	18,732	(18,141)	(96.84)
Total Interest and Other Income (Expense), Net	$ (1,646,807)	$ (743,485)	$ (903,322)	121.50%

Interest Expense

For the three months ended March 31, 2023, we recognized $1,141,429 of interest expense ($762,217 for the three months ended March 31, 2022). The increase is primarily related to growing principal and interest balances with the primary lender Knight. Cash paid for interest expense was $2,193 and none for the three months ended March 31, 2023 and March 31, 2022, respectively.

Change in Fair Value of Derivative Liabilities

For the twelve months ended March 31, 2023, we recognized a change in fair value of derivative liabilities of ($5,134) (none for the three months ended March 31, 2022). The increase is related to derivatives generated from the bridge funding raise in May 2022.

Loss on debt extinguishment

For the three months ended March 31, 2023, we recognized a ($839,887) loss on debt extinguishment (none for the three months ended March 31, 2022). The increase is related to the conversion of the cumulative outstanding debt pursuant to the Knight Debt Conversion Agreement in January 2023.

Change in Fair Value of Promissory Note

For the three months ended March 31, 2023, we recognized a $339,052 gain on the fair value of the promissory note with Knight (none for the three months ended March 31, 2022). Our cumulative debt outstanding with Knight was not measured at fair value on a recurring basis prior to the Knight Debt Conversion Agreement executed in January 2023, hence we recorded a $0 change in fair value for the three months ended March 31, 2022.

Other Income (Expense), Net

For the three months ended March 31, 2023, we recognized $591 in other income compared to $18,732 for the three months ended March 31, 2022.

Twelve Months Ended December 31, 2022, and 2021

The following table sets forth our results of operations for the periods presented:

	Twelve Months Ended December 31,	
Consolidated Statements of Operations Data:	**2022**	**2021**
Product revenues – net of discounts and rebates	$ 192,913	$ 1,078,440
Service revenues	30,295	81,900
Product and service revenues	223,208	1,160,340
Cost of revenues	432,370	850,742
Gross (loss) profit	(209,162)	309,598
Research revenues	288,002	5,192,516
Net revenue	78,840	5,502,114
Operating expenses:		
Research and development	525,563	5,510,866
General and administrative expenses	1,303,722	1,115,350
Total operating expenses	1,829,285	6,626,216
Loss from operations	(1,750,445)	(1,124,102)
Interest and other income (expense), net:		
Interest expense	(3,989,359)	(3,172,712)
Derivative expense	(504,613)	-
Change in fair value of derivative liabilities	(10,312)	-
Gain on debt extinguishment	120,683	-
Other income (expense)	(43,238)	37,515
Total interest and other income (expense), net	(4,426,839)	(3,135,197)
Loss from operations before provision for income taxes	(6,177,284)	(4,259,299)
Provision for income taxes	500	1,000
Net loss including noncontrolling interest	(6,177,784)	(4,260,299)
Net gain (loss) noncontrolling interest	3,936	(8,554)
Net loss - attributed to 60 Degrees Pharmaceuticals Inc	(6,181,720)	(4,251,745)
Comprehensive loss:		
Net loss	(6,177,784)	(4,260,299)
Unrealized foreign currency translation loss	(2,127)	(3,031)
Total comprehensive loss	(6,179,911)	(4,263,330)
Net gain (loss) – noncontrolling interest	3,936	(8,554)
Unrealized foreign currency translation gain from noncontrolling interest	-	1,588
Comprehensive loss - attributed to 60 Degrees Pharmaceuticals, Inc.	$ (6,183,847)	$ (4,256,364)

The following table sets forth our results of operations as a percentage of revenue:

	Twelve Months Ended December 31,	
Consolidated Statements of Operations Data:	**2022**	**2021**
Product revenues – net of discounts and rebates	86.43%	92.94%
Service revenues	13.57	7.06
Product and service revenues	100.00	100.00
Cost of revenues	193.71	73.32
Gross (loss) profit	(93.71)	26.68
Research revenues	129.03	447.50
Net revenue	35.32	474.18
Operating expenses:		
Research and development	235.46	474.94
General and administrative expenses	584.08	96.12
Total operating expenses	819.54	571.06
Loss from operations	(784.22)	(96.88)
Interest and other income (expense), net:		
Interest expense	(1,787.28)	(273.43)
Derivative expense	(226.07)	-
Change in fair value of derivative liabilities	(4.62)	-
Gain on debt extinguishment	54.07	-
Other income (expense)	(19.37)	3.23
Total interest and other income (expense), net	(1,983.27)	(270.20)
Loss from operations before provision for income taxes	(2,767.49)	(367.08)
Provision for income taxes	0.22	0.09
Net loss including noncontrolling interest	(2,767.71)	(367.17)
Net gain (loss) - noncontrolling interest	1.76	(0.74)
Net loss – attributable to 60 Degrees Pharmaceuticals, Inc.	(2,769.47)	(366.43)

Comprehensive loss:		
Net loss including noncontrolling interest	(2,767.71)	(367.17)
Unrealized foreign currency translation loss	(0.95)	(0.26)
Total comprehensive loss	(2,768.66)	(367.43)
Net gain (loss) – noncontrolling interest	1.76	(0.74)
Unrealized foreign currency translation gain from noncontrolling interest	-	0.14
Comprehensive loss - attributed to 60 Degrees Pharmaceuticals, Inc.	(2,770.42)%	(366.83)%

Comparison of the Twelve Months Ended December 31, 2022, and 2021

Product and Service Revenue, Discounts and Rebates, Net Sales Revenue, Cost of Goods Sold, Gross Profit, and Gross Margin

	Twelve Months Ended December 31,			
	2022	2021	$ Change	% Change
Product revenues – net of discounts and rebates	$ 192,913	$ 1,078,440	$ (885,527)	(82.11)%
Service revenues	30,295	81,900	(51,605)	(63.01)
Net product and service revenues	223,208	1,160,340	(937,132)	(80.76)
Cost of revenues	432,370	850,742	(418,372)	(49.18)
Gross (loss) profit	$ (209,162)	$ 309,598	$ (518,760)	(167.56)%
Gross margin	(93.71)%	26.68%		

Product Revenues – Net of Discounts and Rebates, Service Revenue and Net Product and Service Revenues

Our product revenues were $192,913 for the twelve months ended December 31, 2022, as compared to $1,078,440 for the twelve months ended December 31, 2021. As of December 31, 2022, one government customer accounted for 14% (and 95% as of December 31, 2021) of our total sales. The decrease in sales was mainly due to a 3-year Arakoda acquisition contract that involved purchasing a full lot (7,500 boxes) in 2020 and a half lot (3,750 boxes) in 2021, which was fulfilled by August 31, 2021. This contract was executed by the United States Army Medical and Materiel Development Activity (USAMMDA) to support commercialization efforts.

We offer discounts and rebates to the civilian U.S. supply chain distribution channel. We record sales when our third-party logistics (“3PL”) partner transfers boxes into their title model. Discounts and rebates are offered to our 3PL partner amounting to 2%. Then product is transferred normally to one of the three large U.S. pharmaceutical distributors where rebates range form 10-12%. Lastly, we have relationships with several large pharmacy benefit managers (“PBMs”) that allows patients to purchase Arakoda at a discount. The rebate associated with PBMs ranges from 15% to 30% depending on the amount of coverage provided. For the twelve months ending December 31, 2022, discounts and rebates were $59,552 compared to none for the twelve months ending December 31, 2021. There were neither discounts nor rebates on direct sales to USAMMDA.

Although, as of the date of this prospectus, we were not in discussions with the DoD about additional/future procurement, we anticipate that this will be feasible in the future if one or more of the conditions/events described in this paragraph occur. First, the position of Arakoda in the DoD formulary (Tricare, deployed personnel) needs to be improved from second/third tier to at least equivalency with competing products (as is the case for civilian use as recommended by the CDC). Second, the shelf-life of the existing product requires extension, which is known to be technically possible as the shelf-life of Kodatef in Australia is 48 months, but appropriate data must be generated to meet FDA requirements. Finally, a change in the operational footprint of DoD deployments to areas with higher malaria attack rates (e.g., the Liberia deployment to manage the Ebola outbreak in 2014) may lead to a rapid reassessment by DoD of the position of Arakoda in the formulary (advancement of the last approved prophylactic antimalarial to co-equal standard of care took thirteen years).

Arakoda entered the U.S. civilian supply chain in the third quarter of 2019. For the twelve months ended December 31, 2021, 389 boxes were sold to pharmacies and dispensaries. Sales increased by 47% to 570 boxes to patients for the twelve months ended December 31, 2022. Increasing commercial sales reflect organic growth, since no active marketing efforts were made during the pandemic and the wholesale acquisition cost has not changed from launch in 2019 through December 31, 2022.

Kodatef sales to our distributor Biocelect in Australia for the twelve months ended December 31, 2022 were $86,763 ($37,046 for the twelve months ended December 31, 2021). Sales to Biocelect are currently subject to a profit share distribution once the original transfer price has been recouped. As of December 31, 2022, no profit share has been due to us, though we did settle the historical profit share through September 30, 2022 for $24,486 (AUD$35,000) on January 16, 2023.

During 2022, we recorded our first sale of Arakoda/Kodatef to our European distributor Scandinavian Biopharma Distribution AB. Product will be distributed there on a named patient basis. As in Australia a profit distribution share is possible depending on the retail price established.

We also earned $30,295 from storing the Army’s Arakoda purchases through August 31, 2022 (when the contract ended) compared to $81,900 earned through the twelve months ended December 31, 2021 of which $57,000 of revenue was related to shipping stored Arakoda.

Cost of Revenues, Gross (Loss) Profit, and Gross Margin

The cost of goods sold was $432,370 for the twelve months ended December 31, 2022, as compared to $850,742 for the twelve months ended December 31, 2021. The decrease in cost of goods sold was primarily due to sale of a half lot to the government in 2021. The Gross Margin % fell to (94)% for the twelve months ended December 31, 2022 from 27% for the twelve months ended December 31, 2021. This is due to the current low sales volume and the fixed part of cost of goods. As the sales volume continues to grow the gross margin will improve as the variable cost of goods of each Unit sold is substantially less than the sales price.

Other Operating Revenues

	Twelve Months Ended December 31,			
	2022	2021	$ Change	% Change
Research revenues	$ 288,002	$ 5,192,516	$ (4,904,514)	(94.45)%

The research revenues earned by us were $288,002 for the twelve months ended December 31, 2022, as compared to $5,192,516 for the twelve months ended December 31, 2021. Our research revenues are derived mostly from a single, awarded research grant in the amount of $4,999,814 (with an additional $720,000 awarded February 26, 2021) from the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (which may be referred to as "JPEO") at the beginning of December 2020 to study Arakoda in mild-to-moderate COVID-19 patients. The trial was actively recruiting patients from February to September of 2021; hence the majority of the grant revenue was earned in the first nine months of 2021 ending on September 30 ($4,935,335). At the end of 2021, $245,552 remained on the grant. The study was largely completed with the planned lab data analysis and the submission of the final study report completed during the first nine months of 2022 ending on September 30. We also earn research revenues from the Australian Tax Authority for research expenses conducted in Australia. The revenue was $42,250 at the end of twelve months ended December 31, 2022 compared to $19,511 at the twelve months ended December 31, 2021.

Operating Expenses

	Twelve Months Ended December 31,			
	2022	2021	$ Change	% Change
Research and development	$ 525,563	$ 5,510,866	$ (4,985,303)	(90.46)%
General and administrative	1,303,722	1,115,350	188,372	16.89
Total operating expenses	$ 1,829,285	$ 6,626,216	$ (4,796,931)	(72.39)%

Research and Development Expenses

We considerably reduced research and development costs as we completed our Phase II COVID-19 trial in 2022. Direct COVID-19 related trial costs are 49% of the costs through the twelve months ended December 31, 2022 at $256,581 and 86% of the costs for the twelve months ended December 31, 2021 at $4,721,635. Research and development costs are expected to increase substantially in 2023, as the second COVID-19 clinical trial and supporting activities are initiated in the second half of the year.

General and Administrative Expenses

For the twelve months ended December 31, 2022, our general and administrative expenses increased by 17% or $188,372. While the net amounts did not change substantially for the twelve months ended December 31, in 2022 we spent substantially more for accounting and auditing at $173,975 (up from $15,071 for the twelve months ended December 31, 2021) and recorded $410,302 in professional services to be paid in stock (none for the 12 months ended December 31, 2021). Whereas, we spent substantially less for legal, regulatory advice and insurance, $202,974 at twelve months ended December 31, 2022 ($446,884 at twelve months ended December 31, 2021).

Interest and Other Income (Expense), Net

	Twelve Months Ended December 31,			
	2022	2021	$ Change	% Change
Interest expense	(3,989,359)	(3,172,712)	(816,647)	25.74%
Derivative expense	(504,613)	-	(504,613)	NA
Change in fair value of derivative liabilities	(10,312)	-	(10,312)	NA
Gain on debt extinguishment	120,683	-	120,683	NA
Other (expense) income	(43,238)	37,515	(80,753)	215.26
Total Interest and Other Income (Expense), Net	$ (4,426,839)	$ (3,135,197)	$ (1,291,642)	41.20%

Interest Expense

For the twelve months ended December 31, 2022, we recognized $3,989,359 of interest expense ($3,172,712 for the twelve months ended December 31, 2021). The increase is primarily related to growing principal and interest balances with the primary lender Knight. Cash paid for interest expense was $2,193 and none for the twelve months ended December 31, 2022 and December 31, 2021, respectively.

Derivative Expense

For the twelve months ended December 31, 2022, we recognized $504,613 of derivative expense (none for the twelve months ended December 31, 2021). The increase is related to the raising of $1,105,000 of bridge funding.

Change in Fair Value of Derivative Liabilities

For the twelve months ended December 31, 2022, we recognized a change in fair value of derivative liabilities of $10,312 (none for the twelve months ended December 31, 2021). The increase is related to derivatives generated from the bridge funding raise.

Gain on debt extinguishment

For the twelve months ended December 31, 2022, we recognized a $120,683 gain on debt extinguishment (none for the twelve months ended December 31, 2021). The increase is related to the renegotiation of the Xu Yu promissory note.

Other Income (Expense), Net

For the twelve months ended December 31, 2022, we recognized ($43,238) in other income (expense) compared to $37,515 for the twelve months ended December 31, 2021. In 2022, it was uncovered that federal tax form 8992 may have not been properly filed. We have elected to record a $30,000 tax liability for the audit of the twelve months ended December 31, 2022, $10,000 each for the years ended December 31, 2019, 2020 and 2021 (none for the twelve months ended December 31, 2021). For the twelve months ended December 31, 2021 we recorded $38,500 of PPA loan forgiveness income (none for the twelve months ended December 31, 2022).

Liquidity and Capital Resources

We had net cash used in operating activities of $1,009,980 for the twelve months ended December 31, 2022, and the cash balance was $29,993 as of March 31, 2023 ($264,865 as of December 31, 2022). Based on current internal projections, should the full amount of the proceeds from this offering be realized, and if our planned COVID-19 clinical study is eligible to receive Australian government research and development tax rebates and it is possible to borrow and receive funds from a lender ahead of issuance of those tax rebates, we estimate that we will have sufficient funds to remain viable through March 31, 2024 (sufficient to complete an optional futility analysis at 33% enrolment in the clinical study if desired). However, we may not remain viable until March 31, 2024, if we end up being ineligible for research tax credits or cannot borrow against their future issuance. We cannot give assurance that we can increase our cash balances or limit our cash consumption and thus maintain sufficient cash balances for our planned operations or future acquisitions. Future business demands may lead to cash utilization at levels greater than recently experienced. We may need to raise additional capital in the future. However, we cannot assure you that we will be able to raise additional capital on acceptable terms, or at all.

To date, we have funded our operations through debt and equity financings.

Going Concern

As of March 31, 2023, we had an accumulated deficit of $31,415,209. In their audit report for the fiscal year ended December 31, 2022 included in this report, our auditors have expressed their concern as to our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate cashflows from operations and obtain financing.

The accompanying consolidated financial statements for the twelve months ended December 31, 2022, and December 31, 2021, respectively, included an explanatory note referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. Our consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. To date, we have not yet established an ongoing source of revenues and cash flows sufficient to cover our operating costs and allow us to continue as a going concern. These factors among others raise substantial doubt about our ability to continue as a going concern for at least one year from the date of issuance of the accompanying consolidated financial statements.

Our ability to continue as a going concern is dependent upon our ability to generate profitable operations in the future and/or to obtain the necessary financing to meet our obligations and repay our liabilities arising from normal business operations when they become due. The outcome of these matters cannot be predicted with any certainty at this time and raise substantial doubt that we will be able to continue as a going concern. Our consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

Borrowings

On December 10, 2015, we entered into the Loan Agreement and Engagement with Knight, as amended eight times, pursuant to which, we originally borrowed $500,000 at a per annum interest rate of 15% (the "Knight Loan") and a debenture agreement of face value $3 million on April 24, 2018 (the "Knight Debenture"). As of March 31, 2023, the current outstanding balance of the Knight Loan and Knight Debenture, following the Knight Debt Conversion Agreement (described below) is $21,815,841.

Pursuant to the Knight Debt Conversion Agreement, executed January 9, 2023 and modified on January 13, 2023, and again on January 27, 2023, Knight and us agreed, to formalize a previously negotiated term sheet that, in the event of a successful initial public offering, we will fix Knight's cumulative debt to the value as it stood on March 31, 2022, which consisted of $10,770,037 in principal and $8,096,486 in accumulated interest, and to convert the aforementioned amounts, should we consummate an initial public offering that results in gross proceeds of at least $7,000,000 prior to December 31, 2023 as follows:

- We agreed to convert the principal amount into (i) that number of shares of common stock equal to dividing the principal amount by an amount equal to the offering price of the common stock in the initial public offering discounted by 15% (the "Conversion Common Shares"), rounding up for fractional shares, in a number of Conversion Shares up to 19.9% of our outstanding common stock after giving effect of the initial public offering; (ii) we will make a milestone payment of $10 million to Knight if, after the date of a qualifying initial public offering, we sell Arakoda or if a Change of Control (as per the definition included in the original loan agreement dated on December 10, 2015) occurs, provided that the purchaser of Arakoda or individual or entity gaining control of us is not Knight or an affiliate of Knight; (iii) following the License and Supply agreement dated on December 10, 2015 and subsequently amended on January 21, 2019, an expansion of existing distribution rights to Tafenoquine/Arakoda to include COVID-19 indications as well as malaria prevention across the Territory as defined in said documents, subject to U.S. Army approval; and (iv) we will retain Knight or an affiliate of Knight to provide financial consulting services, management, strategic and/or regulatory advice of value $30,000 per month for five years (the parties will negotiate the terms of that consulting agreement separately in good faith).

- The parties agreed to convert the accrued interest into that number of shares (the "Conversion Preferred Shares" and, together with the Conversion Common Shares, the "Conversion Shares") of a new class of preferred stock (the "Preferred Stock") by dividing the Accrued Interest by $100.00, then rounding up. The Preferred Stock shall have the following rights, preferences, and designations: (i) have a 6% cumulative dividend accumulated annually on March 31; (ii) shall be non-voting stock; (iii) are not redeemable, (iv) be convertible to shares of common stock at a price equal to the lower of (1) the price paid for the shares of common stock in the initial public offering and (2) the 10 day volume weighted average share price immediately prior to conversion; and (v) conversion of the preferred stock to common shares will be at our sole discretion. Notwithstanding the foregoing, we shall not convert the Preferred Stock into shares of common stock if as a result of such conversion Knight will own 19.9% or more of our outstanding common stock.

- In addition to the conversion of the debt, for a period commencing on January 1, 2022 and ending upon the earlier of 10 years after the closing of the initial public offering or the conversion or redemption in full of the Conversion Preferred Shares, we shall pay Knight a royalty equal to 3.5% of our net sales (the "Royalty"), where "Net Sales" has the same meaning as in our license agreement with the U.S. Army for Tafenoquine. Upon the qualified initial public offering, we shall calculate the royalty payable to Knight at the end of each calendar quarter. We shall pay to Knight the royalty amounts due with respect to a given calendar quarter within fifteen (15) business days after the end of such calendar quarter. Each payment of royalties due to Knight shall be accompanied by a statement specifying the total gross sales, the net sales and the deductions taken to arrive to net sales. For clarification purposes, the first royalty payment will be performed following the above instructions, on the first calendar quarter in which the qualified initial public offering takes place and will cover the sales of the period from January 1, 2022, until the end of said calendar quarter.

Should an initial public offering not occur by January 1, 2024, then all terms of the original Knight Loan and Knight Debenture would resume including any interest earned after March 31, 2022.

On October 11, 2017, we issued a $750,000 promissory note, as amended (the "Avante Note"), to Avante International Limited ("Avante") with accrued interest at an annual rate of 5.0% for the first six months, and 10% thereafter. On December 23, 2017, Avante transferred the Avante Note to Xu Yu Equity Conversion Note.

On December 11, 2022, Avante and us amended the Avante Note (the "Amendment"). The Amendment added a provision to automatically convert the outstanding principal and accumulated interest through March 31, 2022 to shares of common stock in the event we consummate an initial public offering. The Amendment also provides Avante the option to convert the outstanding principal and accumulated interest through March 31, 2022 to equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest after March 31, 2022 will be forfeited should the lender elect to convert the Note into equity. We evaluated the Amendment and determined that it constitutes an extinguishment as the option to convert interest through March 31, 2022 and is considered the addition of a substantive conversion option. Accordingly, the Amendment resulted in extinguishment accounting and a corresponding extinguishment gain of $120,683, which represents the difference between the carrying value of the Avante Note just prior to the Amendment and the fair value of the Avante Note just after the Amendment.

The extinguishment accounting resulted in a fair value of the Avante Note, including the Amendment of $1,099,578. The discount of $120,683 and costs incurred with third parties directly related to the Amendment of $1,767 will be amortized over the remaining life of the debt using the effective interest method. Amortization of the discount on the Avante Note, including the Amendment for the year ended December 31, 2022 was $4,955 ($0 in 2021). Interest expense related to the Note, including the Amendment, for the year ended December 31, 2022 was $115,546 ($104,558 in 2021). Interest expense related to the Note, for the three months ended March 31, 2023 and March 31, 2022 was $30,262 and $27,413, respectively.

On May 14, 2020, we issued the note to the U.S. Small Business Administration with a principal amount of $150,000 and a per annum interest rate of 3.75%. The current outstanding balance of the COVID-19 Loan is $161,552 as of March 31, 2023.

On May 19, 2022, we issued a Convertible Promissory Note to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 on May 19, 2022 (the "Geoffrey Dow Trust Note"), in the amount of $44,444.44 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of such note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 19, 2022, we issued a Convertible Promissory Note to Mountjoy Trust in the amount of $294,444.42 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of such note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 24, 2022, we issued a note in the amount of $333,333.30 to Bigger Capital Fund, LP. On the date of the pricing of our initial public offering, we will deliver to Bigger Capital Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on July 24, 2023.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Cavalry Investment Fund, LP. On the date of the pricing of our initial public offering, we will deliver to Cavalry Investment Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on July 24, 2023.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Walleye Opportunities Master Fund Ltd. On the date of the pricing of our initial public offering, we will deliver to Walleye Opportunities Master Fund Ltd shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on July 24, 2023.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Cyberbahn Federal Solutions, LLC with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Cyberbahn Federal Solutions, LLC shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Ariana Bakery Inc with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Ariana Bakery Inc shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $333,333.30 to Sabby Volatility Warrant Master Fund, Ltd. with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Sabby Volatility Warrant Master Fund, Ltd. shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $55,555.55 to Steel Anderson with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Steel Anderson shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Bixi Gao & Ling Ling Wang with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Bixi Gao & Ling Ling Wang shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2022:

	Payments Due By Period				
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Principal obligations on the debt arrangements	$ 8,997,383	$ 8,847,383	$ -	$ 1,574	$ 148,426
Interest obligations on the debt arrangements	15,097,215	15,097,215	-	-	-
Operating leases	13,000	13,000	-	-	-
Purchase obligations	1,338,668	1,338,668	-	-	-
Total	$ 25,446,266	$ 25,296,266	$ -	$ 1,574	$ 148,426

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below:

Three Months Ended March 31, 2023, and 2022

	Three Months Ended March 31,			
	2023	2022	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (412,678)	$ (102,558)	$ (310,120)	302%
Investing activities	(3,292)	(826)	(2,466)	299
Financing activities	182,388	-	182,388	N/A
Effect of foreign currency translation on cash flow	(1,290)	96,556	(97,846)	(101)
Net increase (decrease) in cash and cash equivalents	$ (234,872)	$ (6,828)	$ (228,044)	3,340%

Cash Used in Operating Activities

Net cash used in operating activities was $412,678 for the three months ended March 31, 2023, as compared to $102,558 for the three months ended March 31, 2022. The increase in net cash used in operating activities was primarily due to a drop in research revenues from the completion of the Arakoda study under the JPEO research grant in 2022, with no revenue recorded for the three months ended March 31, 2023 ($94,908 recorded for the three months ended March 31, 2022). In addition, while there was an increase in sales volume, net product revenues also decreased from $47,024 during the three months ended March 31, 2022 to $17,172 in the three months ended March 31, 2023 as a result of the per Unit price reduction of Arakoda effective in January 2023.

Cash Used in Investing Activities

Net cash used in investing activities was $3,292 for the three months ended March 31, 2023, as compared to $826 for the three months ended March 31, 2022. The increase in net cash used in investing activities was due to higher costs paid for the acquisition of patents.

Cash Provided by Financing Activities

Net cash provided by financing activities was $182,388 for the three months ended March 31, 2023, as compared to none for the three months ended March 31, 2022. The increase in net cash provided by financing activities was primarily due to $200,000 in related party advances received in March 2023, partially offset by payment of deferred offering costs of ($17,612) during the three months ended March 31, 2023 ($0 and $0 for the three months ended March 31, 2022, respectively).

Effect of foreign currency translation on cash flow

Our foreign operations were small relative to U.S. operations for the three months ended March 31, 2023 and March 31, 2022, thus effects of foreign currency translation have been minor.

Twelve Months Ended December 31, 2022, and 2021

	Twelve Months Ended December 31,			
	2022	2021	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (1,009,980)	$ (649,106)	$ (360,874)	56%
Investing activities	(60,133)	(35,392)	(24,741)	(70)
Financing activities	1,221,706	611,226	610,480	100
Effect of foreign currency translation on cash flow	(2,127)	(3,031)	904	(30)
Net increase (decrease) in cash and cash equivalents	$ 149,466	$ (76,303)	$ 225,769	(296)%

Cash Used in Operating Activities

Net cash used in operating activities was $1,009,980 for the twelve months ended December 31, 2022, as compared to $649,106 for the twelve months ended December 31, 2021. The increase in net cash used in operating activities was primarily due to the drop in product revenues from the end of the DoD procurement contract with none recorded for the twelve months ended December 31, 2022 ($1,068,750 recorded for the twelve months ended December 31, 2021).

Cash Used in Investing Activities

Net cash used in investing activities was $60,133 for the twelve months ended December 31, 2022, as compared to $35,392 for the twelve months ended December 31, 2021. The increase in net cash used in investing activities was primarily due to the acquisition of intangibles of $27,070.

Cash Provided by Financing Activities

Net cash provided by financing activities was $1,221,706 for the twelve months ended December 31, 2022, as compared to $611,226 for the twelve months ended December 31, 2021. The increase in net cash provided by financing activities was primarily due to $1,105,000 in bridge round financing received on May 24, 2022.

Effect of foreign currency translation on cash flow

Our foreign operations were small relative to U.S. operations for the years ended December 31, 2022 and December 31, 2021, thus effects of foreign currency translation have been minor.

Critical Accounting Policies, Significant Judgments, and Use of Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Use of Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

We receive revenues from sales of our Arakoda product to the DoD and resellers in the U.S. and abroad. We record deferred revenues for any advances and then recognize revenue upon shipment to the retailer who orders product for a specific customer. We record a receivable for any amounts to be received pursuant to such sales.

Research revenue was recognized when research expenses against the JPEO grant were recognized at the end of each month. Research revenues would not exceed research expenses for a given period as the grant did not include the general and administrative, overhead or profit components.

Derivative Liabilities

We assessed the classification of our derivative financial instruments as of December 31, 2022, which consist of bridge shares, convertible notes payable and certain warrants (excluding those for compensation) and have determined that such instruments qualify for treatment as derivative liabilities as they meet the criteria for liability classification under ASC 815.

We analyze all financial instruments with features of both liabilities and equity under FASB ASC Topic No. 480, "Distinguishing Liabilities from Equity" and FASB ASC Topic No. 815, ("ASC 815") "Derivatives and Hedging." Derivative liabilities are adjusted to reflect fair value at each reporting period, with any increase or decrease in the fair value recorded in the results of operations (other income/expense) as change in fair value of derivative liabilities. We use a Monte Carlo Simulation Model to determine the fair value of these instruments.

Upon conversion or repayment of a debt or equity instrument in exchange for shares of common stock, where the embedded conversion option has been bifurcated and accounted for as a derivative liability (generally convertible debt and warrants), we record the shares of common stock at fair value, relieve all related debt, derivative liabilities, and debt discounts, and recognize a net gain or loss on debt extinguishment. In connection with the debt extinguishment, we typically record an increase to additional paid-in capital for any remaining liability balance.

Equity instruments that are initially classified as equity that become subject to reclassification under ASC 815 are reclassified to liabilities at the fair value of the instrument on the reclassification date.

Original Issue Discount

For certain notes issued, we may provide the debt holder with an original issue discount. The original issue discount is recorded as a debt discount, reducing the face amount of the note, and is amortized to interest expense over the life of the debt in the Consolidated Statements of Operations and Comprehensive Loss.

Debt Issuance Cost

Debt issuance costs paid to lenders or third parties are recorded as debt discounts and amortized to interest expense over the life of the underlying debt instrument in the Statements of Operations, with the exception of certain debt for which we elected the fair value option.

Income Taxes

From January 1, 2022 to May 31, 2022, 60 Degrees Pharmaceuticals, LLC was a C-corporation for income tax purposes before the incorporation/merger into 60 Degrees Pharmaceuticals, Inc. on June 1, 2022. We account for income taxes under the liability method, and deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying values of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided on deferred tax assets if it is determined that it is more likely than not that the deferred tax asset will not be realized in the following five years. We did not realize any benefits in the year ended December 31, 2022. Most of the deferred tax benefits are abroad and we do not project a profit in our subsidiary by 2026. We record interest, net of any applicable related income tax benefit, on potential income tax contingencies as a component of income tax expense.

We record tax positions taken or expected to be taken in a tax return based upon the amount that is more likely than not to be realized or paid, including in connection with the resolution of any related appeals or other legal processes. Accordingly, we recognize liabilities for certain unrecognized tax benefits based on the amounts that are more likely than not to be settled with the relevant taxing authority. We recognize interest and/or penalties related to unrecognized tax benefits as a component of income tax expense.

Off-Balance Sheet Arrangements

During 2022 and 2021, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

JOBS Act Accounting Election

In April 2012, the JOBS Act was enacted. Section 107(b) of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

The Financial Accounting Standards Board (the "FASB") issues Accounting Standards Update ("ASUs") to amend the authoritative literature in ASC. There have been a number of ASUs to date, that amend the original text of ASC. Management believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, (iii) are not applicable to us or (iv) are not expected to have a significant impact on our consolidated financial statements.

In August 2020, FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity; Own Equity, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Among other changes, the new guidance removes from GAAP separation models for convertible debt that require the convertible debt to be separated into a debt and equity component, unless the conversion feature is required to be bifurcated and accounted for as a derivative or the debt is issued at a substantial premium. As a result, after adopting the guidance, entities will no longer separately present such embedded conversion features in equity and will instead account for the convertible debt wholly as debt. The new guidance also requires use of the "if-converted" method when calculating the dilutive impact of convertible debt on earnings per share, which is consistent with our current accounting treatment under the current guidance. The guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, but only at the beginning of the fiscal year.

We adopted this pronouncement on January 1, 2022; however, the adoption of this standard did not have a material effect on our consolidated financial statements.

In May 2021, the FASB issued ASUs 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. This new standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. Early adoption is permitted, including adoption in an interim period. If an issuer elects to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. We do not expect the adoption of this standard to have a material effect on our consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers, which requires an acquirer in a business combination to recognize and measure contract assets and contract liabilities in accordance with Accounting Standards Codification Topic 606. ASU 2021-08 is effective for fiscal years beginning after December 15, 2022, and early adoption is permitted. While we are continuing to assess the timing of adoption and the potential impacts of ASU 2021-08, we do not expect ASU 2021-08 will have a material effect, if any, on its consolidated financial statements.

BUSINESS

Overview

We are a growth-oriented specialty pharmaceutical company with a goal of using cutting-edge biological science and applied research to further develop and commercialize new therapies for the prevention and treatment of infectious diseases. We have successfully achieved regulatory approval of Arakoda, a malaria preventative treatment that has been on the market since late 2019. Currently, 60P's pipeline under development covers development programs for COVID-19, fungal, tick-borne, and other viral diseases utilizing three of the Company's future products: (i) new products that contain the Arakoda regimen of Tafenoquine; (ii) new products that contain Tafenoquine; and (iii) Celgosivir.

Market Opportunity

In 2018, the FDA approved Arakoda for malaria prevention in individuals 18 years and older, an indication for which there has historically been approximately 550,000 prescriptions (one prescription per three weeks of travel) in the United States each year for the current market-leading product (atovaquone-proguanil). Arakoda entered the U.S. supply chain in the third quarter of 2019, just prior to the COVID-19 pandemic. As the approved indication is for travel medicine, and international travel was substantially impacted by the pandemic, we did not undertake any active marketing efforts for Arakoda. Targeted marketing efforts will commence in the second half of 2023 to promote the malaria indication as resources permit, although we expect our primary efforts to be developing Arakoda for other applications.

We are repositioning the Arakoda regimen of Tafenoquine for new indications to address several therapeutic indications that have substantial U.S. caseloads, as further described below:

- Treatment of COVID-19. According to *The New York Times*, the lowest daily case rate for the COVID-19 virus since March 2020 based on a seven-day average has not typically been below 11,000 cases. Assuming this trend continues, this dynamic translates into a potential market size of at least 4,000,000 cases per year in 2023 and future years. Paxlovid and molnupiravir have received emergency use authorization for the prevention of death and hospitalization in individuals with high risk of disease progression and their use for those purposes continues to be recommended by public health experts. However, to our knowledge, there is not published evidence from randomized controlled clinical trials that either drug reduces the time to sustained clinical recovery for four or more days in standard risk patients infected with contemporary viral strains, and Pfizer has formally abandoned efforts related to this endpoint for paxlovid.[36] Additionally molnupiravir and paxlovid are not approved by FDA for use in patients without risk factors for disease progression, and that excluded lower risk population comprises about 25% of the U.S. population.[37] The economic value of that unsatisfied market may be a multi-billion-dollar opportunity, given that the value of paxlovid and molnupiravir in the 75% of the population in which they can be used was ~ $12 billion in 2022.[38] If proven effective for early relief of COVID-19 symptoms in standard risk COVID-19 patients, Tafenoquine (Arakoda regimen) could fulfill a patient's need unmet by the approved antivirals.

[36] Press release: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reports-additional-data-paxlovidtm-supporting.

[37] See the Paxlovid (www.paxlovid.com) and Lagevrio (www.lagevrio.com) prescribing information and epidemiology data described by Ajufo et al Am J Preventive Cardiol 2021;6:101156.

[38] See 2022 revenue data for Paxlovid in Pfizer (https://investors.pfizer.com/Investors/Financials/SEC-Filings/SEC-Filings-Details/default.aspx?FilingId=16428097) and Lagevrio (https://d18rn0p25nwr6d.cloudfront.net/CIK-0000064978/b390be48-92bf-4595-96da-ac5cd7c3d92e.pdf) in Merck financial reports.

- Treatment and Post-Exposure Prevention of Tick-Borne Diseases. There are at least 47,000 cases of babesiosis (red blood cell infections caused by deer tick bites) in the United States each year. This estimate is based on the observations of Krugeler who reported that 476,000 cases of Lyme disease occur in U.S. states where babesiosis is endemic and Krause et. al. who reported that 10% of Lyme disease patients are co-infected with babesiosis (thus 476,000*10% = 47,600 cases of babesiosis per year).[39] Furthermore, post-exposure prophylaxis following a tick-bite is a recognized indication to prevent Lyme disease, and it is likely that a drug proven to be effective for this indication for babesiosis would also be used in conjunction with Lyme prophylaxis. There may be more than 400,000 tick bites in the United States requiring medical treatment each year. This estimate is based on the observation that approximately 50,000 tick bites are treated in U.S. hospital emergency rooms each year but this calculation represents only about 12% of actual treated tick bites based on observations from comparable ex-U.S health systems.[40] Arakoda has the potential to be added to the existing standard of care for treatment of babesiosis, and to be a market leading product for pre- and post-exposure prophylaxis of babesiosis.

- Prevention of fungal pneumonias. There are up to ~ 91-92,000 new medical conditions each year in the United States including acute lymphoblastic leukemia (up to 6.540 cases) and large B-cell lymphoma (up to 18,000 cases) patients receiving CAR-T therapy, solid organ transplant patients (up to 42,887 cases), allogeneic (~ 9,000 cases) and autologous (~ 15,000 cases) hematopoietic stem cell transplant patients for whom the use of antifungal prophylaxis is recommended.[41] Despite the availability and use of antifungal prophylaxis, the risk of some patient groups contracting fungal pneumonia exceeds the risk of contracting malaria during travel to West Africa.[42] Arakoda has the potential to be added to existing standard of care regimens for the prevention of fungal pneumonias.

- Treatment of *Candida* infections. According to the Centers for Diseases Control (CDC), there are 50,000 cases of candidiasis (a type of fungal infection) each year in the United States and up to 1,900 clinical cases of *C. auris*, for which there are few available treatments, have been reported to date[43] Arakoda has the potential to be a market leading therapy for treatment/prevention of *C. auris*, and to be added to the standard of care regimens for other *Candida* infections.

Dengue and RSV, both afflictions against which 60P's early clinical candidates (e.g., Celgosivir) show potential in non-clinical studies, are associated with at least 4.1 million cases globally according to the European CDC (Dengue) [44] and up t0 200,000 hospitalizations (RSV) in children less than five years of age and adults greater than 65 years of age in the United States each year according to the CDC.[45]

More information about our products is provided in the next section, and the status of various development efforts for the above-mentioned diseases is outlined in Figure A, below.

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39 Krause et al JAMA 1996;275:1657-16602; Krugeler et al. *Emerg Infect Dis* 2021;27:616-619

40 Marx et. al., MMWR 2021;70:612-616.

41 See statistics for solid organ transplants at the Organ Transplant and Procurement Network at: National data - OPTN (hrsa.gov); See statistics for hematopoietic stem cell transplant in Dsouza et al Biology of Blood and Bone Marrow Transplantation 202;26: e177-e182; See statistics for acute lymphoblastic leukemia at: Key Statistics for Acute Lymphocytic Leukemia (ALL) (cancer.org); See statistics for large cell large B-cell lymphoma at; Diffuse Large B-Cell Lymphoma - Lymphoma Research Foundation; Treatment guidelines recommending antifungal prophylaxis for these diseases can be reviewed in (i) Fishman et al Clinical Transplantation. 2019;33:e13587, (ii) Hematopoietic Cell Transplantation (cancernetwork.com), (iii) Cooper et al Journal of the National Comprehensive Cancer Network 2016;14:882-913 and (iv) Los Arcos et al Infection (2021) 49:215–231.

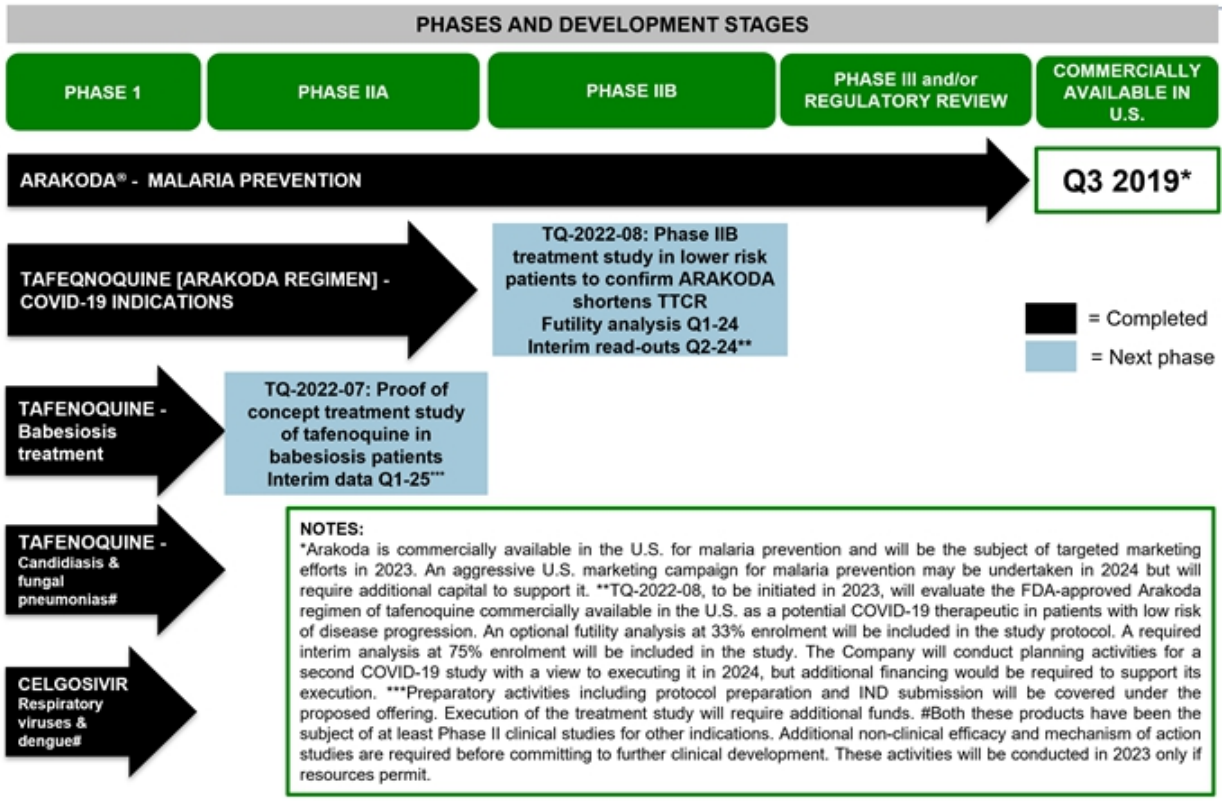
42 Aguilar-Guisado et al Clin Transplant 2011;25:E629–38; Mace et al MMWR 202;70:1–35.

43 https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html.; https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html.

44 https://www.ecdc.europa.eu/en/dengue-monthly#:~:text=This%20is%20an%20increase%20of%2032%20653%20cases%20and%2032,853%20deaths%20have%20been%20reported.

45https://www.cdc.gov/rsv/research/index.html#:~:text=Each%20year%20in%20the%20United,younger%20than%205%20years%20old.&text=58%2C000-80%2C000%20hospitalizations%20among%20children%20younger%20than%205%20years%20old.&text=60%2C000-120%2C000%20hospitalizations%20among%20adults%2065%20years%20and%20older.

Figure A


PHASES AND DEVELOPMENT STAGES
PHASE 1
PHASE IIA
PHASE IIB
PHASE III and/or REGULATORY REVIEW
COMMERCIALLY AVAILABLE IN U.S.
ARAKODA® - MALARIA PREVENTION
Q3 2019*
TAFEQNOQUINE [ARAKODA REGIMEN] - COVID-19 INDICATIONS
TQ-2022-08: Phase IIB treatment study in lower risk patients to confirm ARAKODA shortens TTCR
Futility analysis Q1-24
Interim read-outs Q2-24**
= Completed
= Next phase
TAFENOQUINE - Babesiosis treatment
TQ-2022-07: Proof of concept treatment study of tafenoquine in babesiosis patients
Interim data Q1-25***
TAFENOQUINE - Candidiasis & fungal pneumonias#
CELGOSIVIR Respiratory viruses & dengue#
NOTES:
*Arakoda is commercially available in the U.S. for malaria prevention and will be the subject of targeted marketing efforts in 2023. An aggressive U.S. marketing campaign for malaria prevention may be undertaken in 2024 but will require additional capital to support it. **TQ-2022-08, to be initiated in 2023, will evaluate the FDA-approved Arakoda regimen of tafenoquine commercially available in the U.S. as a potential COVID-19 therapeutic in patients with low risk of disease progression. An optional futility analysis at 33% enrolment will be included in the study protocol. A required interim analysis at 75% enrolment will be included in the study. The Company will conduct planning activities for a second COVID-19 study with a view to executing it in 2024, but additional financing would be required to support its execution. ***Preparatory activities including protocol preparation and IND submission will be covered under the proposed offering. Execution of the treatment study will require additional funds. #Both these products have been the subject of at least Phase II clinical studies for other indications. Additional non-clinical efficacy and mechanism of action studies are required before committing to further clinical development. These activities will be conducted in 2023 only if resources permit.

Products

Arakoda (Tafenoquine) for malaria prevention

We entered into a cooperative research and development agreement with the United States Army in 2014[46] to complete development of Arakoda for prevention of malaria. With the U.S. Army, and other private sector entities as partners, we coordinated the execution of two clinical trials, development of a full manufacturing package, gap-filling non-clinical studies, compilation of a full regulatory dossier, successful defense of its program at an FDA advisory committee meeting, and submitted an NDA to the FDA in 2018. The history of that collaboration has been publicly communicated by the U.S. Army.[47]

The FDA and Australia's medicinal regulatory agency, Therapeutic Goods Administration, subsequently approved Arakoda and Kodatef (brand name in Australia), respectively, for prevention of malaria in travelers in 2018. Prescribing information and guidance for patients can be found at *www.arakoda.com*. The features and benefits of Tafenoquine for malaria prophylaxis (marketed as Arakoda in the United States), some of which have been noted by third-party experts, include: convenient once weekly dosing following a three day load; the absence of reports of drug resistance during malaria prophylaxis; activity against liver and blood stages of malaria as well as both the major malaria species (*Plasmodium vivax* and *Plasmodium falciparum);* absence of any black-box safety warnings; good tolerability including in women and individuals with prior psychiatric medical history, and a comparable adverse event rate to placebo with up to 12 months continuous dosing.[48] Tafenoquine entered the commercial supply chains in the U.S. (as Arakoda) and Australia (as Kodatef) in the third quarter of 2019.

The only limitation of Arakoda is the requirement that a G6PD test be administered to a prospective patient prior to administration of Arakoda in order to prevent the potential occurrence of hemolytic anemia in individuals with G6PD deficiency.[49] The G6PD test must be administered to a prospective patient prior to administration of Arakoda in order to prevent the potential occurrence of hemolytic anemia in individuals with G6PD deficiency.[50] Because G6PD is one of the most common enzyme deficiencies and is implicated in hemolysis following administration/ingestion of a variety of oxidant drugs/food, and must also be ruled out as a possible cause when diagnosing neonatal jaundice, G6PD testing is widely available in the United States through commercial pathology service providers (e.g., Labcorp, Quest Diagnostics, etc.). Although these tests have a turn-around time of up to 72 hours, the test needs only to be administered once. Thus, existing U.S. testing infrastructure is sufficient to support the FDA-approved use of the product (malaria prevention) by members of the armed forces (who automatically have a G6PD test when they enlist), civilian travelers with a long planning horizon or repeat travelers.

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[46] In 2014, we signed a cooperative research and development agreement with the United States Army Medical and Materiel Development Activity (Agreement W81XWH-14-0313). Under this agreement, we agreed to submit a New Drug Application for Tafenoquine to the FDA (as Arakoda), while the US Army agreed to finance the bulk of the necessary development activities in support of that goal.

[47] Zottig et al Military Medicine 2020; 185 (S1): 687.

[48] Tan and Hwang Journal of Travel Medicine, 2018, 1–2; Baird Journal of Travel Medicine 2018:, 1–13; Schlagenhauf et al Travel Medicine and Infectious Disease 2022; 46:102268; See Arakoda prescribing information at www.arakoda.com; McCarthy et al CID 2019:69:480-486; Dow et al. Malar J (2015) 14:473; Dow et al. Malaria Journal 2014, 13:49; Novitt-Moreno et al Travel Med Infect Dis 2022 Jan-Feb;45:102211.

[49] See prescribing information at www.arakoda.com.

[50] See prescribing information at www.arakoda.com.

Tafenoquine (Arakoda regimen) for COVID-19

During the COVID-19 pandemic, since our commercial opportunities were limited, we embarked upon an exploratory research and development campaign to identify new indications for the Arakoda dosing regimen of Tafenoquine. In the second quarter and third quarter of 2020, we commissioned cell culture studies that showed that Tafenoquine, the active ingredient in Arakoda, inhibited replication of SARS-CoV-2 (the virus that causes COVID-19).[51] Then, we commissioned computer simulations, which showed that the predicted concentration of Tafenoquine in the lungs of COVID-19 patients following administration of the first four doses of the approved antimalarial prophylactic regimen of Arakoda exceeded those inhibiting the virus in cell culture. This provided the rationale for seeking approval from the FDA to conduct a Phase II clinical trial in patients with the COVID-19 disease, for which the FDA granted clearance to proceed in October 2020.

In 2021, with financial support from the US Army[52], we conducted a Phase II clinical investigation of the safety and efficacy of Tafenoquine using the Arakoda regimen in outpatients with mild-moderate COVID-19 disease (assumed to be mostly caused by the delta variant of SARS-COV-2). In summary, safety and efficacy of Tafenoquine administered at the approved dose for malaria prevention (200 mg dose once per day on days 1, 2, 3, and 10) was evaluated over a 28-day period in mild-moderate COVID-19 patients. The primary endpoint was day 14 clinical recovery from COVID-19 symptoms, defined as cough mild or absent, respiratory rate < 24 bpm, and no shortness of breath or fever. From March 2021 through September 2021, this study enrolled 87 of an originally planned 275 patients. In October 2021, a data safety monitoring board, after conducting a futility analysis for the primary endpoint and reviewing adverse event data, recommended that the study be continued as planned. However, at the time of the unblinding of this study, topline results from Phase III studies for three oral COVID-19 therapeutics in at risk patients with mild-moderate COVID-19 disease had been announced: Fluvoxamine, molnupiravir, and paxlovid reduced the risk of hospitalization by approximately 30%, 50% (in the first public announcement) and 90%, respectively.[53] As reported in our publication[54], an informal survey of potential funding/commercialization partners for a follow-on program suggested it would be important to know the magnitude of possible benefit prior to initiating such an effort. Primarily for the above reasons, the study was terminated and unblinded early.

The results of the study were accepted for peer-reviewed publication in May 2022.[56] For the primary endpoint, the proportion of patients not recovered on Day 14 was numerically decreased by 27% in the intent to treat population (8/45 v 10/42 not recovered in the Tafenoquine and placebo arms, $P = 0.60$) and 47% in the per protocol population (5/42 v 9/41, $P = 0.25$). Amongst individuals who recorded responses in an electronic diary at Day 28, all Tafenoquine patients were recovered, whereas up to 12% of placebo patients exhibited lingering shortness of breath. Analysis of secondary/exploratory endpoints suggested Arakoda reduced time to clinical recovery from shortness of breath, cough and fever ($P < 0.02$) and numerically improved aggregate symptom scores five days after treatment ($P < 0.1$).[57] The risk of COVID-19-related hospitalization was numerically reduced in the Arakoda arm (by approximately 50%; two instances for placebo versus one for Arakoda). Mild, drug related adverse events occurred in 8.4% of individuals in the Tafenoquine arm (v 2.4%

in the placebo). We plan to confirm that Arakoda accelerates sustained recovery from COVID-19 symptoms in our next study (described in "*Prospectus Summary—Strategy*" beginning on page 4).

[51] U.S. Patent application # 17/189,544, Dow et. al.bioRxiv 2020.07.12.199059; doi: https://doi.org/10.1101/2020.07.12.199059.

[52] Financial support was obtained from Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (which may be referred to as "JPEO") or JPEO via other transactional authority agreement #W911QY-21-9-0011.

[53] Reis et al Lancet Global Health 2022;10:e42-51, Bernal et al New Eng J Med 2021; https://doi.org/10.1056/NEJMoa2116044; Pfizer Inc. Press release (November 5, 2021) – Pfizer's novel COVID 19 oral antiviral treatment candidate reduced risk of hospitalization or death by 89% in interim analysis of Phase 2/3 EPIC-HR study. Accessible at: Pfizer's Novel COVID-19 Oral Antiviral Treatment Candidate Reduced Risk of Hospitalization or Death by 89% in Interim Analysis of Phase 2/3 EPIC-HR Study | Pfizer.

[54] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

[55] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

[56] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

In 2022, we conducted additional analyses of laboratory endpoint data from the clinical study described above and are preparing a manuscript for publication. That analysis and the scientific literature suggest two possible modes of action for Arakoda: (i) down-regulation of cytokines (immune system inflammatory proteins) associated with severe COVID-19 and a greater risk of hospitalization or death and/or (ii) inhibition of viral entry in the lung or elsewhere in the body, perhaps through inhibition of a host enzyme called TMPRSS2 (which facilitates entry of the virus that causes COVID-19, SARS-CoV-2, into human cells).

Assuming the efficacy of Tafenoquine in COVID-19 disease is proven in our next study, some of the features of the Arakoda regimen that make it ideal for malaria prophylaxis might also make it very useful for COVID-19 related indications. Tafenoquine is slowly metabolized and has few important drug-drug interactions, so it might be an ideal partner for standard of care oral COVID-19 therapeutics that reduce hospitalization but have no demonstrated effect on the time to clinical recovery in non-hospitalized patients. The Arakoda regimen requires fewer tablets (8 in the first ten days versus 30 or 40 for paxlovid and molnupiravir) which should make compliance with medication easier for patients. This is an important consideration in the attractiveness of a regimen in standard risk patients at lower risk of hospitalization, and who may be interested in taking a COVID-19 therapeutic primarily to treat early symptoms and accelerate recovery. The potential for better compliance may also suggest suitability for outbreak control in some settings (including, for example, nursing homes).

Tafenoquine for other infectious diseases

During the pandemic, we also worked with NIH to evaluate the utility of Tafenoquine as an antifungal. We, and the NIH, found that Tafenoquine exhibits a Broad Spectrum of Activity in cell culture against *Candida* and other yeast strains via a different Mode of Action than traditional antifungals and also exhibits antifungal activity against some fungal strains at clinically relevant doses in animal models.[53] Our work followed Legacy Studies that show Tafenoquine is effective for treatment and prevention of *Pneumocystis* pneumonia in animal models.[54] We believe that if added to the standard of care for anti-fungal and yeast infection treatments for general use, Tafenoquine has the potential to improve patient outcomes in terms of recovery from yeast infections, and prevention of fungal pneumonias in immunosuppressed patients. There are limited treatment options available for these indications, and Tafenoquine's novel mechanism of action might also mitigate problems of resistance. Clinical trial(s) to prove safety and efficacy, and approval by the FDA and other regulators, would be required before Tafenoquine could be marketed for these indications.

Tafenoquine is effective in animal models of babesiosis (tick borne red blood cell infections). In two of three recent clinical case studies, Tafenoquine administered after failure of conventional antibiotics in immunosuppressed babesiosis patients resulted in cures.[55] Consequently, we believe that (i) if combined with standard of care products, Tafenoquine has the potential to reduce the duration of treatment with antibiotic therapy in immunosuppressed patients and the time to parasite clearance in non-immunosuppressed patients and (ii) that once appropriate clinical studies have been conducted, it is likely that Tafenoquine would be quickly embraced for post-exposure prophylaxis of babesiosis in patients with tick bites and suspected of being co-infected with Lyme disease. Clinical trial(s) to prove safety and efficacy, and approval by FDA and other regulators, would be required before Tafenoquine could be marketed for these indications.

Celgosivir

Celgosivir is a host targeted glucosidase inhibitor that was developed separately by other sponsors for HIV then for hepatitis C.[60] The sponsors abandoned Celgosivir after completion of Phase II clinical trials involving 700+ patients, because other antivirals in development at the time had superior activity. The National University of Singapore initiated development of Celgosivir independently for Dengue fever. A clinical study, conducted in Singapore, and the results of which were accepted for publication in the peer-reviewed journal Lancet Infectious Diseases, confirmed its safety but the observed reduction in viral load was lower than what the study was powered to detect.[61] Celgosivir (as with other Dengue antivirals) exhibits greater capacity to cure Dengue infections in animal models when administered prior to symptom onset compared to post-symptom onset. In animal models, this problem can be addressed for Celgosivir, by administering the same dose of drug split into four doses per day rather than two doses per day (as was the case in the Singaporean clinical trial).[62] This observation led to the filing and approval of a patent related to Dengue, which we licensed from the National University of Singapore.

Additional clinical studies would be required to prove that such a 4x daily dosing regimen would be safe and effective in Dengue patients to regulators' satisfaction. To that end, earlier in our history, we, in partnership with the National University of Singapore, and Singapore General Hospital, successfully secured a grant from the government of Singapore for a follow-on clinical trial, but were unable at that time to raise matching private sector funding. We concluded as a result that development of Repositioned Molecules for Dengue, solely and without simultaneous development for other therapeutic use, despite substantial morbidity and mortality in tropical countries, was an effort best suited for philanthropic entities. Accordingly, during the pandemic, we undertook an effort (in partnership with NIH's Division of Microbiology and Infectious Diseases program and Florida State University) to determine whether Celgosivir might be more broadly useful for respiratory diseases that have impact in both tropical and temperate countries. Preliminary data suggest Celgosivir inhibits the replication of the virus that causes COVID-19 (SARS-CoV-2) in cell culture, and the RSV virus in cell culture and provides benefits in animals. We have filed and/or licensed patents in relation to Celgosivir for these other viruses as we believe there is potential applications to fight respiratory diseases that might have more commercial viability than historical development of Celgosivir to combat Dengue fever.

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[57] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

[58] Queener et al Journal of Infectious Diseases 1992;165:764-8).

[59] Liu et al. Antimicrobial Agents Chemo 2021;65:e00204-21, Marcos et al. IDCases 2022;27:e01460; Rogers et al. Clin Infect Dis. 2022 Jun 10:ciac473.

[60] Sorbera et al, Drugs of the Future 2005; 30:545-552.

[61] Low et. al., Lancet ID 2014; 14:706-715.

[62] Watanabe et al, Antiviral Research 2016; 10:e19.

Strategy

Our general strategy is to demonstrate clinical proof of concept that the FDA-approved Arakoda regimen of Tafenoquine provides clinical benefits in non-malaria therapeutic areas. Our initial focus is on COVID-19, but additional indications have been identified for development, namely babesiosis and fungal infections, pending further data generation. Upon demonstration of clinical proof of concept, we plan to enter into a strategic partnership with a larger entity with commercialization capacity, or raise additional capital to facilitate commercialization of Arakoda, and any additional clinical studies that may be required by regulators, for both travel medicine and broad infectious disease indications. We will continue to develop our portfolio products as resources permit.

Beginning in the second half of 2023, we plan to execute a Phase IIB, randomized, placebo-controlled double blind clinical study powered (at 80%) to prove that the Arakoda regime of Tafenoquine accelerates time to sustained clinical recovery in patients with mild-moderate disease with low risk for disease progression. This trial will utilize the bulk of proceeds raised in this offering. Based on an analysis of unpublished data from our earlier COVID-19 clinical trial,[63] we believe that the Arakoda regimen of Tafenoquine has the potential to reduce the time to sustained clinical recovery by about three days (see Figure B, below). The study will be conducted in out-patient clinics in the United States. The study will utilize the majority of the proceeds of the offering reserved for research and development activities for this purpose. As of the date of this prospectus, we have completed a clinical study synopsis. Submission of the full protocol to the Ethics Committees and to U.S. regulators, and posting of the trial at *clinicaltrials.gov* will follow this initial public offering.

Figure B

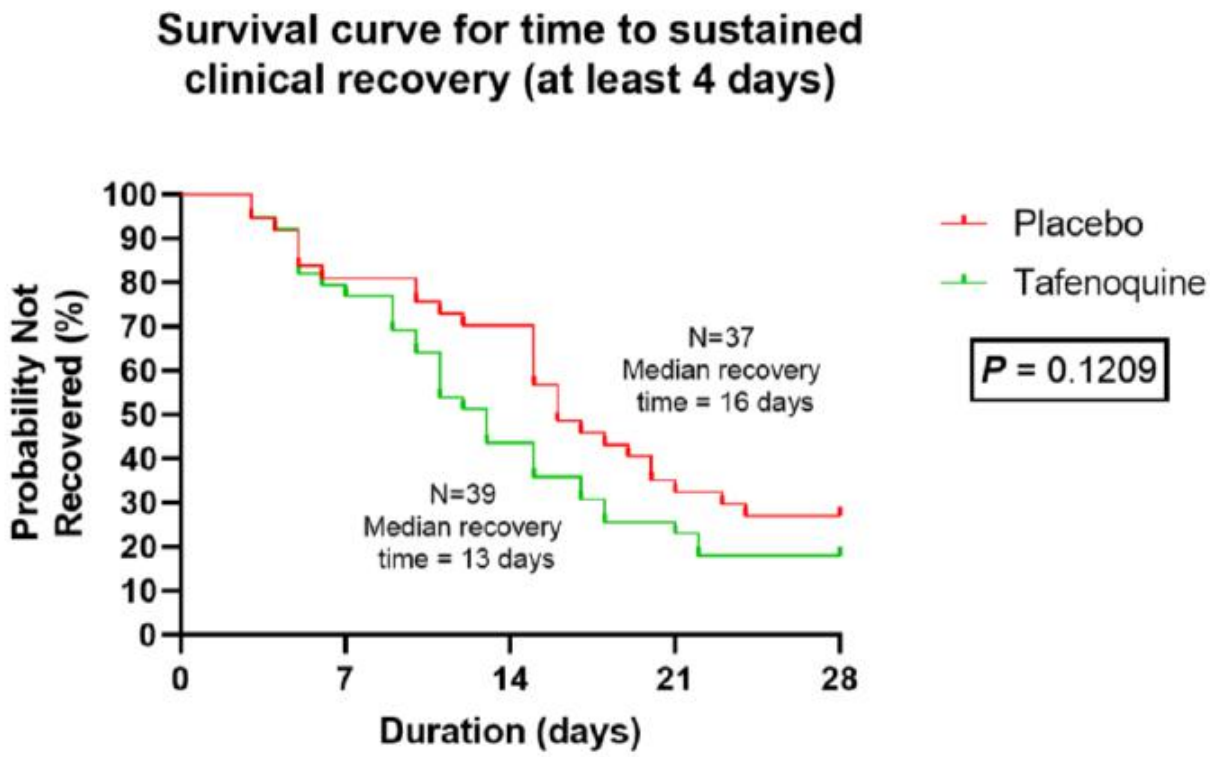

Figure B: Survival curve for sustained clinical recovery in outpatients with mild-moderate COVID-19 disease randomized to receive Tafenoquine (Arakoda regimen) or placebo. Sustained clinical recovery was defined as the first instance of patient reported symptoms scores being < 3 for four or more days, with symptoms scores assessed according to FDA guidance[64]. This analysis utilized unpublished data from our earlier Phase II clinical trial[65]. The analysis excludes individuals hospitalized or loss to follow-up and with a symptom score on the days of dosing < 3. This analysis represents a post-hoc analysis of our Phase II clinical trial data. If this were a formal, pre-conceived primary study endpoint, the *P* value of 0.1209 would imply the associated difference between Tafenoquine (Arakoda regimen) and placebo has a 12.09% chance of occurring by chance.

We intend to design the study, subject to approval by the FDA and Ethics Committee(s) as appropriate, to include two interim endpoints to manage risk. The first will be an optional futility analysis at the earlier of 33% enrollment or six months following the first patient enrolled, which would allow early termination of the study if the conditional power of proving the intended hypothesis is < 20%. The second, mandatory interim analysis will occur at 75% enrollment and follow a step-wise (sponsor-blinded) process involving testing for futility, statistical significance, and sample-size reassessment if required. The test for statistical significance would allow early termination of the study if results are unexpectedly positive and the sample size reassessment would allow the study to enroll more patients within pre-specified limits if variability is more, and/or the magnitude of the expected treatment effect is less, than expected.

We plan to conduct additional non-clinical studies to clarify the process by which Tafenoquine alters the course of COVID-19 illness. Specifically, such studies will attempt to determine whether Tafenoquine acts as an immunomodulator (by decreasing the production of immune system molecules that cause inflammation) and/or exhibits an antiviral effect via inhibition of the host protease TMPRSS2. Antivirals are generally utilized earlier, and immunomodulators later, in treating patients infected with COVID-19. However, the clinical hypothesis of our planned study will be that Arakoda accelerates clinical recovery by three days in individuals who have experienced symptoms for fewer than seven days, thereby confirming observations from our earlier clinical study (see Figure B). Since the potential clinical benefit is already known, the primary purpose of clarifying the manner in which Arakoda works is to (i) address anticipated regulatory questions and (ii) ascertain whether other indications, such as relief of COVID-19 symptoms during vaccination, treatment of long COVID-19 patients, or use during hospitalization, might be plausible.

Following completion of our planned COVID-19 clinical study, if warranted based on the data generated, we intend to request a change in prescribing information to facilitate an expansion of use of Arakoda for malaria prevention from six to twelve months (mirroring our recently published post-marketing safety study) and to include reference to the recently generated COVID-19 treatment data. Prior to doing so, we plan to discuss with the FDA additional labeling related to COVID-19 which might be acceptable.

We intend to design and conduct feasibility assessments for one or more additional studies in the same type of patients as the planned study and/or for a COVID 19-related indication different from that targeted by our clinical study in 2023. One of these additional studies would be conducted in Australia, and would be a requirement to secure tax rebates for the overall COVID-19 program (see next paragraph). A second study is likely to be required by regulators which may or may not be the same as the study conducted in Australia. The value of conducting additional studies, in addition to securing tax credits or for regulatory approvals, would be (i) independently confirming the therapeutic modality/clinical mode of action of Arakoda (i.e. that it accelerates clinical recovery from COVID-19 symptoms and/or acts as an antiviral or disease modulator) and (ii) broadening the COVID-19 indication beyond treatment of lower risk patients (i.e. potentially increasing the volume of annual prescriptions). Thus, possible study designs could be (i) a simple repetition of the planned study with a larger sample size, (ii) a treatment study in higher risk patients or (iii) a pre-treatment loading study in individuals known to be exposed to the virus that causes COVID-19, and/or (iv) amelioration of COVID-19 disease-like symptoms in individuals receiving mRNA COVID-19 vaccines (if it turns out Arakoda is an immunomodulator).

We plan to license ex-U.S. rights to COVID-19 indications to our Australian subsidiary, 60P Australia Pty Ltd. This will facilitate claiming the Australian government's research tax credit for any of our COVID-19-related research activities conducted in Australia. 60P Australia has been successful in securing research tax credits for malaria and Dengue-related research since 2013. Since conducting our planned COVID-19 study in Australia unlikely to be feasible (which at the time of writing we believe to be the case) and must be conducted in the U.S., we plan to apply for an overseas finding to the Australian Tax Office in Q1 2023 to request an overseas finding for the U.S. study. Should such a finding be awarded, it would allow a tax rebate of 43.5% on research and development costs associated with the planned U.S. COVID-19 study to be claimed, but commit the Company to conduct COVID-19 research activities in Australia of a value at least as much as the cost of the planned U.S. clinical study.

We are planning several commercial initiatives for the malaria market in parallel with further clinical development activities. Three routes exist for commercialization of Arakoda for the malaria prevention market are: (i) U.S. civilian travel clinics, travel prescribing centers, and large private sector entities with employees deployed overseas (e.g., mining companies), (ii) the prospect of additional DoD and government agency procurement in the future (noting that as described on page 60 our existing contract with DoD has been fulfilled and has not been extended or modified) and (iii) ex U.S. sales strategy where we currently (or in the future) have exclusive distribution arrangements in overseas markets.

As of the date of this prospectus, we did not have plans to hire a U.S. field sales force, but may explore possible commercial arrangements with contract sales organizations to target U.S. travel clinics for malaria prophylaxis. We will also closely monitor changes in market share in Australia where Kodatef will be actively marketed in 2023 by the local distributor, and a point of care G6PD test is approved. We may request that the DoD Uniform Formulary re-evaluate the formulary position of Arakoda following our recent adjustment of the U.S. WAC pricing to reflect expected international pricing. For US government agencies such as the DoD, the product is expected to meet many of the requirements for occupational malaria prevention identified by the independent parties that have endorsed the product, but they are price sensitive. In the third quarter of 2022, we made our first sale to our European distributor, and made additional sales to our Australian distributor in the second quarter of 2022. We intend to execute a contract with a distribution partner to facilitate named-patient sales in jurisdictions outside Australia, Europe, and the United States. We plan to undertake a focused marketing campaign for Arakoda for malaria prevention in the second half of 2023, consisting of promotion at relevant conferences, email promotion to prescribers, and target print and electronic advertisements.

[63] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

[64] *FDA 2020 Guidance on Assessing COVID-19 Symptoms*-14 Common COVID-19 Symptoms Severity Scale.

[65] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

It is expected that a point of care G6PD test might be required to maximize the economic potential of a COVID-19 indication for Tafenoquine (regardless of regimen). We do not intend to pursue independent development of such a test as there are well resourced development efforts already underway or already approved by the FDA (see "*Risk Factors—Any future clinical trial for Arakoda will require screening for G6PD deficiency in order to safely administer the product. In the United States, G6PD testing can obtained through commercial pathology services which is associated with delays. The use of a third-party diagnostic provider of point of care testing may be required and we may not directly control the timing, conduct and expense of such testing*" beginning on page 18). However, we will continue to monitor the progress of development and U.S. commercialization of G6PD tests. We will seek to pursue collaborative commercial partnerships with the companies involved in commercialization efforts, if such activities can be conducted through resource sharing efforts.

We plan to generate additional validation data for our portfolio products if resources permit. Specifically, we will evaluate whether Celgosivir provides therapeutic benefit in a COVID-19 animal model, and complete critical activities related to confirming GMP process feasibility.

We may elect, as resources permit, to undertake a clinical study of Tafenoquine in combination with standard of care for hospitalized patients with babesiosis. We have developed such a protocol in partnership with academic collaborators and are planning to submit an IND to the FDA and pursue public and philanthropic funding to support our execution. We plan to seek public funding to support additional non-clinical studies to validate the mechanism of action of Tafenoquine against *Candida spp*. and further assess our utility in combination with standard of care agents in cell culture and animal studies.

Most new antimalarial treatment products are developed as drug combinations to proactively combat drug resistance. Tafenoquine, due to its long half-life and activity against all parasite species and strains, would be ideal partner in a drug combination. In the second half of 2023, we will actively seek out a potential partner antimalarial drug for Arakoda, with the goal of pursuing licensure of a new drug combination. We will only enter into a partnership to develop such a drug combination, if clear legal guidance can be obtained that such a combination if developed would have a high probability of securing a priority review voucher upon FDA approval.

There are currently efforts underway, in malaria-endemic countries outside the U.S., to generate datasets supporting the use of Tafenoquine for mass drug administration in asymptomatic individuals to prevent malaria transmission. We believe that such efforts are important to promote community acceptance of Tafenoquine, and may eventually support World Health Organization pre-qualification of Tafenoquine for malaria eradication efforts. To that end, we intend to support, on a case-by-case basis, clinical studies sponsored by others, by providing commercial Arakoda and/or Kodatef for research use (provided such product would not otherwise have been commercially salable, and the study sponsor covers shipping costs). We have previously provided Tafenoquine for such efforts on a limited basis.

We have a post-marketing requirement to conduct a malaria prophylaxis study of Arakoda in pediatric and adolescent subjects. We proposed to the FDA, in late 2021, that this might not be safe to execute given that malaria prevention is administered to asymptomatic individuals and that methemoglobinemia (damage to the hemoglobin in blood that carries oxygen) occurred in 5% of patients, and exceeded a level of 10% in 3% of individuals in a study conducted by another sponsor in pediatric subjects with symptomatic vivax malaria.[66] The FDA has asked us to propose an alternate design, for which we submitted a concept protocol in the fourth quarter of 2022, and plan to submit a full protocol by the end of the second quarter of 2023. We estimate the cost of conducting the study proposed by the FDA, if conducted in the manner suggested by the FDA, would be $2 million and due to the time periods required to secure protocol approvals from the FDA and Ethics Committees, could not be initiated any earlier than the third quarter of 2024. The funds from this offering to be expended on such a pediatric study will be limited to the minimum required to support protocol preparation and regulatory interactions with the FDA.

Competitors and Competitive Advantage

Arakoda is approved by the FDA for malaria prevention in travelers. The major (but not only) competing products are generic atovaquone-proguanil and doxycycline – these products have the benefit of being well established, not requiring a G6PD screen prior to travel (as is the case for Arakoda) and in the case of atovaquone-proguanil being generally recognized as well tolerated and safe. The major limitations of these two established products are the requirement for daily dosing including for up to 30 days post-travel in the case of doxycycline, the requirement to also take Primaquine (a medication used to treat and prevent malaria) for post-exposure prophylaxis to prevent relapse from *P. vivax* malaria, and the potential inconvenience for many patients of complying with a daily dosing regimen during travel. Doxycycline has the added disadvantages of a higher risk of vaginitis, sunburn following sun exposure, contraction of malaria due to missed daily doses, and esophageal necrosis. Drug resistance against the individual components of the atovaquone-proguanil is prevalent in some regions of the work, and the higher doses of atovaquone-proguanil used to treat malaria, are no longer effective in some parts of Southeast Asia.

Arakoda has the benefit of a convenient weekly dosing regimen following a three-day loading dose and a single day of dosing for post-exposure prophylaxis upon return from travel. It is effective against all species of malaria everywhere in the world, which simplifies prescribing decisions. It is the only FDA-approved antimalarial other than mefloquine with a safety profile demonstrated based on continuous dosing for 12 months, but unlike that product, it does not have a black-box safety warning. While G6PD testing is a potential limitation for first time travelers with short planning horizons, this is not the case for institutional occupation travel or repeat business travel, because a G6PD test need only be performed once and can be captured in electronic health records. G6PD testing is routinely available in the United States through commercial laboratory pathology services. Over time, Arakoda is expected to capture a significant share of the antimalarial prophylaxis market as a consequence of these advantages.

We are targeting additional indications for the Arakoda regimen of Tafenoquine, of which the priority is treatment of COVID-19 in ambulatory patients. The main competitor products for this indication are molnupiravir and paxlovid, which have been granted emergency use authorization, and likely full marketing authorization in the future to lower the risk of hospitalization and death, principally in high-risk patients. However, neither of these products have been shown to reduce the time to sustained clinical recovery in non-hospitalized standard risk patients. We are targeting this therapeutic niche with the Arakoda regimen of Tafenoquine, for which we will attempt to confirm clinical benefit in a clinical study in the second half of 2023.

[66] Velez et al 2021 - Lancet Child Adolesc Health 2022; 6: 86–95.

Intellectual Property

We are co-owners, with the U.S. Army, of patents in the United States and certain foreign jurisdictions directed toward use of Tafenoquine for malaria and have obtained an exclusive worldwide license from the U.S. Army to practice these inventions. We also have an exclusive worldwide license to use manufacturing information and non-clinical and clinical data that the U.S. Army possesses relating to use of Tafenoquine for all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. We have submitted patent applications in the United States and certain foreign jurisdictions for use of Tafenoquine for COVID-19, fungal lung infections, tick-borne diseases, and other infectious and non-infectious diseases in which induction of host cytokines/inflammation is a component of the disease process. The United States Patent and Trademark Office ("USPTO") recently allowed our first COVID-19 patent for Tafenoquine. We have optioned or licensed patents involving Celgosivir for the treatment and prevention of Dengue (from the National University of Singapore), COVID-19 & Zika (Florida State University), and have submitted provisional patent applications related to Celgosivir for RSV. We have optioned or own manufacturing methods related to Celgosivir. A detailed list of our intellectual property is as follows:

Patents

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Dosing Regimen For Use Of Celgosivir As An Antiviral Therapeutic For Dengue Virus Infections	2013203400	Australia			2013203400+	10-April-2033*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	2014228035	Australia			2014228035	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	MY-170991-A	Malaysia			PI2015002372	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	378015	Mexico			MX/a/2015/013115	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11201507254V	Singapore			11201507254V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	Pending	Singapore	Pending		10201908089V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	9763921	US		9/19/2017	14/772,873	14-Mar-2034^
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	10517854	US		12/31/2019	15/706,845	14-Mar-2034^
Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11219616	US		1/11/2022	16/725,387	14-Mar-2034^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	2015358566	Australia			2015358566	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Canada	Pending		2968694	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	10342791	US		7/9/2019	15/532,280	02-Dec-2035^
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	10888558	US		1/12/2021	16/504,533	02-Dec-2035^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Singapore	Pending		10201904908Q	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	EP	Pending		15865264.4	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Hong Kong	Pending		18103081.4	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	Pending	US	Pending		17/145,530	02-Dec-2035^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	New Zealand	Pending		731813	02-Dec-2035*
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	2016368580	Australia			2016368580	09-Dec-2036*
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	Pending	Singapore	Pending		10201912141Y	09-Dec-2036*
Dosing Regimens Of Celgosivir For The Prevention Of Dengue	11000516	US		5/11/2011	16/060,945	09-Dec-2036^
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	EP	Pending		21764438.4	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	China	Pending		202180029643.7	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	Australia	Pending		2021231743	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	Pending	US	Pending		17/189,544	02-Mar-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Fungus By Administration Of Tafenoquine	Pending	US	Pending		17/683,679	02-Mar-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Sars-Cov-2 Virus By Administration Of Tafenoquine	Pending	US	Pending		17/683,718	02-Mar-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	11369592	US		6/28/2022	17/180,140#	19-Feb-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	US	Pending		17/664,693#	19-Feb-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	EP	Pending		2021757552#	19-Feb-2041*
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof	*Provisional*	US	*Provisional*		63/461,060	21-Apr-2044&
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	*Provisional*	US	*Provisional*		63/358,341	~05-Jul-2043&
Methods For The Treatment And Prevention Of Diseases Or Infections With Mcp-1 Involvement By Administration Of Tafenoquine	*Provisional*	US	*Provisional*		63/411,654	~30-Sep-2043&
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,328,061+	US		6-25-2019	15/584,952+	2-May-37
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,561,642+	US		2-18-2020	15/856,377+	2-May-37

* = For foreign patents and applications, the estimated and/or anticipated patent expiration is the date that is twenty years from the PCT filing date. For all issued Australian patents, this estimated date was also confirmed through the Australian patent office web database.

^ = For issued U.S. patents, the estimated patent expiration was calculated using information from the front cover of the patent, *i.e.*, 20 years from the date of the nonprovisional filing plus any listed Patent Term Adjustment less any time disclaimed through a Terminal Disclaimer. For pending U.S. applications, the anticipated patent expiration is the date twenty years from the earliest nonprovisional filing date and does not account for possible Patent Term Adjustment (PTA), Patent Term Extension (PTE), or Terminal Disclaimers.

& = For U.S. provisional applications that are not yet the subject of a nonprovisional or PCT application, the anticipated patent expiration was determined using the assumption that a non-provisional application or PCT will be filed one year after filing the provisional application with a term lasting twenty years from the date of that nonprovisional or PCT filing. This does not account for possible Patent Term Adjustment (PTA), Patent Term Extension (PTE), or Terminal Disclaimers.

\+ = 60 Degrees Pharmaceuticals, Inc. is not a listed Applicant and Geoffrey S. Dow, Ph.D. is not a listed inventor.

\# = 60 Degrees Pharmaceuticals, Inc. is not a listed Applicant, but Geoffrey S. Dow, Ph.D. is a listed inventor.

All patents not designated with a "+" list Geoffrey S. Dow, Ph.D. as an inventor.

All patents not designated with a “+” or a “#” list 60 Degrees Pharmaceuticals, Inc. as an applicant.
All estimated patent expiration dates and anticipated patent expiration assume payment of any maintenance/annuity fees during the patent term.

Trademarks

Country	Mark	Status	Application Number	Date Filed	Registration Date	Registration Number	BIR Ref Number	Due Date	Due Date Description
Australia	KODATEF	Registered	1774631	2-Jun-16	6/2/2016	1774631	0081716-000029	2-Jun-26	Renewal Due
Canada	KODATEF	Registered	1785098	1-Jun-16	11/26/2019	TMA1,064,371	0081716-000028	26-Nov-29	Renewal Due
Canada	ARAKODA	Registered	1899317	15-May-18	8/20/2020	TMA1,081,180	0081716-000053	20-Aug-30	Renewal Due
China	KODATEF	Registered	20842242	2-Aug-16	9/28/2017	20842242	0081716-000035	27-Sep-27	Renewal Due
European Union	KODATEF	Registered	15508872	3-Jun-16	9/21/2016	15508872	0081716-000034	3-Jun-26	Renewal Due
European Union	ARAKODA	Registered	17900852	16-May-18	9/20/2018	17900852	0081716-000054	16-May-28	Renewal Due
Israel	KODATEF	Registered	285476	6-Jun-16	6/6/2016	285476	0081716-000033	6-Jun-26	Renewal Due
New Zealand	KODATEF	Registered	1044407	7-Jun-16	12/8/2016	1044407	0081716-000031	6-May-26	Renewal Due
Russian Federation	KODATEF	Registered	2016720181	6-Jun-16	7/10/2017	623174	0081716-000032	6-Jun-26	Renewal Due
Singapore	KODATEF	Registered	40201707950V	2-May-17	11/8/2017	40201707950V	0081716-000040	2-May-27	Renewal Due
United Kingdom	ARAKODA	Registered	17900852	16-May-18	9/20/2018	UK00917900852	0081716-000054	16-May-28	Renewal Due
United Kingdom	KODATEF	Registered	15508872	3-Jun-16	9/21/2016	UK009015508872	0081716-000072	3-Jun-26	Renewal Due
United States of America	TQ 100 & TABLET DESIGN	Registered	87608493	14-Sep-17	9/11/2018	5562900	0081716-000037	11-Sep-24	Section 8 & 15 Due
United States of America	ARAKODA	Registered	87688137	16-Nov-17	12/31/2019	5950691	0081716-000050	31-Dec-25	Section 8 & 15 Due
United States of America	KODATEF	Allowed - 02/16/2021	90072885	24-Jul-20			0081716-000069	16-Aug-23	Statement of Use/3rd Extension of Time Due

Key Relationships & Licenses

On May 30, 2014, we entered into the Exclusive License Agreement (the "2014 NUS-SHS Agreement") with National University of Singapore ("NUS") and Singapore Health Services Pte Ltd ("SHS") in which we were granted a license from NUS and SHS with respect to their share of patent rights regarding "Dosing Regimen for Use of Celgosivir as an Antiviral Therapeutic for Dengue Virus Infection" to develop, market and sell licensed products. The 2014 NUS-SHS Agreement continues in force until the expiration of the last to expire of any patents under the patent rights unless terminated earlier in accordance with the 2014 NUS-SHS Agreement. We are obligated to pay at the rate of 1.5% of gross sales.

On July 15, 2015, we entered into the Exclusive License Agreement with the U.S. Army Medical Materiel Development Activity (the "U.S. Army"), which was subsequently amended (the "U.S. Army Agreement"), in which we obtained a license to develop and commercialize the licensed technology with respect to all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. This exclusion does not impact our ability to market Arakoda for the FDA-approved use, which is the prevention of malaria utilizing the indicated dose in asymptomatic individuals traveling to malarious areas (whereas the license exclusion relates to its use to treat symptomatic vivax malaria in a patient already presenting with that disease). The term of the U.S. Army Agreement will continue until the expiration of the last to expire of the patent application or valid claim of the licensed technology, or 20 years from the start date of the U.S. Army Agreement, unless terminated earlier by the parties. We will be required to make a minimum annual royalty payment of 3% of net sales for net sales < $35 million, and 5% of net sales greater than $35 million, with US government sales excluded from the definition of net sales. In addition, we must pay a milestone fee of $75,000 once cumulative net sales from all sources exceeds $6 million, $100,000 if the company is acquired or merges, and regulatory approval milestone payments once marketing authorizations are achieved in Canada ($5,000) and Europe ($5,000). Also, we will be required to obtain the U.S. Army Medical Materiel Development Activity's consent prior to a change of control of the Company, which consent was obtained on September 2, 2022.

On September 15, 2016, we entered into the Exclusive License Agreement (the "2016 NUS-SHS Agreement") with National University of Singapore ("NUS") and Singapore Health Services Pte Ltd ("SHS") in which we were granted a license from NUS and SHS with respect to their share of patent rights regarding "Novel Dosing Regimens of Celgosivir for The Prevention of Dengue" to develop, market and sell licensed products. The 2016 NUS-SHS Agreement continues in force until the expiration of the last to expire of any patents under the patent rights unless terminated earlier in accordance with the 2016 NUS-SHS Agreement. We are obligated to pay at the rate of 1.5% of gross sales or minimum annual royalty ($5,000 in 2022 and $15,000 in 2023). In July 2022, the Company renegotiated the timing of a license fee of $85,000 Singapore Dollars, payable to the National University of Singapore, such that payment would be due at the earlier of (i) enrollment of a patient in a Phase II clinical trial involving Celgosivir, (ii) two years from the agreement date and (iii) an initial public offering.

On December 4, 2020, we entered into the Other Transaction Authority for Prototype Agreement ("OTAP Agreement") with the Natick Contracting Division of the U.S. government in which we will, among other things, conduct activities for a Phase II clinical trial to assess the safety and efficacy of Tafenoquine for the treatment of mild to moderate COVID-19 disease, with the goal of delivering Tafenoquine with an FDA Emergency Use Authorization ("EUA") approved as a countermeasure against COVID-19. The total amount of the OTAP Agreement is $4,999,814. The term of the OTAP Agreement commences on December 4, 2020, and was completed in the third quarter of 2022. The U.S. government may terminate the OTAP Agreement for any or no reason by providing us with at least thirty (30) calendar days' prior written notice. Pursuant to the OTAP Agreement, we will not offer, sell or otherwise provide the EUA or licensed version of the prototype (Tafenoquine) that is FDA approved for COVID-19 or any like product to any entity at a price lower than that offered to the DoD, which applies only to products sold in the U.S., European Union and Canada related to COVID-19.

On February 15, 2021, we entered into the Inter-Institutional Agreement (the "FSURF Agreement") with the Florida State University Research Foundation ("FSURF") in which FUSRF granted us the right to manage the licensing of intellectual property created at FSURF. The term of the FSURF Agreement expires five years from February 15, 2021. After deduction of a 5% administrative fee by FSURF, capped at $15,000 annually, and reimbursement of patent prosecution expenses, we will receive 20% of license income and FSURF will receive 80% of license income. Payments of license income shall be paid in U.S. dollars quarterly each year. On February 19, 2021, we entered into an agreement with FSURF, subsequently amended on February 15, 2023, that

collectively granted an option, effective through August 19, 2023, to us to license methods for purifying castanospermine and its use for the treatment of COVID-19. On August 19, 2021, we entered into an agreement with FSURF, subsequently amended on February 15, 2023, that collectively granted an option, effective through August 19, 2023, to us to license a patent relating to the use of alpha glucosidase inhibitors (including castanospermine and celgosivir) for treatment of Zika infections.

Pursuant to the Knight Debt Conversion Agreement, for a period commencing on January 1, 2022 and ending upon the earlier of ten years after the closing date of this offering or the conversion or redemption in full of all of the shares of Series A Preferred Stock owned by Knight, we will pay Knight a royalty equal to 3.5% of our net sales, where “net sales” has the same meaning as in our license agreement with the U.S. Army for Tafenoquine. Upon succeeding with the qualified IPO, at the end of the quarter and each thereafter the royalty will be calculated, and payment will be made within fifteen days.

Sales and Marketing

For the remainder of 2023, we are committed to ensuring continuity of supply of Arakoda in the U.S. market for malaria prevention. As resources permit, we will undertake a limited marketing campaign for Arakoda for malaria prevention in the second half of 2023. This effort would consist of promotions at relevant conferences, email promotions to prescribers, targeted print and electronic advertisements, and outreach via social media as appropriate. The focus of promotional efforts would be on the proven features and benefits of Arakoda, and the recent publication demonstrating the good safety and tolerability of Arakoda for continuous weekly dosing for up to one year.[67]

We will be closely monitoring market share growth of Kodatef in Australia in 2023. Unlike Arakoda in the U.S., the Australian product will be actively marketed by a sales team to travel clinics, and the same distributor is also the licensor for the SD Biosensor point of care G6PD test (which is TGA approved). Comparison of Australian to U.S. civilian sales sector growth (the latter of which will be unsupported by sales staff and a marketed point of care G6PD test) over the same period will inform the design of any future commercialization plan for the malaria indication that we may wish to undertake.

Effective January 1, 2023, we have lowered the Arakoda WAC price to $235 USD per 16 x 100 mg tablet box. Although international pricing is independently set by our foreign distributors, we believe that the revised U.S. pricing will be similar relative to competitor products as it is elsewhere. Following this price adjustment, we will attempt to improve the position of Arakoda in the DoD formulary through engagement of a consulting firm with appropriate contacts.

We also plan to enter into contract sales agreements with a(n) appropriate organization(s) to further (i) ex U.S. named patient use.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates.

Australian Research Tax Credit and Overseas Finding Process

Under Section 27 of the Industry Research and Development Act 1986[68], the Australian government offers a research tax credit of 43.5% on registered research and development activities executed in Australia by eligible Australian domiciled entities. Companies are eligible to receive tax credits if they meet the following criteria: (i) are domiciled in Australia, (ii) have incurred at least $20,000 in eligible research and development expenses, (iii) have conducted at least one eligible research and development activity, (iv) beneficial owner(s) with > 40 % beneficial ownership when considered together do not have > $20 million AUD aggregated turnover on an annual basis. 60P Australia Pty Ltd meets all these criteria, and will continue to do so following this offering unless our aggregate turnover, considered together with any of our shareholders who have > 40% beneficial ownership, have > $20 million AUD in aggregate annual turnover.

Under Section 28D of the Industry Research and Development Act 1986[69], research and development activities conducted outside Australia are also potentially eligible if they meet the following criteria: (i) they are approved in advance, (ii) they are linked to a core research and development activity conducted in Australia, (iii) cannot be conducted in Australia for various reasons and (iv) the value of activities conducted overseas is less than the value of activities conducted in Australia. These criteria would be met for the planned COVID-19 study if a population of suitable patients could not be found in Australia, and we conduct research activities linked to the COVID-19 study in Australia in the future which are greater in value than the cost of the planned COVID-19 clinical study.

Government Regulation and Product Approvals

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

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[67] Novitt-Moreno et al. TMAID 2022; 45:102211.

[68] See Industry Research and Development Act 1986 (legislation.gov.au).

[69] See Australian Government R&D Tax Incentive – Overseas R&D: Information Sheet.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates, among other things, the research, development, testing, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post approval monitoring and reporting and import and export of drugs in the U.S. to assure the safety and effectiveness of medical products for their intended use under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and implementing regulations. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, denial of the ability to import and export certain products, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the investigational product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold.

Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA requirements in order to use the study as support for an IND or application for marketing approval.

In addition to the IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, for public dissemination on its *ClinicalTrials.gov* website.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

- Phase 4: Post-approval studies, which are conducted following initial approval, are typically conducted to gain additional experience and data from treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee and the sponsor of an approved NDA is also subject to annual product and establishment user fees. These fees are typically increased annually. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses, an exception from the establishment fee when the establishment does not engage in manufacturing the product during a particular fiscal year, and an exception from the product fee for a product that is the same as another product approved under an abbreviated pathway.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to certain performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Under the FDA Reauthorization Act of 2017 ("FDARA"), the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain drug applications, including applications for drugs in a shortage or drugs for which approval is dependent on remediation of conditions identified in the inspection report.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but is not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast-Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast-track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast-track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast-track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast-track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast-track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast-track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Tropical Disease PRVs

The Tropical Disease Priority Review Voucher ("PRV") program was created by Congress under the Food and Drug Administration Amendments Act of 2007 ("FDAAA") in order to encourage innovation and public access to new medicines. Pursuant to Section 1102 of FDAAA, which amended section 524 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), along with later amendments, the FDA must award a PRV to certain applicants that obtain an approved NDA to treat certain tropical diseases. Congress later expanded the scope of diseases that were eligible for a PRV (e.g., a PRV for obtaining approval for a drug to treat rare pediatric diseases). A PRV entitles the holder of the voucher to designate a different drug application as qualifying for priority review from FDA. When a drug application is designated for priority review through use of a priority review voucher, that application must be reviewed by FDA no later than 6 months after receipt.[70] This guarantees a much more rapid review by FDA compared to the standard review time.

Tropical disease PRVs were created under the FDAAA to encourage pharmaceutical companies to develop treatments for specific neglected tropical diseases. As defined by the statute, tropical diseases refer to certain "infectious disease[s] for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations."[71] Because tropical diseases occur rarely in the United States, obtaining approval from the FDA for treating these diseases would normally be unprofitable for pharmaceutical companies due to the limited domestic market and the scope and significant financial costs of the post-marketing requirements imposed by FDA. Congress intended to incentivize companies to turn their attentions to tropical diseases by providing a PRV to those companies that obtained approval from FDA for a tropical disease drug product, and the granted PRV could then be sold to another company for money.

A PRV is an extremely valuable property interest. For example, Rhythm Pharmaceutical, Inc. announced in 2021 that it had sold a PRV for $100,000,000.[72]

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. There is limited experience with accelerated approvals by the FDA based on intermediate clinical endpoints. However, the FDA has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

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[70] 21 U.S.C. § 360n(a)(1).

[71] 21 U.S.C. § 360n(a)(3).

[72] Ben Adams, *Newly acquired Alexion pays $100M for Rhythm's speedy review voucher*, Fierce Biotech (Jan 6, 2021, 10:23 AM), *available at* https://www.fiercebiotech.com/biotech/newly-acquired-alexion-pays-100m-for-rhythm-s-speedy-review-voucher.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, the FDA's regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), and its implementation regulations, as well as the Drug Supply Chain Security Act ("DSCSA"), which regulates the distribution of and tracing of prescription drugs and prescription drug samples at the federal level, and sets minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an ANDA to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug..."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity ("NCE"), is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

Under FDARA, a priority review track will be established for certain generic drugs, requiring the FDA to review a drug application within eight months for a drug that has three or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The new legislation also authorizes the FDA to expedite review of "competitor generic therapies" or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;

- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Safety and Innovation Act ("FDASIA"), in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. For drugs intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments.

In addition, FDARA requires the FDA to meet early in the development process to discuss pediatric study plans with drug sponsors. The legislation requires the FDA to meet with drug sponsors no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly responds to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. With regard to patents, the six-month pediatric exclusivity period will not attach to any patents for which a generic (ANDA or 505(b)(2) NDA) applicant submitted a paragraph IV patent certification, unless the NDA sponsor or patent owner first obtains a court determination that the patent is valid and infringed by a proposed generic product.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Those circumstances include instances in which another sponsor's application for the same drug product and indication is shown to be "clinically superior" to the previously approved drug. In this context, clinically superior means that the drug provides a significant therapeutic advantage over and above the already approved drug in terms of greater efficacy, greater safety or by providing a major contribution to patient care. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Under FDARA, orphan exclusivity will not bar approval of another orphan drug under certain circumstances, including if a subsequent product with the same drug for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Medical Devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FDCA, a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. If not, it is generally a medical device.

Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices have the lowest level or risk associated with them, and are subject to general controls, including labeling, premarket notification and adherence to the Quality System Regulation ("QSR"). Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are subject to most of the aforementioned requirements as well as to premarket approval.

A 510(k) must demonstrate that the proposed device is substantially equivalent to another legally marketed device, or predicate device, which did not require premarket approval. In evaluating a 510(k), the FDA will determine whether the device has the same intended use as the predicate device, and (a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics, and (i) the data supporting substantial equivalence contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as a legally marketed device, and (ii) does not raise different questions of safety and effectiveness than the predicate device. Most 510(k)s do not require clinical data for clearance, but the FDA may request such data. The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA concludes that a new device is not substantially equivalent to a predicate device, the new device will be classified in Class III and the manufacturer will be most likely required to submit a PMA to market the product.

Under the PMA application process, the applicant must demonstrate that the device is safe and effective for its intended use. This PMA approval process applies to most Class III devices, and generally requires clinical data to support the safety and effectiveness of the device, obtained in conformance with Investigational Device Exemption regulations. The FDA will approve a PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose, and that the proposed manufacturing is in compliance with the QSRs. For novel technologies, the FDA will seek input from an advisory panel of medical experts regarding the safety and effectiveness of, and their benefit-risk analysis for the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process, though both processes can be expensive and lengthy, and require payment of significant user fees, unless an exemption is available.

Modifications to a 510(k)-cleared medical device may require the submission of another 510(k) or a PMA if the changes could significantly affect safety or effectiveness or constitute a major change in the intended use of the device. Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Procedures Governing Approval of Drug Products in the European Union

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an E.U. member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent Ethics Committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a product under European Union regulatory systems, an applicant must submit a marketing authorization application ("MAA"), either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all E.U. member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (the "CHMP"), established at the European Medicines Agency ("EMA"), is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various E.U. member states where such a product has not previously received marketing approval in any E.U. member states. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including Good Clinical Practice, are set forth in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the E.U. member states. Under this system, approval must be obtained from the competent national authority of each E.U. member state in which a study is planned to be conducted. To this end, a clinical trial application is submitted, which must be supported by an investigational medicinal product dossier ("IMPD"), and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent Ethics Committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the European Union passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new E.U. clinical trials legislation was passed as a regulation that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of EMA, the new Clinical Trials Regulation will become applicable in 2019. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old system.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the E.U. portal; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states; a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts—Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned; strictly defined deadlines for the assessment of clinical trial applications; and the involvement of the Ethics Committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Clinical Trials Regulation.

Data and Market Exclusivity in the European Union

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company can complete a full MAA with a complete database of pharmaceutical tests, preclinical tests and clinical trials and obtain marketing approval of its product.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Periods of Authorization and Renewals

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the European Union market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Orphan Drug Designation and Exclusivity

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the European Union. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom (U.K.) voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the U.K. from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the U.K. provides a notice of withdrawal pursuant to the E.U. Treaty. Since the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K.

Regulatory Framework in Australia

The Therapeutic Goods Administration, through the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations is responsible for the efficacy, quality, safety and timely availability of drugs and medical devices in Australia. The mission statement of the TGA is "To ensure the safety, quality and efficacy of therapeutic goods available in Australia at a standard equal to that of comparable countries, and that premarket assessment of therapeutic goods is conducted within a reasonable time."

The drug regulation process in Australia is complex and resource intensive. It must be accountable in terms of the quality, safety and efficacy of drugs made available in Australia. This accountability includes an acceptance of a balance between safety and efficacy. The approval process is a detailed evaluation of the data supplied by the company sponsoring an application.

A drug may first come to the attention of the TGA when an application for marketing is received or when an Australian clinical trial is being planned. For clinical trials, the sponsoring company may submit preliminary data for evaluation to the TGA or notify the TGA that the trial has been approved by an institutional Ethics Committee.

The drug evaluation process for new chemical entities is as follows:

Application

- Check to see data complies with Australian guidelines.
- Invoice sponsor for 75% of evaluation fee.

Evaluation

- Evaluate pharmaceutical and chemical data.
- Evaluate animal pharmacology and toxicology data.
- Evaluate clinical data.
- Evaluation Unit reviews reports (coordinates external evaluations if used), prepares a summary and makes an initial recommendation.
- Pre ADEC consultation with sponsor.
- Prepare approved product information and consider consumer product information.
- Submit final package of summaries and recommendations to the ADEC (six meetings per year).

Approval

- ADEC review and advice to the TGA.
- Final decision by the TGA.
- Finalize conditions of registration.
- Advice to sponsor, invoice final 25% of evaluation fee.
- For new chemical entity, advise drug information centers, forensic laboratories, etc.

Registration

- Sponsor applies to register the product on the Australian Register of Therapeutic Goods.
- Supply is permitted once the applicable number is allocated.

The drug's chemistry, toxicology and clinical use are evaluated using data submitted by the sponsoring company. Most of the evaluations are done within the TGA, but external evaluations can be used. When all the data have been evaluated, the application is considered by the Australian Drug Evaluation Committee ("ADEC"). This committee is a group of doctors appointed by the Minister to advise on the suitability of drugs for marketing in Australia. The TGA takes into consideration the advice received from the ADEC when making a final recommendation.

The evaluation process relates to pre-marketing activity, but the TGA is also responsible for drugs after they are marketed.

Other activities under the control of the TGA include:

- maintenance of the Australian Register of Therapeutic Goods for the registration and listing of products;
- control of drug and device exports from Australia;
- inspection and licensing of manufacturing premises;
- post marketing surveillance;
- adverse drug reaction monitoring;
- reports were received by the Adverse Drug Reactions Advisory Committee;
- medical device complaint reporting;
- drug and device recalls;
- laboratory testing, sample testing;
- complaint reporting and follow up; and
- drug and device advertising controls

The performance of the TGA is monitored in quarterly performance reports which are reviewed by the Industry/Government Consultative Committee. This committee has membership from the TGA, the Department of Finance, the Department of Industry, Science and Technology, and the peak industry organizations representing the manufacturers of prescription drugs, non-prescription drugs, medical devices and herbal and nutritional products.

If the TGA does not meet the statutory timelines in approving a drug, then it forgoes 25% of the evaluation fee as a penalty. The sponsor concerned can also consider the outcome as a "deemed refusal" and appeal to the Administrative Appeals Tribunal for a resolution. For variations to the registration of a drug, the TGA must raise an objection within 45 working days, otherwise the application is deemed to be approved.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for our product candidates will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities and their business associates that associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act (collectively the "ACA"), which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS"), within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians and teaching hospitals and information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures were passed by the U.S. Senate.

In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction ("CSR"), payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA.

A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures have been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

In August 2022, the Inflation Reduction Act of 2022 was signed into law and requires the federal government to negotiate prices for some high-cost drugs covered under Medicare, requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries, and caps Medicare beneficiaries' out-of-pocket spending under the Medicare Part D benefit. We will monitor this issue to determine the effects of this legislation on our business.

Human Capital Resources

As of March 31, 2023, we had a total of two employees, both of which are full-time. We also utilize the services of two part-time contractors.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Properties

Our corporate headquarters are located at 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036. We do not own any physical property, plant or labs. We currently lease two offices at the above address and, as a result of the renewal of our lease for an additional one-year in January 2023, recognized a Right of Use Asset of $51,142 as of March 31, 2023, with offsetting accumulated depreciation of $12,427 ($99,615 and $99,615 as of December 31, 2022 and December 31, 2021, respectively with offsetting accumulated depreciation of $86,968 and $40,948, respectively).

Legal Proceedings

From time to time, we may become involved in various claims and legal proceedings. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

History

60 Degrees Pharmaceuticals, Inc. is a Delaware corporation that was incorporated on June 1, 2022. On June 1, 2022, 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company ("60P LLC"), entered into the Agreement and Plan of Merger with 60 Degrees Pharmaceuticals, Inc., pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. The value of each outstanding member's membership interest in 60P LLC was correspondingly converted into common stock of 60 Degrees Pharmaceuticals, Inc., par value $0.0001 per share, with a cost-basis equal to $5.00 per share.

We also operate one subsidiary. A summary of our majority-owned subsidiary is below.

We own 88% equity in 60P Australia Pty Ltd, a Sydney-Australia based subsidiary ("60P Australia"). 60P Australia holds sub-licensing rights for several ex-U.S. territories for our product.

60P Australia previously solely owned a Singaporean subsidiary company, 60P Singapore Pte. Ltd., which dissolved at our election in the second quarter of 2022.

MANAGEMENT

The following table sets forth the name, age and position of each of our executive officers, directors and director nominees as of June 1, 2023.

Name	Age	Position	Director Since
Geoffrey Dow	49	Chief Executive Officer, President and Director	June 1, 2022
Tyrone Miller	49	Chief Financial Officer	—
Bryan Smith	57	Chief Medical Officer	—
Charles Allen	47	Director Nominee	—
Cheryl Xu	55	Director Nominee	—
Stephen Toovey	69	Director Nominee	—
Paul Field	59	Director Nominee	—

Executive Officers and Directors

Geoffrey Dow is our Chief Executive Officer, President, and is also our sole Director. Dr. Dow has over 20 years of product development experience in tropical diseases and has an extensive publication and patent history. His decades of hands-on experience include 13 years in key leadership and advisory roles in the antimalarial drug development program at the Walter Reed Army Institute of Research and at the U.S. Army Medical Materiel Development Activity. Dr. Dow co-founded 60P in 2010. Since then, he has been involved in various projects, including leading the project development team in securing FDA-regulatory approval for Tafenoquine (as Arakoda) for malaria prophylaxis, securing a supply chain and access relating to Arakoda, managing post-marketing regulatory commitments, ensuring the successful prosecution of supporting patents on which Dr. Dow was an inventor, and ensuring the company adheres to GMP, quality, and pharmacovigilance requirements. Dr. Dow has also published a number of important safety reviews, clinical trials, non-clinical studies, on which he was a thought leader or contributor, which dispelled many of the myths about 8-aminoquinolines. As a scientist, experienced industry project manager and inventor, Dr. Dow's ultimate goal is to develop and secure the regulatory approval and commercial success of products, old and new, for new indications in infectious disease. Dr. Dow received a B.Sc. (Hons) in Veterinary and Biomedical Science from Murdoch University, Perth, Western Australia ("Murdoch") in 1994, a Ph.D. in Veterinary and Biomedical Science from Murdoch in 2000 and an MBA from the University of Maryland at College Park in 2012. We believe that Mr. Dow is well qualified to serve as a Director given his product development experience in tropical diseases.

Tyrone Miller is our Chief Financial Officer. Mr. Miller joined us in 2014 and has held a number of roles since then, including Treasurer. He worked with the founder and Chief Executive Officer of 60P and raised over $6 million in external financing. Mr. Miller also established a multinational financial reporting system and worked with consultants in designing tax and credit strategies. He also provides key strategic advice in areas of financing and business planning to 60P. In addition, he is the founder and Principal of Tax & Accounting Practice at Miller Tax & Advisory since 2011. In that role, Mr. Miller advises owners of closely held businesses on accounting, financial and tax matters and has designed accounting systems for private sector businesses. From 2002 to 2011, he was a Senior Accountant at Sachs Figurelli, LLC, where he prepared and processed corporate and individual tax returns, consulted on reengineering accounting processes for construction, restaurant and professional services businesses and managed staff in preparation and processing of payroll and personal property returns. Mr. Miller is currently a Certified Public Accountant. He received a Bachelor's of Business Administration with a concentration in International Business from Emory University in 1996.

Bryan Smith is our Chief Medical Officer. Dr. Smith is a medical doctor with expertise in clinical pharmacology, pharmacovigilance, regulatory strategy development and translational medicine and is a retired military colonel with over 30 years of governmental research and leadership experience. He joined us in 2016 as Chief Medical Officer and works with other members of the senior management team to establish all functional areas, including complying with national and international laws and regulations and developing and overseeing research and development projects and agenda. He also is currently a Senior Medical Director, Clinical and Regulatory Affairs at Fast-Track Drugs & Biologics, LLC since 2019, where he is responsible for developing clinical development plans for therapeutic products, managing clinical and regulatory projects and designing and writing clinical trial protocols. Since 2016, Dr. Smith has been the Chief Medical Officer and member of Amivas LLC, where he establishes all functional areas required to successfully secure FDA approvals. In addition, from 2016 to 2019, he was the Principal Medical Consultant at Clinical Network Services, Inc., where he provided required medical, clinical pharmacology, regulatory, translational medicine review, oversight and consultation as requested for over 25 unique clients in a range of activities and tasks for devices, small molecules and large molecules in a range of therapeutic areas. Dr. Smith received a Bachelor of Science in General Science, with highest honors, from Oregon State University and a Doctor of Medicine from Uniformed Services University of the Health Sciences.

Director Nominees

Charles Allen is one of our director nominees and since February 5, 2014 has served as the Chief Executive Officer of BTCS Inc. ("BTCS") and the Chairman of the Board of BTCS since September 11, 2014. Mr. Allen is responsible for BTCS' overall corporate strategy and direction. Since December 2, 2022, Mr. Allen has been a director of Innovation1 Biotech Inc. Since January 12, 2018, Mr. Allen has been the Chief Executive Officer of Global Bit Ventures Inc. ("GBV"). Since October 10, 2017, Mr. Allen has been a director of GBV. Mr. Allen has extensive experience in business strategy and structuring and executing a variety of investment banking and capital markets transactions, including financings, initial public offerings, and mergers and acquisitions. Prior to his work in the blockchain industry at BTCS, he worked domestically and internationally on projects in technology, media, natural resources, logistics, medical services, and financial services. He has served as a managing director at numerous boutique investment banks focused on advising and raising capital for small and mid-size companies. Mr. Allen received a Bachelor of Science in Mechanical Engineering from Lehigh University and a Master of Business Administration from the Mason School of Business at the College of William & Mary. The Board concludes that Mr. Allen's background and leadership experiences in the financial industry qualify him to be nominated as a potential member of the Board.

Cheryl Xu is one of our director nominees and until recently served as Biogen's Vice President, Public Policy & Government Affairs since 2020. Ms. Xu was PhRMA's first Representative to China. Subsequently she started a consulting business in 2005, advising well-known multinational companies such as Pfizer, J&J and UnitedHealth Group on their market access and expansion strategies in China. Cheryl has provided consultations to both the U.S. and Chinese governments on pharmaceutical policies including strengthening of IP protection and monitoring system for China's API exports. Prior to that, she was the Director of International Finance at Pharmacia based in New Jersey from 1998 to 2003. Ms. Xu received her Bachelor of Science degree in Physics from Peking University, and Master of Business Administration in Finance from Washington University in St. Louis. The Board concludes that Ms. Xu's background and leadership experiences in the pharmaceutical industry qualify her to be nominated as a potential member of the Board.

Dr. Stephen Toovey is one of our director nominees and is an infectious and tropical disease physician. Dr. Toovey has worked in the pharmaceutical industry and academia in both developed and developing countries, and currently specializes in the research of influenza and other respiratory viruses, malaria, rabies and the neurological aspects of infectious diseases. He is currently the Chief Executive Officer of Pegasus, a medical and scientific services company and has held that position since 2008. Dr. Toovey also advises a number of pharmaceutical companies and biotech organizations on infection and immunology related matters, from translation through Phase IV, and founded numerous pharmaceutical and pharma-related companies, with the most recent being the co-founding of Ark Biosciences in 2014. Dr. Toovey served as Chief Medical Officer of Ark Biosciences from 2014 until 2020. In addition, he held a teaching and clinical post at the Royal Free and University College Medical School in London, United Kingdom, Academic Centre for Travel Medicine and Vaccines, World Health Organization Collaborating Center, appointed in 2008. He has been editor of the journal Travel Medicine and Infectious Disease since its foundation in 2003. Dr. Toovey has authored over 100 publications in peer reviewed medical journals, contributed to a number of textbooks and has presented at over 50 scientific meetings. Dr. Toovey received his PhD from the University of Ghent. The Board concludes that Dr. Toovey's background and leadership experiences in the pharmaceutical industry and academia qualify him to be nominated as a potential member of the Board.

Paul Field is one of our director nominees. Paul has over 30 years of business development experience across a range of disease areas, and a deep network in the global biopharmaceutical industry. He is currently a corporate advisor at Imunexus since 2020, Marinova since 2018, and GARDP (Switzerland) since 2018. He was until recently the Australian representative of FIND (Switzerland) from 2018 to 2021 and a business development advisor to the drug discovery company Biocurate from 2018 to 2020. Paul was previously the life sciences specialist at Austrade from 2014 to 2018, the Australian Government's investment promotion agency, where he facilitated foreign direct investment into Australian research in neglected tropical diseases, infectious diseases, autoimmune diseases, cancer and other therapeutic areas. Paul was the founder and Executive Chairman of Bio-Link from 2005 to 2014, a privately owned biotechnology business development company. His work at Bio-Link involved the commercialization of discovery, pre-clinical and early-stage clinical programs undertaken by Australian biotech companies and medical research institutions. Paul has served on a number of Boards of Directors, and he is a Fellow of the Australian Institute of Company Directors. The Board concludes that Mr. Field's background and leadership experiences in the biotechnology industry qualify him to be nominated as a potential member of the Board.

Significant Employees

We are a virtually managed pharmaceutical company for which the significant employees are its officers.

Code of Ethics

Our Board has adopted a written code of business conduct and ethics (“Code”) that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. We intend to post on our website a current copy of the Code and all disclosures that are required by law in regard to any amendments to, or waivers from, any provision of the Code.

Board Leadership Structure and Risk Oversight

Our Board has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our Board to understand our risk identification, risk management, and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, cybersecurity, strategic, and reputational risk.

Board of Directors

Upon the effectiveness of the registration statement of which this prospectus forms a part, we expect that our Board will consist of five members. Our business and affairs are managed under the direction of our Board.

Directors serve until the next annual meeting and until their successors are elected and qualified. Officers are appointed to serve until their successors have been elected and qualified.

Director Independence

Our Board will be composed of a majority of "independent directors" as defined under the rules of Nasdaq upon completion of this offering. We use the definition of "*independence*" applied by Nasdaq to make this determination. Nasdaq Listing Rule 5605(a)(2) provides that an "*independent director*" is a person other than an officer or employee of the company or any other individual having a relationship which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Nasdaq listing rules provide that a director cannot be considered independent if:

- the director is, or at any time during the past three (3) years was, an employee of the company;
- the director or a family member of the director accepted any compensation from the company in excess of $120,000 during any period of twelve (12) consecutive months within the three (3) years preceding the independence determination (subject to certain exemptions, including, among other things, compensation for board or board committee service);
- the director or a family member of the director is a partner in, controlling shareholder of, or an executive officer of an entity to which the company made, or from which the company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year or $200,000, whichever is greater (subject to certain exemptions);
- the director or a family member of the director is employed as an executive officer of an entity where, at any time during the past three (3) years, any of the executive officers of the company served on the compensation committee of such other entity; or
- the director or a family member of the director is a current partner of the company's outside auditor, or at any time during the past three (3) years was a partner or employee of the company's outside auditor, and who worked on the company's audit.

Under such definitions, our Board has undertaken a review of the independence of each director and director nominee. Based on information provided by each director and director nominee concerning his or her background, employment and affiliations, our Board has determined that Charles Allen, Stephen Toovey and Paul Field, once elected to the Board, will be independent directors of the Company. Our common stock is not currently quoted or listed on any national exchange or interdealer quotation system with a requirement that a majority of our Board be independent and, therefore, we currently are not subject to any director independence requirements; however, we expect to be listed under Nasdaq, in which case we will be subject to director independence requirements.

Committees of the Board of Directors

Upon the effectiveness of the registration statement of which this prospectus forms a part, our Board will have three standing committees: (i) an audit committee (the "Audit Committee"); (ii) a compensation committee (the "Compensation Committee"); and (iii) a nominating and corporate governance committee (the "Nominating and Corporate Governance Committee"). Our Board has not yet adopted procedures by which stockholders may recommend nominees to the Board. The composition and responsibilities of each of the committees of our Board are described below. Members serve on these committees until their resignation or until as otherwise determined by our Board.

Audit Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, we will establish the Audit Committee consisting of Charles Allen, who will be the Chairman of the Audit Committee, Stephen Toovey and Paul Field. Charles Allen qualifies as an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act. Our Board adopted an Audit Committee Charter on March 16, 2023, of which will be effective as of the effectiveness date of the registration statement of which this prospectus forms a part. The Audit Committee's duties, which are specified in our Audit Committee Charter, include, but are not limited to:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in our annual disclosure report;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;

- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- reviewing and approving all related-party transactions;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies; and
- approving reimbursement of expenses incurred by our management team in identifying potential target businesses.

The Audit Committee will be composed exclusively of "independent directors" who are "financially literate" as defined under the Nasdaq listing standards. The Nasdaq listing standards define "financially literate" as being able to read and understand fundamental financial statements, including a company's balance sheet, income statement and cash flow statement.

In addition, we intend to certify to Nasdaq that the committee has, and will continue to have, at least one member who has past employment experience in finance or accounting, requisite professional certification in accounting, or other comparable experience or background that results in the individual's financial sophistication.

Compensation Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, we will establish the Compensation Committee, which will be composed exclusively of independent directors consisting of Paul Field, who will be Chairman of the Compensation Committee, Charles Allen and Stephen Toovey. Each member of the Compensation Committee will be a non-employee director, as defined under Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Code. Our Board adopted a Compensation Committee Charter on March 16, 2023, of which will be effective as of the effectiveness date of the registration statement of which this prospectus forms a part. The Compensation Committee's duties, which are specified in our Compensation Committee Charter, include, but are not limited to:

- reviews, approves and determines, or makes recommendations to our Board regarding, the compensation of our executive officers;
- administers our equity compensation plans;
- reviews and approves, or makes recommendations to our Board, regarding incentive compensation and equity compensation plans; and
- establishes and reviews general policies relating to compensation and benefits of our employees.

Nominating and Corporate Governance Committee

Upon effectiveness of the registration statement of which this prospectus forms a part, we will establish the Nominating and Corporate Governance Committee, which will be composed exclusively of independent directors consisting of Stephen Toovey, who will be the Chairman of the Nominating and Corporate Governance Committee, Charles Allen and Paul Field. Our Board adopted a Nominating and Corporate Governance Committee Charter on March 16, 2023, of which will be effective as of the effectiveness date of the registration statement of which this prospectus forms a part. The Nominating and Corporate Governance Committee's duties, which are specified in our Nominating and Corporate Governance Audit Committee Charter, include, but are not limited to:

- identifying, reviewing and evaluating candidates to serve on our Board consistent with criteria approved by our Board;
- evaluating director performance on our Board and applicable committees of our Board and determining whether continued service on our Board is appropriate;
- evaluating nominations by stockholders of candidates for election to our Board; and
- corporate governance matters.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Involvement in Certain Legal Proceedings

Except as disclosed below, to our knowledge, none of our current directors or executive officers has, during the past ten (10) years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two (2) years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his or her involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

2022 Equity Incentive Plan

On November 22, 2022, the Board and majority stockholder adopted the 60 Degrees Pharmaceuticals, Inc. 2022 Equity Incentive Plan (the "Plan"). The Plan provides for the grant of the following types of stock awards: (i) incentive stock options, (ii) nonstatutory stock options, (iii) stock appreciation rights, (iv) restricted stock awards, (v) restricted stock unit awards and (vi) other stock awards. The Plan is intended to help us secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for our success and any of our affiliates and provide a means by which the eligible recipients may benefit from increases in value of the common stock. The Board reserved 238,601 shares of common stock issuable upon the grant of awards under the Plan.

EXECUTIVE COMPENSATION

The following table illustrates the compensation paid by us to our executive officers. The disclosure is provided for the years ended December 31, 2022, and December 31, 2021.

Name and Principal Position	Year	Base Salary($)[1]	Guaranteed Payments($)[1]	Stock Award($)	Total($)
Geoffrey Dow	2022	$ 54,510	$ -	$ -	$ 54,510
President and Chief Executive Officer	2021	-	519,996	-	519,996
(Principal Executive Officer)					
Tyrone Miller	2022	$ 148,672	$ -	$ -	$ 148,672
Chief Financial Officer	2021	-	363,996	-	363,996
(Principal Financial and Accounting Officer)					
Bryan Smith[2]	2022	$ -	$ -	$ -	$ -
Chief Medical Officer	2021	-	-	-	-
(Outsourced)					

(1) We periodically review, and may increase, base salaries in accordance with our normal annual compensation review for each of our named executive officers.

(2) Bryan Smith's part time services are acquired through a contractual relationship with his direct employer.

Equity Awards

Upon the listing of the shares of our common stock, (i) Dr. Dow will be granted a five-year option to purchase a total of 15,000 shares of our common stock on the last day of each quarter in each calendar year (for a cumulative total or no more than 300,000 shares over five years) and (ii) Mr. Miller will be granted a five-year option to purchase a total of 12,000 shares of our common stock on the last day of each quarter in each calendar year (for a cumulative total or no more than 240,000 shares over five years). The per share exercise price of the option shall be equal to the per share closing price of our common stock on the date of grant and shall have a cashless exercise provision.

Employment Agreements

Dow Employment Agreement. We entered into an Employment Agreement dated as of January 12, 2023, with Geoffrey Dow (the "Dow Employment Agreement"), our Chief Executive Officer and Chairman of our Board. The term of the Dow Employment Agreement began on January 12, 2023, and will continue for a period of two years, with subsequent automatic renewals unless either party thereto provides notice to terminate at least 90 days prior to the applicable renewal date. The Dow Employment Agreement provides Dr. Dow an annual base salary of $228,000, bonuses to the extent certain events occur or if applicable performance goals are met and employee benefits that are generally given to our senior executives. Upon the listing of the shares of our common stock, Dr. Dow will be granted a five-year option to purchase a total of 15,000 shares of our common stock that vest on the last day of each quarter in each calendar year (for a cumulative total or no more than 300,000 shares over five years). The per share exercise price of the option shall be equal to the per share closing price of our common stock on the date of the initial public offering and shall have a cashless exercise provision.

We may terminate Dr. Dow's employment for Cause, as defined in the Dow Employment Agreement, at any time upon notice to Dr. Dow setting forth in reasonable detail the nature of such Cause. We also may terminate Dr. Dow's employment other than for Cause at any time upon thirty (30) days' written notice to him. Dr. Dow may terminate his employment for Good Reason, as defined in the Dow Employment Agreement, at any time upon thirty (30) days' written notice to us. In the event that Dr. Dow's employment is terminated other than for Cause or for Good Reason, Dr. Dow will be entitled to, among other things, a continuation of his annual salary plus health insurance benefits for a period not exceeding 18 months. In addition, in the event of a Change in Control, as defined in the Dow Employment Agreement, on, or at any time during the 24 months following, the Change in Control, (i) we terminate Dr. Dow's employment for any reason other than Cause or Disability, as defined in the Dow Employment Agreement, or (ii) Dr. Dow terminates his employment for Good Reason, Dr. Dow will be entitled to Change in Control severance.

Dr. Dow is subject to non-competition and non-solicitation during the term of his employment and for a period of 24 months after termination of his employment.

Miller Employment Agreement. We entered into an Employment Agreement dated as of January 12, 2023 with Tyrone Miller (the "Miller Employment Agreement"), our Chief Financial Officer. The term of the Miller Employment Agreement began on January 12, 2023 and will continue for a period of two years, with subsequent automatic renewals unless either party thereto provides notice to terminate at least 90 days prior to the applicable renewal date. The Miller Employment Agreement provides Mr. Miller an annual base salary of $204,000, bonuses to the extent certain events occur or if applicable performance goals are met and employee benefits that are generally given to our senior executives. Upon the listing of the shares of our common stock, Mr. Miller will be granted a five-year option to purchase a total of 12,000 shares of our common stock that vest on the last day of each quarter in each calendar year (for a cumulative total or no more than 240,000 shares over five years). The per share exercise price of the option shall be equal to the per share closing price of our common stock on the date of the initial public offering and shall have a cashless exercise provision.

We may terminate Mr. Miller's employment hereunder for Cause, as defined in the Miller Employment Agreement, at any time upon notice to Mr. Miller setting forth in reasonable detail the nature of such Cause. We also may terminate Mr. Miller's employment other than for Cause at any time upon thirty (30) days' written notice to him. Mr. Miller may terminate his employment for Good Reason, as defined in the Miller Employment Agreement, at any time upon thirty (30) days' written notice to us. In the event that Mr. Miller's employment is terminated other than for Cause or for Good Reason, Mr. Miller will be entitled to, among other things, a continuation of his annual salary plus health insurance benefits for a period not exceeding 18 months. In addition, in the event of a Change in Control, as defined in the Miller Employment Agreement, on, or at any time during the 24 months following, the Change in Control, (i) we terminate Mr. Miller's employment for any reason other than Cause or Disability, as defined in the Dow Employment Agreement, or (ii) Mr. Miller terminates his employment for Good Reason, Mr. Miller will be entitled to Change in Control severance.

Mr. Miller is subject to non-competition and non-solicitation during the term of his employment and for a period of 24 months after termination of his employment.

2022 Equity Incentive Plan

Overview

On November 22, 2022, our Board and our stockholders approved the 60 Degrees Pharmaceuticals, Inc. 2022 Equity Incentive Plan. The Plan governs equity awards to our employees, directors, officers, consultants and other eligible participants. Initially, the maximum number of shares of our common stock that may be subject to awards under the Plan is equal to 238,601.

The purpose of the Plan is to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to employees, directors and consultants, and to promote the success of our business. The administrator of the Plan may, in its sole discretion, amend, alter, suspend or terminate the Plan, or any part thereof, at any time and for any reason. We will obtain stockholder approval of any Plan amendment to the extent necessary and desirable to comply with legal and regulatory requirements relating to the administration of equity-based awards. Unless earlier terminated by the administrator, the Plan will terminate ten years from the date it is adopted by our Board.

Authorized Shares

Initially, the maximum number of shares of our common stock that may be subject to awards under the Plan is equal 238,601.

Plan Administration

One or more committees appointed by our Board will administer the Plan. Initially, the Compensation Committee shall administer the Plan. In addition, if we determine it is desirable to qualify transactions under the Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured with the intent that they satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of the Plan, the administrator has the power to administer the Plan and make all determinations deemed necessary or advisable for administering the Plan, including the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2022 Plan, determine the terms and conditions of awards (including the exercise price, the time or times at which the awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of the Plan and awards granted under it, prescribe, amend and rescind rules relating to the Plan, rules and regulations relating to sub-plans established for the purpose of facilitating compliance with applicable non-U.S. laws, easing the administration of the Plan and/or for qualifying for favorable tax treatment under applicable non-U.S. laws, in each case as the administrator may deem necessary or advisable and modify or amend each award (subject to the provisions of the Plan), including the discretionary authority to extend the post-termination exercisability period of awards and to extend the maximum term of an option or stock appreciation right (subject to the provisions of the Plan), to allow Participants to satisfy withholding tax obligations in a manner permissible under the Plan, to authorize any person to execute on behalf of us any instrument required to effect the grant of an award previously granted by the administrator and to allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type which may have a higher or lower exercise price or different terms, awards of a different type or cash, or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants.

Eligibility

Awards under the Plan, other than incentive stock options, may be granted to our employees (including our officers and directors) or a parent or subsidiary, members of our Board, or consultants engaged to render bona fide services to us or a parent or subsidiary. Incentive stock options may be granted only to our employees or a subsidiary, provided the services (i) are not in connection with the offer or sale of securities in a capital-raising transaction, and (ii) do not directly promote or maintain a market for our securities, in each case, within the meaning of Form S-8 promulgated under the Securities Act, and provided further, that a consultant will include only those persons to whom the issuance of shares may be registered under Form S-8 promulgated under the Securities Act.

Stock Options

Stock options may be granted under the Plan. The exercise price of options granted under the Plan generally must at least be equal to the fair market value of our common stock on the date of grant. The term of each option will be as stated in the applicable award agreement; provided, however, that the term may be no more than 10 years from the date of grant. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, they may exercise their option for the period of time stated in their option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the termination of service. An option may not be exercised later than the expiration of its term. Subject to the provisions of the Plan, the administrator determines the other terms of options.

Stock Appreciation Rights

Stock appreciation rights may be granted under the Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, they may exercise their stock appreciation right for the period of time stated in their stock appreciation right agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of the Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock

Restricted stock may be granted under the Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of the Plan, will determine the terms and conditions of such awards. The administrator may impose whatever conditions to vesting it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units

RSUs may be granted under the Plan. RSUs are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of the Plan, the administrator determines the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of Company-wide, divisional, business unit or individual goals (including continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned RSUs in the form of cash, in shares of our common stock or in some combination thereof. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any vesting requirements will be deemed satisfied.

Performance Awards

Performance awards may be granted under the Plan. Performance awards are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will set objectives or vesting provisions, that, depending on the extent to which they are met, will determine the value the payout for the performance awards. The administrator may set vesting criteria based on the achievement of Company-wide, divisional, business Unit, or individual goals (including, but not limited to, continued employment or service), or any other basis determined by the administrator in its discretion. Each performance award’s threshold, target, and maximum payout values are established by the administrator on or before the grant date. After the grant of a performance award, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance award. The administrator, in its sole discretion, may pay earned performance awards in the form of cash, in shares, or in some combination thereof.

Non-transferability of Awards

Unless the administrator provides otherwise, the Plan generally does not allow for the transfer of awards other than by will or by the laws of descent and distribution and only the recipient of an award may exercise an award during their lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments

In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the Plan, the administrator will adjust the number and class of shares that may be delivered under the Plan or the number, and price of shares covered by each outstanding award and the numerical share limits set forth in the Plan.

Dissolution or Liquidation

In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control

The Plan provides that in the event of our merger with or into another corporation or entity or a "change in control" (as defined in the Plan), each outstanding award will be treated as the administrator determines, including, without limitation, that (i) awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and kind of shares and prices; (ii) upon written notice to a participant, that the participant's awards will terminate upon or immediately prior to the consummation of such merger or change in control; (iii) outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon consummation of such merger or change in control and, to the extent the administrator determines, terminate upon or immediately prior to the effectiveness of such merger or change in control; (iv) (A) the termination of an award in exchange for an amount of cash or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated by us without payment) or (B) the replacement of such award with other rights or property selected by the administrator in its sole discretion; or (v) any combination of the foregoing. The administrator will not be obligated to treat all awards, all awards a participant holds, or all awards of the same type, similarly. In the event that awards (or portion thereof) are not assumed or substituted for in the event of a merger or change in control, the participant will fully vest in and have the right to exercise all of their outstanding options and stock appreciation rights, including shares as to which such awards would not otherwise be vested or exercisable, all restrictions on restricted stock and RSUs or performance awards will lapse and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met, in all cases, unless specifically provided otherwise under the applicable award agreement or other written agreement between the participant and us or any of our subsidiaries or parents, as applicable. If an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that the option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the vested option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, the outside director will fully vest in and have the right to exercise options and/or stock appreciation rights as to all of the shares underlying such award, including those shares which would not be vested or exercisable, all restrictions on restricted stock and RSUs will lapse, and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met, unless specifically provided otherwise under the applicable award agreement or other written agreement between the participant and us or any of our subsidiaries or parents, as applicable.

Clawback

Awards will be subject to any clawback policy that we are required to adopt pursuant to the listing standards of any national securities exchange or association on which our securities are listed or as is otherwise required by the Dodd-Frank Act or other applicable laws. The administrator also may specify in an award agreement that the participant's rights, payments or benefits with respect to an award will be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain specified events. The administrator may require a participant to forfeit, return or reimburse us all or a portion of the award or shares issued under the award, any amounts paid under the award and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment and Termination

The administrator has the authority to amend, suspend or terminate the Plan provided such action does not impair the existing rights of any participant. The Plan automatically will terminate on November 22, 2032, unless it is terminated sooner.

Board Compensation

In November and December 2022, we signed agreements with four director nominees (Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey) which come into effect on the date the registration statement of which this prospectus forms a part becomes effective. Each director will receive cash compensation of $11,250 per quarter. In addition, the two non-audit committee chairs (Mr. Toovey and Mr. Field) will receive $1,250 per quarter and the audit committee chair (Mr. Allen) will receive an additional $2,000 per quarter. Each director will receive a one-off issuance of common stock of value $50,000 (share price is the lower of $5 per share or the initial public offering price) and a non-qualified option to purchase an additional $50,000 of common stock (exercise price is the initial public offering price). Each director will also receive annual equity compensation beginning on the effective date of the registration statement of which this prospectus forms a part, and renewing annually thereafter unless determined otherwise by the Board, in the form of restricted stock units valued at $40,000 (vesting quarterly over twelve months, with the share price being the lower of $5 per share or the initial public offering price) and a non-qualified option to purchase $40,000 of common stock (twelve month vesting with an exercise price equal to the initial public offering price).

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information, as of June 1, 2023 with respect to the holdings of (1) each person who is the beneficial owner of more than 5% of our voting stock, (2) each of our directors, (3) each executive officer, and (4) all of our current directors and executive officers as a group.

Beneficial ownership of the voting stock is determined in accordance with the rules of the SEC and includes any shares of company voting stock over which a person exercises sole or shared voting or investment power, or of which a person has a right to acquire ownership at any time within 60 days of June 1, 2023. Except as otherwise indicated, we believe that the persons named in this table have sole voting and investment power with respect to all shares of voting stock held by them. Applicable percentage ownership in the following table is based on 2,378,009 shares of common stock issued and outstanding on June 1, 2023 (excludes shares of common stock to be issued on the conversion of our interim financing notes which automatically converts upon the consummation of this offering and shares of common stock to be issued prior to the closing of this offering as a success fee pursuant to the Investment Agreement), and 5,569,528 shares of common stock after the offering assuming an offering of 1,415,095 Units (excluding shares which may be sold upon exercise of the underwriters' over-allotment option), plus, for each individual, any securities that individual has the right to acquire within 60 days of June 1, 2023.

To the best of our knowledge, except as otherwise indicated, each of the persons named in the table has sole voting and investment power with respect to the shares of our common stock beneficially owned by such person, except to the extent such power may be shared with a spouse. To our knowledge, none of the shares listed below are held under a voting trust or similar agreement, except as noted. To our knowledge, there is no arrangement, including any pledge by any person of our securities, the operation of which may at a subsequent date result in a change in control of the Company.

Name and Address of Beneficial Owner[1]	Title	Beneficially Owned Before Offering	Beneficially Owned After Offering	Percent of Class Before Offering	Percent of Class After Offering
Officers and Directors					
Geoffrey Dow	President, Chief Executive Officer and Director	667,143[2]	703,107[3]	28.05%	12.57%
Tyrone Miller	Chief Financial Officer	101,928	113,928[4]	4.29%	2.04%
Bryan Smith	Chief Medical Officer	—	—	—%	—%
Charles Allen	Director Nominee	—[5]	23,334[5]	—%	*%
Cheryl Xu	Director Nominee	—[6]	23,334[6]	—%	*%
Stephen Toovey	Director Nominee	—[7]	23,334[7]	—%	*%
Paul Field	Director Nominee	—[8]	23,334[8]	—%	*%
Officers and Directors as a Group (total of 7 persons)		769,071	910,371	32.34%	16.24%
5%+ Stockholders					
Kentucky Technology Inc.[9]		525,000	525,000	22.08%	9.43%
Florida State University Research Foundation, Inc.[10]		405,000	405,000	17.03%	7.27%
Douglas Loock		165,938	165,938	6.98%	2.98%
Trevally, LLC[11]		120,000	120,000	5.05%	2.15%
Knight Therapeutics International S.A.[12]		—	1,108,337	—%	19.90%

* Less than 1%

(1) Unless otherwise indicated, the principal address of the named directors and directors and 5% stockholders of the Company is c/o 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036.

(2) Includes 667,143 shares of common stock held by the Geoffrey S. Dow Revocable Trust (the "Dow Trust"), of which Geoffrey Dow is the trustee and has control over the voting and disposition of the shares of common stock held by the Dow Trust.

(3) Includes (i) 667,143 shares of common stock held by the Geoffrey S. Dow Revocable Trust (the "Dow Trust"), of which Geoffrey Dow is the trustee and has control over the voting and disposition of the shares of common stock held by the Dow Trust, (ii) 10,482 shares upon mandatory conversion of a convertible note issued to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 immediately prior to the consummation of the initial public offering, (iii) 10,482 shares of common stock issuable upon exercise of warrants issued to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 and (iv) 15,000 shares of common stock issuable upon exercise of options issued to Geoffrey Dow on the Nasdaq listing date of our common stock and tradeable warrants pursuant to Geoffrey Dow's executive employment agreement.

(4) Includes 12,000 shares of common stock issuable upon exercise of options issued to Tyrone Miller on the Nasdaq listing date of our common stock and tradeable warrants pursuant to Tyrone Miller's executive employment agreement.

(5) Mr. Allen will beneficially own a total of 23,334 shares of common stock on the date of effectiveness of the registration statement of which this prospectus forms a part, of which includes (i) 10,000 shares of common stock held in the name of Mr. Allen, (ii) 11,334 shares of common stock issuable upon the exercise of vested options and (iii) 2,000 shares of restricted stock units that vests within 60 days of the date of this prospectus.

(6) Ms. Xu will beneficially own a total of 23,334 shares of common stock on the date of effectiveness of the registration statement of which this prospectus forms a part, of which includes (i) 10,000 shares of common stock held in the name of Ms. Xu, (ii) 11,334 shares of common stock issuable upon the exercise of vested options and (iii) 2,000 shares of restricted stock units that vests within 60 days of the date of this prospectus.

(7) Mr. Toovey will beneficially own a total of 23,334 shares of common stock on the date of effectiveness of the registration statement of which this prospectus forms a part, of which includes (i) 10,000 shares of common stock held in the name of Mr. Toovey, (ii) 11,334 shares of common stock issuable upon the exercise of vested options and (iii) 2,000 shares of restricted stock units that vests within 60 days of the date of this prospectus.

(8) Mr. Field will beneficially own a total of 23,334 shares of common stock on the date of effectiveness of the registration statement of which this prospectus forms a part, of which includes (i) 10,000 shares of common stock held in the name of Mr. Field, (ii) 11,334 shares of common stock issuable upon the exercise of vested options and (iii) 2,000 shares of restricted stock units that vests within 60 days of the date of this prospectus.

(9) Kentucky Technology Inc.'s Board of Directors has voting and dispositive control over the shares held by Kentucky Technology Inc. The members of the Board of Directors of Kentucky Technology Inc. are Kevin Adkins, Lisa Cassis, Nancy Cox, Penny Cox, Judy Duncan, John Farris, Taunya Phillips, Gene Strong and George Ward. Because the Board of Directors acts by consensus and majority approval, none of the members of Kentucky Technology Inc.'s Board of Directors has individual voting or dispositive control with respect to such shares. The principal address of Kentucky Technology Inc. is 824 Bull Lea Run, Suite 2100, Lexington, KY 40511.

(10) Stacey Peterson has voting and dispositive control over the shares held by Florida State University Research Foundation Inc. The principal address of Florida State University Research Foundation Inc. is 2000 Levy Avenue, Building A, Suite 351, Tallahassee, FL 32310.

(11) Gary Ostrander and Eric Holmes have shared equal voting and dispositive control over the shares held by Trevally, LLC. The principal address of Trevally, LLC is 8999 Winged Foot Drive, Tallahassee, FL 32312.

(12) Knight Therapeutics Inc. wholly owns Knight Therapeutics International S.A. Arvind Utchanah has voting and dispositive control over the shares held by Knight Therapeutics International S.A. The principal address of Knight is 3400 de Maisonneuve W. Suite 1055, Montreal, QC Canada H3Z 3B8.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

On May 19, 2022, we issued the Convertible Promissory Note to Mountjoy Trust in the amount of $294,444.42 and a per annum interest rate of 6%. As of March 31, 2023, the outstanding balance of this note was $309,705.19. Upon the occurrence of our initial public offering, the balance of such note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering. We also issued to Mountjoy Trust a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 100% of the common stock issued to Mountjoy Trust as a result of the conversion of the note on the pricing date of our initial public offering at the exercise price equal to 110% of the initial public offering price, or if we fail to complete the initial public offering prior to May 31, 2023, 90% of the initial public offering price. John Dow, a relative of Geoffrey Dow, our President, Chief Executive Officer and Director, is the trustee of the Mountjoy Trust.

On December 31, 2021, the majority member, Geoffrey Dow, converted cumulative borrowings and interest into 3,942,919 member units with a par value of $1.00 and thus all debt owed to the majority member was extinguished. We issued 37,067 shares to Geoffrey Dow (at $5.00 per share) on August 28, 2022, in recognition of capital contributions of $185,335 made between January 1, 2022 and April 1, 2022. There are no other outstanding related party debt or obligations.

On January 2, 2023, we issued a total of 100,000 shares of our common stock to our legal counsel for payment of legal fees.

In March 2023, we received a $200,000 short term advance from the Geoffrey S. Dow Revocable Trust. In April and May 2023, we received a $23,000 short term advance from the Geoffrey S. Dow Revocable Trust and $27,000 from Tyrone Miller. These were reimbursed on May 11, 2023.

The above summary description of related part transactions includes some of the general terms and provisions of the agreements related to such transactions. For a more detailed description of those agreements, you should refer to such agreements which are included as exhibits to the registration statement of which this prospectus forms a part.

DESCRIPTION OF SECURITIES

The following description of our securities is only a summary and is qualified in its entirety by reference to the actual terms and provisions of the capital stock contained in our Certificate of Incorporation and our Bylaws.

General

We are authorized to issue one class of stock. The total number of shares of stock which we are authorized to issue is 151,000,000 shares of capital stock, 150,000,000 of which are common stock, $0.0001 par value per share, and 1,000,000 of which are “blank check” preferred stock. As of June 1, 2023, 2,378,009 shares of common stock were issued and outstanding and held by 15 stockholders of record.

Common Stock

The holders of our common stock are entitled to the following rights:

Voting Rights. Each share of our common stock entitles its holder to one vote per share on all matters to be voted or consented upon by the stockholders.

Dividend Rights. Subject to limitations under Delaware law, holders of our common stock are entitled to receive ratably such dividends or other distributions, if any, as may be declared by our Board out of funds legally available therefor.

Liquidation Rights. In the event of liquidation, dissolution or winding up of our business, the holders of our common stock are entitled to share ratably in the assets available for distribution after the payment of all of our debts and other liabilities.

Other Matters. The holders of our common stock have no subscription, redemption or conversion privileges; in addition, such common stock does not entitle its holders to pre-emptive rights. All of the outstanding shares of our common stock are fully paid and non-assessable.

Preferred Stock

Our Certificate of Incorporation authorizes 1,000,000 shares of "blank check" preferred stock, par value $0.0001 per share. Upon the consummation of this initial public offering, we will have authorized 80,965 shares of Series A Preferred Stock with the following terms and rights: (i) 6% dividend, (ii) non-voting; (iii) not redeemable; and (iv) convertible into shares of common stock, solely at the Company's discretion, determined by (A) multiplying the number of shares of Series A Preferred Stock to be converted by $100, (B) adding to the result all accrued and accumulated and unpaid dividends on such shares to be converted, if any, and then (C) dividing the result by a price equal to the lower of (1) $100, (2) the price paid for the shares of common stock in this offering and (3) the 10-day volume weighted average share price immediately preceding our election to convert the shares of Series A Preferred Stock; provided that the conversion of the shares of Series A Preferred Stock does not result in the holder's ownership of common stock exceeding 19.9%.

The Board may provide for the issue of any or all of the unissued and undesignated shares of the preferred stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board providing for the issuance of such shares and as may be permitted by law, without stockholder approval. Our Board is able to determine, with respect to any series of preferred stock, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate, if any, of the series;
- the dates at which dividends, if any, will be payable;
- the redemption rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;
- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of the affairs of our Company;
- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of our Company or any other entity, and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates and provisions for any adjustments to such prices or rates, the date or dates as of which the shares will be convertible, and all other terms and conditions upon which the conversion may be made;
- the ranking of such series with respect to dividends and amounts payable on our liquidation, dissolution or winding-up, which may include provisions that such series will rank senior to our common stock with respect to dividends and those distributions;
- restrictions on the issuance of shares of the same series or any other class or series; or
- voting rights, if any, of the holders of the series.

The issuance of preferred stock could adversely affect, among other things, the voting power of holders of common stock and the likelihood that stockholders will receive dividend payments and payments upon our liquidation, dissolution or winding up. The issuance of preferred stock could also have the effect of delaying, deferring or preventing a change in control of us.

Warrants Issued in this Offering

Overview

The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrant Agent Agreement and the form of warrant, both of which are filed as exhibits to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the Warrant Agent Agreement, including the annexes thereto, and form of warrant.

The following summary of certain terms and provisions of the warrants included in the Units offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrant Agent Agreement between us and our transfer agent and the forms of Tradeable Warrant and Non-tradeable Warrant, all of which are filed as exhibits to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the Warrant Agent Agreement, including the annexes thereto, and forms of warrant. The Tradeable Warrant and the Non-tradeable Warrant have identical terms except that (i) unlike the Non-tradeable Warrant, the Tradeable Warrant will be tradeable and has been applied for listing on The Nasdaq Capital Market, and (ii) the exercise price per share of common stock is $6.095 per share (based on an assumed public offering price of $5.30 per Unit) for the Tradeable Warrant and $6.36 for the Non-tradeable Warrant (based on an assumed public offering price of $5.30 per Unit).

The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuances of common stock at prices below its exercise price.

Exercisability

The warrants are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the Warrant Agent, by utilizing the exercise form on the reverse side of the warrant certificate completing and executing as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. Under the terms of the Warrant Agent Agreement, we must use our best efforts to maintain the effectiveness of the registration statement and current prospectus relating to common stock issuable upon exercise of the warrants until the expiration of the warrants. If we fail to maintain the effectiveness of the registration statement and current prospectus relating to the common stock issuable upon exercise of the warrants, the holders of the warrants shall have the right to exercise the warrants solely via a cashless exercise feature provided for in the warrants, until such time as there is an effective registration statement and current prospectus relating to common stock issuable upon exercise of the warrants.

Exercise Limitation

A holder may not exercise any portion of a warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of the outstanding common stock after exercise, as such percentage ownership is determined in accordance with the terms of the warrant, except that upon prior notice from the holder to us, the holder may waive such limitation up to a percentage not in excess of 9.99%.

Exercise Price

The exercise price per whole share of common stock purchasable upon exercise of the Tradeable Warrants is $6.095 per share (based on an assumed public offering price of $5.30 per Unit) or 115% of the public offering price of the common stock. The exercise price per whole share of common stock purchasable upon exercise of the Non-tradeable Warrants is $6.36 per share (based on an assumed public offering price of $5.30 per Unit) or 120% of the public offering price of the common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Fractional Shares

No fractional shares of common stock will be issued upon exercise of the warrants. If, upon exercise of the warrant, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, pay a cash adjustment in respect of such fraction in an amount equal to such fraction multiplied by the exercise price. If multiple warrants are exercised by the holder at the same time, we shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Transferability

Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

Our Tradeable Warrants have been applied for listing on The Nasdaq Capital Market under the symbol “SXTPW.”

Warrant Agent; Global Certificate

The warrants will be issued in registered form under a Warrant Agent Agreement between the Warrant Agent and us. The warrants shall initially be represented only by one or more global warrants deposited with the Warrant Agent, as custodian on behalf of The Depository Trust Company (“DTC”) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. Our transfer agent, Equity Stock Transfer, LLC, will serve as the Warrant Agent.

Fundamental Transactions

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another

person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Rights as a Stockholder

The warrant holders do not have the rights or privileges of holders of common stock or any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

Governing Law

The warrants and the Warrant Agent Agreement are governed by New York law.

Notes Outstanding

On December 10, 2015, we entered into the Loan Agreement and Engagement with Knight, as amended eight times, pursuant to which, we originally borrowed $500,000 at a per annum interest rate of 15% (the "Knight Loan") and a debenture agreement of face value $3 million on April 24, 2018. As of March 31, 2023, the current outstanding balance of the Knight Loan and Knight Debenture is $21,815,841.

Pursuant to the Knight Debt Conversion Agreement, executed January 9, 2023 and modified on January 13, 2023, and again on January 27, 2023, Knight and us agreed, to formalize a previously negotiated term sheet that, in the event of a successful initial public offering, we will fix Knight's cumulative debt to the value as it stood on March 31, 2022, which consisted of $10,770,037 in principal and $8,096,486 in accumulated interest, and to convert the aforementioned amounts, should we consummate an initial public offering that results in gross proceeds of at least $7,000,000 prior to January 1, 2024 as follows:

- We agreed to convert the principal amount into (i) that number of shares of common stock equal to dividing the principal amount by an amount equal to the offering price of the common stock in the initial public offering discounted by 15% (the "Conversion Common Shares"), rounding up for fractional shares, in a number of Conversion Shares up to 19.9% of our outstanding common stock after giving effect of the initial public offering; (ii) we will make a milestone payment of $10 million to Knight if, after the date of a qualifying initial public offering, we sell Arakoda or if a Change of Control (as per the definition included in the original loan agreement dated on December 10, 2015) occurs, provided that the purchaser of Arakoda or individual or entity gaining control of us is not Knight or an affiliate of Knight; (iii) following the License and Supply agreement dated on December 10, 2015 and subsequently amended on January 21, 2019, an expansion of existing distribution rights to Tafenoquine/Arakoda to include COVID-19 indications as well as malaria prevention across the Territory as defined in said documents, subject to U.S. Army approval; and (iv) we will retain Knight or an affiliate of Knight to provide financial consulting services, management, strategic and/or regulatory advice of value $30,000 per month for five years (the parties will negotiate the terms of that consulting agreement separately in good faith).

- The parties agreed to convert the accrued interest into that number of shares of a new class of preferred stock by dividing the Accrued Interest by $100.00, then rounding up. The Preferred Stock shall have the following rights, preferences, and designations: (i) have a 6% cumulative dividend accumulated annually on March 31; (ii) shall be non-voting stock; (iii) are not redeemable, (iv) be convertible to shares of common stock at a price equal to the lower of (1) the price paid for the shares of common stock in the initial public offering and (2) the 10 day volume weighted average share price immediately prior to conversion; and (v) conversion of the preferred stock to common shares will be at our sole discretion. Notwithstanding the foregoing, we shall not convert the Preferred Stock into shares of common stock if as a result of such conversion Knight will own 19.9% or more of our outstanding common stock.

- In addition to the conversion of the debt, for a period commencing on January 1, 2022 and ending upon the earlier of 10 years after the closing of the initial public offering or the conversion or redemption in full of the Conversion Preferred Shares, we shall pay Knight a royalty equal to 3.5% of our net sales, where "Net Sales" has the same meaning as in our license agreement with the U.S. Army for Tafenoquine. Upon the qualified initial public offering, we shall calculate the royalty payable to Knight at the end of each calendar quarter. We shall pay to Knight the royalty amounts due with respect to a given calendar quarter within fifteen (15) business days after the end of such calendar quarter. Each payment of royalties due to Knight shall be accompanied by a statement specifying the total gross sales, the net sales and the deductions taken to arrive to net sales. For clarification purposes, the first royalty payment will be performed following the above instructions, on the first calendar quarter in which the qualified initial public offering takes place and will cover the sales of the period from January 1, 2022, until the end of said calendar quarter.

Should an initial public offering not occur by January 1, 2024, then all terms of the original Knight Loan and Knight Debenture would resume including any interest earned after March 31, 2022.

On October 11, 2017, we issued a $750,000 promissory note, as amended, to Avante International Limited with accrued interest at an annual rate of 5.0% for the first six months, and 10% thereafter. On December 23, 2017, Avante transferred the Avante Note to Xu Yu Equity Conversion Note. On December 11, 2022, Avante and us amended the Avante Note. The Amendment added a provision to automatically convert the outstanding principal and accumulated interest through March 31, 2022 to shares of common stock in the event we consummate an initial public offering. The Amendment also provides Avante the option to convert the outstanding principal and accumulated interest through March 31, 2022 to equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest after March 31, 2022 will be forfeited should the lender elect to convert the Note into equity.

We evaluated the Amendment and determined that it constitutes an extinguishment as the option to convert interest through March 31, 2022 and is considered the addition of a substantive conversion option. Accordingly, the Amendment resulted in extinguishment accounting and a corresponding extinguishment gain of $120,683, which represents the difference between the carrying value of the Avante Note just prior to the Amendment and the fair value of the Avante Note just after the Amendment.

The extinguishment accounting resulted in a fair value of the Avante Note, including the Amendment of $1,099,578. The discount of $120,683 and costs incurred with third parties directly related to the Amendment of $1,767 will be amortized over the remaining life of the debt using the effective interest method. Amortization of the discount on the Avante Note, including the Amendment for the year ended December 31, 2022 was $4,955 ($0 in 2021). Amortization of the discount on the Avante Note, for the three months ended March 31, 2023 and 2022 was $24,146 and $0, respectively. Interest expense related to the Note, including the Amendment, for the year ended December 31, 2022 was $115,546 ($104,558 in 2021). Interest expense related to the Note, for the three months ended March 31, 2023 and 2022 was $30,262 and $27,413, respectively.

On May 14, 2020, we issued the note to the U.S. Small Business Administration with a principal amount of $150,000 and a per annum interest rate of 3.75%. The current outstanding balance of the COVID-19 Loan is $161,552 as of March 31, 2023 ($163,022 as of December 31, 2022).

On May 19, 2022, we issued a Convertible Promissory Note to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 on May 19, 2022 (the "Geoffrey Dow Trust Note"), in the amount of $44,444.44 and a per annum interest rate of 6%. Upon the occurrence of our initial

public offering, the balance of such note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 19, 2022, we issued a Convertible Promissory Note to Mountjoy Trust in the amount of $294,444.42 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of such note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 24, 2022, we issued a note in the amount of $333,333.30 to Bigger Capital Fund, LP. On the date of the pricing of our initial public offering, we will deliver to Bigger Capital Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on July 24, 2023.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Cavalry Investment Fund, LP. On the date of the pricing of our initial public offering, we will deliver to Cavalry Investment Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on July 24, 2023.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Walleye Opportunities Master Fund Ltd. On the date of the pricing of our initial public offering, we will deliver to Walleye Opportunities Master Fund Ltd shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on July 24, 2023.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Cyberbahn Federal Solutions, LLC with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Cyberbahn Federal Solutions, LLC shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Ariana Bakery Inc with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Ariana Bakery Inc shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $333,333.30 to Sabby Volatility Warrant Master Fund, Ltd. with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Sabby Volatility Warrant Master Fund, Ltd. shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $55,555.55 to Steel Anderson with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Steel Anderson shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Bixi Gao & Ling Ling Wang with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Bixi Gao & Ling Ling Wang shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

Warrants

On May 19, 2022, we issued to Geoffrey Dow a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. If the initial public offering is not completed by May 31, 2023, the exercise price is 90% of the initial public offering price. 10,482 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 19, 2022, we issued to Mountjoy Trust a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. If the initial public offering is not completed by May 31, 2023, the exercise price is 90% of the initial public offering price. 69,444 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 24, 2022, we issued to Bigger Capital Fund, LP a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. 31,447 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 24, 2022, we issued to Cavalry Investment Fund, LP a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. 26,205 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 24, 2022, we issued to Walleye Opportunities Master Fund Ltd a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. 26,205 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 8, 2023, we issued to Cyberbahn Federal Solutions, LLC a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. 10,482 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 8, 2023, we issued to Ariana Bakery Inc. a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. 10,482 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 8, 2023, we issued to Sabby Volatility Warrant Master Fund, Ltd. a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. 31,447 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 8, 2023, we issued to Steel Anderson a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. 5,241 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

On May 8, 2023, we issued to Bixi Gao & Ling Ling Wang a right to receive five-year (5) warrants upon the closing of an initial public offering, with an exercise price of 110% of the initial public offering price. 10,482 shares of common stock issuable upon the exercise of the warrants are being registered in the registration statement of which the resale prospectus forms a part.

Options

None.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

- our Board approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction; or
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock.

Potential Effects of Authorized but Unissued Stock

Our shares of common and preferred stock are available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions, payment as a dividend on the capital stock or as equity compensation to our service providers under our equity compensation plans.

The existence of unissued and unreserved common stock and preferred stock may enable our Board to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, our Board has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our Certificate of Incorporation. The purpose of authorizing the Board to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Also, if we issue additional shares of our authorized, but unissued, common stock, these issuances will dilute the voting power and distribution rights of our existing common stockholders.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Equity Stock Transfer, LLC ("Equity Stock Transfer"), located at 237 West 37th Street, Suite 602, New York, NY 10018. The phone number and facsimile number for Equity Stock Transfer are (212) 575-5757 and (347) 584-3644, respectively. Additional information about Equity Stock Transfer can be found on its website at *www.equitystock.com*.

Listing

We have applied to have our common stock and Tradeable Warrants listed on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively, which listing is a condition to this offering. We do not intend to apply for listing of the Non-tradeable Warrants on any exchange or market.

SHARES ELIGIBLE FOR FUTURE SALE

There is not currently an established U.S. trading market for our common stock. We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding warrants, in the public market after this offering, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon completion of the sale of 1,415,095 shares of common stock pursuant to this offering, we will have 5,569,528 shares of common stock issued and outstanding. In the event the underwriters exercise the over-allotment option in full, we will have 5,781,793 shares of common stock issued and outstanding. The common stock sold in this offering will be freely tradable without restriction or further registration or qualification under the Securities Act.

All previously issued shares of common stock that were not offered and sold in this offering, are or will be upon issuance, "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if such public resale is registered under the Securities Act or if the resale qualifies for an exemption from registration under Rule 144 under the Securities Act, which are summarized below.

In general, a person who has beneficially owned restricted shares of our common stock for at least six months in the event we have been a reporting company under the Exchange Act for at least ninety (90) days before the sale, would be entitled to sell such securities, provided that such person is not deemed to be an affiliate of ours at the time of sale or to have been an affiliate of ours at any time during the ninety (90) days preceding the sale. A person who is an affiliate of ours at such time would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of shares that does not exceed the greater of the following:

1% of the number of shares of our common stock then outstanding; or

1% of the average weekly trading volume of our common stock during the four calendar weeks preceding the filing by such person of a notice on Form 144 with respect to the sale;

provided that, in each case, we are subject to the periodic reporting requirements of the Exchange Act for at least 90 days before the sale. Rule 144 trades must also comply with the manner of sale, notice and other provisions of Rule 144, to the extent applicable.

Lock-Up Agreements

We have agreed not to, subject to certain limited exceptions, until sixteen months following the effective date of the registration statement for this offering (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; (ii) file or caused to be filed any registration statement with the SEC relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; (iii) complete any offering of our debt securities, other than entering into a line of credit with a traditional bank or (iv) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our capital stock, whether any such transaction described in clause (i), (ii), (iii) or (iv) above is to be settled by delivery of shares of our capital stock or such other securities, in cash or otherwise.

Also, our executive officers and directors have agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for six months following the effective date of the registration statement for this offering. Any other holders of more than 5% of the outstanding shares of our common stock have also agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for six months following the effective date of the registration statement for this offering without the prior written consent of the underwriters.

Selling Stockholder Resale Prospectus

As described in the Explanatory Note to the registration statement of which this prospectus forms a part, the registration statement also contains the Resale Prospectus to be used in connection with the potential resale by certain selling stockholders of our common stock. These shares of common stock have been registered to permit public resale of such shares, and the Selling Stockholders may offer the shares for resale from time to time pursuant to the Resale Prospectus. The Selling Stockholders may also sell, transfer or otherwise dispose of all or a portion of their shares in transactions exempt from the registration requirements of the Securities Act or pursuant to another effective registration statement covering those shares. Any shares sold by the Selling Stockholders will occur at prevailing market prices or in privately negotiated prices.

UNDERWRITING

We are offering our securities described in this prospectus through the underwriters named below. WallachBeth Capital LLC is acting as representative of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, each of the underwriters has severally agreed to purchase, and we have agreed to sell to the underwriters, the number of common stock and warrants listed next to its name in the following table.

Underwriters	Number of Shares	Number of Tradeable Warrants	Number of Non-Tradeable Warrants
WallachBeth Capital LLC			
Total			

The underwriting agreement provides that the underwriters must buy all of the securities being sold in this offering if they buy any of them. However, the underwriters are not required to take or pay for the securities covered by the underwriters' option to purchase additional securities as described below.

Our securities are offered subject to a number of conditions, including:

- receipt and acceptance of our common stock and warrants by the underwriters; and
- the underwriters' right to reject orders in whole or in part.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses electronically.

Indemnification

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the Units, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have granted the underwriters an option exercisable for 45 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of (i) 212,265 shares of common stock included in the Units at a price of $5.30 per share (the midpoint of the estimated range of $4.30 and $6.30) and/or (ii) Tradeable Warrants to purchase 212,265 shares of common stock included in the Units at a price of $0.15 per Tradeable Warrant (15% of the shares of common stock and warrants included in the Units sold in this offering) and/or (iii) Non-tradeable Warrants to purchase 212,265 shares of common stock included in the Units at a price of $0.15 per Non-tradeable Warrant (15% of the shares of common stock and warrants included in the Units sold in this offering) from us in any combination thereof to cover over allotments, if any, at the public offering price, less underwriting discounts and commissions and the non-accountable expense allowance payable to the underwriters. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to purchase its pro rata portion of these additional shares or warrants based on the underwriter's percentage

underwriting commitment in this offering as indicated in the table at the beginning of this Underwriting Section. If this option is exercised in full, the total underwriting discounts and commissions payable will be $, and the total proceeds to us, before expenses, will be $.

Underwriting Discount

Securities sold by the underwriters to the public will initially be offered at the initial Unit offering price set forth on the cover of this prospectus. Any securities sold by the underwriters to securities dealers may be sold at a discount of up to $ per Unit from the initial public offering price. The underwriters may offer the securities through one or more of their affiliates or selling agents. If all the Units are not sold at the initial public offering price, WallachBeth Capital LLC may change the offering price and the other selling terms. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the securities at the prices and upon the terms stated therein.

The following table shows the per Unit and total underwriting discount we will pay to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase up to 212,265 additional common stock and/or 212,265 additional Tradeable Warrants and/or 212,265 additional Non-tradeable Warrants.

	Per Unit	Total without Over-Allotment Option	Total with Over-Allotment Option
Public offering price	$	$	$
Underwriting discounts and commissions (8%)	$	$	$
Proceeds, before expenses to us	$	$	$

We have agreed to pay WallachBeth Capital LLC a non-accountable expense allowance of 1.5% of the gross proceeds of the offering. We also have agreed to pay WallachBeth Capital LLC's reasonable out-of-pocket fees and expenses up to a maximum amount of $145,000. In accordance with FINRA Rule 5110, the reimbursement fee described in the preceding sentence is deemed underwriting compensation for this offering. We have paid $10,000 to WallachBeth Capital LLC as an advance to be applied towards reasonable out-of-pocket expenses, or the advance. Any portion of the advance shall be returned back to us to the extent not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

We estimate that the total expenses of the offering payable by us, not including the underwriting discount, will be approximately $. We have also agreed to reimburse the underwriters for certain expenses incurred by them.

Representative Warrants

In connection with this offering, WallachBeth Capital LLC is entitled to receive the Representative Warrants to purchase an aggregate of 84,906 shares of our common stock (equal to 6% of the common stock sold in the offering, including any exercise of any shares in the over-allotment option). The Representative Warrants have a five-year term and an exercise price of 110% of the initial public offering price. The Representative Warrants will expire on the fifth anniversary of the commencement date of sales in this offering in accordance with FINRA Rule 5110(g)(8)(A). In accordance with FINRA Rule 5110(e)(1), WallachBeth Capital LLC has agreed not sell, transfer, assign, pledge or hypothecate, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the Representative Warrants or the shares underling the Representative Warrants for a period of 180 days beginning on the date of commencement of sales of this initial public offering.

Tail

If we, within the six (6) months following the termination of the Letter of Engagement dated as of May 18, 2023 and effective as of March 7, 2023 (the "Letter of Engagement"), issued by WallachBeth Capital LLC to us, effect a sale of securities with an investor or a transaction with an entity that was introduced by WallachBeth Capital LLC to us for discussions or negotiations regarding an offering, we will pay WallachBeth Capital LLC the following: (i) an aggregate cash discount equal to eight percent (8.0%) of the aggregate sales price of securities sold in any offering plus one and one-half percent (1.5%) of the aggregate sales price of securities sold in any offering as non-accountable expenses; and (ii) a number of warrants equal to six percent (6.0%) of the number of securities of common stock sold in the offering.

Private Placement Fees

We have also agreed to pay WallachBeth Capital LLC a cash commission equal to 10% of the aggregate sales price of securities sold in any private placement, inclusive of any commission paid to third parties who assist in identifying investors in such private placement. In connection with the bridge financing that occurred in May 2023, we paid WallachBeth Capital LLC a placement fee of $67,000.

In connection with the May 2023 bridge financing, WallachBeth Capital LLC will receive warrants to purchase 13,627 shares of our common stock (equal to 10% of the number of shares of common stock issued in connection with the May 2023 bridge financing). These warrants have a five-year term and an exercise price of 110% of the initial public offering price, and will expire on the fifth anniversary of the commencement date of sales in this offering in accordance with FINRA Rule 5110(g)(8)(A). In accordance with FINRA Rule 5110(e)(1), WallachBeth Capital LLC has agreed not to sell, transfer, assign, pledge or hypothecate, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of these warrants or the shares underlying the warrants for a period of 180 days beginning on the commencement of sales of the initial public offering.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

No Public Market

Prior to this offering, there has not been a public market for our securities in the U.S. and the public offering price for our Units will be determined through negotiations between us and the underwriters. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which our common stock will trade in the public market subsequent to this offering or that an active trading market for our common stock will develop and continue after this offering.

Stock Exchange

We have applied to have our common stock and Tradeable Warrants listed on The Nasdaq Capital Market under the symbols “SXTP” and “SXTPW,” respectively. There can be no assurance that we will be successful in listing our common stock and Tradeable Warrants on The Nasdaq Capital Market. We do not intend to apply for listing of the Non-tradeable Warrants on any exchange or market.

Electronic Distribution

A prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriters of this offering, or by their affiliates. Other than the prospectus in electronic format, the information on any underwriter’s website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Price Stabilization, Short Positions

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock during and after this offering, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. These transactions may also include making short sales of our common stock, which involve the sale by the underwriters of a greater number of common stock than they are required to purchase in this offering and purchasing common stock on the open market to cover short positions created by short sales. Short sales may be “covered short sales,” which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked short sales,” which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are short sales made in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because has repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on The Nasdaq Capital Market, in the over-the-counter market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. Neither we, nor any of the underwriters make any representation that the underwriters will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice.

Determination of Offering Price

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation between us and WallachBeth Capital LLC. The principal factors to be considered in determining the initial public offering price include, but are not limited to:

- the information set forth in this prospectus and otherwise available to WallachBeth Capital LLC;
- our history and prospects and the history and prospects for the industry in which we compete;
- our past and present financial performance;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities market at the time of this offering;
- the recent market prices of, and demand for, publicly traded shares of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

The estimated public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock or that the common stock will trade in the public market at or above the initial public offering price.

Affiliations

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and their affiliates may from time to time in the future engage with us and perform services for us or in the ordinary course of their business for which they will receive customary fees and expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of us. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of these securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in these securities and instruments.

Offer Restrictions Outside the United States

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of the common stock the possession, circulation or distribution of this prospectus or any other material relating to us or the common stock in any jurisdiction where action for that purpose is required. Accordingly, the common stock may not be offered or sold, directly or indirectly, and neither this prospectus nor any other material or advertisements in connection with the common stock may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

INTERESTS OF NAMED EXPERTS AND COUNSEL

Carmel, Milazzo & Feil LLP, New York, New York, our counsel, owns 100,000 shares of our common stock for payment of legal fees.

EXPERTS

RBSM LLP, an independent registered public accounting firm, audited our financial statements for the years ended December 31, 2022 and 2021, respectively. We have included our financial statements in this prospectus and elsewhere in the registration statement in reliance on the reports of RBSM LLP, given their authority as experts in accounting and auditing.

LEGAL MATTERS

Certain legal matters with respect to the validity of the securities being offered by this prospectus will be passed upon by Carmel, Milazzo & Feil LLP, New York, New York. TroyGould PC, Los Angeles, California, is acting as counsel for the underwriters with respect to the offering.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

We are subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, are required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at *https://60degreespharma.com/*. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

60 DEGREES PHARMACEUTICALS, INC

CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2022 AND 2021

60 DEGREES PHARMACEUTICALS, INC
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
60 Degrees Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 60 Degrees Pharmaceuticals, Inc. (formerly known as 60 Degrees Pharmaceuticals, LLC) and subsidiaries ("the Company") as of December 31, 2022 and 2021, and the related statements of operations and comprehensive loss, shareholders' and members' deficit, and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Change in Reporting Entity

As described in Note 6, the Company operated as a Limited Liability Company, LLC, from January 1, 2022 to May 31, 2022 and converted to a "C" Corporation starting from June 1, 2022 through December 31, 2022. Prior to the Company's conversion from an LLC to a Corporation, the LLC equity structure consisted of "Membership Units.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has an accumulated deficit, recurring losses and expects future losses that raise substantial doubt about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RBSM LLP

We have served as the Company's auditor since 2022.

Las Vegas, Nevada

April 3, 2023

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash	$ 264,865	$ 115,399
Accounts Receivable	45,965	146,362
Prepaid and Other	200,967	225,869
Deferred Offering Costs	68,629	-
Inventory (Note 3)	518,578	689,042
Total Current Assets	**1,099,004**	**1,176,672**
Property and Equipment, net (Note 4)	21,300	48,948
Other Assets:		
Right of Use Asset (Note 11)	12,647	58,667
Intangible Assets, net (Note 5)	164,255	109,240
Total Other Assets	**176,902**	**167,907**
Total Assets	**$ 1,297,206**	**$ 1,393,527**
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current Liabilities:		
Accounts Payable and Accrued Expenses	$ 758,668	$ 588,678
Lease Liability (Note 11)	13,000	46,795
Deferred Compensation (Note 7)	325,000	-
Related Party Notes, net *(including accrued interest)* (Note 9)	195,097	-
Debenture (Note 8)	4,276,609	-
SBA EIDL *(including accrued interest)* (Note 8)	2,750	-
Promissory Notes *(including accrued interest)* (Notes 8 and 9)	16,855,887	-
Derivative Liabilities (Note 9)	1,129,840	-
Derivative Liabilities – Related Parties (Note 9)	364,360	-
Total Current Liabilities	**23,921,211**	**635,473**
Long-Term Liabilities:		
Deferred Compensation (Note 7)	255,000	154,743
Lease Liability (Note 11)	-	13,000
Debenture (Note 8)	-	3,388,570
SBA EIDL *(including accrued interest)* (Note 8)	160,272	159,161
Promissory Notes *(including accrued interest)* (Note 8)	1,109,783	15,197,064
Total Long-Term Liabilities	**1,525,055**	**18,912,538**
Total Liabilities	**25,446,266**	**19,548,011**
Commitments and Contingencies (Note 11)		
SHAREHOLDERS' DEFICIT		
Members' Capital	-	4,979,365
Preferred stock, $0.0001 par value, 1,000,000 shares authorized; no shares issued and outstanding	-	-
Class A common stock, $0.0001 par value, 150,000,000 shares authorized; 2,386,009 and no shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively (Note 6)	239	-
Additional Paid-in-Capital	5,164,461	-
Accumulated Other Comprehensive Income	73,708	75,835
Accumulated Deficit	(28,815,148)	(22,633,428)
60P Shareholders' Deficit	(23,576,740)	(17,578,228)
Noncontrolling interest	(572,320)	(576,256)
Total Shareholders' Deficit	**(24,149,060)**	**(18,154,484)**
Total Liabilities and Shareholders' Deficit	**$ 1,297,206**	**$ 1,393,527**

The accompanying notes are an integral part of these audited consolidated financial statements.

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

For Fiscal Years Ended December 31,	**2022**	**2021**
Product Revenues – net of Discounts and Rebates	$ 192,913	$ 1,078,440
Service Revenues	30,295	81,900
Product and Service Revenues	223,208	1,160,340
Cost of Revenues	432,370	850,742
Gross (Loss) Profit	(209,162)	309,598
Research Revenues	288,002	5,192,516
Net Revenue	78,840	5,502,114
Operating Expenses		
Research and Development	525,563	5,510,866
General and Administrative Expenses	1,303,722	1,115,350
Total Operating Expenses	1,829,285	6,626,216
Loss from Operations	(1,750,445)	(1,124,102)
Interest Expense	(3,989,359)	(3,172,712)
Derivative Expense	(504,613)	-
Change in Fair Value of Derivative Liabilities	(10,312)	-
Gain on Debt Extinguishment	120,683	-
Other (Expense) Income	(43,238)	37,515
Total Interest and Other Expense (Income), net	(4,426,839)	(3,135,197)
Loss from Operations before Provision for Income Taxes	(6,177,284)	(4,259,299)
Provision for Income Taxes (Note 10)	500	1,000
Net Loss including Noncontrolling interest	(6,177,784)	(4,260,299)
Net Gain (Loss) – Noncontrolling Interest	3,936	(8,554)
Net Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	(6,181,720)	(4,251,745)
Comprehensive Loss:		
Net Loss	(6,177,784)	(4,260,299)
Unrealized Foreign Currency Translation Gain (Loss)	(2,127)	(3,031)
Total Comprehensive Loss	(6,179,911)	(4,263,330)
Net Gain (Loss) – Noncontrolling Interest	3,936	(8,554)
Unrealized Foreign Currency Translation (Loss) Gain from Noncontrolling Interest	-	1,588
Comprehensive Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	**$ (6,183,847)**	**$ (4,256,364)**
Net loss (June 1 – December 31, 2022) per common share		
Basic and Diluted	$ 1.78	$ -
Weighted average number of common shares outstanding (June 1 – December 31, 2022)		
Basic and Diluted	2,380,986	-

The accompanying notes are an integral part of these audited consolidated financial statements.

For Fiscal Years Ended December 31, 2022 and 2021

	Members' Equity		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit) Attributable to 60P	Noncontrolling Interest on Shareholders	Total Shareholders' Deficit
	Units	Amount	Shares	Amount						
Balance—December 31, 2020	**14,675,500**	**$ 799,700**	**-**	**$ -**	**$ -**	**$ (18,381,683)**	**$ 80,454**	**$ (17,501,529)**	**$ (569,290)**	**$ (18,070,819)**
Conversion of Debt into Member Units	4,179,665	4,179,665	-	-	-	-	-	4,179,665		4,179,665
Foreign Translation (Loss) Gain	-	-	-	-	-	-	(4,619)	(4,619)	1,588	(3,031)
Net loss	-	-	-	-	-	(4,251,745)	-	(4,251,745)	(8,554)	(4,260,299)
Balance—December 31, 2021	**18,855,165**	**$ 4,979,365**	**-**	**$ -**	**$ -**	**(22,633,428)**	**$ 75,835**	**$ (17,578,228)**	**$ (576,256)**	**(18,154,484)**
Net Foreign Translation Loss through May 31, 2022	-	-	-	-	-	-	(28,654)	(28,654)	(611)	(29,265)
Net (Loss) Gain through May 31, 2022	-	-	-	-	-	(1,949,246)	-	(1,949,246)	1,370	(1,947,876)
Business Combination: June 1, 2022 (60P, LLC into 60P, Inc.)	(18,855,165)	(4,979,365)	2,348,942	235	4,979,130	-	-	-	-	-
Issuance of Shares June 30, 2022	-	-	37,067	4	185,331	-	-	185,335	-	185,335
Net Foreign Translation Gain after June 1, 2022	-	-	-	-	-	-	26,527	26,527	611	27,138
Net (Loss) Gain after June 1, 2022	-	-	-	-	-	(4,232,474)	-	(4,232,474)	2,566	(4,229,908)
Balance—December 31, 2022	**-**	**$ -**	**2,386,009**	**$ 239**	**$ 5,164,461**	**$ (28,815,148)**	**$ 73,708**	**$ (23,576,740)**	**$ (572,320)**	**$ (24,149,060)**

The accompanying notes are an integral part of these audited consolidated financial statements.

For the Years Ended December 31,	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (6,177,784)	$ (4,260,299)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation	27,648	27,528
Amortization	5,118	3,310
Amortization of Debt Discount	1,090,387	604,595
Amortization of ROU Asset	46,020	40,947
Amortization of Note Issuance Costs	74,496	-
Gain on Debt Extinguishment	(120,683)	-
Derivative expense	504,613	-
Change in fair value of derivative liabilities	10,312	-
Inventory Reserve	223,400	38,322
Changes in Operating Assets and Liabilities:		
Accounts Receivable	100,397	713,063
Prepaid and Other	24,902	135,844
Inventory	(52,936)	312,226
Accounts Payable and Accrued Liabilities	169,990	(844,670)
Accrued Interest	2,685,678	2,568,118
Reduction of Lease Liability	(46,795)	(39,820)
Deferred Compensation	425,257	51,730
Net Cash Used in Operating Activities	**(1,009,980)**	**(649,106)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Capitalization of Patents	(33,063)	(32,324)
Purchases of Property and Equipment	-	(3,068)
Acquisition of Intangibles	(27,070)	-
Net Cash Used in Investing Activities	**(60,133)**	**(35,392)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of Deferred Offering Costs	(68,629)	-
Proceeds from Notes Payable	800,000	-
Proceeds from Notes Payable – Related Parties	305,000	683,226
Repayments on Notes Payable – Related Party	-	(72,000)
Proceeds from Advances – Related Party	185,335	-
Net Cash Provided by Financing Activities	**1,221,706**	**611,226**
Foreign Currency Translation Loss	(2,127)	(3,031)
Change in Cash	149,466	(76,303)
Cash—Beginning of Year	115,399	191,702
Cash—End of Year	**$ 264,865**	**$ 115,399**
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid During the Year for Interest	$ 2,193	$ -
Cash paid During the Year for Income Taxes	1,000	750
NONCASH INVESTING/FINANCING ACTIVITIES		
Right-of-use asset obtained in exchange for new operating lease liability	-	99,615
Debt discount recorded in connection with derivative liabilities	1,105,000	-
Conversion of Debt into Shares	185,335	-
Conversion of Debt into Member Units	$ -	$ 4,179,665

The accompanying notes are an integral part of these audited consolidated financial statements.

1. NATURE OF OPERATIONS

60 Degrees Pharmaceuticals, Inc. was incorporated in Delaware on June 1, 2022 and merged on the same day with 60^{o} Pharmaceuticals, LLC which was organized on September 9, 2010 in the District of Columbia. The financial statements of 60 Degrees Pharmaceuticals, Inc. and its subsidiaries (which may be referred to as the "Company", "we", "us", "our", "60P" or "60 Degrees Pharmaceuticals") are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company's headquarters are located in Washington, DC.

60 Degrees Pharmaceuticals, Inc. was formed to develop new medicines for the treatment and prevention of infectious diseases. Since its founding, the Company has developed Arakoda™ for the prevention of malaria. The Company continues to develop its novel products targeting the effects and treatment of diseases such as Coronaviruses.

Going Concern

The Company's financial statements are prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of obligations in the normal course of business. However, the Company has not demonstrated the ability to generate enough revenues to date to cover operating expenses and has accumulated losses to date. This condition, among others, raises substantial doubt about the ability of the Company to continue as a going concern for one year from the date the financial statements are issued.

In view of these matters, continuation as a going concern is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financial requirements, raise additional capital, and the success of its future operations. The financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company not continue as a going concern.

Management plans to fund operations of the Company through third-party and related party debt/advances, private placement of restricted securities and the issuance of stock in a public offering until such a time as a business combination or other profitable investment may be achieved. There currently is a plan in place to take the Company public in an IPO transaction in the first half of 2023. Management believes that this plan provides an opportunity for the Company to continue as a going concern.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accounting and reporting policies of the Company and its subsidiaries are presented on a consolidated basis and conform to GAAP after elimination of intercompany transactions and accounts. These consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. The Company has adopted the calendar year as its basis of reporting.

Principles of Consolidation and Non-Controlling Interest

The Company's consolidated financial statements include the financial statements of its majority-owned (87.53%) subsidiary 60P Australia Pty Ltd, as well as the financial statements of 60P Singapore Pty Lte, a wholly owned subsidiary of 60P Australia Pty Ltd. 60P Singapore Pty Lte was closed via dissolution as of March 31, 2022. All significant intercompany accounts and transactions have been eliminated in consolidation. 60P Singapore Pty Lte was originally set up to conduct research in Singapore. The entity had no assets and its liabilities were to both 60P Australia Pty Ltd, its direct owner, and 60P. Through consolidation accounting the closure of the business Unit resulted in a currency exchange gain.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Principles of Consolidation and Non-Controlling Interest (Continued)

For entities that are consolidated, but not 100% owned, a portion of the income or loss and corresponding equity is allocated to owners other than the Company. The aggregate of the income or loss and corresponding equity that is not owned by us is included in Non-controlling Interest in the consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates, and those estimates may be material. Significant estimates include the reserve for inventory, deferred compensation, derivative liabilities and valuation allowance for the deferred tax asset.

Cash and Cash Equivalents

Cash and cash equivalents include all cash in banks and short-term highly liquid investments (with original maturities of three months or less) as cash equivalents. The Company's cash is deposited in demand accounts at financial institutions that management believes are creditworthy. The Company's cash and cash equivalents in bank deposit accounts, at times, may exceed federally insured limits. On December 31, 2022, the Company's cash and cash equivalents did not exceed FDIC insured limits (did not exceed FDIC insured limits at December 31, 2021). The Company also held cash at its subsidiaries in Australia and Singapore though the amounts were minimal. The Company has not experienced any losses related to amounts in excess of FDIC limits. The Company does not hold any cash equivalents, which would consist of highly liquid investments with original maturities of three months or less at the time of purchase.

Accounts Receivable and Allowance for Doubtful Accounts

The Company records accounts receivable at net realizable value. This value includes an appropriate allowance for estimated uncollectible accounts to reflect any loss anticipated on the trade accounts receivable balances and charged to the provision for doubtful accounts. Based on the Company's history there has been no need to make a recording to allowance for doubtful accounts. Most of the Company's revenue has been earned via government contracts, and with a large American pharmaceutical distributor. As the Company continues to engage with smaller distributors, we will continue to analyze whether an entry should be recorded in Allowance for Doubtful Accounts. There was no allowance as of December 31, 2022 and December 31, 2021. At the year ended December 31, 2022, the US government accounted for 66% of the outstanding AR balance (84% at December 31, 2021) and the American pharmaceutical distributor accounted for 30% of the outstanding AR balance at the year ended December 31, 2022 (15% at the year ended December 31, 2021).

Inventory

Inventories are stated at the lower of cost or net realizable value. Cost comprises direct materials and, where applicable, costs that have been incurred in bringing the inventories to their present location and condition. The Company uses the Specific Identification method per lot. A box price is calculated per lot number and sales are recognized by their lot number.

Property and Equipment

Property and equipment are stated at cost. Normal repairs and maintenance costs are charged to earnings as incurred and additions and major improvements are capitalized. The cost of assets retired or otherwise disposed of and the related depreciation are eliminated from the accounts in the period of disposal and the resulting gain or loss is credited or charged to earnings.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Property and Equipment (Continued)

Depreciation is computed over the estimated useful lives of the related asset type or term of the operating lease using the straight-line method for financial statement purposes. The estimated service lives for Property and Equipment is either three (3), five (5) or seven (7) years.

Impairment of Long-lived Assets

Long-lived assets, such as property and equipment and identifiable intangibles with finite useful lives, are periodically evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We look for indicators of a trigger event for asset impairment and pay attention to any adverse change in the extent or manner in which the asset is being used or in its physical condition. Assets are grouped and evaluated for impairment at the lowest level of which there are identifiable cash flows, which is generally at a location level. Assets are reviewed using factors including, but not limited to, our future operating plans and projected cash flows. The determination of whether impairment has occurred is based on an estimate of undiscounted future cash flows directly related to the assets, compared to the carrying value of the assets. If the sum of the undiscounted future cash flows of the assets does not exceed the carrying value of the assets, full or partial impairment may exist. If the asset's carrying amount exceeds its fair value, an impairment charge is recognized in the amount by which the carrying amount exceeds the fair value of the asset. Fair value is determined using an income approach, which requires discounting the estimated future cash flows associated with the asset.

Intangible Assets

The Company capitalizes its patent and filing fees and legal patent and prosecution fees in connection with internally developed pending patents. When pending patents are issued, patents will be amortized over the expected period to be benefitted, not to exceed the patent lives, which may be as long as ten to fifteen years.

Website Development Costs

The Company accounts for website development costs in accordance with ASC 350-50 "Website Development Costs". Accordingly, all costs incurred in the planning stage are expensed as incurred, costs incurred in the website application and infrastructure development stage that meet specific criteria are capitalized and costs incurred in the day-to-day operation of the website are expensed as incurred. All costs associated with the websites are subject to straight-line amortization over a three-year period.

For the years ended December 31, 2022 and 2021, the Company capitalized website development or related costs of $27,070 and none, respectively, in connection with the upgrade and enhancement of functionality of corporate website at www.60-p.com.

Derivative Liabilities

The Company assessed the classification of its derivative financial instruments as of December 31, 2022 and December 31, 2021, which consist of bridge shares, convertible notes payable and certain warrants (excluding those for compensation) and has determined that such instruments qualify for treatment as derivative liabilities as they meet the criteria for liability classification under ASC 815.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Derivative Liabilities (Continued)

The Company analyzes all financial instruments with features of both liabilities and equity under FASB ASC Topic No. 480, ("ASC 480"), "Distinguishing Liabilities from Equity" and FASB ASC Topic No. 815, ("ASC 815") "Derivatives and Hedging". Derivative liabilities are adjusted to reflect fair value at each reporting period, with any increase or decrease in the fair value recorded in the results of operations (other income/expense) as change in fair value of derivative liabilities. The Company uses a Monte Carlo Simulation Model ("MCSM") to determine the fair value of these instruments.

Upon conversion or repayment of a debt or equity instrument in exchange for shares of common stock, where the embedded conversion option has been bifurcated and accounted for as a derivative liability (generally convertible debt and warrants), the Company records the shares of common stock at par value, relieves all related debt, derivative liabilities, and debt discounts, and recognizes a net gain or loss on debt extinguishment. In connection with the debt extinguishment, the Company typically records an increase to additional paid-in capital for any remaining liability balance.

Equity instruments that are initially classified as equity that become subject to reclassification under ASC Topic 815 are reclassified to liabilities at the fair value of the instrument on the reclassification date.

Original Issue Discount ("OID")

For certain notes issued, the Company may provide the debt holder with an original issue discount. The original issue discount is recorded as a debt discount, and is amortized to interest expense over the life of the debt, in the Consolidated Statements of Operations and Comprehensive Loss.

Debt Issuance Cost

Debt issuance costs paid to lenders, or third parties are recorded as debt discounts and amortized to interest expense over the life of the underlying debt instrument, in the Consolidated Statements of Operations and Comprehensive Loss.

Income Taxes

60 Degrees Pharmaceuticals, Inc. is a corporation and has accepted the default taxation status of C corporation. The merger does not materially impact tax matters in 2022 as the LLC had elected to be taxed as a C corporation for income tax purposes at the beginning of 2022. Previously, the LLC was taxed as a partnership in which for federal purposes, all income tax benefits of a partnership are passed through to the members. The District of Columbia taxes partnerships on form D-30 (District of Columbia Unincorporated Business Franchise Tax Return) and corporations on form D-20 (District of Columbia (DC) Corporation Franchise Tax Return) and both returns have a minimum tax due of $250 if gross receipts are at $1 million or less and a $1,000 if above. The tax years that remain subject to examination by major tax jurisdictions include the years ended December 31, 2019, 2020 and 2021.

60P Australia Pty Ltd is subject to the taxes of the Australian Taxation Office and the now closed 60P Singapore Pte Ltd was subject to the taxes of the Inland Revenue Authority of Singapore.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, accounts receivable, inventory purchases, and lending.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Concentrations (Continued)

Significant customers represent any customer whose business makes up 10% of our receivables or revenues. 96% of receivables (consisting of three customers and two significant at 66% and 30%) and 100% of revenues (consisting of four customers and three significant at 40%, 39% and 14% respectively) were generated by significant customers for the year ended December 31, 2022. 99% of the Company's receivables (consisting of three customers and two significant at 84% and 15%) and 100% of the revenues (consisting of three customers and all of them significant at 95%, 3% and 2% respectively) were generated by the Company from significant customers during the year ended December 31, 2021. Currently, the Company has exclusive relationships with distributors in Australia and Europe. A failure to perform by any of our current distributors would create disruption for patients in those markets. The US government has historically been the Company's largest customer through a purchase support contract and a clinical study. Both of those activities ended as during 2022 and near-term receivables and revenues from the government are not anticipated to be significant.

Since the Company first started working on tafenoquine all inventory has been acquired in a collaborative relationship from a sole vendor. Should the vendor cease to supply tafenoquine it would take time and be expensive to rebuild the supply chain with a new sole vendor sourcing the active pharmaceutical ingredient (API).

As of December 31, 2022, 85% (93% at December 31, 2021) of the Company's non-related party debt is held by Knight Therapeutics, the senior secured lender and also a publicly traded Canadian company. The amount of senior secured debt with Knight Therapeutics currently limits the Company's ability to access additional credit and management has been informed that additional lending with Knight Therapeutics is not currently possible.

Business Segments

The Company uses the "management approach" to identify its reportable segments. The management approach requires companies to report segment financial information consistent with information used by management for making operating decisions and assessing performance as the basis for identifying the Company's reportable segments. The Company manages its business in one identifiable segment.

Revenue Recognition

The Company recognizes revenue in accordance with the Financial Accounting Standards Board's ("FASB"), Accounting Standards Codification ("ASC") ASC 606, Revenue from Contracts with Customers ("ASC 606"). Revenues are recognized when control is transferred to customers in amounts that reflect the consideration the Company expects to be entitled to receive in exchange for those goods. Revenue recognition is evaluated through the following five steps: (i) identification of the contract, or contracts, with a customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the performance obligations in the contract; and (v) recognition of revenue when or as a performance obligation is satisfied.

The Company received the majority of its revenues from sales of its Arakoda™ product to the US Department of Defense (the "DoD") and resellers in the US and abroad. The Company records US commercial revenues as a receivable when our American distributor transfers shipped product to their title model for 60P. Sales to the DoD are recognized upon their acceptance after product is shipped to them. Foreign sales to both Australia and Europe are recognized as a receivable at the point product is shipped to distributor. The shipments to Australia and Europe are further subject to profit sharing agreements for boxes sold to customers.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Research and Development Costs

The Company accounts for research and development costs in accordance with ASC subtopic 730-10, Research and Development ("ASC 730-10"). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred.

The Company recorded $525,563 in research and development costs during the year ended December 31, 2022 ($5,510,866 for the year ended December 31, 2021).

Fair Value of Financial Instruments

The carrying value of the Company's financial instruments included in current assets and current liabilities (such as cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses) approximate their fair value due to the short-term nature of such instruments.

The inputs used to measure fair value are based on a hierarchy that prioritizes observable and unobservable inputs used in valuation techniques. These levels, in order of highest to lowest priority, are described below:

Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities.

Level 2—Observable prices that are based on inputs not quoted on active markets but corroborated by market data

Level 3—Unobservable inputs reflecting the Company's assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

See Note 9 regarding Derivative Liabilities.

Liabilities measured at fair value at December 31, 2022 and December 31, 2021 are as follows:

	December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Derivative Liabilities	$ -	$ -	$ 1,494,200	$ 1,494,200
Total	$ -	$ -	$ 1,494,200	$ 1,494,200

Foreign Currency Transactions and Translation

The individual financial statements of each group entity are measured and presented in the currency of the primary economic environment in which the entity operates (its functional currency). The consolidated financial statements of the group and the statement of financial position and equity of the company are presented in US dollars, which is the functional currency of the Company and the presentation currency for the consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Foreign Currency Transactions and Translation (Continued)

For the purpose of presenting consolidated financial statements, the assets and liabilities of the group's foreign operations are mostly translated at exchange rates prevailing on the reporting date. Income and expense items are

translated at the average exchange rates for the period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the dates of the transactions are used. Exchange differences arising, if any, are recognized in other income. Exchange rates along with historical rates used in these financial statements are as follows:

	Average Exchange Rate as of December 31,		December 31,	December 31,
Currency	**2022**	**2021**	**2022**	**2021**
1 AUD =	0.6948 USD	0.7513 USD	0.6805 USD	0.72644959 USD
1 SGD =	1.015 AUD*	0.9912 AUD	1.023 AUD*	1.02069301 AUD
	* Through 4/30/2022 (account closure date)			

Reclassifications

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no material effect on the consolidated results of operations and comprehensive loss, shareholders' deficit, or cash flows.

Accumulated Comprehensive Income (Loss)

Other comprehensive loss consists of foreign currency translation adjustments, unrealized gains and losses from cash flow hedges.

2022 Equity Incentive Plan

On November 22, 2022, the Company adopted a 2022 Equity Incentive Plan also referred to as ("2022 Plan"). The maximum shares available under the 2022 Plan is equal to 10% of the currently outstanding shares or 238,601.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through April 3, 2023, which is the date the financial statements were issued.

Recently Issued and Adopted Accounting Pronouncements

The FASB issues ASUs to amend the authoritative literature in ASC. There have been a number of ASUs to date, that amend the original text of ASC. Management believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, (iii) are not applicable to us or (iv) are not expected to have a significant impact on our consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Recently Issued and Adopted Accounting Pronouncements (Continued)

In August 2020, FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity; Own Equity ("ASU 2020-06"), as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Among other changes, the new guidance removes from GAAP separation models for convertible debt that require the convertible debt to be separated into a debt and equity component, unless the conversion feature is required to be bifurcated and accounted for as a derivative or the debt is issued at a substantial premium. As a result, after adopting the guidance, entities will no longer separately present such embedded conversion features in equity and will instead account for the convertible debt wholly as debt. The new guidance also requires use of the "if-converted" method when calculating the dilutive impact of convertible debt on earnings per share, which is consistent with the Company's current accounting treatment under the current guidance. The guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, but only at the beginning of the fiscal year.

We adopted this pronouncement on January 1, 2022; however, the adoption of this standard did not have a material effect on the Company's consolidated financial statements.

In May 2021, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. This latter standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. Early adoption is permitted, including adoption in an interim period. If an issuer elects to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company does not expect the adoption of this standard to have a material effect on the Company's consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers, which requires an acquirer in a business combination to recognize and measure contract assets and contract liabilities in accordance with Accounting Standards Codification Topic 606. ASU 2021-08 is effective for fiscal years beginning after December 15, 2022 and early adoption is permitted. While the Company is continuing to assess the timing of adoption and the potential impacts of ASU 2021-08, it does not expect ASU 2021-08 will have a material effect, if any, on its consolidated financial statements.

Related Parties

Parties are considered to be related to the Company if the parties, directly or indirectly, through one or more intermediaries, control, are controlled by, or are under common control with the Company. Related parties also include principal owners of the Company, its management, members of the immediate families of principal owners of the Company and its management and other parties with which the Company may deal with if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests.

3. INVENTORY

Inventory consists of the following major classes:

	December, 31 2022	December 31, 2021
Raw Material (API)	$ 397,487	$ 538,320
Packaging	97,486	88,468
Finished Goods	183,943	37,514
Clinical Trial Supplies	63,062	63,062
Total Inventory	**741,978**	**727,364**
Reserve for Expiring Inventory	(223,400)	(38,322)
Inventory, net	**$ 518,578**	**$ 689,042**

4. PROPERTY AND EQUIPMENT

As of December 31, 2022 and December 31, 2021, Property and Equipment consists of:

	December 31, 2022	December 31, 2021
Lab Equipment	$ 132,911	$ 132,911
Computer Equipment	12,261	12,261
Furniture	3,030	3,030
Property and Equipment, at Cost	**148,202**	**148,202**
Accumulated depreciation	(126,902)	(99,254)
Property and Equipment, Net	**$ 21,300**	**$ 48,948**

Depreciation expenses for Lab and Computer Equipment for the years ended December 31, 2022, and 2021 were in the amount of $27,648 and $27,528 respectively.

5. INTANGIBLE ASSETS

As of December 31, 2022 and December 31, 2021, Intangible Assets consist of:

	December 31, 2022	December 31, 2021
Patents	$ 145,613	$ 112,550
Website Development Costs	27,070	-
Intangible Assets, at Cost	172,683	-
Accumulated Amortization	(8,428)	(3,310)
Intangible Assets, Net	**$ 164,255**	**$ 109,240**

Amortization expense for the years ended December 31, 2022, and 2021 was in the amount of $5,118 and $3,310, respectively.

5. INTANGIBLE ASSETS (CONTINUED)

The following table summarizes the estimated future amortization expense related to our patents and website development costs for the years ended December 31:

Year	Patents	Website Development Costs
2023	$ 4,033	$ 9,023
2024	4,033	9,023
2025	4,033	7,520
2026	4,033	-
Thereafter	31,345	-
Total	**$ 47,477**	**$ 25,566**

The Company additionally has $91,644 in capitalized patent expenses that will be amortizable as the patents they are associated with are awarded.

6. CAPITALIZATION AND EQUITY TRANSACTIONS

Business Combination – Subsidiary

On June 1, 2022, 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company ("60P LLC"), entered into the Agreement and Plan of Merger with 60 Degrees Pharmaceuticals, Inc, pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. The value of each outstanding member's membership interest in 60P LLC was correspondingly converted into common stock of 60 Degrees Pharmaceuticals, Inc, par value $0.0001 per share, with a cost basis equal to $5 per share.

On June 30, 2022 the Company issued 37,067 shares of common stock to its Chief Executive Officer for $185,335 ($5/share).

7. DEFERRED COMPENSATION

In 2020, the Company received consulting services from Biointelect Pty Ltd of Australia with a value of $100,000, which is payable contingent upon a future capital raise and is non-interest bearing. On May 5, 2022, the Company agreed to modify their contract with Biointelect Pty Ltd. Previously, Biointelect potentially could earn $60,000 in deferred cash compensation and $400,000 in warrants in connection with a fundraise and other services provided. As the Company considered this compensation unlikely, it agreed to restructure by increasing the cash component to $100,000, tying $155,000 in equity compensation to an IPO/future qualifying transaction while leaving $245,000 in equity compensation with the original triggering events. The Company took a deferred compensation charge for the $155,000 in equity compensation in Q2 of 2022.

7. DEFERRED COMPENSATION (CONTINUED)

Also in 2020, the Company entered into an agreement with Latham Biopharma for contingent compensation. As of June 17, 2022, $57,198 had been earned and was due ($54,743 was earned as of December 31, 2021). On June 17, 2022 the Company and Latham Biopharma agreed to convert the deferred compensation of $57,198 and $12,500 of accrued expense into a 100% contingent deferred compensation amount of $38,900 in cash and $60,000 in shares of the Company if within the next five years the Company nets at least $10,000,000 in an IPO or any private financing that secures the retirement and/or conversion to equity of all secured debt excluding the loans advanced by the Small Business Administration. Then before the end of the year the Company and Latham Biopharma initiated an agreement that converted the entire deferred compensation into 65,000 shares valued at $5 per share. The Company has taken a contingent deferred compensation charge of $226,100 in Q4 of 2022 to reflect this subsequent agreement.

8. DEBT

Promissory Notes

On December 27, 2019 the Company restructured its cumulative borrowing with its senior secured lender, Knight Therapeutics, Inc, into a note for the principal amount of $6,309,823 and accrued interest of $4,160,918 and a debenture of $3,483,851, collectively referred to as the 'Knight Loan'. The Knight Loan matures on December 31, 2023. The Knight Loan bears an annual interest rate of 15% compounded quarterly. Under the Knight Loan, the Company is required to pay the lender 15% of cumulative gross profits of above $7,000,000. At the end of December 31, 2022, the Company had reached cumulative gross profits of $1,583,231 ($1,790,744 at December 31, 2021).

On October 11, 2017 the Company issued a promissory note ("Note") with an individual investor in the amount of $750,000. The Note matures 60 days after the Knight Loan is repaid. The Note bore an interest rate of 5% from inception for the first six months and 10% per annum thereafter both compounded quarterly on a calendar basis. The lender has an option to convert the Note into equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest would have originally been forfeited prior to the Amendment (discussed below), should the lender have elected to convert the Note into equity.

On December 11, 2022, the Company and the individual investor amended the Note ("the Amendment"). The Amendment added a provision to automatically convert the outstanding principal and accumulated interest through March 31, 2022 into common shares in the event the Company consummates an IPO. The Amendment also provides the lender the option to convert the outstanding principal and accumulated interest through March 31, 2022 into equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest after March 31, 2022 will be forfeited should the lender elect to convert the Note into equity. The Company evaluated the Amendment and determined that it constitutes an extinguishment as the option to convert interest through March 31, 2022 is considered the addition of a substantive conversion option. Accordingly, the Amendment resulted in extinguishment accounting and a corresponding extinguishment gain of $120,683, which represents the difference between the carrying value of the Note just prior to the Amendment and the fair value of the Note just after the Amendment. The extinguishment accounting resulted in a fair value of the Note, including the Amendment of $1,099,578. The discount of $120,683 and costs incurred with third parties directly related to the Amendment of $1,767 will be amortized over the remaining life of the debt using the effective interest method. Amortization of the discount on the Note for the year ended December 31, 2022 was $4,955 ($0 in 2021). Interest expense related to the Note, including the Amendment, for the year ended December 31, 2022 was $115,546 ($104,558 in 2021).

Promissory notes are summarized as follows at December 31, 2022:

	Knight Therapeutics	Note, including amendment	Bridge Notes	Total
Promissory Notes and Interest less Discounts	16,319,986	1,109,783	535,901	17,965,670
Less Current Maturities	16,319,986	-	535,901	16,855,887
Long Term Promissory Notes	-	1,109,783	-	1,109,783

8. DEBT (CONTINUED)

Promissory Notes (Continued)

Promissory notes are summarized as follows at December 31, 2021:

	Knight Therapeutics	Note, including amendment	Total
Promissory Notes and Interest less Discounts	14,085,333	1,111,731	15,197,064
Less Current Maturities	-	-	-
Long Term Promissory Notes	14,085,333	1,111,731	15,197,064

Debenture

On April 24, 2019 60P entered into the Knight debenture of $3,000,000 with an original issue discount ("OID") of $2,100,000. The OID is being amortized using the effective interest method. The Company subsequently restructured the Knight Loan (see Subsequent Events footnote 13). $500,103 of the original issue discount was amortized to interest expense during the twelve months ended December 31, 2022 ($431,625 during twelve months ended December 31, 2021) and the unamortized original issue discount at December 31, 2022 was $279,061 ($779,164 at December 31, 2021

	December 31, 2022	December 31, 2021
Original Debenture	$ 3,000,000	$ 3,000,000
Unamortized debt discount	(279,061)	(779,164)
Debenture Prior to Accumulated Interest	2,720,939	2,220,836
Accumulated Interest	1,555,670	1,167,734
Debenture	**$ 4,276,609**	**$ 3,388,570**

SBA COVID-19 EIDL

On May 14, 2020, the Company received COVID-19 EIDL lending from the Small Business Administration (SBA) in the amount of $150,000. The loan bears interest at an annual rate of 3.75% calculated on a monthly basis. The Company was committed to make $731 monthly payments first due June 4, 2021. On March 31, 2021, the SBA announced the deferment period has been extended an additional eighteen months. Thus, the Company was first obligated to start making payments of $731 on November 4, 2022. The current balance is $163,022 for the year ended December 31, 2022 ($159,161 at December 31, 2021). The current maturity is $2,750 and the long-term liability is $160,272. The current future payment obligations of the principal are as follows:

Period	Principal Payments
2023	$ -
2024	-
2025	-
2026	250
2027	3,211
Thereafter	146,539
Total	**$ 150,000**

Due to the deferral, the Company is expected to make a balloon payment of $32,283 to be due on 10/12/2050.

9. DERIVATIVE LIABILITIES

Promissory Notes, Bridge Shares and Warrants

During May 2022, the Company executed promissory notes having a face amount of $888,889. The notes contain an original issue discount of 10% ($88,889) and debt issuance costs of $91,436, resulting in net proceeds of $708,564. These notes bear interest at 10% with a default interest rate of 15% and are unsecured. The notes are due at the earlier of one-year (1) from the issuance date or the closing of an initial public offering ("IPO"). In connection with the issuance of these notes, the Company will also issue common stock to each note holder equivalent to (a) 100% of the face amount of the note divided by the IPO price per share, or (b) if the Company fails to complete the IPO prior to May 24, 2023, the number of shares of the Company's common stock calculated using a $27,000,000 pre-money valuation of the Company and the number of the Company's outstanding shares of common stock on May 24, 2023. Additionally, each of these note holders are entitled to receive five-year (5) fully vested warrants upon the closing of an IPO, with an exercise price of 110% of the IPO price.

Convertible Promissory Notes and Warrants - Related Parties

During May 2022, the Company executed convertible promissory notes with the Company's Chief Executive Officer and a family member related to the Chief Executive Officer, having a face amount of $338,889. The notes contain an original issue discount of 10% ($33,888) and debt issuance costs of $34,289, resulting in net proceeds of $270,711. These notes bear interest at 6% with a default interest rate of 15% and are unsecured. The notes are due at the earlier of one-year (1) from the issuance date or the closing of an IPO. Upon the closing of an IPO, these notes are mandatorily redeemable at the lesser of (a) 20% discount to the IPO price or (b) $27,000,000 pre-money valuation. Additionally, each of these note holders are entitled to receive five-year (5) fully vested warrants upon the closing of an IPO, with an exercise price of 110% of the IPO price. If the IPO is not completed by May 31, 2023, the exercise price is 90% of the IPO price.
Promissory notes and Convertible notes – related parties are summarized as follows at December 31, 2022:

	Promissory Notes	Convertible Notes
Issuance date of promissory notes	May 2022	May 2022
Maturity date of promissory notes	1	1
Interest rate	10%	6%
Default interest rate	15%	15%
Collateral	Unsecured	Unsecured
Conversion Rate	2	2
Balance - December 31, 2021	$ -	$ -
Face amount of notes	888,889	338,889
Less: unamortized debt discount	(407,555)	(155,443)
Add: accrued interest on promissory notes	54,567	11,651
Balance - December 31, 2022	$ 535,901	$ 195,097

For the twelve months ended December 31, 2022, the Company recorded amortization of debt discount of $664,780.

1 - earlier of 1 year from date of issuance or closing of IPO.
2 - see discussion above in (a) and (b)

9. DERIVATIVE LIABILITIES (CONTINUED)

Convertible Promissory Notes and Warrants - Related Parties (Continued)

As noted above, certain of the Company's bridge shares, warrants and convertible notes (containing an embedded conversion feature) are accounted for as derivative liabilities since there is an unknown exercise price associated with each instrument. The exercise price is dependent upon a yet to be completed IPO or a failed IPO. In both cases, the possible exercise prices contain different conditions (related to the success or failure of the IPO) that could result in issuing an undeterminable amount of common stock to settle any conversions.

A reconciliation of the beginning and ending balances for the derivative liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows at December 31, 2022 and December 31, 2021:

	Bridge Shares	Warrants	Convertible Notes Payable	Total
Derivative liabilities - December 31, 2021	$ -	$ -	$ -	$ -
Fair value - commitment date	823,687	565,007	95,194	1,483,888
Fair value - mark to market adjustment	10,665	13,157	(13,510)	10,312
Derivative liabilities - December 31, 2022	$ 834,352	$ 578,164	$ 81,684	$ 1,494,200

Changes in fair value of derivative liabilities (mark to market adjustment) are included in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss.

During the year ended December 31, 2022, the Company recorded a change in fair of derivative liabilities of $10,312. In connection with the valuation of the Company's derivative liabilities, and accounting for these instruments at fair value, the Company computed a fair value on the commitment date of $1,483,888, and upon the initial valuation of these instruments, determined that the fair value of the liabilities exceeded the cash value raised of $979,275. As a result, the Company recorded a debt discount at the maximum amount allowed (the face amount of the debt less the OID and debt issuance costs), which required the excess to be recorded as a derivative expense.

For the year ended December 31, 2022, the Company recorded a derivative expense of $504,613.

Derivative expense is summarized as follows:

Commitment Date	May 2022
Fair value of derivative liabilities	1,483,888
Less: face amount of debt	(979,275)
Derivative expense	504,613

On the commitment date (Day 1 valuation), the fair value of the Company's potential future issuances of common stock related to common stock issued with promissory notes, warrants and embedded conversion features in convertible promissory notes is established with an estimate using the Monte Carlo Simulation Model to compute fair value. The

Monte Carlo simulation requires the input of assumptions, including our stock price, the volatility of our stock price, remaining term in years, expected dividend yield, and risk-free rate.

In addition, the valuation model considers the probability of the occurrence or nonoccurrence of an IPO within the terms of our liability-classified financial instruments, as an IPO event can potentially impact the settlement.

9. DERIVATIVE LIABILITIES (CONTINUED)

Convertible Promissory Notes and Warrants - Related Parties (Continued)

Additionally, at each subsequent reporting period, we remeasure the fair value of our liability-classified bridge shares, warrants and embedded conversion features in convertible promissory notes using the Monte Carlo simulation.

The assumptions used to perform the Monte-Carlo Simulation were as follows at the Commitment Date as well as for the year ended December 31, 2022:

Commitment Date	**May 2022**
Stock price	$ 5.00
Volatility	99.7%
Expected term (in years) – Notes	1.00 - 1.03
Expected term (in years) – Warrants	5
Risk-free interest rate	2.76% - 2.84%
Dividend yield	0%
IPO probability (prior to note maturity date)	95%

Mark to Market	**December 31, 2022**
Stock price	$ 5.00
Volatility	101.9%
Expected term (in years) – Notes	0.39 - 0.41
Expected term (in years) – Warrants	4.39
Risk-free interest rate	4.06%
Dividend yield	0%
IPO probability (prior to note maturity date)	95%

10. INCOME TAXES

The Company currently pays taxes at the federal level as a “C Corporation”. Previously, for federal income tax purposes, 60 Degrees Pharmaceuticals, LLC filed as a partnership whereby all liability and benefit was attached to the Members’ returns through December 31, 2021. The District of Columbia, however, taxed the entity separately as an unincorporated business on a D-30 franchise tax return when income was over $12,000 annually. Additionally, there was a minimum tax of $250 for revenues at and below $1,000,000 and $1,000 for those revenues above.

60P, LLC elected to be taxed as a C-Corporation as of January 1, 2022. A final DC return of the LLC (five-month period ended May 31, 2022) will be filed on the District of Columbia’s D-20 Corporation Franchise Tax Return, which also has minimum taxes for revenues above $1,000,000 ($1,000) and at or below ($250). As a result of the merger of 60P, LLC into 60P, Inc., all accumulated DC net operating losses incurred prior to January 1, 2022 are not transferable (irreversibly vacated). Prospectively, DC net operating loss will not be considered in deferred tax asset computations as the 12/31/2021 balance of $577,978 has been written off to reflect the relinquished DC net operating loss. The provision for income taxes for the year ended December 31, 2022 consists of the following:

10. INCOME TAXES (CONTINUED)

	Federal	DC
Taxable loss	$(5,807,867)	$(5,807,367)
DC Franchise tax	-	500
Provision (added) used	(1,219,652)	(479,108)
Allowance added (used)	1,219,652	479,108
Net Provision for income tax	**$ -**	**$ 500**

Federally the Company has a cumulative net loss of $5,807,867 as of December 31, 2022 (none as of December 31, 2021). The net tax benefit associated with loss accumulated through the year ending December 31, 2022 is $1,219,652 (none as of December 31, 2021) with the federal tax rate of 21%.

The Company has cumulative net loss in DC of $5,807,367 for the twelve months ended December 31, 2022 ($6,996,799 as of December 31, 2021). The net tax benefit is the cumulative net loss multiplied by the District of Columbia corporate tax rate of 8.25%. The Company's net tax benefit at December 31, 2022 is $479,108 ($577,978 at December 31, 2021.

Australian subsidiary has cumulative losses of AUD9,640,315 at December 31, 2022 (and AUD8,997,499 at December 31, 2021). The Australian subsidiary has also measured a deferred tax benefit associated with the cumulative losses of AUD2,410,079 at December 31, 2022 (and AUD2,249,375 at December 31, 2021). The current tax rate in Australia is now 25% for businesses with an aggregated turnover (ordinary income of the Company and its affiliates) of AUD50 million. The Company projects to continue to qualify for the lower tax rate in the near future.")

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. On the basis of this evaluation, the Company has determined that it is more likely than not that the Company will not recognize the benefits of the foreign and state net deferred tax assets, and, as a result, full valuation allowance has been set against its net deferred tax assets as of December 31, 2022, and December 31, 2021. The amount of the deferred tax asset to be realized could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased.

As of the Period Ended	**December 31, 2022**	**December 31, 2021**
Federal Deferred Tax Asset	$ 1,219,652	$ -
DC Deferred Tax Asset	479,108	577,978
Australian Deferred Tax Asset (USD)	1,640,059	1,634,058
	3,338,819	2,212,036
Allowance	3,338,819	2,212,036
Net Value of Deferred Tax Asset	**$ -**	**$ -**

The Company recognizes the impact of a tax position in the financial statements if that position is more likely than not to be sustained on a tax return upon examination by the relevant taxing authority, based on the technical merits of the position. As of December 31, 2022, and December 31, 2021, the Company had no recognized tax benefits. The Company recognizes interest and penalties related to income tax matters as other expense and non-deductible penalties, respectively. As of December 31, 2022, the Company has recognized a potential tax penalty regarding a US foreign tax reporting form of $30,000 and none at December 31, 2021.

11. COMMITMENTS AND CONTINGENCIES

Operating Lease

On February 3, 2016, the Company entered into the lease agreement with CXI Corp to rent business premises. The contract most recently amended on December 10, 2020 with an additional term of twelve months that was set to expire on March 31, 2023 has been extended for an additional one year term until March 31, 2024. As a result of our adoption of ASC 842, the operating leases are reflected on our balance sheet within operating lease right-of-use (ROU) assets and the related current and non-current operating lease liabilities. ROU assets represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments arising from lease agreement. Lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectation regarding the terms. Variable lease costs such as common area maintenance, property taxes and insurance are expensed as incurred.

When the new accounting standard was adopted on December 31, 2021 the Company had current and long-term operating lease liabilities of $46,795 and $13,000, respectively, and right of use of asset of $58,667.

Future minimum lease payments on a discounted and undiscounted basis under this lease are as follows:

	Undiscounted Cash Flows
Discount rate	15.00%
2023 (January 1 to March 31)	13,326
Total undiscounted minimum future payments	13,326
Imputed interest	(326)
Total operating lease payments	13,000
Short-term lease liabilities	13,000
Long-term lease liabilities	$ -

Other information related to our operating lease is as follows:

	December 31, 2022
Weighted average remaining lease term in years	0.25 years
Weighted average discount rate	15.00%

Rent expenses were in the amount of $51,894 and $51,894 as of the years ended December 31, 2022, and December 31, 2021, respectively.

Board of Directors

In November and December 2022, the Company signed agreements with four director nominees (Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey) which come into effect on the date the Company's S-1 becomes effective. Each director will receive cash compensations of $11,250 quarterly. In addition, the two non-audit committee chairs (Toovey, Field) will receive $1,250 per quarter and the audit committee chair (Allen) will receive an additional $2,000 per quarter. Each director will receive a one-off issuance of common stock of value $50,000 and a non-qualified option to purchase an additional $50,000 of common stock. Each director will receive equity compensation in the form of restricted stock Units valued at $40,000 and a non-qualified option to purchase $40,000 of common stock.

11. COMMITMENTS AND CONTINGENCIES (CONTINUED)

Contingencies

The Company's operations are subject to a variety of local and state regulations. Failure to comply with one or more of those regulations could result in fines, restrictions on its operations, or losses of permits that could result in the Company ceasing operations.

Contingent Compensation

Prior to 2015 the Company agreed with certain vendors, advisors and employees to deferred compensation that expires on December 31, 2023. The net amount of these contingent payments is $43,581. The Company does not anticipate the trigger for these payments to be reached prior to expiration.

In 2020, the Company engaged with two vendors to help secure COVID-19 trial funding for the Company's Phase II COVID trial. Ultimately, the efforts were unsuccessful but a tail does remain. If one Australian fund participates in the Company's IPO a maximum of $520,000 would be due as of December 31, 2021. Due to subsequent agreement the maximum amount due would be $305,000 as of December 31, 2022. Currently, the Company is not engaged with the Australian fund to solicit their participation in the Company's IPO.

Litigation, Claims and Assessments

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of December 31, 2022, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the results of the Company's operations.

12. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through April 3, 2023, which is the date the financial statements were issued.

On January 1, 2023 the Company lowered the wholesale acquisition cost [WAC] price of a box of Arakoda™ [16 x 100 mg tablets] from $285 to $235 per box, to better align the cost of utilizing Arakoda™ for malaria prophylaxis with competing products including atovaquone-proguanil.

On January 9, 2023, and in two subsequent amendments, the Company and Knight Therapeutics agreed to extinguish Knight's debt in the event of an IPO. Key points of this agreement are as follows:

- The Parties agreed to fix Knight's cumulative debt to the value as it stood on March 31, 2022, which consisted of $10,770,037 in principal and $8,096,486 in accumulated interest should the Company execute an IPO that results in gross proceeds of at least $7,000,000 prior to December 31, 2023. Should an IPO not occur by January 1, 2024 then all terms of the original loans would resume including any interest earned after March 31, 2022. From April 1, 2022 through December 31, 2022 the Company has recorded $2,009,133 in accumulated Interest that would be subject to reversal should the IPO be successfully executed.

- The Parties agreed to convert the Principal Amount into (i) that number of shares of Common Stock equal to dividing the Principal Amount by an amount equal to the offering price of the Common Stock in the IPO discounted by 15% (the "Conversion Common Shares"), rounding up for fractional shares, in a number of Conversion Shares up to 19.9% of the Company's outstanding Common Stock after giving effect of the IPO; (ii) the Company will make a milestone payment of $10 million to Knight if, after the date of a Qualifying IPO, the Company sells Arakoda™ or if a Change of Control (as per the definition included in the original loan agreement dated on December 10, 2015) occurs, provided that the purchaser of Arakoda™ or individual or entity gaining control of the Borrower is not the Lender or an affiliate of the Lender; (iii) following the License and Supply agreement dated on December 10, 2015 and subsequently amended on January 21, 2019, an expansion of existing distribution rights to tafenoquine/Arakoda™ to include COVID-19 indications as well as malaria prevention across the Territory as defined in said documents, subject to US Army approval; and (iv) Company will retain Lender or an affiliate to provide financial consulting services, management, strategic and/or regulatory advice of value $30,000 per month for five years (the parties will negotiate the terms of that consulting agreement separately in good faith).

12. SUBSEQUENT EVENTS (CONTINUED)

- The Parties agreed to convert the accrued interest into that number of shares (the "Conversion Preferred Shares" and, together with the Conversion Common Shares, the "Conversion Shares") of a new class of preferred stock (the "Preferred Stock") by dividing the Accrued Interest by [$100.00], then rounding up (resulting in the issuance of 80,965 preferred shares at the IPO). The Preferred Stock shall have the following rights, preferences, and designations: (i) have a 6% [cumulative] dividend accumulated annually on March 31; (ii) shall be non-voting stock; (iii) are not redeemable, (iv) be convertible to shares of Common Stock at a price equal to the lower of (1) the price paid for the shares of Common Stock in the IPO and (2) the 10 day volume weighted average share price immediately prior to conversion; and (v) conversion of the preferred stock to common shares will be at the sole discretion of the Company. Notwithstanding the foregoing, the Company shall not convert the Preferred Stock into shares of Common Stock if as a result of such conversion Lender will own 19.9% or more of the Company's outstanding Common Stock.

- In addition to the conversion of the Debt, for a period commencing on January 1, 2022 and ending upon the earlier of 10 years after the Closing or the conversion or redemption in full of the Conversion Preferred Shares, Company shall pay Lender a royalty equal to 3.5% of the Company's net sales (the "Royalty"), where "Net Sales" has the same meaning as in the Company's license agreement with the U.S. Army for tafenoquine. Upon success of the Qualified IPO, the Company shall calculate the royalty payable to Knight Therapeutics International S.A. ("Knight") at the end of each calendar quarter. The Company shall pay to Knight the royalty amounts due with respect to a given calendar quarter within fifteen (15) Business Days after the end of such calendar quarter. Each payment of royalties due to Knight shall be accompanied by a statement specifying the total gross sales, the net sales and the deductions taken to arrive to net sales. For clarification purposes, the first royalty payment will be performed following the above instructions, on the first calendar quarter in which the Qualified IPO takes place and will cover the sales of the period from January 1, 2022 until the end of said calendar quarter.

On January 12, 2023 Geoff Dow signed an updated employment agreement as Chief Executive Officer with a two-year agreement subject to automatic annual renewals unless either party provides notice within 90 days of expiration. Notable provisions are as follows:

- Annual salary will be $228,000 per year with a cash bonus of up to 25% of base pay should performance goals be met.

- Upon the Company becoming public, Geoff Dow will be awarded 300,000 options which will vest at the end of each quarter over five years. The exercise price will be the closing price of the stock on the day of the IPO.

- The Executive will be awarded a two times base salary cash bonus if in a change of control transaction, the Company's share price is two times the closing price on the day of the IPO.

12. SUBSEQUENT EVENTS (CONTINUED)

On January 12, 2023 Tyrone Miller signed an updated employment agreement as Chief Financial Officer with a two-year agreement subject to automatic annual renewals unless either party provides notice within 90 days of expiration. Notable provisions are as follows:

- Annual salary will be $204,000 per year with a cash bonus of up to 25% of base pay should performance goals be met.
- Upon the Company becoming public, Tyrone Miller will be awarded 240,000 options which will vest at the end of each quarter over five years. The exercise price will be the closing price of the stock on the day of the IPO.
- The Executive will be awarded a two times base salary cash bonus if in a change of control transaction, the Company's share price is two times the closing price on the day of the IPO.

The Company must meet a NASDAQ listing requirement of a minimum public float of $15 million. As of December 31, 2022, the value of the Company's potentially freely tradable shares was $1,715,246 representing 165,938 shares of value $829,690 owned by Douglas Loock, and an obligation to the three interim investors (Bigger, Calvary and Walleye) to issue common shares of value $885,556 at the IPO. Subsequently the Company issued common shares in exchange for services to the following organizations in the indicated amounts: Carmel, Milazzo & Feil LLP (100,000 shares), Florida State University Research Foundation (405,000 shares), Trevally LLC (120,000 shares), ENA Healthcare Communications LLC (8,500 shares), 4C Pharma Solutions LLC (54,000 shares), Hybrid Financial Inc. (65,000 shares), Method Health Communications LLC (20,000 shares), Kentucky Technology Inc. (525,000 shares), Ludlow Business Services Inc. (37,500 shares), and Delve Innovation Pty Ltd (13,000 shares). We also issued 30,000 shares of our common shares to Elliot Berman in exchange for services provided by Berman Accounting & Advisory P.A. Additionally, the Company issued Latham BioPharm Group LLC 65,000 common shares in exchange for extinguishment of $98,900 in deferred compensation that would otherwise have been payable in the event of an IPO.

On January 16, 2023 the Company and their Australian distributor agreed to settle historical profit share through September 30, 2022 for $24,486 (AUD$35,000) through the issuance of a onetime pandemic credit of $18,637 (AUD$26,640). On March 3, 2023, the Company's Board, with the consent of Geoffrey S. Dow decided to cancel 18,217 common shares issued to the Geoffrey S. Dow Revocable Trust and, with the consent of Tyrone Miller, decided to cancel 2,783 shares issued to Tyrone Miller.

On January 21, 2023, the Company's Board, with the consent of Geoffrey S. Dow decided to cancel 1,240,682 common shares issued to the Geoffrey S. Dow Revocable Trust and, with the consent of Tyrone Miller, decided to cancel 189,318 shares issued to Tyrone Miller.

On March 1, 2023, the Company signed an investment relations consulting agreement with Red Chip. This Agreement obligates the Company to issue Red Chip $40,000 of Rule 144 stock, based on the 30-day average of the publicly traded common shares after the IPO. All shares are deemed earned immediately upon signing, acceptance, and execution of this Agreement.

In March 2023, the Company received $200,000 in paid-in capital from the Geoffrey S. Dow Revocable Trust. As of the day of finalization of these statements, the Board had not made a decision regarding the capitalization of the aforementioned paid-in capital.

There have been no other events or transactions during this time which would have a material effect on these financial statements.

60 DEGREES PHARMACEUTICALS, INC

CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
THREE MONTHS ENDED MARCH 31, 2023 AND 2022

Page

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED CONDENSED BALANCE SHEETS

	March 31, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current Assets:		
Cash	$ 29,993	$ 264,865
Accounts Receivable	82,855	45,965
Prepaid and Other	4,973,280	200,967
Deferred Offering Costs	86,241	68,629
Inventory (Note 3)	622,455	518,578
Total Current Assets	**5,794,824**	**1,099,004**
Property and Equipment, net (Note 4)	14,399	21,300
Other Assets:		
Right of Use Asset (Note 11)	51,142	12,647
Long-Term Prepaid Research	1,532,342	-
Intangible Assets, net (Note 5)	194,267	164,255
Total Other Assets	**1,777,751**	**176,902**
Total Assets	**$ 7,586,974**	**$ 1,297,206**
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current Liabilities:		
Accounts Payable and Accrued Expenses	$ 835,706	$ 758,668
Related Party Advances	200,000	-
Lease Liability (Note 11)	51,675	13,000
Deferred Compensation (Note 7)	40,000	325,000
Related Party Notes, net *(including accrued interest)* (Note 9)	294,166	195,097
Debenture (Note 8)	-	4,276,609
SBA EIDL *(including accrued interest)* (Note 8)	3,147	2,750
Promissory Notes *(including accrued interest)*, at fair value (Note 8)	21,815,841	-
Promissory Notes *(including accrued interest)* (Notes 8 and 9)	802,394	16,855,887
Derivative Liabilities (Note 9)	1,135,459	1,129,840
Derivative Liabilities - Related Parties (Note 9)	363,875	364,360
Total Current Liabilities:	**25,542,263**	**23,921,211**
Long-Term Liabilities:		
Deferred Compensation (Note 7)	255,000	255,000
SBA EIDL *(including accrued interest)* (Note 8)	158,405	160,272
Promissory Notes *(including accrued interest)* (Notes 8 and 9)	1,164,190	1,109,783
Total Long-Term Liabilities	**1,577,595**	**1,525,055**
Total Liabilities	**27,119,858**	**25,446,266**
Commitments and Contingencies (Note 11)		
SHAREHOLDERS' DEFICIT:		
Preferred stock, $0.0001 par value, 1,000,000 shares authorized, no shares issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
Class A common stock, $0.0001 par value, 150,000,000 shares authorized; 2,378,009 and 2,386,009 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively (Note 6)	238	239
Additional Paid-in Capital	12,379,462	5,164,461
Accumulated Other Comprehensive Income	72,418	73,708
Accumulated Deficit	(31,415,209)	(28,815,148)
60P Shareholders' Deficit:	(18,963,091)	(23,576,740)
Noncontrolling interest	(569,793)	(572,320)
Total Shareholders' Deficit	**(19,532,884)**	**(24,149,060)**
Total Liabilities and Shareholders' Deficit	**$ 7,586,974**	**$ 1,297,206**

See the accompanying notes to the unaudited consolidated condensed financial statements.

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

For The Three Months Ended March 31,	**2023**	**2022**
Product Revenues – net of Discounts and Rebates	$ 17,172	$ 47,024
Cost of Revenues	73,120	90,134
Gross Loss	(55,948)	(43,110)
Research Revenues	4,292	117,147
Net (Loss) Revenue	(51,656)	74,037
Operating Expenses		
Research and Development	123,994	63,057
General and Administrative Expenses	775,014	174,692
Total Operating Expenses	899,008	237,749
Loss from Operations	(950,664)	(163,712)
Interest Expense	(1,141,429)	(762,217)
Change in Fair Value of Derivative Liabilities	(5,134)	-
Loss on Debt Extinguishment	(839,887)	-
Change in Fair Value of Promissory Note	339,052	-
Other Income	591	18,732
Total Interest and Other Income (Expense), net	(1,646,807)	(743,485)
Loss from Operations before Provision for Income Taxes	(2,597,471)	(907,197)
Provision for Income Taxes (Note 10)	63	250
Net Loss including Noncontrolling Interest	(2,597,534)	(907,447)
Net Gain – Noncontrolling Interest	2,527	4,835
Net Loss – attributed to 60 Degrees Pharmaceuticals	(2,600,061)	(912,282)
Comprehensive Loss:		
Net Loss	(2,597,534)	(907,447)
Unrealized Foreign Currency Translation (Loss) Gain	(1,290)	96,556
Total Comprehensive Loss	(2,598,824)	(810,891)
Net Gain – Noncontrolling Interest	2,527	4,835
Comprehensive Loss – attributed to 60 Degrees Pharmaceuticals	**$ (2,601,351)**	**$ (815,726)**
Net Loss (January 1 – March 31, 2023) per common share		
Basic and Diluted	$ (1.13)	$ -
Weighted average number of common shares outstanding (January 1 – March 31, 2023)		
Basic and Diluted	2,304,131	-

See the accompanying notes to the unaudited consolidated condensed financial statements.

60 DEGREES PHARMACEUTICALS, INC

CONSOLIDATED CONDENSED STATEMENTS OF SHAREHOLDERS' AND MEMBERS' DEFICIT

	Members' Equity Units	Members' Equity Amount	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit) Attributable to 60P	Noncontrolling Interest on Shareholders	Total Shareholders' Deficit
Balance—December 31, 2021	**18,855,165**	**$4,979,365**	**-**	**$ -**	**$ -**	**$ (22,633,428)**	**$ 75,835**	**$ (17,578,228)**	**$ (576,256)**	**$ (18,154,484)**
Net Foreign Translation Gain	-	-	-	-	-	-	96,556	96,556	-	96,556
Net (Loss) Gain	-	-	-	-	-	(912,282)	-	(912,282)	4,835	(907,447)
Balance—March 31, 2022	**18,855,165**	**$4,979,365**	**-**	**$ -**	**$ -**	**$(23,545,710)**	**$ 172,391**	**$ (18,393,954)**	**$ (571,421)**	**$(18,965,375)**
Balance—December 31, 2022	**-**	**$ -**	**2,386,009**	**$ 239**	**$ 5,164,461**	**$ (28,815,148)**	**$ 73,708**	**$ (23,576,740)**	**$ (572,320)**	**$ (24,149,060)**
Cancellation of common stock	-	-	(1,451,000)	(145)	145	-	-	-	-	-
Issuance of common stock	-	-	1,443,000	144	7,214,856	-	-	7,215,000	-	7,215,000
Net Foreign Translation Loss	-	-	-	-	-	-	(1,290)	(1,290)	-	(1,290)
Net (Loss) Gain	-	-	-	-	-	(2,600,061)	-	(2,600,061)	2,527	(2,597,534)
Balance—March 31, 2023	**-**	**$ -**	**2,378,009**	**$ 238**	**$12,379,462**	**$ (31,415,209)**	**$ 72,418**	**$ (18,963,091)**	**$ (569,793)**	**$ (19,532,884)**

See the accompanying notes to the unaudited consolidated condensed financial statements.

For the Three Months Ended March 31,	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (2,597,534)	$ (907,447)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation	6,901	6,945
Amortization	7,175	1,010
Amortization of Debt Discount	343,510	118,209
Amortization of ROU Asset	12,427	10,862
Amortization of Note Issuance Costs	31,757	-
Amortization of Capitalized Services	320,825	-
Stock-based Compensation	212,605	-
Gain on Debt Extinguishment	839,887	-
Change in Fair Value of Derivative Liabilities	5,134	-
Change in Fair Value of Promissory Note	(339,052)	-
Inventory Reserve	4,205	38,322
Changes in Operating Assets and Liabilities:		
Accounts Receivable	(36,890)	(32,313)
Prepaid and Other	18,020	(26,993)
Inventory	(108,082)	(36,870)
Accounts Payable and Accrued Liabilities	77,038	93,933
Accrued Interest	761,643	642,364
Reduction of Lease Liability	(12,247)	(10,580)
Deferred Compensation	40,000	-
Net Cash Used in Operating Activities	**(412,678)**	**(102,558)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Capitalization of Patents	(3,292)	(826)
Net Cash Used in Investing Activities	**(3,292)**	**(826)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of Deferred Offering Costs	(17,612)	-
Advances from Related Parties	200,000	-
Net Cash Provided by Financing Activities	**182,388**	-
Foreign Currency Translation (Loss) Gain	(1,290)	96,556
Change in Cash	(234,872)	(6,828)
Cash—Beginning of Period	264,865	115,399
Cash—End of Period	**$ 29,993**	**$ 108,571**
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid During the Period for Interest	$ 2,193	$ -
Cash paid During the Period for Income Taxes	-	1,000
NONCASH INVESTING/FINANCING ACTIVITIES		
Common Stock Issued as Prepayment for Services	7,215,000	-
Additions to ROU Assets for Lease Renewal	50,922	-
Additions to Lease Liabilities for Lease Renewal	50,570	-
Stock Issued for Payment of Deferred Compensation	$ 325,000	$ -

See the accompanying notes to the unaudited consolidated condensed financial statements

1. NATURE OF OPERATIONS

60 Degrees Pharmaceuticals, Inc. was incorporated in Delaware on June 1, 2022 and merged on the same day with 60^{o} Pharmaceuticals, LLC which was organized on September 9, 2010 in the District of Columbia. The financial statements of 60 Degrees Pharmaceuticals, Inc. and its subsidiaries (which may be referred to as the "Company", "we", "us", "our", "60P" or "60 Degrees Pharmaceuticals") are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company's headquarters are located in Washington, DC.

60 Degrees Pharmaceuticals, Inc. was formed to develop new medicines for the treatment and prevention of infectious diseases. Since its founding, the Company has developed Arakoda™ for the prevention of malaria. The Company continues to develop its novel products targeting the effects and treatment of diseases such as Coronaviruses.

Going Concern

The Company's financial statements are prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of obligations in the normal course of business. However, the Company has not demonstrated the ability to generate enough revenues to date to cover operating expenses and has accumulated losses to date. This condition, among others, raises substantial doubt about the ability of the Company to continue as a going concern for one year from the date the financial statements are issued.

In view of these matters, continuation as a going concern is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financial requirements, raise additional capital, and the success of its future operations. The financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company not continue as a going concern.

Management plans to fund operations of the Company through third party and related party debt/advances, private placement of restricted securities and the issuance of stock in a public offering until such a time as a business combination or other profitable investment may be achieved. There currently is a plan in place to take the Company public in an IPO transaction in the first half of 2023. Management believes that this plan provides an opportunity for the Company to continue as a going concern.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company has prepared the accompanying condensed financial statements pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial reporting. These financial statements are unaudited and, in our opinion, include all adjustments consisting of normal recurring adjustments and accruals necessary for a fair presentation of our condensed balance sheets, statements of operations and other comprehensive loss, statements of stockholders' deficit and cash flows for the periods presented. Operating results for the periods presented are not necessarily indicative of the results that may be expected for 2023 due to various factors. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been omitted in accordance with the rules and regulations of the SEC. These condensed financial statements should be read in conjunction with the 2022 audited financial statements and accompanying notes filed with the SEC.

Principles of Consolidation and Non-Controlling Interest

The Company's consolidated financial statements include the financial statements of its majority owned (87.53%) subsidiary 60P Australia Pty Ltd, as well as the financial statements of 60P Singapore Pty Lte, a wholly owned subsidiary of 60P Australia Pty Ltd. All significant intercompany accounts and transactions have been eliminated in consolidation. 60P Singapore Pty Lte was closed via dissolution as of March 31, 2022. 60P Singapore Pty Lte was originally set up to conduct research in Singapore. The entity had no assets and its liabilities were to both 60P Australia Pty Ltd, its direct owner, and 60P. Through consolidation accounting the closure of the business unit resulted in a currency exchange gain.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Principles of Consolidation and Non-Controlling Interest (Continued)

For entities that are consolidated, but not 100% owned, a portion of the income or loss and corresponding equity is allocated to owners other than the Company. The aggregate of the income or loss and corresponding equity that is not owned by us is included in Non-controlling Interest in the consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates, and those estimates may be material. Significant estimates include the reserve for inventory, deferred compensation, derivative liabilities, and valuation allowance for the deferred tax asset.

Cash and Cash Equivalents

Cash and cash equivalents include all cash in banks and short-term highly liquid investments (with original maturities of three months or less) as cash equivalents. The Company's cash is deposited in demand accounts at financial institutions that management believes are creditworthy. The Company's cash and cash equivalents in bank deposit accounts, at times, may exceed federally insured limits. On March 31, 2023, the Company's cash and cash equivalents did not exceed FDIC insured limits (did not exceed FDIC insured limits at December 31, 2022). The Company also held cash at its subsidiary in Australia though the amounts were minimal. The Company has not experienced any losses related to amounts in excess of FDIC limits. The Company does not hold any cash equivalents, which would consist of highly liquid investments with original maturities of three months or less at the time of purchase.

Accounts Receivable and Allowance for Doubtful Accounts

The Company records accounts receivable at net realizable value. This value includes an appropriate allowance for estimated uncollectible accounts to reflect any loss anticipated on the trade accounts receivable balances and charged to the provision for doubtful accounts. Based on the Company's history there has been no need to make a recording to Allowance for Doubtful Accounts. Most of the Company's revenue has been earned via government contracts, and with a large American pharmaceutical distributor. As the Company continues to engage with smaller distributors, we will continue to analyze whether an entry should be recorded in Allowance for Doubtful Accounts. There was no allowance as of March 31, 2023 and December 31, 2022. At March 31, 2023, the US government accounted for 37% of the outstanding AR balance (66% at December 31, 2022) and the American pharmaceutical distributor accounted for 55% of the outstanding AR balance (30% at the year ended December 31, 2022).

Inventory

Inventories are stated at the lower of cost or net realizable value. Cost comprises direct materials and, where applicable, costs that have been incurred in bringing the inventories to their present location and condition. The Company uses the Specific Identification method per lot. A box price is calculated per lot number and sales are recognized by their lot number.

Property and Equipment

Property and equipment are stated at cost. Normal repairs and maintenance costs are charged to earnings as incurred and additions and major improvements are capitalized. The cost of assets retired or otherwise disposed of and the related depreciation are eliminated from the accounts in the period of disposal and the resulting gain or loss is credited or charged to earnings.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Property and Equipment (Continued)

Depreciation is computed over the estimated useful lives of the related asset type or term of the operating lease using the straight-line method for financial statement purposes. The estimated service lives for Property and Equipment is either three (3), five (5) or seven (7) years.

Impairment of Long-lived Assets

Long-lived assets, such as property and equipment and identifiable intangibles with finite useful lives, are periodically evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We look for indicators of a trigger event for asset impairment and pay attention to any adverse change in the extent or manner in which the asset is being used or in its physical condition. Assets are grouped and evaluated for impairment at the lowest level of which there are identifiable cash flows, which is generally at a location level. Assets are reviewed using factors including, but not limited to, our future operating plans and projected cash flows. The determination of whether impairment has occurred is based on an estimate of undiscounted future cash flows directly related to the assets, compared to the carrying value of the assets. If the sum of the undiscounted future cash flows of the assets does not exceed the carrying value of the assets, full or partial impairment may exist. If the asset's carrying amount exceeds its fair value, an impairment charge is recognized in the amount by which the carrying amount exceeds the fair value of the asset. Fair value is determined using an income approach, which requires discounting the estimated future cash flows associated with the asset.

Intangible Assets

The Company capitalizes its patent and filing fees and legal patent and prosecution fees in connection with internally developed pending patents. When pending patents are issued, patents will be amortized over the expected period to be benefitted, not to exceed the patent lives, which may be as long as ten to fifteen years.

Website Development Costs

The Company accounts for website development costs in accordance with ASC 350-50 "Website Development Costs". Accordingly, all costs incurred in the planning stage are expensed as incurred, costs incurred in the website application and infrastructure development stage that meet specific criteria are capitalized and costs incurred in the day-to-day operation of the website are expensed as incurred. All costs associated with the websites are subject to straight-line amortization over a three-year period.

For the three months ended March 31, 2023 and 2022, the Company capitalized website development or related costs of $33,895 and none, respectively, in connection with the upgrade and enhancement of functionality of corporate website at www.60-p.com.

Derivative Liabilities

The Company assessed the classification of its derivative financial instruments as of March 31, 2023 and December 31, 2022, which consist of bridge shares, convertible notes payable and certain warrants (excluding those for compensation) and has determined that such instruments qualify for treatment as derivative liabilities as they meet the criteria for liability classification under ASC 815.

The Company analyzes all financial instruments with features of both liabilities and equity under FASB ASC Topic No. 480, ("ASC 480"), "Distinguishing Liabilities from Equity" and FASB ASC Topic No. 815, ("ASC 815") "Derivatives and Hedging". Derivative liabilities are adjusted to reflect fair value at each reporting period, with any increase or decrease in the fair value recorded in the results of operations (other income/expense) as change in fair value of derivative liabilities. The Company uses a Monte Carlo Simulation Model ("MCSM") to determine the fair value of these instruments.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Derivative Liabilities (Continued)

Upon conversion or repayment of a debt or equity instrument in exchange for shares of common stock, where the embedded conversion option has been bifurcated and accounted for as a derivative liability (generally convertible debt and warrants), the Company records the shares of common stock at par value, relieves all related debt, derivative liabilities, and debt discounts, and recognizes a net gain or loss on debt extinguishment. In connection with the debt extinguishment, the Company typically records an increase to additional paid-in capital for any remaining liability balance.

Equity instruments that are initially classified as equity that become subject to reclassification under ASC Topic 815 are reclassified to liabilities at the fair value of the instrument on the reclassification date.

Original Issue Discount ("OID")

For certain notes issued, the Company may provide the debt holder with an original issue discount. The original issue discount is recorded as a debt discount and is amortized to interest expense over the life of the debt, in the Consolidated Statements of Operations and Comprehensive Loss.

Debt Issuance Cost

Debt issuance costs paid to lenders, or third parties are recorded as debt discounts and amortized to interest expense over the life of the underlying debt instrument, in the Consolidated Statements of Operations and Comprehensive Loss, with the exception of certain debt for which we elected the fair value option.

Income Taxes

60 Degrees Pharmaceuticals, Inc. is a corporation and has accepted the default taxation status of C corporation. The merger in 2022 did not materially impact tax matters as the LLC had elected to be taxed as a C corporation for income tax purposes at the beginning of 2022. Previously, the LLC was taxed as a partnership in which for federal purposes, all income tax benefits of a partnership are passed through to the members. The District of Columbia taxes partnerships on form D-30 (District of Columbia Unincorporated Business Franchise Tax Return) and corporations on form D-20 (District of Columbia (DC) Corporation Franchise Tax Return) and both returns have a minimum tax due of $250 if gross receipts are at $1 million or less and a $1,000 if above. The tax years that remain subject to examination by major tax jurisdictions include the years ended December 31, 2019, 2020, 2021 and 2022.

60P Australia Pty Ltd is subject to the taxes of the Australian Taxation Office and the now closed 60P Singapore Pte Ltd was subject to the taxes of the Inland Revenue Authority of Singapore.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, accounts receivable, inventory purchases, and lending.

Significant customers represent any customer whose business makes up 10% of our receivables or revenues. 98% of receivables as of March 31, 2023 (consisting of three significant customers and two at 55% and 37%) and 100% of total net revenues for the three months ended March 31, 2023 were generated by two significant customers at 212% and (112%). At December 31, 2022, 98% of the Company's receivables, consisting of three customers and two significant at 59% and 39%, were generated from significant customers. 100% of the revenues (consisting of one customer) were generated by the Company from significant customers during the three months ended March 31, 2022. Currently, the Company has exclusive relationships with distributors in Australia and Europe.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Concentrations (Continued)

A failure to perform by any of our current distributors would create disruption for patients in those markets. The US government has historically been the Company's largest customer through a purchase support contract and a clinical study. Both of those activities ended during 2022 and near-term receivables and revenues from the government are not anticipated to be significant.

Since the Company first started working on tafenoquine all inventory has been acquired in a collaborative relationship from a sole vendor. Should the vendor cease to supply tafenoquine it would take time and be expensive to rebuild the supply chain with a new sole vendor sourcing the active pharmaceutical ingredient (API).

As of March 31, 2023, 84% (85% at December 31, 2022) of the Company's non-related party debt is held by Knight Therapeutics, the senior secured lender and also a publicly traded Canadian company. The amount of senior secured debt with Knight Therapeutics currently limits the Company's ability to access additional credit and management has been informed that additional lending with Knight Therapeutics is not currently possible.

Business Segments

The Company uses the "management approach" to identify its reportable segments. The management approach requires companies to report segment financial information consistent with information used by management for making operating decisions and assessing performance as the basis for identifying the Company's reportable segments. The Company manages its business in one identifiable segment.

Revenue Recognition

The Company recognizes revenue in accordance with the Financial Accounting Standards Board's ("FASB"), Accounting Standards Codification ("ASC") ASC 606, "Revenue from Contracts with Customers" ("ASC 606"). Revenues are recognized when control is transferred to customers in amounts that reflect the consideration the Company expects to be entitled to receive in exchange for those goods. Revenue recognition is evaluated through the following five steps: (i) identification of the contract, or contracts, with a customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the performance obligations in the contract; and (v) recognition of revenue when or as a performance obligation is satisfied.

The Company receives the majority of its revenues from sales of its Arakoda™ product to the US Department of Defense (the "DoD") and resellers in the US and abroad. The Company records US commercial revenues as a receivable when our American distributor transfers shipped product to their title model for 60P. Sales to the DoD are recognized upon their acceptance after the product is shipped to them. Foreign sales to both Australia and Europe are recognized as a receivable at the point product is shipped to distributor. The shipments to Australia and Europe are further subject to profit sharing agreements for boxes sold to customers.

Research and Development Costs

The Company accounts for research and development costs in accordance with ASC subtopic 730-10, "Research and Development" ("ASC 730-10"). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Prepaid research and development costs are deferred and amortized over the service period, as the services are provided.

The Company recorded $123,994 in research and development costs expense during the three months ended March 31, 2023 ($63,057 for the three months ended March 31, 2022). During the three months ended March 31, 2023, the Company deferred prepaid research and development costs in exchange for share-based payments to nonemployees. At March 31, 2023, the Company recorded $3,030,000 current unamortized deferred prepaid research and development costs ($0 at March 31, 2022) and $1,532,342 non-current unamortized deferred prepaid research and development costs ($0 at March 31, 2022).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Fair Value of Financial Instruments and the Fair Value Option ("FVO")

The carrying value of the Company's financial instruments included in current assets and current liabilities (such as cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses) approximate their fair value due to the short-term nature of such instruments.

The inputs used to measure fair value are based on a hierarchy that prioritizes observable and unobservable inputs used in valuation techniques. These levels, in order of highest to lowest priority, are described below:

Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities.

Level 2—Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3—Unobservable inputs reflecting the Company's assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The Company may choose to elect the FVO for certain eligible financial instruments, such as Promissory Notes, in order to simplify the accounting treatment. Items for which the FVO has been elected are presented at fair value in the consolidated balance sheets and any change in fair value unrelated to credit risk is recorded in other income in the consolidated statements of operations. Changes in fair value related to credit risk are recognized in other comprehensive income.

The Company's financial instruments recorded at fair value on a recurring basis at March 31, 2023, and December 31, 2022 include the certain convertible promissory notes for which the Company elected the FVO and Derivative Liabilities, which are carried at fair value based on Level 3 inputs. See Notes 8 and 9 regarding Promissory Notes, at fair value and Derivative Liabilities, respectively.

Liabilities measured at fair value at March 31, 2023 and December 31, 2022 are as follows:

	March 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Promissory Notes (including accrued interest), at fair value	$ -	$ -	$ 21,815,841	$ 21,815,841
Derivative Liabilities	-	-	1,499,334	1,499,334
Total	$ -	$ -	$ 23,315,175	$ 23,315,175

	December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Derivative Liabilities	$ -	$ -	$ 1,494,200	$ 1,494,200
Total	$ -	$ -	$ 1,494,200	$ 1,494,200

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Foreign Currency Transactions and Translation

The individual financial statements of each group entity are measured and presented in the currency of the primary economic environment in which the entity operates (its functional currency). The consolidated financial statements of the group and the statement of financial position and equity of the company are presented in US dollars, which is the functional currency of the Company and the presentation currency for the consolidated financial statements.

For the purpose of presenting consolidated financial statements, the assets and liabilities of the group's foreign operations are mostly translated at exchange rates prevailing on the reporting date. Income and expense items are translated at the average exchange rates for the period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the dates of the transactions are used. Exchange differences arising, if any, are recognized in other income.

Exchange rates along with historical rates used in these financial statements are as follows:

	Average Exchange Rate as of March 31,		March 31,	December 31,
Currency	**2023**	**2022**	**2023**	**2022**
1 AUD =	0.6841 USD	0.7241 USD	0.6688 USD	0.6805 USD
1 SGD =	NA	1.015 AUD	NA	1.023 AUD*
* Through 4/30/2022 (account closure date)				

Reclassifications

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no material effect on the consolidated results of operations and comprehensive loss, shareholders' deficit, or cash flows.

Accumulated Comprehensive Income (Loss)

Other comprehensive loss consists of foreign currency translation adjustments and unrealized gains and losses from cash flow hedges.

2022 Equity Incentive Plan

On November 22, 2022, the Company adopted a 2022 Equity Incentive Plan also referred to as ("2022 Plan"). The maximum shares available under the 2022 Plan is equal to 238,601.

Share-Based Payments

The Company measures compensation for all share-based payment awards granted to employees, directors, and nonemployees, based on the estimated fair value of the awards on the date of grant. For awards that vest based on continued service, the service-based compensation cost is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the awards. For service vesting awards with compensation expense recognized on a straight-line basis, at no point in time does the cumulative grant date value of vested awards exceed the cumulative amount of compensation expense recognized. The Company accounts for forfeitures as they occur.

For awards that vest upon a liquidity event or a change in control, the performance condition is not probable of being achieved until the event occurs. As a result, no compensation expense is recognized until the performance-based vesting condition is achieved, at which time the cumulative compensation expense will be recognized.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through May 19, 2023, which is the date the financial statements were issued.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Recently Issued and Adopted Accounting Pronouncements

The FASB issues ASUs to amend the authoritative literature in ASC. There have been a number of ASUs to date, that amend the original text of ASC. Management believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, (iii) are not applicable to us or (iv) are not expected to have a significant impact on our consolidated condensed financial statements.

In August 2020, FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity; Own Equity ("ASU 2020-06"), as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Among other changes, the new guidance removes from GAAP separation models for convertible debt that require the convertible debt to be separated into a debt and equity component, unless the conversion feature is required to be bifurcated and accounted for as a derivative or the debt is issued at a substantial premium. As a result, after adopting the guidance, entities will no longer separately present such embedded conversion features in equity and will instead account for the convertible debt wholly as debt. The new guidance also requires use of the "if-converted" method when calculating the dilutive impact of convertible debt on earnings per share, which is consistent with the Company's current accounting treatment under the current guidance. The guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, but only at the beginning of the fiscal year.

We adopted this pronouncement on January 1, 2022; however, the adoption of this standard did not have a material effect on the Company's consolidated condensed financial statements.

In May 2021, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options.

This latter standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard.

Early adoption is permitted, including adoption in an interim period. If an issuer elects to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company's adoption of this standard in 2022 did not have a material effect on the Company's consolidated condensed financial statement.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Recently Issued and Adopted Accounting Pronouncements (Continued)

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers, which requires an acquirer in a business combination to recognize and measure contract assets and contract liabilities in accordance with Accounting Standards Codification Topic 606. ASU 2021-08 is effective for fiscal years beginning after December 15, 2022 and early adoption is permitted. The Company's adoption of ASU 2021-08 did not have an effect on its consolidated condensed financial statements.

Related Parties

Parties are considered to be related to the Company if the parties, directly or indirectly, through one or more intermediaries, control, are controlled by, or are under common control with the Company. Related parties also include principal owners of the Company, its management, members of the immediate families of principal owners of the Company and its management and other parties with which the Company may deal with if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests.

3. INVENTORY

Inventory consists of the following major classes:

	March 31, 2023	December 31, 2022
Raw Material (API)	$ 397,487	$ 397,487
Packaging	132,917	97,486
Finished Goods	178,228	183,943
Clinical Trial Supplies	141,428	63,062
Total Inventory	**850,060**	**741,978**
Reserve for Expiring Inventory	(227,605)	(223,400)
Inventory, net	**$ 622,455**	**$ 518,578**

4. PROPERTY AND EQUIPMENT

As of March 31, 2023 and December 31, 2022, Property and Equipment consists of:

	March 31, 2023	December 31, 2022
Lab Equipment	$ 132,911	$ 132,911
Computer Equipment	12,261	12,261
Furniture	3,030	3,030
Property and Equipment, at Cost	**148,202**	**148,202**
Accumulated depreciation	(133,803)	(126,902)
Property and Equipment, Net	**$ 14,399**	**$ 21,300**

Depreciation expenses for Lab and Computer Equipment for the three months ended March 31, 2023, and 2022 were in the amount of $6,901 and $6,945, respectively.

5. INTANGIBLE ASSETS

As of March 31, 2023 and December 31, 2022, Intangible Assets consist of:

	March 31, 2023	December 31, 2022
Patents	$ 148,905	$ 145,613
Website Development Costs	60,965	27,070
Intangible Assets, at Cost	209,870	172,683
Accumulated Amortization	(15,603)	(8,428)
Intangible Assets, Net	**$ 194,267**	**$ 164,255**

Amortization expense for the three months ended March 31, 2023, and 2022 was in the amount of $7,175 and $1,010, respectively.

The following table summarizes the estimated future amortization expense related to our patents and website development costs as of March 31, 2023:

Period	Patents	Website Development Costs
2023 (remaining nine months)	$ 2,993	$ 15,241
2024	3,991	20,322
2025	3,991	17,208
2026	3,991	411
Thereafter	31,589	-
Total	**$ 46,555**	**$ 53,182**

The Company additionally has $94,530 in capitalized patent expenses that will be amortizable as the patents they are associated with are awarded.

6. CAPITALIZATION AND EQUITY TRANSACTIONS

Shareholder Shares

On June 1, 2022, 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company (“60P LLC”), entered into the Agreement and Plan of Merger with 60 Degrees Pharmaceuticals, Inc, pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. The value of each outstanding member’s membership interest in 60P LLC was correspondingly converted into common stock of 60 Degrees Pharmaceuticals, Inc, par value $0.0001 per share, with a cost basis equal to $5 per share. On June 30, 2022 the Company issued 37,067 shares of common stock to its Chief Executive Officer for $185,335 ($5/share).

During the three months ended March 31, 2023, the Board of Directors approved a resolution to cancel an aggregate of 1,451,000 shares of common stock issued to certain executives, representing approximately 61% of the issued and outstanding shares as of December 31, 2022. During the three months ended March 31, 2023, the Company issued a total of 1,443,000 shares of common stock to certain vendors as prepayment for services to be provided to the Company. As of March 31, 2023, 2,378,009 shares have been issued and were outstanding.

7. DEFERRED COMPENSATION

In 2020, the Company received consulting services from Biointelect Pty Ltd. of Australia with a value of $100,000, which is payable contingent upon a future capital raise and is non-interest bearing. On May 5, 2022, the Company agreed to modify their contract with Biointelect Pty Ltd. Previously, Biointelect potentially could earn $60,000 in deferred cash compensation and $400,000 in warrants in connection with a fundraise and other services provided.

As the Company considered this compensation unlikely, it agreed to restructure by increasing the cash component to $100,000, tying $155,000 in equity compensation to an IPO/future qualifying transaction while leaving $245,000 in equity compensation with the original triggering events. The Company took a deferred compensation charge for the $155,000 in equity compensation in Q2 of 2022.

Also in 2020, the Company entered into an agreement with Latham Biopharma for contingent compensation. As of June 17, 2022, $57,198 had been earned and was due ($54,743 was earned as of December 31, 2021). On June 17, 2022 the Company and Latham Biopharma agreed to convert the deferred compensation of $57,198 and $12,500 of accrued expense into a 100% contingent deferred compensation amount of $38,900 in cash and $60,000 in shares of the Company if within the next five years the Company nets at least $10,000,000 in an IPO or any private financing that secures the retirement and/or conversion to equity of all secured debt excluding the loans advanced by the Small Business Administration. Then before the year ended December 31, 2022, the Company and Latham Biopharma initiated an agreement that converted the entire deferred compensation into 65,000 shares valued at $5 per share. The Company has taken a contingent deferred compensation charge of $226,100 in Q4 of 2022 to reflect this subsequent agreement.

8. DEBT

Promissory Notes

On December 27, 2019 the Company restructured its cumulative borrowing with its senior secured lender, Knight Therapeutics, Inc, into a note for the principal amount of $6,309,823 and accrued interest of $4,160,918 and a debenture of $3,483,851, collectively referred to as the 'Knight Loan'. The Knight Loan had a maturity date of December 31, 2023. The Knight Loan bears an annual interest rate of 15% compounded quarterly. As of December 31, 2022, the outstanding balance of the Knight Loan, including the debenture was $20,596,595. In January 2023, the Company and Knight executed the Knight Debt Conversion Agreement, pursuant to which the parties agreed to add a conversion feature to the cumulative outstanding Knight Loan, which was accounted for as a debt extinguishment, described further below.
On October 11, 2017 the Company issued a promissory note ("Note") with an individual investor in the amount of $750,000. The Note matures 60 days after the Knight Loan is repaid. The Note bore an interest rate of 5% from inception for the first six months and 10% per annum thereafter both compounded quarterly. The lender has an option to convert the Note into equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest would have originally been forfeited prior to the Amendment (discussed below), should the lender have elected to convert the Note into equity.

On December 11, 2022, the Company and the individual investor amended the Note ("the Amendment"). The Amendment added a provision to automatically convert the outstanding principal and accumulated interest through March 31, 2022 into common shares in the event the Company consummates an IPO. The Amendment also provides the lender the option to convert the outstanding principal and accumulated interest through March 31, 2022 into equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest after March 31, 2022 will be forfeited should the lender elect to convert the Note into equity. The Company recorded a discount of $120,683 related to the excess fair value of the Note on the Amendment date and incurred costs with third parties directly related to the Amendment of $1,767, which is being amortized over the remaining life of the debt using the effective interest method. Amortization of the discount on the Note for the three months ended March 31, 2023 and 2022 was $24,145 and $0, respectively. Interest expense related to the Note, for the three months ended March 31, 2023 and 2022 was $30,262 and $27,413, respectively.

Promissory notes are summarized as follows at March 31, 2023:

	Knight Therapeutics	Note, including amendment	Bridge Notes	Total
Promissory Notes (including accrued interest), at fair value	$ 21,815,841	$ -	$ -	$ 21,815,841
Promissory Notes (including accrued interest)	-	1,164,190	802,394	1,966,584
Less Current Maturities	21,815,841	-	802,394	22,618,235
Long Term Promissory Notes	$ -	$ 1,164,190	$ -	$ 1,164,190

8. DEBT (CONTINUED)

Promissory Notes (Continued)

Promissory notes are summarized as follows at December 31, 2022:

	Knight Therapeutics	Note, including amendment	Bridge Notes	Total
Promissory Notes (including accrued interest), at fair value	$ -	$ -	$ -	$ -
Promissory Notes (including accrued interest)	16,319,986	1,109,783	535,901	17,965,670
Less Current Maturities	16,319,986	-	535,901	16,855,887
Long Term Promissory Notes	$ -	$ 1,109,783	$ -	$ 1,109,783

Knight Debt Conversion

On January 9, 2023, and in two subsequent amendments, the Company and Knight Therapeutics agreed to extinguish Knight's debt in the event of an IPO. Key points of this agreement are as follows:

- The Parties agreed to fix Knight’s cumulative debt to the value as it stood on March 31, 2022, which consisted of $10,770,037 in principal and $8,096,486 in accumulated interest should the Company execute an IPO that results in gross proceeds of at least $7,000,000 prior to December 31, 2023. Should an IPO not occur by January 1, 2024 then all terms of the original debt would resume including any interest earned after March 31, 2022.
- The Parties agreed to convert the Principal Amount into (i) that number of shares of Common Stock equal to dividing the Principal Amount by an amount equal to the offering price of the Common Stock in the IPO discounted by 15% (the “Conversion Common Shares”), rounding up for fractional shares, in a number of Conversion Shares up to 19.9% of the Company’s outstanding Common Stock after giving effect of the IPO; (ii) the Company will make a milestone payment of $10 million to Knight if, after the date of a Qualifying IPO, the Company sells Arakoda™ or if a Change of Control (as per the definition included in the original loan agreement dated on December 10, 2015) occurs, provided that the purchaser of Arakoda™ or individual or entity gaining control of the Borrower is not the Lender or an affiliate of the Lender; (iii) following the License and Supply agreement dated on December 10, 2015 and subsequently amended on January 21, 2019, an expansion of existing distribution rights to tafenoquine/Arakoda™ to include COVID-19 indications as well as malaria prevention across the Territory as defined in said documents, subject to US Army approval; and (iv) Company will retain Lender or an affiliate to provide financial consulting services, management, strategic and/or regulatory advice of value $30,000 per month for five years (the parties will negotiate the terms of that consulting agreement separately in good faith).
- In addition to the conversion of the Debt, for a period commencing on January 1, 2022 and ending upon the earlier of 10 years after the Closing or the conversion or redemption in full of the Conversion Preferred Shares, Company shall pay Lender a royalty equal to 3.5% of the Company’s net sales (the “Royalty”), where “Net Sales” has the same meaning as in the Company’s license agreement with the U.S. Army for tafenoquine. Upon success of the Qualified IPO, the Company shall calculate the royalty payable to Knight at the end of each calendar quarter. The Company shall pay to Knight the royalty amounts due with respect to a given calendar quarter within fifteen (15) Business Days after the end of such calendar quarter. Each payment of royalties due to Knight shall be accompanied by a statement specifying the total gross sales, the net sales and the deductions taken to arrive to net sales. For clarification purposes, the first royalty payment will be performed following the above instructions, on the first calendar quarter in which the Qualified IPO takes place and will cover the sales for the period from January 1, 2022 until the end of said calendar quarter.

8. DEBT (CONTINUED)

Knight Debt Conversion (Continued)

The Company evaluated the January 9, 2023 exchange agreement for debt modification in accordance with ASC 470-50 and concluded that the debt qualified for debt extinguishment because a substantial conversion feature was added to the debt terms. Upon extinguishment, the Company recorded a loss upon extinguishment in the amount of $839,887 and elected to recognize the new debt under the ASC 825 fair value option until it is settled.

A reconciliation of the beginning and ending balances for the Convertible Knight Note, which is measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows for the three months ended March 31, 2023:

	Convertible Knight Note, at fair value
Promissory Notes, at fair value at December 31, 2022	$ -
Fair value at modification date - January 9, 2023	21,520,650
Fair value - mark to market adjustment	(339,052)
Accrued interest recognized	634,243
Promissory Notes, at fair value at March 31, 2023	$21,815,841

From the modification date of January 9, 2023 to March 31, 2023, the Company recorded a change in the fair of the Convertible Knight Note of ($339,052) and recorded interest expense of $634,243.

Debenture

On April 24, 2019, 60P entered into the Knight debenture of $3,000,000 with an original issue discount ("OID") of $2,100,000. The OID was being amortized using the effective interest method. The Company subsequently restructured the Knight Loan, including the OID pursuant to the Knight Debt Conversion Agreement (see above). $13,696 of the original issue discount was amortized to interest expense during the three months ended March 31, 2023 prior to the amendment ($118,209 during the three months ended March 31, 2022) and the unamortized original issue discount at March 31, 2023 was $0 ($279,061 at December 31, 2022) as a result of the debt conversion (discussed above), which was accounted for as a debt extinguishment.

The Knight debenture as of March 31, 2023 and December 31, 2022 consisted of the following:

	March 31, 2023	December 31, 2022
Original Debenture	$ -	$ 3,000,000
Unamortized debt discount	-	(279,061)
Debenture Prior to Accumulated Interest	-	2,720,939
Accumulated Interest	-	1,555,670
Debenture	**$ -**	**$ 4,276,609**

8. DEBT (CONTINUED)

SBA COVID-19 EIDL

On May 14, 2020, the Company received COVID-19 EIDL lending from the Small Business Administration (SBA) in the amount of $150,000. The loan bears interest at an annual rate of 3.75% calculated on a monthly basis. The Company was committed to make $731 monthly payments first due June 4, 2021. On March 31, 2021, the SBA announced the deferment period has been extended an additional eighteen months. Thus, the Company was first obligated to start making interest payments of $731 on November 4, 2022. The balance as of March 31, 2023 is $161,552 ($163,022 at December 31, 2022). The current maturity at March 31, 2023 is $3,147 and the long-term liability is $158,405 ($2,750 and $160,272 at December 31, 2022, respectively).

The current future payment obligations of the principal are as follows:

Period	Principal Payments
2023 (remaining nine months)	$ -
2024	-
2025	-
2026	250
2027	3,211
Thereafter	146,539
Total	**$ 150,000**

Due to the deferral, the Company is expected to make a balloon payment of $32,383 to be due on 10/12/2050.

9. DERIVATIVE LIABILITIES

Promissory Notes, Bridge Shares and Warrants

During May 2022, the Company executed promissory notes having a face amount of $888,889. The notes contain an original issue discount of 10% ($88,889) and debt issuance costs of $91,436, resulting in net proceeds of $708,564. These notes bear interest at 10% with a default interest rate of 15% and are unsecured. The notes are due at the earlier of one-year (1) from the issuance date or the closing of an initial public offering ("IPO").

In connection with the issuance of these notes, the Company will also issue common stock to each note holder equivalent to (a) 100% of the face amount of the note divided by the IPO price per share, or (b) if the Company fails to complete the IPO prior to May 24, 2023, the number of shares of the Company's common stock calculated using a $27,000,000 pre-money valuation of the Company and the number of the Company's outstanding shares of common stock on May 24, 2023. Additionally, each of these note holders are entitled to receive five-year (5) fully vested warrants upon the closing of an IPO, with an exercise price of 110% of the IPO price.

Convertible Promissory Notes and Warrants - Related Parties

During May 2022, the Company executed convertible promissory notes with the Company's Chief Executive Officer and a family member related to the Chief Executive Officer, having a face amount of $338,889. The notes contain an original issue discount of 10% ($33,888) and debt issuance costs of $34,289, resulting in net proceeds of $270,711. These notes bear interest at 6% with a default interest rate of 15% and are unsecured. The notes are due at the earlier of one-year (1) from the issuance date or the closing of an IPO. Upon the closing of an IPO, these notes are mandatorily redeemable at the lesser of (a) 20% discount to the IPO price or (b) $27,000,000 pre-money valuation. Additionally, each of these note holders are entitled to receive five-year (5) fully vested warrants upon the closing of an IPO, with an exercise price of 110% of the IPO price. If the IPO is not completed by May 31, 2023, the exercise price is 90% of the IPO price.

9. DERIVATIVE LIABILITIES (CONTINUED)

Convertible Promissory Notes and Warrants - Related Parties (Continued)

Promissory notes and Convertible notes – related parties are summarized as follows at March 31, 2023 and December 31, 2022:

	Promissory Notes	Convertible Notes
Issuance date of promissory notes	May 2022	May 2022
Maturity date of promissory notes	**1**	**1**
Interest rate	10%	6%
Default interest rate	15%	15%
Collateral	Unsecured	Unsecured
Conversion rate	**2**	**2**
Face amount of notes	$ 888,889	$ 338,889
Less: unamortized debt discount	(407,555)	(155,443)
Add: accrued interest on promissory notes	54,567	11,651
Balance - December 31, 2022	$ 535,901	$ 195,097
Face amount of notes	888,889	338,889
Less: unamortized debt discount	(163,284)	(62,288)
Add: accrued interest on promissory notes	76,789	17,565
Balance - March 31, 2023	$ 802,394	$ 294,166

1 - earlier of 1 year from date of issuance or closing of IPO.
2 - see discussion above in (a) and (b)

For the three months ended March 31, 2023, the Company recorded amortization of debt discounts of $337,426.

As noted above, certain of the Company's bridge shares, warrants and convertible notes (containing an embedded conversion feature) are accounted for as derivative liabilities since there is an unknown exercise price associated with each instrument. The exercise price is dependent upon a yet to be completed IPO or a failed IPO. In both cases, the possible exercise prices contain different conditions (related to the success or failure of the IPO) that could result in issuing an undeterminable amount of common stock to settle any conversions.

A reconciliation of the beginning and ending balances for the derivative liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows at March 31, 2023 and December 31, 2022:

	Bridge Shares	Warrants	Convertible Notes Payable	Total
Derivative liabilities - December 31, 2022	$ 834,352	$ 578,164	$ 81,684	$ 1,494,200
Fair value - mark to market adjustment	4,902	1,689	(1,457)	5,134
Derivative liabilities - March 31, 2023	$ 839,254	$ 579,853	$ 80,227	$ 1,499,334

Changes in fair value of derivative liabilities (mark to market adjustment) are included in other income (expense) in the accompanying consolidated condensed statements of operations and comprehensive loss. During the three months ended March 31, 2023, the Company recorded a net change in the fair of derivative liabilities of $5,134.

9. DERIVATIVE LIABILITIES (CONTINUED)

Convertible Promissory Notes and Warrants - Related Parties (Continued)

The fair value of the Company's potential future issuances of common stock related to common stock issued with promissory notes, warrants and embedded conversion features in convertible promissory notes is established with an estimate using the Monte Carlo Simulation Model to compute fair value. The Monte Carlo simulation requires the input of assumptions, including our stock price, the volatility of our stock price, remaining term in years, expected dividend yield, and risk-free rate.

In addition, the valuation model considers the probability of the occurrence or nonoccurrence of an IPO within the terms of our liability-classified financial instruments, as an IPO event can potentially impact the settlement.

At each subsequent reporting period, we remeasure the fair value of our liability-classified bridge shares, warrants and embedded conversion features in convertible promissory notes using the Monte Carlo simulation. The assumptions used to perform the Monte-Carlo Simulation as of December 31, 2022 and March 31, 2023 were as follows:

Mark to Market	**March 31, 2023**	**December 31, 2022**
Stock price	$ 5.00	$ 5.00
Volatility	103.5%	101.90%
Expected term (in years) - Notes	0.15 - 0.17	0.39 - 0.41
Expected term (in years) - Warrants	4.14	4.39
Risk-free interest rate	3.69%	4.06%
Dividend yield	0%	0%
IPO probability (prior to note maturity date)	95%	95%

10. INCOME TAXES

The Company pays taxes at the federal level as a “C Corporation”. In the District of Columbia, there is a minimum tax of $250 for incomes at and below $1,000,000 and $1,000 for those incomes above. The provision for income taxes for the three months ended March 31, 2023 consists of the following:

	Federal	**DC**
Taxable loss	$(2,506,427)	$(2,506,364)
DC Franchise tax	-	63
Provision (added) used	(526,350)	(206,775)
Allowance added (used)	526,350	206,775
Net Provision for Income Taxes	**$ -**	**$ 63**

10. INCOME TAXES (CONTINUED)

Federally the Company has a cumulative net loss of $2,506,427 as of March 31, 2023 ($5,807,867 as of December 31, 2022). The net tax benefit associated with loss accumulated through the three months ending March 31, 2023 is $526,350 ($1,219,652 as of December 31, 2022) with the federal tax rate of 21%.

The Company has cumulative net loss in DC of $2,506,364 for the three months ended March 31, 2023 ($5,807,367 as of December 31, 2022). The net tax benefit is the cumulative net loss multiplied by the District of Columbia corporate tax rate of 8.25%. The Company's net tax benefit at March 31, 2023 is $206,775 ($479,108 at December 31, 2022).

Australian subsidiary has cumulative losses of AUD9,773,494 at March 31, 2023 (and AUD9,640,315 at December 31, 2022). The Australian subsidiary has also measured a deferred tax benefit associated with the cumulative losses of AUD2,443,374 at March 31, 2023 (and AUD2,410,079 at December 31, 2022). The current tax rate in Australia is now 25% for businesses with an aggregated turnover (ordinary income of the Company and its affiliates) of AUD50 million. The Company projects to continue to qualify for the lower tax rate in the near future.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. On the basis of this evaluation, the Company has determined that it is more likely than not that the Company will not recognize the benefits of the foreign and state net deferred tax assets, and, as a result, full valuation allowance has been set against its net deferred tax assets as of March 31, 2023 and December 31, 2022. The amount of the deferred tax asset to be realized could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased.

As of the Period Ended	March 31, 2023	December 31, 2022
Federal Deferred Tax Asset	$ 1,746,002	$ 1,219,652
DC Deferred Tax Asset	685,883	479,108
Australian Deferred Tax Asset (USD)	1,634,128	1,640,059
	4,066,013	3,338,819
Allowance	4,066,013	3,338,819
Net Value of Deferred Tax Asset	**$ -**	**$ -**

The Company recognizes the impact of a tax position in the financial statements if that position is more likely than not to be sustained on a tax return upon examination by the relevant taxing authority, based on the technical merits of the position. As of March 31, 2023, and December 31, 2022, the Company had no recognized tax benefits. The Company recognizes interest and penalties related to income tax matters as other expense and non-deductible penalties, respectively. As of March 31, 2023, the Company has recognized a potential tax penalty regarding a US foreign tax reporting form of $30,000 ($30,000 at December 31, 2022).

11. COMMITMENTS AND CONTINGENCIES

Operating Lease

On February 3, 2016, the Company entered into the lease agreement with CXI Corp to rent business premises. The contract was most recently amended on December 10, 2020 for an additional term of twenty-four months that was set to expire on March 31, 2023. In January 2023, the lease was extended for an additional twelve-month term until March 31, 2024. The Company applies ASC 842 to our operating leases, which are reflected on our balance sheet within operating lease right-of-use (ROU) assets and the related current and non-current operating lease liabilities. ROU assets represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments arising from lease agreement. Lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectation regarding the terms. Variable lease costs such as common area maintenance, property taxes and insurance are expensed as incurred.

Future minimum lease payments on a discounted and undiscounted basis under this lease are as follows:

	Undiscounted Cash Flows
Discount rate	15.00%
2023 (remaining nine months)	$ 41,977
2024	13,992
Thereafter	-
Total undiscounted minimum future payments	55,969
Imputed interest	(4,294)
Total operating lease payments	51,675
Short-term lease liabilities	51,675
Long-term lease liabilities	$ -

11. COMMITMENTS AND CONTINGENCIES (CONTINUED)

Operating Lease (Continued)

Other information related to our operating lease is as follows:

	March 31, 202 3
Weighted average remaining lease term in years	1 year
Weighted average discount rate	15.00%

Operating lease costs were in the amount of $13,507 and $12,974 for the three months ended March 31, 2023, and March 31, 2022, respectively.

Board of Directors

In November and December 2022, the Company signed agreements with four director nominees (Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey) which come into effect on the date the Company's S-1 becomes effective. Each director will receive cash compensations of $11,250 quarterly. In addition, the two non-audit committee chairs (Toovey, Field) will receive $1,250 per quarter and the audit committee chair (Allen) will receive an additional $2,000 per quarter. Each director will receive a one-off issuance of common stock of value $50,000 and a non-qualified option to purchase an additional $50,000 of common stock. Each director will receive equity compensation in the form of restricted stock units valued at $40,000 and a non-qualified option to purchase $40,000 of common stock.

Contingencies

The Company's operations are subject to a variety of local and state regulations. Failure to comply with one or more of those regulations could result in fines, restrictions on its operations, or losses of permits that could result in the Company ceasing operations.

Contingent Compensation

Prior to 2015 the Company agreed with certain vendors, advisors and employees to deferred compensation that expires on December 31, 2023. The net amount of these contingent payments is $43,581. The Company does not anticipate the trigger for these payments to be reached prior to expiration.

In 2020, the Company engaged with two vendors to help secure COVID-19 trial funding for the Company's Phase II COVID trial. Ultimately, the efforts were unsuccessful but a tail does remain. If one Australian fund participates in the Company's IPO a maximum of $520,000 would be due as of December 31, 2021. Due to subsequent agreement the maximum amount due would be $305,000 as of March 31, 2023. Currently, the Company is not engaged with the Australian fund to solicit their participation in the Company's IPO.

Litigation, Claims and Assessments

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of March 31, 2023, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the results of the Company's operations.

12. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through May 19, 2023, which is the date the financial statements were issued.

In April 2023, the Company received $50,000 as a short-term advance from management. The Geoffrey S. Dow Revocable Trust contributed $23,000 and Tyrone Miller contributed $27,000. On May 11, 2023, these short term advances were refunded. Additionally, on May 11, 2023, the $200,000 short term advance from the Geoffrey S. Dow Revocable Trust contributed in March 2023, was refunded.

During May 2023, the Company executed promissory notes having a face amount of $722,222. The notes contain an original issue discount of 10% ($72,222) and debt issuance costs of $95,000, resulting in net proceeds of $555,000. These notes bear interest at 10% with a default interest rate of 15% and are unsecured. The notes are due at the earlier of one-year (1) from the issuance date or the closing of an initial public offering ("IPO").

In connection with the issuance of these notes, the Company will also issue common stock to each note holder equivalent to (a) 100% of the face amount of the note divided by the IPO price per share, or (b) if the Company fails to complete the IPO prior to May 4, 2024, the number of shares of the Company's common stock calculated using a $27,000,000 pre-money valuation of the Company and the number of the Company's outstanding shares of common stock on May 4, 2024. Additionally, each of these note holders are entitled to receive five-year (5) fully vested warrants upon the closing of an IPO, with an exercise price of 110% of the IPO price.

There have been no other events or transactions during this time which would have a material effect on these financial statements.

1,415,095 Units
Each Unit Consisting of
One Share of Common Stock,
One Warrant to Purchase One share of Common Stock, and
One Non-tradeable Warrant to Purchase One Share of Common Stock
and the 2,830,190 Shares of Common Stock underlying such Warrants

60 Degrees Pharmaceuticals, Inc.

PRELIMINARY PROSPECTUS

WallachBeth Capital LLC

, 2023

Through and including, _____, 2023, (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 1, 2023

PRELIMINARY PROSPECTUS

2,224,763 Shares of Common Stock

60 Degrees Pharmaceuticals, Inc.

This prospectus relates to the resale of 2,224,763 shares of common stock, par value $0.0001 per share, by the selling stockholders (the "Selling Stockholders") of 60 Degrees Pharmaceuticals, Inc., consisting of (i) 10,482 shares of common stock to be issued upon conversion of a convertible note immediately prior to the consummation of the initial public offering, (ii) 373,426 shares of common stock to be issued in conjunction with the conversion or extinguishment of interim financing notes on the date of the effectiveness of the registration statement of which this prospectus forms a part, (iii) 1,608,938 shares of common stock held by certain of the Selling Stockholders and (iv) 231,917 shares of common stock issuable upon the exercise of warrants that are to be issued on the date of effectiveness of the registration statement of which this prospectus forms a part. For additional information regarding the warrants, please see "*Description of Securities—Warrants*" beginning on page 114 of the public offering prospectus.

Prior to the initial public offering, there has been no public market for our common stock or warrants. We have applied to list our common stock and Tradeable Warrants for trading on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively. There is no guarantee or assurance that our shares of common stock and Tradeable Warrants will be approved for listing on The Nasdaq Capital Market. This offering is contingent upon receiving approval of our listing from The Nasdaq Stock Market LLC ("Nasdaq") and the closing of our initial public offering. We will not receive any proceeds from the sale of shares by the Selling Stockholders.

Any shares sold by the Selling Stockholders until our common stock and Tradeable Warrants are listed or quoted on an established public trading market will take place at $ per share, which is the per unit public offering price we are selling in our initial public offering. Thereafter, any sales will occur at prevailing market prices or in privately negotiated prices. The distribution of securities offered hereby may be effected in one or more transactions that may take place in ordinary brokers' transactions, privately negotiated transactions or through sales to one or more dealers for resale of such securities as principals. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the Selling Stockholders. No sales of the shares covered by this prospectus shall occur until the common stock and Tradeable Warrants sold in our initial public offering begins trading on The Nasdaq Capital Market. The Selling Stockholders have represented to us that they will not offer or sell their shares prior to the closing of the initial public offering.

On , 2023, a registration statement under the Securities Act of 1933, as amended (the "Securities Act") with respect to our initial public offering of units, with each unit consisting of one share of common stock, one Tradeable Warrant to purchase one share of common stock and one Non-tradeable Warrant to purchase one share of common stock, was declared effective by the Securities and Exchange Commission (the "SEC"). We received approximately $ million in net proceeds from the offering (assuming no exercise of the underwriters' over-allotment option) after payment of underwriting discounts and commissions and estimated expenses of the offering.

Investing in our common stock involves a high degree of risk, including the risk of losing your entire investment. See "*Risk Factors*" beginning on page 18 of the primary offering prospectus contained in the registration statement of which this prospectus forms a part, to read about factors you should consider before buying our common stock.

Neither the SEC nor any state securities commission nor any other regulatory body has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2023

PROSPECTUS SUMMARY

This summary provides a brief overview of the key aspects of our business and our securities. The reader should read the entire prospectus carefully, especially the risks of investing in our securities discussed under "Risk Factors." Some of the statements contained in this prospectus, including statements under "Summary" and "Risk Factors" as well as those noted in the documents incorporated herein by reference, are forward-looking statements and may involve a number of risks and uncertainties. Our actual results and future events may differ significantly based upon a number of factors. The reader should not put undue reliance on the forward-looking statements in this document, which speak only as of the date on the cover of this prospectus.

Unless the context otherwise requires, references in this prospectus to "60P," the "Company," "we," "us" and "our" refer to 60 Degrees Pharmaceuticals, Inc., a Delaware corporation, and its majority-owned subsidiary.

Overview

We are a growth-oriented specialty pharmaceutical company with a goal of using cutting-edge biological science and applied research to further develop and commercialize new therapies for the prevention and treatment of infectious diseases. We have successfully achieved regulatory approval of Arakoda, a malaria preventative treatment that has been on the market since late 2019. Currently, 60P's pipeline under development covers development programs for COVID-19, fungal, tick-borne, and other viral diseases utilizing three of the Company's future products: (i) new products that contain the Arakoda regimen of Tafenoquine; (ii) new products that contain Tafenoquine; and (iii) Celgosivir.

Mission

Our mission is to address the unmet medical need associated with infectious diseases, through the development and commercialization of new small molecule therapeutics, focusing on synthetic drugs (made by chemists in labs, excluding biologics) with good safety profiles based on prior clinical studies, in order to reduce cost, risk, and capitalize on existing research. We are seeking to expand Arakoda's use for malaria prevention and to demonstrate clinical benefit for other disease indications. We are further testing the viability of another product (Celgosivir) to determine whether to advance it into further clinical development, and may seek to develop and license other molecules in the future. Celgosivir is being developed for COVID-19, RSV and Dengue.

Market Opportunity

In 2018, the FDA approved Arakoda for malaria prevention in individuals 18 years and older, an indication for which there has historically been approximately 550,000 prescriptions (one prescription per three weeks of travel) in the United States each year for the current market-leading product (atovaquone-proguanil). Arakoda entered the U.S. supply chain in the third quarter of 2019, just prior to the COVID-19 pandemic. As the approved indication is for travel medicine, and international travel was substantially impacted by the pandemic, we did not undertake any active marketing efforts for Arakoda. Targeted marketing efforts will commence in the second half of 2023 to promote the malaria indication as resources permit, although we expect our primary efforts to be developing Arakoda for other applications.

We are repositioning the Arakoda regimen of Tafenoquine for new indications to address several therapeutic indications that have substantial U.S. caseloads, as further described below:

- Treatment of COVID-19. According to *The New York Times*, the lowest daily case rate for the COVID-19 virus since March 2020 based on a seven-day average has not typically been below 11,000 cases. Assuming this trend continues, this dynamic translates into a potential market size of at least 4,000,000 cases per year in 2023 and future years. Paxlovid and molnupiravir have received emergency use authorization for the prevention of death and hospitalization in individuals with high risk of disease progression and their use for those purposes continues to be recommended by public health experts. However, to our knowledge, there is not published evidence from randomized controlled clinical trials that either drug reduces the time to sustained clinical recovery for four or more days in standard risk patients infected with contemporary viral strains, and Pfizer has formally abandoned efforts related to this endpoint for paxlovid.[2] Additionally molnupiravir and paxlovid are not approved by FDA for use in patients without risk factors for disease progression, and that excluded lower risk population comprises about 25% of the U.S. population.[3] The economic value of that unsatisfied market may be a multi-billion-dollar opportunity, given that the value of paxlovid and molnupiravir in the 75% of the population in which they can be used was ~ $12 billion in 2022.[4] If proven effective for early relief of COVID-19 symptoms in standard risk COVID-19 patients, Tafenoquine (Arakoda regimen) could fulfill a patient's need unmet by the approved antivirals.

[2] Press release: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reports-additional-data-paxlovidtm-supporting.

[3] See the Paxlovid (www.paxlovid.com) and Lagevrio (www.lagevrio.com) prescribing information and epidemiology data described by Ajufo et al Am J Preventive Cardiol 2021;6:101156.

[4] See 2022 revenue data for Paxlovid in Pfizer (https://investors.pfizer.com/Investors/Financials/SEC-Filings/SEC-Filings-Details/default.aspx?FilingId=16428097) and Lagevrio (https://d18rn0p25nwr6d.cloudfront.net/CIK-0000064978/b390be48-92bf-4595-96da-ac5cd7c3d92e.pdf) in Merck financial reports.

- Treatment and Post-Exposure Prevention of Tick-Borne Diseases. There are at least 47,000 cases of babesiosis (red blood cell infections caused by deer tick bites) in the United States each year. This estimate is based on the observations of Krugeler who reported that 476,000 cases of Lyme disease occur in U.S. states where babesiosis is endemic and Krause et. al. who reported that 10% of Lyme disease patients are co-infected with babesiosis (thus 476,000*10% = 47,600 cases of babesiosis per year).[5] Furthermore, post-exposure prophylaxis following a tick-bite is a recognized indication to prevent Lyme disease, and it is likely that a drug proven to be effective for this indication for babesiosis would also be used in conjunction with Lyme prophylaxis. There may be more than 400,000 tick bites in the United States requiring medical treatment each year. This estimate is based on the observation that approximately 50,000 tick bites are treated in U.S. hospital emergency rooms each year but this calculation represents only about 12% of actual treated tick bites based on observations from comparable ex-U.S health systems.[6] Arakoda has the potential to be added to the existing standard of care for treatment of babesiosis, and to be a market leading product for pre- and post-exposure prophylaxis of babesiosis.

- Prevention of fungal pneumonias. There are up to ~ 91-92,000 new medical conditions each year in the United States including acute lymphoblastic leukemia (up to 6.540 cases) and large B-cell lymphoma (up to 18,000 cases) patients receiving CAR-T therapy, solid organ transplant patients (up to 42,887 cases), allogeneic (~ 9,000 cases) and autologous (~ 15,000 cases) hematopoietic stem cell transplant patients for whom the use of antifungal prophylaxis is recommended.[7] Despite the availability and use of antifungal prophylaxis, the risk of some patient groups contracting fungal pneumonia exceeds the risk of contracting malaria during travel to West Africa.[6] Arakoda has the potential to be added to existing standard of care regimens for the prevention of fungal pneumonias.

- Treatment of *Candida* infections. According to the Centers for Diseases Control (CDC), there are 50,000 cases of candidiasis (a type of fungal infection) each year in the United States and up to 1,900 clinical cases of *C. auris*, for which there are few available treatments, have been reported to date[9] Arakoda has the potential to be a market leading therapy for treatment/prevention of *C. auris*, and to be added to the standard of care regimens for other *Candida* infections.

Dengue and RSV, both afflictions against which 60P's early clinical candidates (e.g., Celgosivir) show potential in non-clinical studies, are associated with at least 4.1 million cases globally according to the European CDC (Dengue) [10] and up to 240,000 hospitalizations (RSV) in children less than five years of age and adults greater than 65 years of age in the United States each year according to the CDC.[11]

More information about our products is provided in the next section, and the status of various development efforts for the above-mentioned diseases is outlined in Figure A, below.

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[5] Krause et al JAMA 1996 ;275 :1657-16602. Krugeler et al *Emerg Infect Dis* 2021 ;27 :616-619

[6] Marx et. al., MMWR 2021;70:612-616.

[7] See statistics for solid organ transplants at the Organ Transplant and Procurement Network at: National data – OPTN (hrsa.gov); See statistics for hematopoietic stem cell transplant in Dsouza et al Biology of Blood and Bone Marrow Transplantation 202;26: e177-e182; See statistics for acute lymphoblastic leukemia at: Key Statistics for Acute Lymphocytic Leukemia (ALL) (cancer.org); See statistics for large cell large B-cell lymphoma at; Diffuse Large B-Cell Lymphoma – Lymphoma Research Foundation; Treatment guidelines recommending antifungal prophylaxis for these diseases can be reviewed in (i) Fishman et al Clinical Transplantation. 2019;33:e13587, (ii) Hematopoietic Cell Transplantation (cancernetwork.com), (iii) Cooper et al Journal of the National Comprehensive Cancer Network 2016;14:882-913 and (iv) Los Arcos et al Infection (2021) 49:215–231.

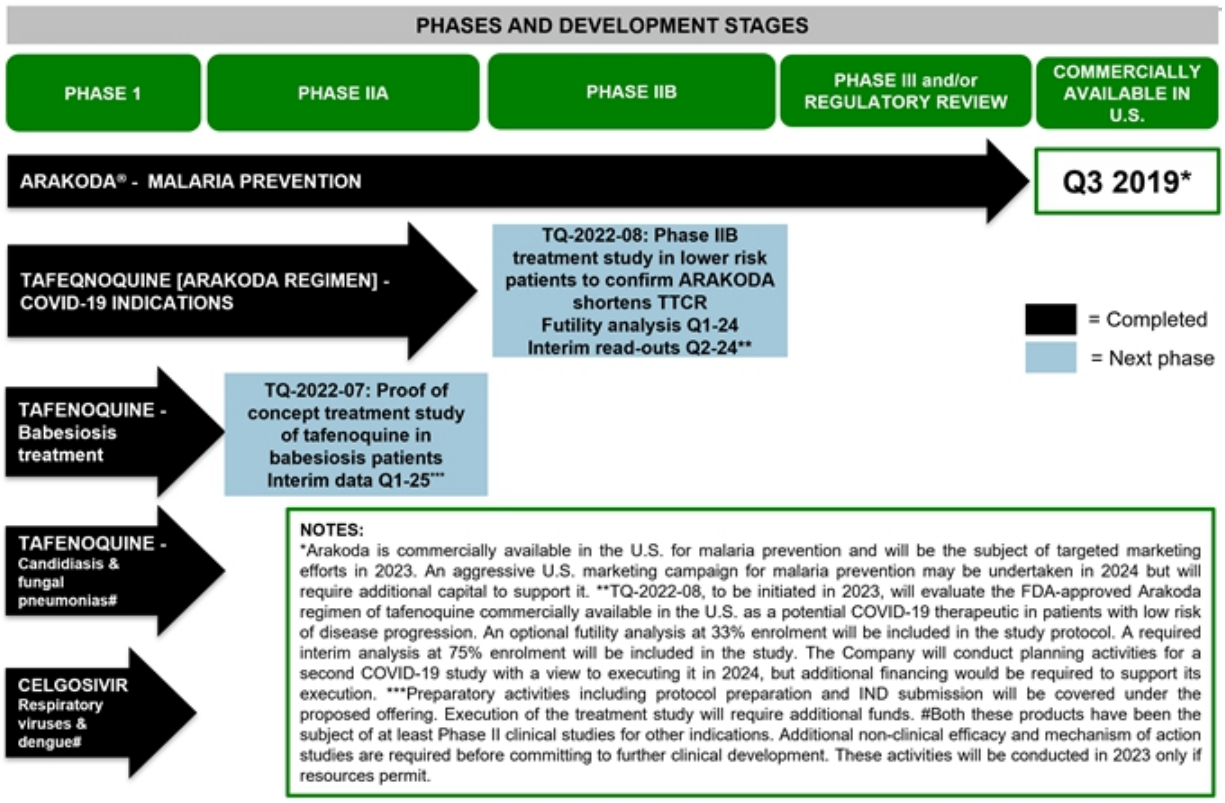
[8] Aguilar-Guisado et al Clin Transplant 2011;25:E629–38; Mace et al MMWR 202;70:1–35

[9] https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html.; https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html.

[10] https://www.ecdc.europa.eu/en/dengue-monthly#:~:text=This%20is%20an%20increase%20of%2032%20653%20cases%20and%2032,853%20deaths%20have%20been%20reported.

[11] https://www.cdc.gov/rsv/research/index.html#:~:text=Each%20year%20in%20the%20United,younger%20than%205%20years%20old.&text=58%2C000-80%2C000%20hospitalizations%20among%20children%20younger%20than%205%20years%20old.&text=60%2C000-120%2C000%20hospitalizations%20among%20adults%2065%20years%20and%20older.

Figure A



Products

Arakoda (Tafenoquine) for malaria prevention

We entered into a cooperative research and development agreement with the United States Army in 2014 to complete development of Arakoda for prevention of malaria.[12] With the U.S. Army, and other private sector entities as partners, we coordinated the execution of two clinical trials, development of a full manufacturing package, gap-filling non-clinical studies, compilation of a full regulatory dossier, successful defense of our program at an FDA advisory committee meeting, and submitted a new drug application ("NDA") to the FDA in 2018. The history of that collaboration has been publicly communicated by the U.S. Army.[13]

The FDA and Australia's medicinal regulatory agency, Therapeutic Goods Administration, subsequently approved Arakoda and Kodatef (brand name in Australia), respectively, for prevention of malaria in travelers in 2018. Prescribing information and guidance for patients can be found at *www.arakoda.com*. The features and benefits of Tafenoquine for malaria prophylaxis (marketed as Arakoda in the United States), some of which have been noted by third-party experts, include: convenient once weekly dosing following a three day load; the absence of reports of drug resistance during malaria prophylaxis; activity against liver and blood stages of malaria as well as both the major malaria species (*Plasmodium vivax* and *Plasmodium falciparum);* absence of any black-box safety warnings; good tolerability including in women and individuals with prior psychiatric medical history, and a comparable adverse event rate to placebo with up to 12 months continuous dosing.[14] Tafenoquine entered the commercial supply chains in the U.S. (as Arakoda) and Australia (as Kodatef) in the third quarter of 2019.

The only limitation of Arakoda is the requirement for a G6PD test prior to administration.[15] The G6PD test must be administered to a prospective patient prior to administration of Arakoda in order to prevent the potential occurrence of hemolytic anemia in individuals with G6PD deficiency.[16] G6PD is one of the most common enzyme deficiencies and is implicated in hemolysis following administration/ingestion of a variety of oxidant drugs/food. G6PD must also be ruled out as a possible cause when diagnosing neonatal jaundice. As a consequence, G6PD testing is widely available in the United States through commercial pathology service providers (e.g., Labcorp, Quest Diagnostics, etc.). Although these tests have a turn-around time of up to 72 hours, the test needs only to be administered once. Thus, existing U.S. testing infrastructure is sufficient to support the FDA-approved use of the product (malaria prevention) by members of the armed forces (who automatically have a G6PD test when they enlist), civilian travelers with a long planning horizon or repeat travelers.

Tafenoquine (Arakoda regimen) for COVID-19

During the COVID-19 pandemic, since our commercial opportunities were limited, we embarked upon an exploratory research and development campaign to identify new indications for the Arakoda dosing regimen of Tafenoquine. In the second quarter and third quarter of 2020, we commissioned cell culture studies that showed that Tafenoquine, the active ingredient in Arakoda, inhibited replication of SARS-CoV-2 (the virus that causes COVID-19).[17] Then, we commissioned computer simulations, which showed that the predicted concentration of Tafenoquine in the lungs of COVID-19 patients following administration of the first four doses of the approved antimalarial prophylactic regimen of Arakoda exceeded those inhibiting the virus in cell culture. The foregoing provided the rationale for seeking approval from the FDA to conduct a Phase II clinical trial in patients with the COVID-19 disease, for which the FDA granted clearance to proceed in October 2020.

In 2021, with financial support from the U.S. Army[16], we conducted a Phase II clinical investigation of the safety and efficacy of Tafenoquine using the Arakoda regimen in outpatients with mild-moderate COVID-19 disease (assumed to be mostly caused by the delta variant of SARS-COV-2). In summary, safety and efficacy of Tafenoquine administered at the approved dose for malaria prevention (200 mg dose once per day on days 1, 2, 3, and 10) was

evaluated over a 28-day period in mild-moderate COVID-19 patients. The primary endpoint was day 14 clinical recovery from COVID-19 symptoms, defined as cough mild or absent, respiratory rate < 24 bpm, and no shortness of breath or fever. From March 2021 through September 2021, this study enrolled 87 of the originally planned 275 patients. In October 2021, a data safety monitoring board, after conducting a futility analysis for the primary endpoint and reviewing adverse event data, recommended that the study be continued as planned. However, at the time of the unblinding of this study, topline results from Phase III studies for three oral COVID-19 therapeutics in at risk patients with mild-moderate COVID-19 disease had been announced: Fluvoxamine, molnupiravir, and paxlovid reduced the risk of hospitalization by approximately 30%, 50% (in the first public announcement) and 90%, respectively.[19] As reported in our publication[18], an informal survey of potential funding/commercialization partners for a follow-on program suggested it would be important to know the magnitude of possible benefit prior to initiating such an effort. Primarily for the above reasons, the study was terminated and unblinded early.

The results of the study were accepted for peer-reviewed publication in May 2022.[21] For the primary endpoint, the proportion of patients not recovered on Day 14 was numerically decreased by 27% in the intent to treat population (8/45 v 10/42 not recovered in the Tafenoquine and placebo arms, $P = 0.60$) and 47% in the per protocol population (5/42 v 9/41, $P = 0.25$). Amongst individuals who recorded responses in an electronic diary on day 28, all Tafenoquine patients were recovered, whereas up to 12% of placebo patients exhibited lingering shortness of breath. Analysis of secondary/exploratory endpoints suggested Arakoda reduced time to clinical recovery from shortness of breath, cough and fever ($P < 0.02$) and numerically improved aggregate symptom scores five days after treatment ($P < 0.1$).[22] The risk of COVID-19-related hospitalization was numerically reduced in the Arakoda arm (by approximately 50%; two instances for placebo versus one for Arakoda). Mild, drug related adverse events occurred in 8.4% of individuals in the Tafenoquine arm (v 2.4% in the placebo). We plan to confirm that Arakoda accelerates sustained recovery from COVID-19 symptoms in our next study (described in "*Prospectus Summary—Strategy*" beginning on page 4).

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[12] In 2014, we signed a cooperative research and development agreement with the United States Army Medical and Materiel Development Activity (Agreement W81XWH-14-0313). Under this agreement, we agreed to submit an NDA for Tafenoquine to the FDA (as Arakoda), while the US Army agreed to finance the bulk of the necessary development activities in support of that goal.

[13] Zottig et al Military Medicine 2020; 185 (S1): 687.

[14] Tan and Hwang Journal of Travel Medicine, 2018, 1–2; Baird Journal of Travel Medicine 2018:, 1–13; Schlagenhauf et al Travel Medicine and Infectious Disease 2022; 46:102268; See Arakoda prescribing information at www.arakoda.com; McCarthy et al CID 2019:69:480-486; Dow et al. Malar J (2015) 14:473; Dow et al. Malaria Journal 2014, 13:49; Novitt-Moreno et al Travel Med Infect Dis 2022 Jan-Feb;45:102211.

[15] See prescribing information at www.arakoda.com.

[16] See prescribing information at www.arakoda.com.

[17] U.S. Patent application # 17/189,544, Dow et. al. bioRxiv 2020.07.12.199059; doi: https://doi.org/10.1101/2020.07.12.199059.

[18] Financial support was obtained from Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (which may be referred to as "JPEO") or JPEO via other transactional authority agreement #W911QY-21-9-0011.

[19] Reis et al Lancet Global Health 2022;10:e42-51, Bernal et al New Eng J Med 2021; https://doi.org/10.1056/NEJMoa2116044; Pfizer Inc. Press release (November 5, 2021) – Pfizer's novel COVID 19 oral antiviral treatment candidate reduced risk of hospitalization or death by 89% in interim analysis of Phase 2/3 EPIC-HR study. Accessible at: Pfizer's Novel COVID-19 Oral Antiviral Treatment Candidate Reduced Risk of Hospitalization or Death by 89% in Interim Analysis of Phase 2/3 EPIC-HR Study | Pfizer.

[20] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

[21] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

[22] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

In 2022, we conducted additional analyses of laboratory endpoint data from the clinical study described above and are preparing a manuscript for publication. That analysis and the scientific literature suggest two possible modes of action for Arakoda: (i) down-regulation of cytokines (immune system inflammatory proteins) associated with severe COVID-19 and a greater risk of hospitalization or death and/or (ii) inhibition of viral entry in the lung or elsewhere in the body, perhaps through inhibition of a host enzyme called TMPRSS2 (which facilitates entry of the virus that causes COVID-19, SARS-CoV-2, into human cells).

Assuming the efficacy of Tafenoquine in COVID-19 disease is proven in our next study, some of the features of the Arakoda regimen that make it ideal for malaria prophylaxis might also make it very useful for COVID-19 related indications. Tafenoquine is slowly metabolized and has few important drug-drug interactions, so it might be an ideal partner for standard of care oral COVID-19 therapeutics that reduce hospitalization but have no demonstrated effect on the time to clinical recovery in non-hospitalized patients. The Arakoda regimen requires fewer tablets (8 in the first ten days versus 30 or 40 for paxlovid and molnupiravir) which should make compliance with medication easier for patients. This is an important consideration in the attractiveness of a regimen in standard risk patients at lower risk of hospitalization, and who may be interested in taking a COVID-19 therapeutic primarily to treat early symptoms and accelerate recovery. The potential for better compliance may also suggest suitability for outbreak control in some settings (including, for example, nursing homes).

Tafenoquine for other infectious diseases

During the pandemic, we also worked with NIH to evaluate the utility of Tafenoquine as an antifungal. We, and the NIH, found that Tafenoquine exhibits a Broad Spectrum of Activity in cell culture against *Candida* and other yeast strains via a different Mode of Action than traditional antifungals and also exhibits antifungal activity against some fungal strains at clinically relevant doses in animal models.[23] Our work followed Legacy Studies that show Tafenoquine is effective for treatment and prevention of *Pneumocystis* pneumonia in animal models.[24] We believe that if added to the standard of care for anti-fungal and yeast infection treatments for general use, Tafenoquine has the potential to improve patient outcomes in terms of recovery from yeast infections, and prevention of fungal pneumonias in immunosuppressed patients. There are limited treatment options available for these indications, and Tafenoquine's novel mechanism of action might also mitigate problems of resistance. Clinical trial(s) to prove safety and efficacy, and approval by the FDA and other regulators, would be required before Tafenoquine could be marketed for these indications.

Tafenoquine is effective in animal models of babesiosis (tick borne red blood cell infections). In two of three recent clinical case studies, Tafenoquine administered after failure of conventional antibiotics in immunosuppressed babesiosis patients resulted in cures.[25] Consequently, we believe that (i) if combined with standard of care products, Tafenoquine has the potential to reduce the duration of treatment with antibiotic therapy in immunosuppressed patients and the time to parasite clearance in non-immunosuppressed patients and (ii) that once appropriate clinical studies have been conducted, it is likely that Tafenoquine would be quickly embraced for post-exposure prophylaxis of babesiosis in patients with tick bites and suspected of being co-infected with Lyme disease. Clinical trial(s) to prove safety and efficacy, and approval by FDA and other regulators, would be required before Tafenoquine could be marketed for these indications.

Celgosivir

Celgosivir is a host targeted glucosidase inhibitor that was developed separately by other sponsors for HIV then for hepatitis C.[26] The sponsors abandoned Celgosivir after completion of Phase II clinical trials involving 700+ patients, because other antivirals in development at the time had superior activity. The National University of Singapore initiated development of Celgosivir independently for Dengue fever. A clinical study, conducted in Singapore, and the results of which were accepted for publication in the peer-reviewed journal Lancet Infectious Diseases, confirmed its safety but the observed reduction in viral load was lower than what the study was powered to detect.[27] Celgosivir (as with other Dengue antivirals) exhibits greater capacity to cure Dengue infections in animal models when administered prior to symptom onset compared to post-symptom onset. In animal models, this problem can be addressed for Celgosivir, by administering the same dose of drug split into four doses per day rather than two doses per day (as was the case in the Singaporean clinical trial).[28] This observation led to the filing and approval of a patent related to Dengue, which we licensed from the National University of Singapore.

[23] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

[24] Queener et al Journal of Infectious Diseases 1992;165:764-8).

[25] Liu et al. Antimicrobial Agents Chemo 2021;65:e00204-21, Marcos et al. IDCases 2022;27:e01460; Rogers et al. Clin Infect Dis. 2022 Jun 10:ciac473, Prasad and Wormsner. Pathogens 2022;11:1015.

[26] Sorbera et al, Drugs of the Future 2005; 30:545-552.

[27] Low et. al., Lancet ID 2014; 14:706-715.

[28] Watanabe et al, Antiviral Research 2016; 10:e19.

Additional clinical studies would be required to prove that such a 4x daily dosing regimen would be safe and effective in Dengue patients to regulators' satisfaction. To that end, earlier in our history, we, in partnership with the National University of Singapore, and Singapore General Hospital, successfully secured a grant from the government of Singapore for a follow-on clinical trial, but were unable at that time to raise matching private sector funding. We concluded as a result that development of Repositioned Molecules for Dengue, solely and without simultaneous development for other therapeutic use, despite substantial morbidity and mortality in tropical countries, was an effort best suited for philanthropic entities. Accordingly, during the pandemic, we undertook an effort (in partnership with NIH's Division of Microbiology and Infectious Diseases program and Florida State University) to determine whether Celgosivir might be more broadly useful for respiratory diseases that have impact in both tropical and temperate countries. Preliminary data suggest Celgosivir inhibits the replication of the virus that causes COVID-19 (SARS-CoV-2) in cell culture, and the RSV virus in cell culture and provides benefits in animals. We have filed and/or licensed patents in relation to Celgosivir for these other viruses as we believe there is potential applications to fight respiratory diseases that might have more commercial viability than historical development of Celgosivir to combat Dengue fever.

Competitive Strengths

Our main competitive strength has been our ability to achieve important clinical milestones inexpensively in therapeutic areas that other entities have found extremely challenging. With a small virtual management team, we have successfully built productive research partnerships with public and academic entities, and licensed products with well characterized safety profiles in prior clinical studies, thereby reducing the cost and risk of clinical development. This business and product model enabled Arakoda to be approved in 2018, with a total operating expense of < $10 million. We plan to focus in the future on generating proof of concept clinical data sets for the approved Arakoda regimen of Tafenoquine in other therapeutic areas, all of which is expected to foster and continue our existing tradition of inexpensive product development.

Strategy

Our general strategy is to demonstrate clinical proof of concept that the FDA-approved Arakoda regimen of Tafenoquine provides clinical benefits in non-malaria therapeutic areas. Our initial focus is on COVID-19, but additional indications have been identified for development, namely babesiosis and fungal infections, pending further data generation. Upon demonstration of clinical proof of concept, we plan to enter into a strategic partnership with a larger entity with commercialization capacity, or raise additional capital to facilitate commercialization of Arakoda, and any additional clinical studies that may be required by regulators, for both travel medicine and broad infectious disease indications. We will continue to develop our portfolio products as resources permit.

Beginning in the second half of 2023, we plan to execute a Phase IIB, randomized, placebo-controlled double blind clinical study powered (at 80%) to prove that the Arakoda regimen of Tafenoquine accelerates time to sustained clinical recovery in patients with mild-moderate disease with low risk for disease progression. This trial will utilize the bulk of proceeds raised in this offering. Based on an analysis of unpublished data from our earlier COVID-19 clinical trial,[29] we believe that the Arakoda regimen of Tafenoquine has the potential to reduce the time to sustained clinical recovery by about three days (see Figure B, below). The study will be conducted in out-patient clinics in the United States. The study will utilize the majority of the proceeds of the offering reserved for research and development activities for this purpose. As of the date of this prospectus, we have completed a clinical study synopsis. Submission of the full protocol to the Ethics Committees and to U.S. regulators, and posting of the trial at *clinicaltrials.gov* will follow this initial public offering.

Figure B

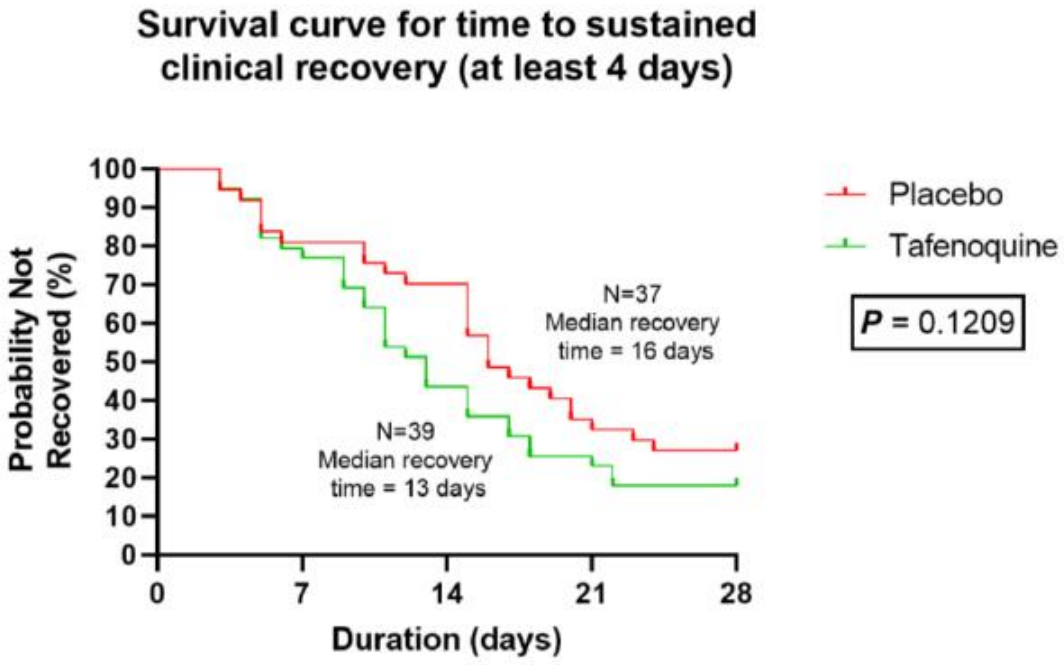

Figure B: Survival curve for sustained clinical recovery in outpatients with mild-moderate COVID-19 disease randomized to receive Tafenoquine (Arakoda regimen) or placebo. Sustained clinical recovery was defined as the first instance of patient reported symptoms scores being < 3 for four or more days, with symptoms scores assessed according to FDA guidance.[30] This analysis utilized unpublished data from our earlier Phase II clinical trial.[31] The analysis excludes individuals hospitalized or loss to follow-up and with a symptom score on the days of dosing < 3. This analysis represents a post-hoc analysis of our Phase II clinical trial data. If this were a formal, pre-conceived primary study endpoint, the *P* value of 0.1209 would imply the associated difference between Tafenoquine (Arakoda regimen) and placebo has a 12.09% chance of occurring by chance.

We intend to design the study, subject to approval by the FDA and Ethics Committee(s) as appropriate, to include two interim endpoints to manage risk. The first will be an optional futility analysis at the earlier of 33% enrollment or six months following the first patient enrolled, which would allow early

termination of the study if the conditional power of proving the intended hypothesis is < 20%. The second, mandatory interim analysis will occur at 75% enrollment and follow a step-wise (sponsor-blinded) process involving testing for futility, statistical significance, and sample-size reassessment if required. The test for statistical significance would allow early termination of the study if results are unexpectedly positive and the sample size reassessment would allow the study to enroll more patients within pre-specified limits if variability is more, and/or the magnitude of the expected treatment effect is less, than expected.

We plan to conduct additional non-clinical studies to clarify the process by which Tafenoquine alters the course of COVID-19 illness. Specifically, such studies will attempt to determine whether Tafenoquine acts as an immunomodulator (by decreasing the production of immune system molecules that cause inflammation) and/or exhibits an antiviral effect via inhibition of the host protease TMPRSS2. Antivirals are generally utilized earlier, and immunomodulators later, in treating patients with COVID-19 disease. However, the clinical hypothesis of our planned study will be that Arakoda accelerates clinical recovery by three days in individuals who have experienced symptoms for fewer than seven days, thereby confirming observations from our earlier clinical study (see Figure B). Since the potential clinical benefit is already known, the primary purpose of clarifying the manner in which Arakoda works is to (i) address anticipated regulatory questions and (ii) ascertain whether other indications, such as relief of COVID-19 symptoms during vaccination, treatment of long COVID-19 patients, or use during hospitalization, might be plausible.

Following completion of our planned COVID-19 clinical study, if warranted based on the data generated, we intend to request a change in prescribing information to facilitate an expansion of use of Arakoda for malaria prevention from six to twelve months (mirroring our recently published post-marketing safety study) and to include reference to the recently generated COVID-19 treatment data. Prior to doing so, we plan to discuss with the FDA additional labeling related to COVID-19 which might be acceptable.

We intend to design and conduct feasibility assessments for one or more additional studies in the same type of patients as the planned study and/or for a COVID 19-related indication different from that targeted by our clinical study in 2023. One of these additional studies would be conducted in Australia, and would be a requirement to secure tax rebates for the overall COVID-19 program (see next paragraph). A second study is likely to be required by regulators which may or may not be the same as the study conducted in Australia. The value of conducting additional studies, in addition to securing tax credits or for regulatory approvals, would be (i) independently confirming the therapeutic modality/clinical mode of action of Arakoda (i.e. that it accelerates clinical recovery from COVID-19 symptoms and/or acts as an antiviral or disease modulator) and (ii) broadening the COVID-19 indication beyond treatment of lower risk patients (i.e. potentially increasing the volume of annual prescriptions). Thus, possible study designs could be (i) a simple repetition of the planned study with a larger sample size, (ii) a treatment study in higher risk patients or (iii) a pre-treatment loading study in individuals known to be exposed to the virus that causes COVID-19, and/or (iv) amelioration of COVID-19 disease-like symptoms in individuals receiving mRNA COVID-19 vaccines (if it turns out Arakoda is an immunomodulator).

We plan to license ex-U.S. rights to COVID-19 indications to our Australian subsidiary, 60P Australia Pty Ltd. This will facilitate claiming the Australian government's research tax credit for any of our COVID-19-related research activities conducted in Australia. 60P Australia has been successful in securing research tax credits for malaria and Dengue-related research since 2013. Since conducting our planned COVID-19 study in Australia is likely to be unfeasible and must be conducted in the U.S., we plan to apply for an overseas finding to the Australian Tax Office in the second quarter of 2023 to request an overseas finding for the U.S. study. Should such a finding be awarded, it would allow a tax rebate of 43.5% on research and development costs associated with the planned U.S. COVID-19 study to be claimed, but commit the Company to conduct COVID-19 research activities in Australia of a value at least as much as the cost of the planned U.S. clinical study.

[29] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

[30] *FDA 2020 Guidance on Assessing COVID-19 Symptoms*-14 Common COVID-19 Symptoms Severity Scale.

[31] Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

We are planning several commercial initiatives for the malaria market in parallel with further clinical development activities. Three routes exist for commercialization of Arakoda for the malaria prevention market are: (i) U.S. civilian travel clinics, travel prescribing centers, and large private sector entities with employees deployed overseas (e.g., mining companies), (ii) the prospect of additional U.S. Department of Defense ("DoD") and government agency procurement in the future (noting that as described on page 60 our existing contract with DoD has been fulfilled and has not been extended or modified) and (iii) ex U.S. sales strategy where we currently (or in the future) have exclusive distribution arrangements in overseas markets.

As of the date of this prospectus, we did not have plans to hire a U.S. field sales force, but are exploring possible commercial arrangements with contract sales organizations to target U.S. travel clinics for malaria prophylaxis. We may consummate a contract with a lobbying firm/contract sales organization to attempt to improve the position of Arakoda in the DoD formulary and to raise awareness of Arakoda amongst other U.S. government agencies. For such agencies, the product is expected to meet many of the requirements for occupational malaria prevention identified by the independent parties that have endorsed the product. We have been successful in securing procurement contracts with U.S. government agencies for Arakoda, and anticipate continued success in the future. In the third quarter of 2022, we made our first sale to our European distributor, and made additional sales to our Australian distributor in the second quarter of 2022. We are actively exploring the possibility of named-patient sales in jurisdictions outside Australia, Europe, and the United States. We plan to undertake a focused marketing campaign for Arakoda for malaria prevention in the second half of 2023. This will consist of promotion at relevant conferences, email promotion to prescribers, and target print and electronic advertisements.

It is expected that a point of care G6PD test might be required to maximize the economic potential of a COVID-19 indication for Tafenoquine (regardless of regimen). We do not intend to pursue independent development of such a test as there are well resourced development efforts already underway (see "*Risk Factors—Any future clinical trial for Arakoda will require screening for G6PD deficiency in order to safely administer the product. In the United States, G6PD testing can obtained through commercial pathology services which is associated with delays. The use of a third-party diagnostic provider of point of care testing may be required and we may not directly control the timing, conduct and expense of such testing*" beginning on page 18). However, we will continue to monitor the progress of development and U.S. commercialization of G6PD tests. We will seek to pursue collaborative commercial partnerships with the companies involved in commercialization efforts, if such activities can be conducted through resource sharing efforts.

We plan to generate additional validation data for our portfolio products if resources permit. Specifically, we will evaluate whether Celgosivir provides therapeutic benefit in a COVID-19 animal model, and complete critical activities related to confirming GMP process feasibility.

We may elect, as resources permit, to undertake a clinical study of Tafenoquine in combination with standard of care for hospitalized patients with babesiosis. We have developed such a protocol concept in partnership with academic collaborators and are planning to submit an investigational new drug application ("IND") to the FDA and pursue public and philanthropic funding to support our execution. We plan to seek public funding to support additional non-clinical studies to validate the mechanism of action of Tafenoquine against *Candida spp*. and further assess our utility in combination with standard of care agents in cell culture and animal studies.

Most new antimalarial treatment products are developed as drug combinations to proactively combat drug resistance. Tafenoquine, due to its long half-life and activity against all parasite species and strains, would be ideal partner in a drug combination. In the second half of 2023, we will actively seek out a potential partner antimalarial drug for Arakoda, with the goal of pursuing licensure of a new drug combination. We will only enter into a partnership to develop such a drug combination, if clear legal guidance can be obtained that such a combination if developed would have a high probability of securing a priority review voucher upon FDA approval.

There are currently efforts underway, in malaria-endemic countries outside the U.S., to generate datasets supporting the use of Tafenoquine for mass drug administration in asymptomatic individuals to prevent malaria transmission. We believe that such efforts are important to promote community acceptance of Tafenoquine and may eventually support World Health Organization pre-qualification of Tafenoquine for malaria eradication efforts. To that end, we intend to support, on a case-by-case basis, clinical studies sponsored by others, by providing commercial Arakoda and/or Kodatef for research use (provided such product would not otherwise have been commercially salable, and the study sponsor covers shipping costs). We have previously provided Tafenoquine for such efforts on a limited basis.

We have a post-marketing requirement to conduct a malaria prophylaxis study of Arakoda in pediatric and adolescent subjects. We proposed to the FDA, in late 2021, that this might not be safe to execute given that malaria prevention is administered to asymptomatic individuals and that methemoglobinemia (damage to the hemoglobin in blood that carries oxygen) occurred in 5% of patients, and exceeded a level of 10% in 3% of individuals in a study conducted by another sponsor in pediatric subjects with symptomatic vivax malaria.[32] The FDA has asked us to propose an alternate design, for which we submitted a concept protocol in the fourth quarter of 2022, and plan to submit a full protocol by the end of the second quarter of 2023. We estimate the cost of conducting the study proposed by the FDA, if conducted in the manner suggested by the FDA, would be $2 million, and, due to the time periods required to secure protocol approvals from the FDA and Ethics Committees, could not be initiated any earlier than the third quarter of 2024. The funds from this offering to be expended on such a pediatric study will be limited to the minimum required to support protocol preparation and regulatory interactions with the FDA.

[32] Velez et al 2021 - Lancet Child Adolesc Health 2022; 6: 86–95.

Intellectual Property

We are co-owners, with the U.S. Army, of patents in the United States and certain foreign jurisdictions directed toward use of Tafenoquine for malaria and have obtained an exclusive worldwide license from the U.S. Army to practice these inventions. We also have an exclusive worldwide license to use manufacturing information and non-clinical and clinical data that the U.S. Army possesses relating to use of Tafenoquine for all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. We have submitted patent applications in the United States and certain foreign jurisdictions for use of Tafenoquine for COVID-19, fungal lung infections, tick-borne diseases, and other infectious and non-infectious diseases in which induction of host cytokines/inflammation is a component of the disease process. The United States Patent and Trademark Office ("USPTO") recently allowed our first COVID-19 patent for Tafenoquine. We have optioned or licensed patents involving Celgosivir for the treatment and prevention of Dengue (from the National University of Singapore), COVID-19 & Zika (Florida State University), and have submitted provisional patent applications related to Celgosivir for RSV. We have optioned or own manufacturing methods related to Celgosivir. A detailed list of our intellectual property is as follows:

Patents

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Dosing Regimen For Use Of Celgosivir As An Antiviral Therapeutic For Dengue Virus Infections	2013203400	Australia			2013203400[+]	10-April-2033*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	2014228035	Australia			2014228035	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	MY-170991-A	Malaysia			PI2015002372	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	378015	Mexico			MX/a/2015/013115	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11201507254V	Singapore			11201507254V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	Pending	Singapore	Pending		10201908089V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	9763921	US		9/19/2017	14/772,873	14-Mar-2034^
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	10517854	US		12/31/2019	15/706,845	14-Mar-2034^
Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11219616	US		1/11/2022	16/725,387	14-Mar-2034^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	2015358566	Australia			2015358566	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Canada	Pending		2968694	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	10342791	US		7/9/2019	15/532,280	02-Dec-2035^
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	10888558	US		1/12/2021	16/504,533	02-Dec-2035^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Singapore	Pending		10201904908Q	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	EP	Pending		15865264.4	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Hong Kong	Pending		18103081.4	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	Pending	US	Pending		17/145,530	02-Dec-2035^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	New Zealand	Pending		731813	02-Dec-2035*
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	2016368580	Australia			2016368580	09-Dec-2036*
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	Pending	Singapore	Pending		10201912141Y	09-Dec-2036*
Dosing Regimens Of Celgosivir For The Prevention Of Dengue	11000516	US		5/11/2011	16/060,945	09-Dec-2036^
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	EP	Pending		21764438.4	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	China	Pending		202180029643.7	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	Australia	Pending		2021231743	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	Pending	US	Pending		17/189,544	02-Mar-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Fungus By Administration Of Tafenoquine	Pending	US	Pending		17/683,679	02-Mar-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Sars-Cov-2 Virus By Administration Of Tafenoquine	Pending	US	Pending		17/683,718	02-Mar-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	11369592	US		6/28/2022	17/180,140[#]	19-Feb-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	US	Pending		17/664,693[#]	19-Feb-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	EP	Pending		2021757552[#]	19-Feb-2041*
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof	*Provisional*	US	*Provisional*		63/461,060	~21-Apr-2044[&]
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	*Provisional*	US	*Provisional*		63/358,341	~05-Jul-2043[&]
Methods For The Treatment And Prevention Of Diseases Or Infections With Mcp-1 Involvement By Administration Of Tafenoquine	*Provisional*	US	*Provisional*		63/411,654	~30-Sep-2043[&]
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,328,061[+]	US		6-25-2019	15/584,952[+]	2-May-37
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,561,642[+]	US		2-18-2020	15/856,377[+]	2-May-37

*= For foreign patents and applications, the estimated and/or anticipated patent expiration is the date that is twenty years from the PCT filing date. For all issued Australian patents, this estimated date was also confirmed through the Australian patent office web database.

^= For issued U.S. patents, the estimated patent expiration was calculated using information from the front cover of the patent, *i.e.*, 20 years from the date of the nonprovisional filing plus any listed Patent Term Adjustment less any time disclaimed through a Terminal Disclaimer. For pending U.S. applications, the anticipated patent expiration is the date twenty years from the earliest nonprovisional filing date and does not account for possible Patent Term Adjustment (PTA), Patent Term Extension (PTE), or Terminal Disclaimers.

&= For U.S. provisional applications that are not yet the subject of a nonprovisional or PCT application, the anticipated patent expiration was determined using the assumption that a non-provisional application or PCT will be filed one year after filing the provisional application with a term lasting twenty years from the date of that nonprovisional or PCT filing. This does not account for possible Patent Term Adjustment (PTA), Patent Term Extension (PTE), or Terminal Disclaimers.

+= 60 Degrees Pharmaceuticals, Inc. is not a listed Applicant and Geoffrey S. Dow, Ph.D. is not a listed inventor.

#= 60 Degrees Pharmaceuticals, Inc. is not a listed Applicant, but Geoffrey S. Dow, Ph.D. is a listed inventor.

All patents not designated with a "+" list Geoffrey S. Dow, Ph.D. as an inventor.
All patents not designated with a "+" or a "#" list 60 Degrees Pharmaceuticals, Inc. as an applicant.
All estimated patent expiration dates and anticipated patent expiration assume payment of any maintenance/annuity fees during the patent term.

Trademarks

COUNTRY	MARK	STATUS	APPLICATION NUMBER	DATE FILED	REGISTRATION DATE	REGISTRATION NUMBER	BIR REF NUMBER	DUE DATE	DUE DATE DESCRIPTION
Australia	KODATEF	Registered	1774631	2-Jun-16	6/2/2016	1774631	0081716-000029	**2-Jun-26**	**Renewal Due**
Canada	KODATEF	Registered	1785098	1-Jun-16	11/26/2019	TMA1,064,371	0081716-000028	**26-Nov-29**	**Renewal Due**
Canada	ARAKODA	Registered	1899317	15-May-18	8/20/2020	TMA1,081,180	0081716-000053	**20-Aug-30**	**Renewal Due**
China	KODATEF	Registered	20842242	2-Aug-16	9/28/2017	20842242	0081716-000035	**27-Sep-27**	**Renewal Due**
European Union	KODATEF	Registered	15508872	3-Jun-16	9/21/2016	15508872	0081716-000034	**3-Jun-26**	**Renewal Due**
European Union	ARAKODA	Registered	17900852	16-May-18	9/20/2018	17900852	0081716-000054	**16-May-28**	**Renewal Due**
Israel	KODATEF	Registered	285476	6-Jun-16	6/6/2016	285476	0081716-000033	**6-Jun-26**	**Renewal Due**
New Zealand	KODATEF	Registered	1044407	7-Jun-16	12/8/2016	1044407	0081716-000031	**6-May-26**	**Renewal Due**
Russian Federation	KODATEF	Registered	2016720181	6-Jun-16	7/10/2017	623174	0081716-000032	**6-Jun-26**	**Renewal Due**
Singapore	KODATEF	Registered	40201707950V	2-May-17	11/8/2017	40201707950V	0081716-000040	**2-May-27**	**Renewal Due**
United Kingdom	ARAKODA	Registered	17900852	16-May-18	9/20/2018	UK00917900852	0081716-000054	**16-May-28**	**Renewal Due**
United Kingdom	KODATEF	Registered	15508872	3-Jun-16	9/21/2016	UK009015508872	0081716-000072	**3-Jun-26**	**Renewal Due**
United States of America	TQ 100 & TABLET DESIGN	Registered	87608493	14-Sep-17	9/11/2018	5562900	0081716-000037	**11-Sep-24**	**Section 8 & 15 Due**
United States of America	ARAKODA	Registered	87688137	16-Nov-17	12/31/2019	5950691	0081716-000050	**31-Dec-25**	**Section 8 & 15 Due**
United States of America	KODATEF	Allowed - 02/16/2021	90072885	24-Jul-20			0081716-000069	**16-Aug-23**	**Statement of Use/3rd Extension of Time Due**

Key Relationships & Licenses

On May 30, 2014, we entered into the Exclusive License Agreement (the "2014 NUS-SHS Agreement") with National University of Singapore ("NUS") and Singapore Health Services Pte Ltd ("SHS") in which we were granted a license from NUS and SHS with respect to their share of patent rights regarding "Dosing Regimen for Use of Celgosivir as an Antiviral Therapeutic for Dengue Virus Infection" to develop, market and sell licensed products. The 2014 NUS-SHS Agreement continues in force until the expiration of the last to expire of any patents under the patent rights unless terminated earlier in accordance with the 2014 NUS-SHS Agreement. We are obligated to pay at the rate of 1.5% of gross sales.

On July 15, 2015, we entered into the Exclusive License Agreement with the U.S. Army Medical Materiel Development Activity (the "U.S. Army"), which was subsequently amended (the "U.S. Army Agreement"), in which we obtained a license to develop and commercialize the licensed technology with respect to all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. This exclusion does not impact our ability to market Arakoda for the FDA-approved use, which is the prevention of malaria utilizing the indicated dose in asymptomatic individuals traveling to high-malaria or malaria-prone regions (whereas the license exclusion relates to its use to treat symptomatic vivax malaria in a patient already presenting with that disease). The term of the U.S. Army Agreement will continue until the expiration of the last to expire of the patent application or valid claim of the licensed technology, or 20 years from the start date of the U.S. Army Agreement, unless terminated earlier by the parties. We will be required to make a minimum annual royalty payment of 3% of net sales for net sales < $35 million, and 5% of net sales greater than $35 million, with US government sales excluded from the definition of net sales. In addition, we must pay a milestone fee of $75,000 once cumulative net sales from all sources exceeds $6 million, $100,000 if we are acquired or merge, and regulatory approval milestone payments once marketing authorizations are achieved in Canada ($5,000) and Europe ($5,000). Also, we will be required to obtain the U.S. Army Medical Materiel Development Activity's consent prior to a change of control of the Company, which consent was obtained on September 2, 2022.

On September 15, 2016, we entered into the Exclusive License Agreement (the "2016 NUS-SHS Agreement") with National University of Singapore and Singapore Health Services Pte Ltd ("SHS") in which we were granted a license from NUS and SHS with respect to their share of patent rights regarding "Novel Dosing Regimens of Celgosivir for The Prevention of Dengue" to develop, market and sell licensed products. The 2016 NUS-SHS Agreement continues in force until the expiration of the last to expire of any patents under the patent rights unless terminated earlier in accordance with the 2016 NUS-SHS Agreement. We are obligated to pay at the rate of 1.5% of gross sales or minimum annual royalty ($5,000 in 2022 and $15,000 in 2023). In July 2022, we renegotiated the timing of a license fee of $85,000 Singapore Dollars, payable to NUS, such that payment would be due at the earlier of (i) enrollment of a patient in a Phase II clinical trial involving Celgosivir, (ii) two years from the agreement date and (iii) an initial public offering.

On December 4, 2020, we entered into the Other Transaction Authority for Prototype Agreement ("OTAP Agreement") with the Natick Contracting Division of the U.S. government in which we will, among other things, conduct activities for a Phase II clinical trial to assess the safety and efficacy of Tafenoquine for the treatment of mild to moderate COVID-19 disease, with the goal of delivering Tafenoquine with an FDA Emergency Use Authorization ("EUA") approved as a countermeasure against COVID-19. The total amount of the OTAP Agreement is $4,999,814. The term of the OTAP Agreement commences on December 4, 2020 and was completed in the third quarter of 2022. Pursuant to the OTAP Agreement, we will not offer, sell or otherwise provide the EUA or licensed version of the prototype (Tafenoquine) that is FDA approved for COVID-19 or any like product to any entity at a price lower than that offered to the DoD, which applies only to products sold in the U.S., European Union and Canada related to COVID-19.

On February 15, 2021, we entered into the Inter-Institutional Agreement (the "FSURF Agreement") with the Florida State University Research Foundation ("FSURF") in which FUSRF granted us the right to manage the licensing of intellectual property created at FSURF. The term of the FSURF Agreement expires five years from February 15, 2021. After deduction of a 5% administrative fee by FSURF, capped at $15,000 annually, and reimbursement of patent prosecution expenses, we will receive 20% of license income and FSURF will receive 80% of license income. Payments of license income shall be paid in U.S. dollars quarterly each year. On February 19, 2021, we entered into an agreement with FSURF, subsequently amended on February 15, 2023, that collectively granted an option, effective through August 19, 2023, to us to license methods for purifying castanospermine and its use for the treatment of COVID-19. On August 19, 2021, we entered into an agreement with FSURF, subsequently amended on February 15, 2023, that collectively granted an option, effective through August 19, 2023, to us to license a patent relating to the use of alpha glucosidase inhibitors (including castanospermine and Celgosivir) for treatment of Zika infections.

Pursuant to the Knight Debt Conversion Agreement, for a period commencing on January 1, 2022 and ending upon the earlier of ten years after the closing date of this offering or the conversion or redemption in full of all of the shares of Series A Preferred Stock owned by Knight, we will pay Knight a royalty equal to 3.5% of our net sales, where "net sales" has the same meaning as in our license agreement with the U.S. Army for Tafenoquine. Upon succeeding with the qualified IPO, at the end of the quarter and each thereafter the royalty will be calculated, and payment will be made within fifteen days.

Corporate Structure

60 Degrees Pharmaceuticals, Inc. is a Delaware corporation that was incorporated on June 1, 2022.

On June 1, 2022, 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company ("60P LLC"), entered into the Agreement and Plan of Merger with 60 Degrees Pharmaceuticals, Inc., pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. The value of each outstanding member's membership interest in 60P LLC was correspondingly converted into common stock of 60 Degrees Pharmaceuticals, Inc., par value $0.0001 per share, with a cost-basis equal to $5.00 per share.

Our majority-owned subsidiary, 60P Australia Pty Ltd, an Australian proprietary company limited by shares ("60P Australia"), was formed and registered in Queensland on December 3, 2013, and conducts operations in Australia.

60P Australia previously solely owned a Singaporean subsidiary company, 60P Singapore Pte. Ltd., which dissolved at our election in the second quarter of 2022.

Going Concern

Our independent auditors have issued a report raising substantial doubt of our ability to continue as a going concern. We anticipate that we will require additional capital to continue as a going concern and expand our operations in accordance with our current business plan.

Suppliers

We have quality and contract manufacturing agreements relating to Arakoda in place with Piramal Enterprises Limited (API, tablets) and PCI Pharma Services (secondary packaging) ("PCI") and supply/quality/pharmacovigilance agreements in place with Biocelect Pty Ltd, Scandinavian Biopharma, and Knight Therapeutics Inc. (to allow supply of Arakoda/Kodatef to Australia, Europe and Canada/Israel/Latin America and Russia, respectively). As of the date of this prospectus, we have not supplied any of our products to Russia nor do we anticipate supplying any of our products to Russia in the near future.

Recent Developments

Effects of COVID-19 Outbreak. In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China, which has and is continuing to spread throughout China and other parts of the world, including the United States. On January 30, 2020, the World Health Organization declared the outbreak of COVID-19 a "Public Health Emergency of International Concern." On January 31, 2020, U.S. Health and Human Services Secretary Alex M. Azar II declared a public health emergency for the United States to aid the U.S. healthcare community in responding to COVID-19, and on March 11, 2020 the World Health Organization characterized the outbreak as a "pandemic." A significant outbreak of COVID-19 and other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide.

We are monitoring the global outbreak and spread of COVID-19 and taking steps in an effort to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and the governmental and community reactions thereto. The current outbreak of COVID-19 has globally resulted in loss of life, business closures, restrictions on travel, and widespread cancellation of social gatherings. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted at this time, including:

- new information which may emerge concerning the severity of the disease;

- the duration and spread of the outbreak;
- the severity of travel restrictions imposed by geographic areas in which we operate, mandatory or voluntary business closures;
- regulatory actions taken in response to the pandemic, which may impact our product offerings;
- other business disruptions that affect our workforce and supply chain;
- the impact on capital and financial markets; and
- actions taken throughout the world, including in markets in which we operate, to contain the COVID-19 outbreak or treat its impact.

In addition, the current outbreak of COVID-19 has resulted in a widespread global health crisis and adversely affected global economies and financial markets, and similar public health threats could do so in the future. Such events have impacted, and could in the future impact, demand for our products, which in turn could adversely affect our revenue and results of operations.

The spread of COVID-19 has caused us to modify our business practices, including employee travel, employee work locations in certain cases, and cancellation of physical participation in certain meetings, events and conferences and further actions may be taken as required or recommended by government authorities or as we determine are in the best interests of our employees, customers and other business partners. We are monitoring the global outbreak of the pandemic and are taking steps in an effort to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and the governmental and community reactions thereto. See "*Risk Factors—Our financial condition and results of operations may be adversely affected by the COVID-19 pandemic*."

2023 Financings

On May 8, 2023, we issued a note in the amount of $111,111.10 to Cyberbahn Federal Solutions, LLC with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Cyberbahn Federal Solutions, LLC shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Ariana Bakery Inc with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Ariana Bakery Inc shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $333,333.30 to Sabby Volatility Warrant Master Fund, Ltd. with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Sabby Volatility Warrant Master Fund, Ltd. shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $55,555.55 to Steel Anderson with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Steel Anderson shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Bixi Gao & Ling Ling Wang with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Bixi Gao & Ling Ling Wang shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

Summary Risk Factors

Our business is subject to a number of risks. You should be aware of these risks before making an investment decision. These risks are discussed more fully in the section of this prospectus titled "*Risk Factors*," which begins on page 18 of this prospectus. These risks include, among others, that:

- Our financial statements have been prepared on a going-concern basis and our continued operations are in doubt;
- We have incurred net losses since our inception and if we continue to incur net losses in the foreseeable future, the market price of our common stock may decline;
- There is no assurance that we will be profitable;
- There is no assurance that we will be eligible for Australian government research and development tax rebates;
- Our financial condition and results of operations may be adversely affected by the COVID-19 pandemic;
- If we are not able to successfully develop, obtain FDA approval for, and provide for the commercialization of non-malaria prevention indications for Tafenoquine (Arakoda or other regimen) or Celgosivir in a timely manner, we may not be able to expand our business operations;
- Our clinical trials for our product candidates may not yield results that will enable us to further develop our products and obtain regulatory approvals necessary to sell them;

- The mechanisms of actions of some of our products, and interactions with other antiviral products are not known, which may restrict regulatory label claims;

- We expect to depend on existing and future collaborations with third parties for the development of some of our product candidates. If those collaborations are not successful, we may not be able to complete the development of these product candidates;

- Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable;

- Any future clinical trial for Arakoda will require screening for G6PD deficiency in order to safely administer the product. In the United States, G6PD testing can obtained through commercial pathology services which is associated with delays. The use of a third-party diagnostic provider of point of care testing may be required and we do not directly control the timing, conduct, expense of such testing or the timing of market entry into the US;

- Our product candidates are subject to extensive regulation, which can be costly and time-consuming, and unsuccessful or delayed regulatory approvals could increase our future development costs or impair our future revenue;

- If our product candidates receive regulatory approval, we would be subject to ongoing regulatory obligations and restrictions, which will continue to change, and which may result in significant expenses and limit our ability to develop and commercialize other potential products;

- We have no manufacturing capacity which puts us at risk of lengthy and costly delays of bringing our products to market;

- We rely on relationships with third-party contract manufacturers and raw material suppliers, which limits our ability to control the availability of, and manufacturing costs for, our product candidates;

- Our future growth depends on our ability to successfully commercialize Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir and our other product candidates, and we can provide no assurance that we will successfully commercialize Arakoda, Tafenoquine (Arakoda or other regimen) for non-malaria prevention indications, Celgosivir and other product candidates;

- Health care reform measures could materially and adversely affect our business;

- Our competitors may be better positioned in the marketplace and thereby may be more successful than us at developing, manufacturing and marketing approved products;

- We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive;

- We would be subject to applicable regulatory approval requirements of the foreign countries in which we market our products, which are costly and may prevent or delay us from marketing our products in those countries;
- Defending against claims relating to improper handling, storage or disposal of hazardous chemicals, radioactive or biological materials could be time consuming and expensive;

- Geopolitical conditions, including direct or indirect acts of war or terrorism could have an adverse effect on our operations and financial results;

- If product liability lawsuits are successfully brought against us, then we will incur substantial liabilities and may be required to limit commercialization of Arakoda, Celgosivir or other product candidates;

- Our intellectual property rights may not preclude competitors from developing competing products and our business may suffer;

- If the manufacture, use or sale of our products infringe on the intellectual property rights of others, we could face costly litigation, which could cause us to pay substantial damages or licensing fees and limit our ability to sell some or all of our products;
- We may not be able to protect our intellectual property rights throughout the world;
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- The earliest Paragraph IV certification date for Arakoda has passed. Generic companies may file an ANDA at any time, and successful challenge of our malaria use patents would negatively impact our business;
- There has been no public market for our common stock prior to this offering, and we cannot assure you that an active trading market will develop in the near future. An active market in which investors can resell their shares may not develop. If there is no viable public market for our common stock, you may be unable to sell your shares at or above the initial public offering price;
- We may not be able to satisfy listing requirements of Nasdaq to maintain a listing of our common stock or Tradeable Warrants;
- There is no public market for the Non-tradeable Warrants being offered in this offering;
- The warrants may have an adverse effect on the market price of our common stock and make it more difficult to effect a business combination;
- Any failure to maintain effective internal controls over financial reporting could have an adverse impact on us; and
- We are an "emerging growth company" and a "smaller reporting company" under the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

Information Regarding our Capitalization

As of June 1, 2023, we had 2,378,009 shares of common stock issued and outstanding. Additional information regarding our issued and outstanding securities may be found under "*Market for Common Equity and Related Stockholder Matters*" and "*Description of Securities*."

Unless otherwise specifically stated, information throughout this prospectus does not assume the exercise of outstanding options or warrants to purchase shares of our common stock.

Corporate Information

Our principal executive offices are located at 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036. Our corporate website address is *60degreespharma.com*. Our telephone number is (202) 327-5422. The information included on our website is not part of this prospectus.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act; (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure requirements that are applicable to other public companies that are not emerging growth companies.

These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" disclosure;
- not being required to comply with the requirement of auditor attestation of our internal controls over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

An emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act to comply with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the dates on which adoption of such standards is required for other public reporting companies.

We are also a "smaller reporting company" as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and have elected to take advantage of certain of the scaled disclosure available for smaller reporting companies. We will remain a smaller reporting company until the end of the fiscal year in which (1) we have a public common equity float of more than $250 million, or (2) we have annual revenues for the most recently completed fiscal year of more than $100 million and a public common equity float or public float of more than $700 million. We also would not be eligible for status as a smaller reporting company if we become an investment company, an asset-backed issuer or a majority-owned subsidiary of a parent company that is not a smaller reporting company.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

THE RESALE OFFERING

Common stock offered	2,224,763 shares
Shares of common stock outstanding before this offering	2,378,009 shares.
Shares of common stock outstanding after this offering	5,569,528 shares[(1)]
Use of proceeds	We will not receive any proceeds from the sale of common stock held by the Selling Stockholder being registered in this prospectus.
Proposed Trading Symbol	We have applied to list our common stock and Tradeable Warrants for trading on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively. The initial public offering, and therefore this resale offering, will not be consummated until we have received Nasdaq's approval of our application for the listing of our common stock and Tradeable Warrants. No assurance can be given that our application will be approved.
Risk factors	An investment in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 18 of the primary offering prospectus contained in the registration statement of which this prospectus forms a part, and other information included in this prospectus and the registration statement of which this prospectus forms a part, for a discussion of factors you should carefully consider before deciding to invest in our common stock.

(1) Assumes the issuance and sale by us of 1,415,095 shares of our common stock underlying the units, pursuant to the primary offering prospectus filed contemporaneously herewith and assumes the 212,265 over-allotment options available for sale to the underwriters in the primary offering prospectus have not been exercised. In addition, assumes the issuance of (i) 29,245 shares of our common stock issued to BioIntelect Pty Ltd ("BioIntelect") pursuant to the Master Consultancy Agreement dated as of May 29, 2013 (the "BioIntelect Agreement"), which provides that in connection with our initial public offering, BioIntelect will be entitled to receive deferred equity compensation in the amount equal to $155,000 (or $245,000 if Australian VC Horizon Biotech participates in the offering), (ii) 1,108,337 shares of our common stock that are to be issued to Knight Therapeutics International S.A. (formerly known as Knight Therapeutics (Barbados) Inc.) ("Knight") determined by dividing the outstanding principal amount as of March 31, 2022 of $10,770,037 by the public offering price discounted by 15%, up to 19.9% of our outstanding common stock after giving effect to the initial public offering, for a total value of common shares to be issued of $5,874,186 pursuant to the Debt Conversion Agreement dated as of January 9, 2023, as amended on January 19, 2023 and January 27, 2023 (the "Knight Debt Conversion Agreement"), (iii) 383,908 shares of our common stock that are to be issued prior to the closing of this offering as a result of either the conversion or extinguishment of our convertible promissory notes totaling $1,949,991 excluding the Xu Yu Equity Conversion Note, (iv) 214,934 shares of our common stock that are to be issued prior to the closing of this offering as a result of the conversion of certain debt totaling $1,164,190 pursuant to the Equity Conversion Note dated as of October 11, 2017, as amended on December 23, 2017 and December 11, 2022 (the "Xu Yu Equity Conversion Note") entered into with Xu Yu and (v) 40,000 shares of our common stock valued at $5.00 per share that are to be issued to four of our directors on the date of effectiveness of the registration statement of which this prospectus forms a part.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the common stock held by the Selling Stockholders.

SELLING STOCKHOLDERS

This prospectus relates to the sale or other disposition of up to 2,224,763 shares of our common stock by the Selling Stockholders and their donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a Selling Stockholder as a gift, pledge, partnership distribution or other transfer.

The table below sets forth information as of the date of this prospectus, to our knowledge, the Selling Stockholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) of the shares of common stock held by the Selling Stockholders. The second column lists the number of shares of common stock beneficially owned by the Selling Stockholders, as of April 27, 2023. The third column lists the maximum number of shares of common stock that may be sold or otherwise disposed of by the Selling Stockholders pursuant to the registration statement of which this prospectus forms a part. The Selling Stockholders may sell or otherwise dispose of some, all or none of their shares. Pursuant to Rules 13d-3 and 13d-5 of the Exchange Act, beneficial ownership includes any shares of our common stock as to which a stockholder has sole or shared voting power or investment power, and also any shares of our common stock which the stockholder has the right to acquire within 60 days.

The percentage of beneficial ownership for the Selling Stockholders is based on shares of common stock outstanding as of the date of this prospectus, which gives effect to: the issuance of (i) 29,245 shares of our common stock issued to BioIntelect pursuant to the BioIntelect Agreement, which provides that in connection with our initial public offering, BioIntelect will be entitled to receive deferred equity compensation in the amount equal to $155,000 (or $245,000 if Australian VC Horizon Biotech participates in the offering), (ii) 1,064,545 shares of our common stock issued to Knight as a result of the conversion of certain of our outstanding debt owed to Knight pursuant to the Knight Debt Conversion Agreement, (iii) 383,908 shares of our common stock that are to be issued prior to the closing of this offering as a result of either the conversion or extinguishment of our convertible promissory notes excluding the Xu Yu Equity Conversion Note, (iv) 214,934 shares of our common stock that are to be issued prior to the closing of this offering pursuant to the Xu Yu Equity Conversion Note entered into with Xu Yu and (v) 40,000 shares of our common stock that are to be issued to four of our directors on the date of effectiveness of the registration statement of which this prospectus forms a part.

Except as described below, to our knowledge, none of the Selling Stockholders have had any material relationship with us within the past three years. Our knowledge is based on information provided by the Selling Stockholders in registration statement questionnaires.

The shares of common stock being covered hereby may be sold or otherwise disposed of from time to time during the period the registration statement of which this prospectus is a part remains effective, by or for the account of the Selling Stockholders. After the date of effectiveness of the registration statement of which this prospectus forms a part, the Selling Stockholders may have sold or transferred, in transactions covered by this prospectus, some or all of their common stock.

Information about the Selling Stockholders may change over time. Any changed information will be set forth in an amendment to the registration statement or supplement to this prospectus, to the extent required by law.

	Shares Beneficially Owned as of the date of this Prospectus		Shares Offered by this	Shares Beneficially Owned After the Offering[1]	
Name of Selling Stockholder	**Number**	**Percent**	**Prospectus**	**Number**	**Percent**
Geoffrey S. Dow Revocable Trust[2]	667,143	28.05%	10,482	703,107	12.57%
Douglas Loock[3]	165,938	6.98%	165,938	0	0%
Carmel, Milazzo & Feil LLP[4]	100,000	4.21%	100,000	0	0%
Florida State University Research Foundation, Inc.[5]	405,000	17.03%	405,000	0	0%
Latham BioPharm Group, LLC[6]	65,000	2.73%	65,000	0	0%
Trevally, LLC[7]	120,000	5.05%	120,000	0	0%
Edward Newland	8,500	*%	8,500	0	0%
4C Pharma Solutions, LLC[8]	54,000	2.27%	54,000	0	0%
Hybrid Financial Ltd.[9]	65,000	2.73%	65,000	0	0%
Sheila Burke[10]	20,000	*%	20,000	0	0%
Kentucky Technology Inc.[11]	525,000	22.08%	525,000	0	0%
Mountjoy Trust[12]	0	0%	69,444	100,891	1.78%
Walleye Opportunities Master Fund Ltd.[13]	0	0%	52,411	78,616	1.39%
Bigger Capital Fund, LP[14]	0	0%	62,893	94,340	1.66%
Cavalry Investment Fund, LP.[15]	0	0%	52,411	78,616	1.39%
Cyberbahn Federal Solutions, LLC[16]	0	0%	20,964	31,446	*%
Ariana Bakery Inc[17]	0	0%	20,964	31,446	*%
Sabby Volatility Warrant Master Fund, Ltd.[18]	0	0%	62,893	94,340	1.66%
Steel Anderson[19]	0	0%	10,482	15,723	*%
Bixi Gao & Ling Ling Wang[20]	0	0%	20,964	31,446	*%
Ludlow Business Services, Inc.[21]	37,500	1.58%	37,500	0	0%
Elliot Berman	30,000	1.26%	30,000	0	0%
Delve Innovation Pty Ltd[22]	13,000	*%	13,000	0	0%

* Less than 1%.

(1) Assumes the sale of all shares offered pursuant to the primary offering prospectus, except that those issued to the Geoffrey S. Dow Revocable Trust upon mandatory conversion of the Geoffrey Dow Trust Note which will subject to a lock-up agreement.

(2) Geoffrey S. Dow Revocable Trust owns 667,143 shares as of the date of this prospectus, and will be issued 10,482 shares upon mandatory conversion of a convertible note issued to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 immediately prior to the consummation of the initial public offering. All 677,625 shares will be subject to lock-up. Geoffrey Dow has voting and dispositive control over the shares held by the Geoffrey S. Dow Revocable Trust. Shares beneficially owned after the offering includes 10,482 shares of common stock issuable upon exercise of warrants issued to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 and 15,000 shares of common stock issuable upon exercise of options issued to Geoffrey Dow on the Nasdaq listing date of our common stock and tradeable warrants pursuant to Geoffrey Dow's executive employment agreement. The 10,482 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part.

(3) Douglas Loock is one of our former directors.

(4) Carmel, Milazzo & Feil LLP is our legal counsel, of which is controlled by Ross D. Carmel, Esq.

(5) Florida State University Research Foundation Inc. provides research and development services to us. Stacey Peterson has voting and dispositive control over the shares held by Florida State University Research Foundation Inc. The principal address of Florida State University Research Foundation Inc. is 2000 Levy Avenue, Building A, Suite 351, Tallahassee, FL 32310.

(6) Latham BioPharm Group, LLC provides research and development services to us. Matthieu Courtecuisse has voting and dispositive control over the shares held by Latham BioPharm Group, LLC. The principal address of Latham BioPharm Group, LLC is 6810 Deerpath Road, Suite 405, Elkridge, MD 21075.

(7) Trevally, LLC provides research chemicals to us. Gary Ostrander and Eric Holmes have shared equal voting and dispositive control over the shares held by Trevally, LLC. The principal address of Trevally, LLC is 8999 Winged Foot Drive, Tallahassee, FL 32312.

(8) Yathendra Kumar Madineni is the Chief Executive Officer of 4C Pharma Solutions LLC and has voting and dispositive control over the shares held by 4C Pharma Solutions LLC. The principal address of 4C Pharma Solutions LLC is 15 Corporate Place South, Suite 110, Piscataway, NJ 08854. 4C Pharma Solutions LLC provides pharmacovigilance services for us.

(9) Hybrid Financial Ltd. provides investor relations services to us following the IPO. Steven Marshall has voting and dispositive control over the shares held by Hybrid Financial Ltd. The principal address of Hybrid Financial Ltd. is 222 Bay Street, Suite 2600, PO 37, Toronto, ON M5K 1B7.

(10) Method Health Communications LLC provides public relations services to us, of which Sheila Burke is the president.

(11) Kentucky Technology Inc. provides research and development services to us. Kentucky Technology Inc.'s Board of Directors has voting and dispositive control over the shares held by Kentucky Technology Inc. The members of the Board of Directors of Kentucky Technology Inc. are Kevin Adkins, Lisa Cassis, Nancy Cox, Penny Cox, Judy Duncan, John Farris, Taunya Phillips, Gene Strong and George Ward. Because the Board of Directors acts by consensus and majority approval, none of the members of Kentucky Technology Inc.'s Board of Directors has individual voting or dispositive control with respect to such shares. The principal address of Kentucky Technology Inc. is 824 Bull Lea Run, Suite 2100, Lexington, KY 40511.

(12) On the effective date of the registration statement of which this prospectus forms a part, we will issue (i) 69,444 shares of our common stock to the Mountjoy Trust as a result of the conversion of the Convertible Promissory Note we issued to Mountjoy Trust on May 19, 2022 and (ii) warrants to purchase 69,444 shares of our common stock. Shares beneficially owned after the offering includes 69,444 shares of common stock issuable upon exercise of the warrants. The 69,444 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 69,444 shares of common stock and 69,444 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus. John Dow has voting and dispositive control over the shares held by the Mountjoy Trust.

(13) On the effective date of this registration statement of which this prospectus forms a part, we will issue (i) 52,411 shares of our common stock to Walleye Opportunities Master Fund Ltd. as a result of the conversion of the Convertible Promissory Note we issued to Walleye Opportunities Master Fund Ltd. on May 24, 2022 and (ii) warrants to purchase 26,205 shares of our common stock. Shares beneficially owned after the offering includes 26,205 shares of common stock issuable upon exercise of the warrants. The 26,205 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 52,411 shares of common stock and 26,205 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus. William England has voting and dispositive control over the shares held by Walleye Opportunities Master Fund Ltd. The principal address of Walleye Opportunities Master Fund Ltd. is 2800 Niagara Ln. N., Plymouth, MN 55447.

(14) On the effective date of this registration statement of which this prospectus forms a part, we will issue (i) 62,893 shares of our common stock to Bigger Capital Fund, LP as a result of the conversion of the Convertible Promissory Note we issued to Bigger Capital Fund, LP on May 24, 2022 and (ii) warrants to purchase 31,447 shares of our common stock. Shares beneficially owned after the offering includes 31,447 shares of common stock issuable upon exercise of the warrants. The 31,447 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 62,893 shares of common stock and 31,447 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus. Michael Bigger has voting and dispositive control over the shares held by Bigger Capital Fund, LP. The principal address of Bigger Capital Fund, LP is 11700 West Charleston Blvd. #170-659, Las Vegas, NV 89135.

(15) On the effective date of this registration statement of which this prospectus forms a part, we will issue (i) 52,411 shares of our common stock to Cavalry Investment Fund, LP. as a result of the conversion of the Convertible Promissory Note we issued to Cavalry Investment Fund, LP. on May 24, 2022 and (ii) warrants to purchase 26,205 shares of our common stock. Shares beneficially owned after the offering includes 26,205 shares of common stock issuable upon exercise of the warrants. The 26,205 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 52,411 shares of common stock and 26,205 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus. Thomas Walsh has voting and dispositive control over the shares held by Cavalry Investment Fund, LP. The principal address of Cavalry Investment Fund, LP. Is 82 E. Allendale Rd., Ste 5B Saddle River, NJ 07458.

(16) On the effective date of this registration statement of which this prospectus forms a part, we will issue (i) 20,964 shares of our common stock to Cyberbahn Federal Solutions, LLC as a result of the conversion of the Convertible Promissory Note we issued to Cyberbahn Federal Solutions, LLC on May 8, 2023 and (ii) warrants to purchase 10,482 shares of our common stock. Shares beneficially owned after the offering includes 10,482 shares of common stock issuable upon exercise of the warrants. The 10,482 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 20,964 shares of common stock and 10,482 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus. Jamuna Sundararajan has voting and dispositive control over the shares held by Cyberbahn Federal Solutions, LLC. The principal address of Cyberbahn Federal Solutions, LLC is 4601 N. Fairfax Drive Ste. 1200, Arlington, VA 22203.

(17) On the effective date of this registration statement of which this prospectus forms a part, we will issue (i) 20,964 shares of our common stock to Ariana Bakery Inc as a result of the conversion of the Convertible Promissory Note we issued to Ariana Bakery Inc on May 8, 2023 and (ii) warrants to purchase 10,482 shares of our common stock. Shares beneficially owned after the offering includes 10,482 shares of common stock issuable upon exercise of the warrants. The 10,482 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 20,964 shares of common stock and 10,482 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus. Abdullah Rasool has voting and dispositive control over the shares held by Ariana Bakery Inc. The principal address of Ariana Bakery Inc is 9104 Manassas Dr Unit I, Manassas Park, VA 20111, USA.

(18) On the effective date of this registration statement of which this prospectus forms a part, we will issue (i) 62,893 shares of our common stock to Sabby Volatility Warrant Master Fund, Ltd. (“Sabby”) as a result of the conversion of the Convertible Promissory Note we issued to Sabby on May 8, 2023 and (ii) warrants to purchase 31,447 shares of our common stock. Shares beneficially owned after the offering includes 31,447 shares of common stock issuable upon exercise of the warrants. The 31,447 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 62,893 shares of common stock and 31,447 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus. Sabby Management, LLC is the investment manager of Sabby and shares voting and investment power with respect to these shares in this capacity. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of Sabby. Each of Sabby Management, LLC and Mr. Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein. The principal address of Sabby Volatility Warrant Master Fund, Ltd. is 115 Hidden Hills Dr., Spicewood, TX 78669.

(19) On the effective date of this registration statement of which this prospectus forms a part, we will issue (i) 10,482 shares of our common stock to Steel Anderson as a result of the conversion of the Convertible Promissory Note we issued to Steel Anderson on May 8, 2023 and (ii) warrants to purchase 5,241 shares of our common stock. Shares beneficially owned after the offering includes 5,241 shares of common stock issuable upon exercise of the warrants. The 5,241 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 10,482 shares of common stock and 5,241 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus.

(20) On the effective date of this registration statement of which this prospectus forms a part, we will issue (i) 20,964 shares of our common stock to Bixi Gao & Ling Ling Wang as a result of the conversion of the Convertible Promissory Note we issued to Bixi Gao & Ling Ling Wang on May 8, 2023 and (ii) warrants to purchase 10,482 shares of our common stock. Shares beneficially owned after the offering includes 10,482 shares of common stock issuable upon exercise of the warrants. The 10,482 shares of common stock underlying the warrants are being registered in the registration statement of which this prospectus forms a part. All 20,964 shares of common stock and 10,482 shares of common stock issuable upon exercise of the warrant will be subject to a 90 day lock-up from the date of this prospectus.

(21) Ludlow Business Services, Inc. provides investor relations services to us. Patrick Gaynes has voting and dispositive control over the shares held by Ludlow Business Services, Inc. The principal address of Ludlow Business Services, Inc. is 1632 1st Ave #20260, New York, NY 10028.

(22) Delve Innovation Pty Ltd provides consulting services to us. David Mason and Tracey Murray have voting and dispositive control over the shares held by Delve Innovation Pty Ltd. The principal address of Delve Innovation Pty Ltd is Level 29, 12 Creek Street, Comalco Place, Brisbane City QLD 4000, Australia.

SELLING STOCKHOLDER PLAN OF DISTRIBUTION

The Selling Stockholders may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The Selling Stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a Selling Stockholder. The Selling Stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing or amending the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus.

The Selling Stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing or amending the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus.

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares of common stock held by the Selling Stockholders or its transferees, pledgees or other successors in interest may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of common stock held by the Selling Stockholders. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The Selling Stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of common stock by any Selling Stockholder. If we are notified by any Selling Stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of his, her, or its common stock, if required, we will file a supplement to this prospectus. If the Selling Stockholders use this prospectus for any sale of their shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

In order to comply with the securities laws of some states, if applicable, the common stock held by the Selling Stockholders or its transferees, pledgees or other successors in interest may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the Selling Stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the Selling Stockholders and their affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the Selling Stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Selling Stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed with the Selling Stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earliest of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement and (2) the date on which all of the shares may be sold without restriction pursuant to Rule 144 of the Securities Act.

LEGAL MATTERS

Certain legal matters with respect to the validity of the securities being offered by this prospectus will be passed upon by Carmel, Milazzo & Feil LLP, New York, New York.

2,224,763 Shares of Common Stock

60 Degrees Pharmaceuticals, Inc.

RESALE PROSPECTUS

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is correct only as of the date of this prospectus, regardless of the time of the delivery of this prospectus or the sale of these securities.

, 2023

Part II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission ("SEC") registration fee and the Financial Industry Regulatory Authority, Inc. ("FINRA") filing.

	Amount
Securities and Exchange Commission registration fee	$ 5,410.37
FINRA filing fee	7,864.39
NASDAQ listing fee	75,000
Accountants' fees and expenses	140,000
Legal fees and expenses	200,000
Printing and engraving expenses	10,500
Miscellaneous	11,999.24
Total expenses	$ 450,774

Item 14. Indemnification of Directors and Officers.

Section 102 of the General Company Law of the State of Delaware ("DGCL") permits a company to eliminate the personal liability of directors of a company to the company or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our charter provides that none of our directors shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a company has the power to indemnify a director, officer, employee, or agent of the company, or a person serving at the request of the company for another company, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the company, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the company, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the company unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our charter provides that we will indemnify to the fullest extent permitted from time to time by the DGCL or any other applicable laws as presently or hereafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, including, without limitation, an action by or in the right of the Company, by reason of his acting as a director or officer of the Company or any of its subsidiaries (and the Company, in the discretion of the Board, may so indemnify a person by reason of the fact that he is or was an employee or agent of the Company or any of its subsidiaries or is or was serving at the request of the Company in any other capacity for or on behalf of the Company) against any liability or expense actually and reasonably incurred by such person in respect thereof. Note that for liabilities arising under the Securities Act, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933 (the "Securities Act"), against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding securities issued by us within the last three years which were not registered under the Securities Act of 1933, as amended.

(a) Issuance of Capital Stock.

- On June 1, 2022, 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company ("60P LLC"), entered into the Agreement and Plan of Merger with 60 Degrees Pharmaceuticals, Inc., a Delaware corporation, pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. (the "Company"). The value of each outstanding members' membership interest in 60P LLC was automatically converted into common stock of the Company, par value $0.0001 per share, with a cost-basis equal to $5.00 per share.

- We issued 37,067 shares to Geoffrey Dow (at $5.00 per share) on August 28, 2022 in recognition of capital contributions of $185,335 made between January 1, 2022 and April 1, 2022. There are no other outstanding related party debt or obligations.

- On January 2, 2023, we issued a total of 100,000 shares of our common stock to our legal counsel for payment of certain legal fees.

- On January 21, 2023, we cancelled 1,240,682 common shares owned by the Geoffrey S. Dow Revocable Trust.

- On January 21, 2023, we cancelled 189,318 common shares owned by Tyrone Miller.

- On January 26, 2023, we issued 405,000 shares of our common stock to Florida State University Research Foundation Inc. in exchange for its research and development services.

- On January 26, 2023, we issued 65,000 shares of our common stock to Latham BioPharm Group, LLC in exchange for its research and development services.

- On January 26, 2023, we issued 120,000 shares of our common stock to Trevally, LLC in exchange for provision of research chemicals.

- On January 26, 2023, we issued 8,500 shares of our common stock to ENA Healthcare Communications, LLC in exchange for marketing services.

- On January 26, 2023, we issued 54,000 shares of our common stock to 4C Pharma Solutions, LLC in exchange for the cancellation of debt and credit for pharmacovigilance services to be provided.

- On January 26, 2023, we issued 65,000 shares of our common stock to Hybrid Financial in exchange for its investor relations services.

- On January 26, 2023, we issued 20,000 shares of our common stock to Sheila Burke in exchange for public relations services provided by Method Health Communications LLC.

- On January 26, 2023, we issued 525,000 shares of our common stock to University of Kentucky School of Pharmacy in exchange for its research and development services.

- On January 26, 2023, we issued 37,500 shares of our common stock to Ludlow Business Services, Inc. in exchange for its investor relations services.

- On January 26, 2023, we issued 30,000 shares of our common stock to Elliot Berman in exchange for accounting services provided by Berman Accounting & Advisory P.A.

- On March 19, 2023, we issued 13,000 shares of our common stock to Delve Innovation Pty Ltd in exchange for its research and development services.

- On March 22, 2023, we cancelled 18,217 shares of our common stock owned by Geoffrey Dow.

- On March 22, 2023, we cancelled 2,783 shares of our common stock owned by Ty Miller.

- On the effective date of this registration statement, we issued 10,482 of our common stock to Geoffrey S. Dow Revocable Trust as a result of the conversion of the Convertible Promissory Note we issued to the Geoffrey S. Dow Revocable Trust on May 19, 2022 (the "Geoffrey S. Dow Revocable Trust Note").

- On the effective date of this registration statement, we issued 69,444 shares of our common stock to Mountjoy Trust as a result of the conversion of the Convertible Promissory Note we issued to Mountjoy Trust on May 19, 2022 (the "Mountjoy Note").

- On the effective date of this registration statement, we issued 52,411 shares of our common stock to Walleye Opportunities Master Fund Ltd. as a result of the conversion of the Convertible Promissory Note we issued to Walleye Opportunities Master Fund Ltd. on May 24, 2022 (the "Walleye Note").

- On the effective date of this registration statement, we issued 62,893 shares of our common stock to Bigger Capital Fund, LP as a result of the conversion of the Convertible Promissory Note we issued to Bigger Capital Fund, LP on May 24, 2022 (the "Bigger Capital Fund Note").

- On the effective date of this registration statement, we issued 52,411 shares of our common stock to Cavalry Investment Fund, LP. as a result of the conversion of the Convertible Promissory Note we issued to Cavalry Investment Fund, LP. on May 24, 2022 (the "Cavalry Note").

- On the effective date of this registration statement, we issued 20,964 shares of our common stock to Cyberbahn Federal Solutions, LLC. as a result of the conversion of the Convertible Promissory Note we issued to Cyberbahn Federal Solutions, LLC on May 8, 2023 (the "Cyberbahn Note").

- On the effective date of this registration statement, we issued 20,964 shares of our common stock to Ariana Bakery Inc as a result of the conversion of the Convertible Promissory Note we issued to Ariana Bakery Inc on May 8, 2023 (the "Ariana Note").

- On the effective date of this registration statement, we issued 62,893 shares of our common stock to Sabby Volatility Warrant Master Fund, Ltd. as a result of the conversion of the Convertible Promissory Note we issued to Sabby Volatility Warrant Master Fund, Ltd. on May 8, 2023 (the "Sabby Note").

- On the effective date of this registration statement, we issued 10,482 shares of our common stock to Steel Anderson as a result of the conversion of the Convertible Promissory Note we issued to Steel Anderson on May 8, 2023 (the "Anderson Note").

- On the effective date of this registration statement, we issued 20,964 shares of our common stock to Bixi Gao & Ling Ling Wang as a result of the conversion of the Convertible Promissory Note we issued to Bixi Gao & Ling Ling Wang on May 8, 2023 (the "Gao & Wang Note").

The issuance of the capital stock listed above was deemed exempt from registration under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder in that the issuance of securities were made to an accredited investor and did not involve a public offering. The recipient of such securities represented its intention to acquire the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof.

(b) Warrants.

On May 19, 2022, we issued to Geoffrey Dow a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to (i) the total number of common stock issued to Geoffrey Dow as a result of the conversion of the Dow Note, which will occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price, or (ii) if we fail to complete the initial public offering prior to May 31, 2023, 90% of the initial public offering price.

On May 19, 2022, we issued to Mountjoy Trust a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to (i) the total number of common stock issued to Mountjoy Trust as a result of the conversion of the Mountjoy Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price, or (ii) if we fail to complete the initial public offering prior to May 31, 2023, 90% of the initial public offering price.

On May 24, 2022, we issued to Bigger Capital Fund, LP a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Bigger Capital Fund, LP as a result of the conversion of the Bigger Capital Fund Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 24, 2022, we issued to Cavalry Investment Fund, LP a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Cavalry Investment Fund, LP as a result of the conversion of the Cavalry Investment Fund Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 24, 2022, we issued to Walleye Opportunities Master Fund Ltd a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Walleye Opportunities Master Fund Ltd as a result of the conversion of the Walleye Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 8, 2023, we issued to Cyberbahn Federal Solutions, LLC a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Cyberbahn Federal Solutions, LLC as a result of the conversion of the Cyberbahn Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 8, 2023, we issued to Ariana Bakery Inc a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Ariana Bakery Inc as a result of the conversion of the Ariana Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 8, 2023, we issued to Sabby Volatility Warrant Master Fund, Ltd. a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Sabby Volatility Warrant Master Fund, Ltd. as a result of the conversion of the Sabby Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 8, 2023, we issued to Steel Anderson a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Steel Anderson as a result of the conversion of the Anderson Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 8, 2023, we issued to Bixi Gao & Ling Ling Wang a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Bixi Gao & Ling Ling Wang as a result of the conversion of the Gao & Wang Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

The warrants described above were deemed exempt from registration in reliance on Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder in that the issuance of securities were made to an accredited investor and did not involve a public offering. The recipients of such securities represented its intention to acquire the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof.

(c) Option Grants.

None.

(d) Issuance of Notes.

On May 14, 2020, we issued the Note to the U.S. Small Business Administration with a principal amount of $150,000 and a per annum interest rate of 3.75%.

On May 19, 2022, we issued the Convertible Promissory Note to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 on May 19, 2022 (the "Dow Note"), in the amount of $44,444.44 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of the Dow Note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 19, 2022, we issued the Mountjoy Note in the amount of $294,444.42 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of the Mountjoy Note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 24, 2022, we issued the Bigger Capital Fund Note in the amount of $333,333.30 to Bigger Capital Fund, LP. On the date of the pricing of our initial public offering, we will deliver to Bigger Capital Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of common stock calculated using a $27 million pre-money valuation and the number of outstanding shares of common stock on July 24, 2023.

On May 24, 2022, we issued the Cavalry Investment Fund Note a note in the amount of $277,777.78 to Cavalry Investment Fund, LP. On the date of the pricing of our initial public offering, we will deliver to Cavalry Investment Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of common stock calculated using a $27 million pre-money valuation and the number of outstanding shares of common stock on July 24, 2023.

On May 24, 2022, we issued the Walleye Note in the amount of $277,777.78 to Walleye Opportunities Master Fund Ltd. On the date of the pricing of our initial public offering, we will deliver to Walleye Opportunities Master Fund Ltd shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to July 24, 2023, the number of shares of common stock calculated using a $27 million pre-money valuation and the number of outstanding shares of common stock on July 24, 2023.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Cyberbahn Federal Solutions, LLC with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Cyberbahn Federal Solutions, LLC shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Ariana Bakery Inc with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Ariana Bakery Inc shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $333,333.30 to Sabby Volatility Warrant Master Fund, Ltd. with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Sabby Volatility Warrant Master Fund, Ltd. shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $55,555.55 to Steel Anderson with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Steel Anderson shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Bixi Gao & Ling Ling Wang with a 10% original issue discount. On the date of the pricing of our initial public offering, we will deliver to Bixi Gao & Ling Ling Wang shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 4, 2024, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 4, 2024.

The notes described above were deemed exempt from registration in reliance on Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder in that the issuance of securities were made to an accredited investor and did not involve a public offering. The recipients of such securities represented its intention to acquire the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof.

Item 16. Exhibits and Financial Statement Schedules.

(a) ***Exhibits***: Reference is made to the Exhibit Index following Item 17 of Part II hereto, which Exhibit Index is hereby incorporated into this Item.

(b) ***Financial Statement Schedules***: All schedules are omitted because the required information is inapplicable or the information is presented in the financial statements and the related notes.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to any charter provision, by law or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of

appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement
3.1*	Certificate of Incorporation of the Registrant
3.2*	Certificate of Designation of Series A Preferred Stock
3.3*	Certificate of Correction to Certificate of Incorporation of the Registrant
3.4*	Amended and Restated Bylaws of the Registrant
4.1*	Form of Tradeable Warrant
4.2*	Form of Non-Tradeable Warrant
4.3*	Form of Representative Warrant
4.4*	Warrant Agent Agreement
5.1	Opinion of Counsel to the Registrant
10.1*++	Securities Purchase Agreement dated as of May 19, 2022, by and between the Registrant and Geoffrey Dow
10.2*++	Common Stock Purchase Warrant dated as of May 19, 2022, issued by the Registrant to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018
10.3*++	Convertible Promissory Note dated as of May 19, 2022, issued by the Registrant to Geoffrey Dow
10.4*++	Securities Purchase Agreement dated as of May 19, 2022, by and between Registrant and Mountjoy Trust
10.5*	Common Stock Purchase Warrant dated as of May 19, 2022, issued by the Registrant to Mountjoy Trust
10.6*	Convertible Promissory Note dated as of May 19, 2022, issued by the Registrant to Mountjoy Trust
10.7*++	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Bigger Capital Fund, LP
10.8*	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Bigger Capital Fund, LP
10.9*	Promissory Note dated as of May 24, 2022, issued by the Registrant to Bigger Capital Fund, LP
10.10*++	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Cavalry Investment Fund, LP
10.11*	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Cavalry Investment Fund, LP
10.12*	Promissory Note dated as of May 24, 2022, issued by the Registrant to Cavalry Investment Fund, LP
10.13*++	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Walleye Opportunities Master Fund Ltd
10.14*	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Walleye Opportunities Master Fund Ltd
10.15*	Promissory Note dated as of May 24, 2022, issued by the Registrant to Walleye Opportunities Master Fund Ltd
10.16*++	Debt Conversion Agreement dated as of January 9, 2023, by and between the Registrant to Knight Therapeutics International S.A.
10.17*++	First Amendment to the Debt Conversion Agreement dated as of January 19, 2023, by and between the Registrant to Knight Therapeutics International S.A.
10.18*++	Second Amendment to The Debt Conversion Agreement dated as of January 27, 2023, by and between the Registrant to Knight Therapeutics International S.A.
10.19*++	Inter-Institutional Agreement dated as of February 15, 2021, by the Registrant and Florida State University Research Foundation
10.20*++	Exclusive License Agreement dated as of September 15, 2016, between National University of Singapore, Singapore Health Services Pte Ltd, the Registrant and 60P Australia Pty Ltd
10.21*+	Master Consultancy Agreement dated as of May 29, 2013, by and between the Registrant and BioIntelect Pty Ltd
10.22*+	Employment Agreement dated as of January 12, 2023, between the Registrant and Geoffrey Dow
10.23*+	Employment Agreement dated as of January 12, 2023, between the Registrant and Tyrone Miller
10.24*++	Subscription Agreement dated as of October 11, 2017, by and between the Registrant and Avante International Limited
10.25*++	Promissory Note dated as of October 11, 2017, issued by the Registrant to Avante International Limited

10.26*++	Convertible Promissory Note dated as of December 31, 2016, issued by the Registrant to Geoffrey Dow
10.27*++	Agreement to Consolidate and Convert Existing Debt dated as of December 31, 2021, between the Registrant and Geoffrey Dow
10.28*++	Agreement to Convert Debt to Equity dated as of December 31, 2021, issued by the Registrant to Geoffrey Dow
10.29*++	Convertible Promissory Note dated as of December 31, 2016, issued by the Registrant to Tyrone Miller
10.30*++	Agreement to Convert Debt to Equity dated as of December 31, 2021, issued by the Registrant to Tyrone Miller
10.31*	Convertible Promissory Note dated as of December 31, 2016, issued by the Registrant to Douglas Loock
10.32*	Agreement to Convert Debt to Equity dated as of August 31, 2021, issued by the Registrant to Douglas Loock
10.33*	Agreement and Plan of Merger dated as of June 1, 2022, by and between the Registrant and 60 Degrees Pharmaceuticals, LLC
10.34*++	Exclusive License Agreement dated as of May 30, 2014, between National University of Singapore, Singapore Health Services Pte Ltd, the Registrant and 60P Australia Pty Ltd
10.35*+	2022 Equity Incentive Plan
10.36*	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Cyberbahn Federal Solutions, LLC
10.37*	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Cyberbahn Federal Solutions, LLC
10.38*	Promissory Note dated as of May 8, 2023, issued by the Registrant to Cyberbahn Federal Solutions, LLC
10.39*	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Ariana Bakery Inc
10.40*	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Ariana Bakery Inc
10.41*	Promissory Note dated as of May 8, 2023, issued by the Registrant to Ariana Bakery Inc
10.42*	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Sabby Volatility Warrant Master Fund, Ltd.
10.43	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Sabby Volatility Warrant Master Fund, Ltd.
10.44*	Promissory Note dated as of May 8, 2023, issued by the Registrant to Sabby Volatility Warrant Master Fund, Ltd.
10.45*	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Steel Anderson
10.46*	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Steel Anderson
10.47*	Promissory Note dated as of May 8, 2023, issued by the Registrant to Steel Anderson
10.48*	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Bixi Gao & Ling Ling Wang
10.49*	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Bixi Gao & Ling Ling Wang
10.50*	Promissory Note dated as of May 8, 2023, issued by the Registrant to Bixi Gao & Ling Ling Wang
10.51	Form of Common Stock Purchase Warrant to be issued by the Registrant to WallachBeth Capital LLC
10.52	Note Extension Agreement dated as of May 22, 2023, by and between the Registrant and Bigger Capital Fund, LP
10.53	Note Extension Agreement dated as of May 22, 2023, by and between the Registrant and Cavalry Investment Fund, LP
10.54	Note Extension Agreement dated as of May 22, 2023, by and between the Registrant and Walleye Opportunities Master Fund Ltd
10.55	Note Extension Agreement dated as of May 18, 2023, by and between the Registrant and the Geoffrey S. Dow Revocable Trust
10.56	Note Extension Agreement dated as of May 18, 2023, by and between the Registrant and Mountjoy Trust
21.1*	List of Subsidiaries of the Registrant
23.1	Consent of RBSM LLP dated as of June 1, 2023
23.2	Consent of Counsel to the Registrant (included in Exhibit 5.1)
99.1*	Consent of Director Nominee of Charles Allen
99.2*	Consent of Director Nominee of Cheryl Xu
99.3*	Consent of Director Nominee of Stephen Toovey
99.4*	Consent of Director Nominee of Paul Field
99.5*	Audit Committee Charter
99.6*	Compensation Committee Charter
99.7*	Nominating and Corporate Governance Committee Charter
99.8*	Code of Conduct
107*	Filing Fee Table

*Previously filed.
+ Management contract or compensatory plan.
++Parts of certain information have been redacted.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Washington, District of Columbia, on June 1, 2023.

60 DEGREES PHARMACEUTICALS, INC.

By: */s/ Geoffrey Dow*
Geoffrey Dow
President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Position	Date
/s/ Geoffrey Dow Geoffrey Dow	President, Chief Executive Officer and Director (Principal Executive Officer)	June 1, 2023
/s/ Tyrone Miller Tyrone Miller	Chief Financial Officer (Principal Financial and Accounting Officer)	June 1, 2023

Exhibit 1.1

60 DEGREES PHARMACEUTICALS, INC.
UNDERWRITING AGREEMENT
[●] Units,
Each Consisting of
One Share of Common Stock,
One Warrant to Purchase One Share of Common Stock, and
One Non-tradeable Warrant to Purchase One Share of Common Stock

[●], 2023

WallachBeth Capital LLC
Harborside Financial Center Plaza 5
185 Hudson Street, Ste 1410
Jersey City, NJ 07311

As Representative of the Several Underwriters Named on Schedule I hereto

Ladies and Gentlemen:

60 DEGREES PHARMACEUTICALS, INC., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions stated herein, to issue and sell to the underwriters named in **Schedule I** hereto (the "Underwriters," or each, an "Underwriter"), for whom WallachBeth Capital LLC is acting as Representative (the "Representative"), an aggregate of [●] Units (the "Firm Units"), each Firm Unit consisting of: (i) one share of the Company's common stock, $0.0001 par value per share (the "Common Stock"); (ii) one tradeable warrant to purchase one share of Common Stock (the "Firm Tradeable Warrants"); and, one non-tradeable warrant the "Firm Non-tradeable Warrants" and together with the Firm Tradeable Warrants, the "Firm Warrants"). The [●] shares of Common Stock referred to in this Section are hereinafter referred to as the "Firm Shares" together with the Firm Units and the Firm Warrants, the "Firm Securities." The Firm Warrants shall be issued pursuant to and shall have the rights and privileges set forth in, a warrant agent agreement, dated on or before the Closing Date, between the Company and Equity Stock Transfer, LLC, as warrant agent (the "Warrant Agreement"). The Company also proposes to grant to the Underwriters, upon the terms and conditions set forth in Section 4 hereof, an option (the "Over-allotment Option") to purchase up to an additional [●] shares of Common Stock, representing up to fifteen percent (15%) of the Firm Shares sold in the offering (the "Option Shares"), and/or [●] tradeable warrants at a price of $0.01 per tradeable warrant (the "Option Tradeable Warrants"), and/or [●] non-tradeable warrants at $0.01 per non-tradeable warrant (the "Option Non-tradeable Warrants" and together with the Option Tradeable Warrants, the "Option Warrants"), or any combination thereof, in each case for the purpose of covering over-allotments of such securities, if any. The Over-allotment Option is, at the Underwriters' sole discretion, for Option Shares and Option Warrants together, solely Option Shares, solely Option Tradeable Warrants, solely Option Non-tradeable Warrants, or any combination thereof (each, an "Option Security" and collectively, the "Option Securities"). The Firm Securities and the Option Securities are collectively referred to as the "Securities." The Securities shall be issued directly by the Company and shall have the rights and privileges described in the Registration Statement, the Pricing Prospectus and the Prospectus (as defined below). The offering and sale of the Securities is herein referred to as the "Offering." The Units have no stand-alone rights or obligations and will not be certificated or issued as stand-alone securities. The shares of Common Stock, the tradeable warrant and non-tradeable warrant comprising the Units are immediately separable and will be issued separately at the closing.

In addition, the Company shall pay the Representative an aggregate cash discount equal to eight percent (8%) of the aggregate sales price of securities sold in the Offering plus one and one-half percent (1.5%) of the aggregate sales price of securities sold in the Offering. In addition, the Company shall issue to the Representative that number of warrants equal to six percent (6%) of the number of securities of common stock sold in the Offering. In the event the Company engages the Representative in a private offering, the Company shall issue to the Representative that number of warrants equal to ten percent (10%) of the number of securities sold in such private offering.

The Company and the several Underwriters hereby confirm their agreement as follows:

1. Registration Statement and Prospectus.

The Company has prepared and filed with the Securities and Exchange Commission (the "Commission") a registration statement covering the Securities (as defined in Section 4(f) hereof) on Form S-1 (File No. 333-269483) under the Securities Act of 1933, as amended (the "Securities Act"), and the rules and regulations (the "Rules and Regulations") of the Commission thereunder, including a preliminary prospectus relating to the Securities and such amendments to such registration statement (including post effective amendments) as may have been required to be filed prior to or after the date of this Agreement. Such registration statement, as amended (including any post effective amendments), has been declared effective by the Commission. Such registration statement, including amendments thereto (including post effective amendments thereto) and all documents and information deemed to be a part of the Registration Statement through incorporation by reference or otherwise at the time of effectiveness thereof (the "Effective Time"), the exhibits and any schedules thereto at the Effective Time or thereafter during the period of effectiveness and the documents and information otherwise deemed to be a part thereof or included therein by the Securities Act or otherwise pursuant to the Rules and Regulations at the Effective Time or thereafter during the period of effectiveness, is herein called the "Registration Statement." If the Company has filed or files an abbreviated registration statement pursuant to Rule 462(b) under the Securities Act (the "Rule 462 Registration Statement"), then any reference herein to the term Registration Statement shall include such Rule 462 Registration Statement. Any preliminary prospectus included in the Registration Statement or filed with the Commission pursuant to Rule 424(a) under the Securities Act is hereinafter called a "Preliminary Prospectus." The Preliminary Prospectus relating to the Securities that was included in the Registration Statement immediately prior to the pricing of the offering contemplated hereby is hereinafter called the "Pricing Prospectus."

The Company is filing with the Commission pursuant to Rule 424 under the Securities Act a final prospectus covering the Securities, which includes the information permitted to be omitted therefrom at the Effective Time by Rule 430A under the Securities Act. Such final prospectus, as so filed, is hereinafter called the "Final Prospectus." The Final Prospectus, the Pricing Prospectus and any preliminary prospectus in the form in which they were included in the Registration Statement or filed with the Commission pursuant to Rule 424 under the Securities Act is hereinafter called a "Prospectus." Reference made herein to any Preliminary Prospectus, the Pricing Prospectus or to the Prospectus shall be deemed to refer to and include any documents incorporated by reference therein.

2. Representations and Warranties of the Company Regarding the Offering.

(a) The Company represents and warrants to, and agrees with, the several Underwriters, as of the date hereof and as of the Closing Date (as defined in Section 4(d) below) and as of each Option Closing Date (as defined in Section 4(b) below), as follows:

(i) **No Material Misstatements or Omissions**. At each time of effectiveness, at the date hereof, at the Closing Date, and at each Option Closing Date, if any, the Registration Statement and any post-effective amendment thereto complied or will comply in all material respects with the requirements of the Securities Act and the Rules and Regulations and did not, does not, and will not, as the case may be, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Time of Sale Disclosure Package (as defined below) as of the date hereof and at the Closing Date and on each Option Closing Date, any roadshow or investor presentations delivered to and approved by the Underwriter for use in connection with the marketing of the offering of the Securities (the "Marketing Materials"), if any, and the Final Prospectus, as amended or supplemented, as of its date, at the time of filing pursuant to Rule 424(b) under the Securities Act, at the Closing Date, and at each Option Closing Date, if any, did not, does not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences shall not apply to statements in or omissions from the Registration Statement, the Time of Sale Disclosure Package or any Prospectus in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f). The Registration Statement contains all exhibits and schedules required to be filed by the Securities Act or the Rules and Regulations. No order preventing or suspending the effectiveness or use of the Registration Statement or any Prospectus is in effect and no proceedings for such purpose have been instituted or are pending, or, to the knowledge of the Company, are contemplated or threatened by the Commission.

(ii) **Marketing Materials**. The Company has not distributed any prospectus or other offering material in connection with the offering and sale of the Securities other than the Time of Sale Disclosure Package and the roadshow or investor presentations delivered to and approved by the Representative for use in connection with the marketing of the offering of the Securities.

(iii) **Accurate Disclosure**. (A) The Company has provided a copy to the Underwriters of each Issuer Free Writing Prospectus (as defined below) used in the sale of Securities. The Company has filed all Issuer Free Writing Prospectuses required to be so filed with the Commission, and no order preventing or suspending the effectiveness or use of any Issuer Free Writing Prospectus is in effect and no proceedings for such purpose have been instituted or are pending, or, to the knowledge of the Company, are contemplated or threatened by the Commission. When taken together with the rest of the Time of Sale Disclosure Package or the Final Prospectus, no Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Securities, has, does or will include (1) any untrue statement of a material fact or omission to state any material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading, or (2) information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Final Prospectus. The representations and warranties set forth in the immediately preceding sentence shall not apply to statements in or omissions from the Time of Sale Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus in reliance upon, and in conformity with, written information furnished to the Company by any Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f). As used in this paragraph and elsewhere in this Agreement:

(1) "Time of Sale Disclosure Package" means the Prospectus most recently filed with the Commission before the time of this Agreement, including any preliminary prospectus supplement deemed to be a part thereof, each Issuer Free Writing Prospectus, and the description of the transaction provided by the Underwriters included on **Schedule II**.

(2) "Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 under the Securities Act, relating to the Securities that (A) is required to be filed with the Commission by the Company, or (B) is exempt from filing pursuant to Rule 433(d)(5)(i) or (d)(8) under the Securities Act, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) under the Securities Act.

(B) At the time of filing of the Registration Statement and at the date hereof, the Company is an "ineligible issuer," as defined in Rule 405 under the Securities Act.

(C) Each Issuer Free Writing Prospectus listed on **Schedule III** satisfied, as of its issue date and at all subsequent times through the Prospectus Delivery Period (as defined in Section 5(a) hereof), all other conditions as may be applicable to its use as set forth in Rules 164 and 433 under the Securities Act, including any legend, record-keeping or other requirements.

(iv) **Financial Statements**. The financial statements of the Company, together with the related notes and schedules, included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus comply in all material respects with the applicable requirements of the Securities Act and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations of the Commission thereunder, and fairly present in all material respects the financial condition of the Company as of the dates indicated and the results of operations and changes in cash flows for the periods therein specified in conformity with U.S. generally accepted accounting principles ("GAAP") consistently applied throughout the periods involved (provided that unaudited interim financial statements are subject to year-end audit adjustments that are not expected to be material in the aggregate and do not contain all footnotes required by GAAP). No other financial statements, pro forma financial information or schedules are required under the Securities Act, the Exchange Act, or the Rules and Regulations to be included in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus.

(v) **Pro Forma Financial Information**. The pro forma financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus include assumptions that provide a reasonable basis for presenting the significant effects directly attributable to the transactions and events described therein, the related pro forma adjustments give appropriate effect to those assumptions, and the pro forma adjustments reflect the proper application of those adjustments to the historical financial statements amounts in the pro forma financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. The pro forma financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus comply as to form in all material respects with the application requirements of Regulation S-X under the Exchange Act.

(vi) **Independent Accountants**. To the Company's knowledge, RBSM LLP, which has expressed its opinion with respect to the audited financial statements and schedules included as a part of the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, is an independent public accounting firm with respect to the Company within the meaning of the Securities Act and the Rules and Regulations.

(vii) **Accounting Controls**. The Company will maintain a system of "internal control over financial reporting" (as defined under Rules 13a-15 and 15d-15 under the Exchange Act) that complies with the requirements of the Exchange Act and has been designed by, or under the supervision of, its principal executive and principal financial officer, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (A) transactions are executed in accordance with management's general or specific authorizations; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(viii) **Forward-Looking Statements**. The Company had a reasonable basis for, and made in good faith, each "forward-looking statement" (within the meaning of Section 27A of the Securities Act or Section 21E of the Exchange Act) contained or incorporated by reference in the Registration Statement, the Time of Sale Disclosure Package, the Final Prospectus or the Marketing Materials.

(ix) **Statistical and Marketing-Related Data**. All statistical or market-related data included or incorporated by reference in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, or included in the Marketing Materials, are based on or derived from sources that the Company reasonably believes to be reliable and accurate, and the Company has obtained the written consent to the use of such data from such sources, to the extent required.

(x) **Stock Exchange Listing**. The shares of Common Stock and tradeable warrants have been approved for listing on The Nasdaq Capital Market, and the Company has taken no action designed to, or likely to have the effect of, delisting the shares of Common Stock from The Nasdaq Capital Market, nor has the Company received any written notification that The Nasdaq Stock Market LLC ("Nasdaq") is contemplating terminating such listing.

(xi) **Absence of Manipulation**. The Company has not taken, directly or indirectly, any action that is designed to or that has constituted or that would reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(xii) **Investment Company Act**. The Company is not and, after giving effect to the offering and sale of the Securities and the application of the net proceeds thereof, will not be an "investment company," as such term is defined in the Investment Company Act of 1940, as amended.

(b) Any certificate signed by any officer of the Company and delivered to the Underwriters or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

3. Representations and Warranties Regarding the Company.

(a) The Company represents and warrants to, and agrees with, the several Underwriters, as of the date hereof and as of the Closing Date and as of each Option Closing Date, if any, as follows:

(i) **Good Standing**. The Company has been duly organized and is validly existing as a corporation or other entity in good standing under the laws of its jurisdiction of incorporation or organization. The Company has the power and authority (corporate or otherwise) to own its properties and conduct its business as currently being carried on and as described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, and is duly qualified to do business as a foreign corporation or other entity in good standing in each jurisdiction in which it owns or leases real property or in which the conduct of its business makes such qualification necessary, except where the failure to so qualify would not have or be reasonably likely to result in a material adverse effect upon the business, prospects, properties, operations, condition (financial or otherwise) or results of operations of the Company, or in its ability to perform its obligations under this Agreement, the Warrants and the Warrant Agreement ("Material Adverse Effect").

(ii) **Validity and Binding Effect of Agreements**. This Agreement, the Warrant Agreement and the Warrants have been duly and validly authorized by the Company, and, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with their respective terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(iii) **Contracts**. The execution, delivery and performance of this Agreement, the Warrant Agreement, the Warrants and the consummation of the transactions herein and therein contemplated will not (A) result in a breach or violation of any of the terms and provisions of, or constitute a default under, any law, order, rule or regulation to which the Company is subject, or by which any property or asset of the Company is bound or affected, except to the extent that such conflict, breach or default is not reasonably likely to result in a Material Adverse Effect, (B) conflict with, result in any violation or breach of, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any right of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) (a "Default Acceleration Event") of, any agreement, lease, credit facility, debt, note, bond, mortgage, indenture or other instrument (the "Contracts") or obligation or other understanding to which the Company is a party or by which any property or asset of the Company is bound or affected, except to the extent that such conflict, default, or Default Acceleration Event is not reasonably likely to result in a Material Adverse Effect, or (C) result in a breach or violation of any of the terms and provisions of, or constitute a default under, the Company's Certificate of Incorporation, as corrected ("Certificate of Incorporation"), or Bylaws ("Bylaws").

(iv) **No Violations of Governing Documents**. The Company is not in violation, breach or default under its Certificate of Incorporation, Bylaws or other equivalent organizational or governing documents.

(v) **Consents**. No consents, approvals, orders, authorizations or filings are required on the part of the Company in connection with the execution, delivery or performance of this Agreement, the Warrant Agreement, the Warrants and the issue and sale of the Securities, except (A) the registration under the Securities Act of the Securities and the warrants issued to the Representative (the "Representative Warrants," and together with the Firm Warrants and Option Warrants, the "Warrants"), which has been effected, (B) the necessary filings and approvals from Nasdaq to list the shares of Common Stock and tradeable warrants underlying the Units and the shares of Common Stock underlying the Warrants, (C) such consents, approvals, authorizations, registrations or qualifications as may be required under state or foreign securities or Blue Sky laws and the rules of the Financial Industry Regulatory Authority, Inc. ("FINRA") in connection with the purchase and distribution of the Securities by the several Underwriters, (D) such consents and approvals as have been obtained and are in full force and effect, and (E) such consents, approvals, orders, authorizations and filings the failure of which to make or obtain is not reasonably likely to result in a Material Adverse Effect.

(vi) **Capitalization**. The Company has an authorized capitalization as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. All of the issued and outstanding shares of capital stock of the Company are duly authorized and validly issued, fully paid and nonassessable, and have been issued in compliance with all applicable securities laws, and conform to the description thereof in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. Since the respective dates as of which information is provided in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, the Company has not entered into or granted any convertible or exchangeable securities, options, warrants, agreements, contracts or other rights in existence to purchase or acquire from the Company any shares of the capital stock of the Company. The Firm Securities and the Option Securities have been duly authorized for issuance and sale and, when issued and paid for, will be validly issued, fully paid and non-assessable, free and clear of all liens imposed by the Company; the holders thereof are not and will not be subject to personal liability by reason of being such holders; the Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company; and all corporate action required to be taken for the authorization, issuance and sale of the Securities has been duly and validly taken; the shares of Common Stock issuable upon exercise of the Warrants have been duly authorized and reserved for issuance by all necessary corporate action on the part of the Company and when paid for and issued in accordance with the applicable instrument, such shares of Common Stock will be validly issued, fully paid and non-assessable; and the Securities and the Warrant Agreement conform in all material respects to all statements with respect thereto contained in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(vii) **Taxes**. The Company has (A) filed all foreign, federal, state and local tax returns (as hereinafter defined) required to be filed with taxing authorities prior to the date hereof or has duly obtained extensions of time for the filing thereof (except where the failure to file would not, individually or in the aggregate, have a Material Adverse Effect) and (B) paid all taxes (as hereinafter defined) shown as due and payable on such returns that were filed and has paid all taxes imposed on or assessed against the Company (except where the failure to pay would not, individually or in the aggregate, have a Material Adverse Effect). The provisions for taxes payable, if any, shown on the financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. To the knowledge of the Company, no issues have been raised (and are currently pending) by any taxing authority in connection with any of the returns or taxes asserted as due from the Company, and no waivers of statutes of limitation with respect to the returns or collection of taxes have been given by or requested from the Company. The term "taxes" mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(viii) **Material Change**. Since the respective dates as of which information is given in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, and except as disclosed in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, (A) the Company has not incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions other than in the ordinary course of business, (B) the Company has not declared or paid any dividends or made any distribution of any kind with respect to its capital stock; (C) there has not been any change in the capital stock of the Company (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares upon the exercise of outstanding options or warrants, upon the conversion of outstanding shares of preferred stock or other convertible securities, due to the vesting of outstanding stock grants or the issuance of restricted stock awards or restricted stock units under the Company's existing stock awards plan, or any new grants thereof in the ordinary course of business), (D) there has not been any material change in the Company's long-term or short-term debt, other than periodic accruals in the ordinary course pursuant to the terms of the Company's outstanding debt, and (E) there has not been the occurrence of any Material Adverse Effect.

(ix) **Absence of Proceedings**. There is no action, suit, proceeding, inquiry, arbitration, investigation, litigation or governmental proceeding pending or, to the Company's knowledge, threatened against, or involving the Company or, to the Company's knowledge, any executive officer or director which has not been disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus.

(x) **Regulatory**. Except as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus: (A) the Company has not received notice from any Governmental Entity (as defined below) alleging or asserting noncompliance with any Applicable Regulations (as defined below) or Authorizations (as defined below); (B) the Company is and has been in material compliance with federal, state or foreign statutes, laws, ordinances, rules and regulations applicable to the Company (collectively, "Applicable Regulations"); (C) the Company possesses all licenses, certificates, approvals, clearances, consents, authorizations, qualifications, registrations, permits, and supplements or amendments thereto required by any such Applicable Regulations and/or to carry on its businesses as now conducted ("Authorizations") and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iv) the Company has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product, operation or activity is in violation of any Applicable Regulations or Authorizations or has any knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, has there been any material noncompliance with or violation of any Applicable Regulations by the Company that could reasonably be expected to require the issuance of any such communication or result in an investigation, corrective action, or enforcement action by any Governmental Entity; and (v) the Company has not received notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such Governmental Entity has threatened or is considering such action. Neither the Company nor, to the Company's knowledge, any of its directors, officers, employees or agents has been convicted of any crime under any Applicable Regulations. "Governmental Entity" shall be defined as any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency (whether foreign or domestic) having jurisdiction over the Company or any of its properties, assets or operations.

(xi) **Good Title**. The Company has good and marketable title to all property (whether real or personal) described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus as being owned by it that are material to the business of the Company, in each case free and clear of all liens, claims, security interests, other encumbrances or defects, except those that are disclosed in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus and those that are not reasonably likely to result in a Material Adverse Effect. The property held under lease by the Company is held by it under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Company.

(xii) **Intellectual Property**. The Company owns or possesses or has valid rights to use all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, inventions, trade secrets and similar rights ("Intellectual Property Rights") necessary for the conduct of the business of the Company as currently carried on and as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. To the knowledge of the Company, no action or use by the Company necessary for the conduct of its business as currently carried on and as described in the Registration Statement and the Final Prospectus will involve or give rise to any infringement of, or license or similar fees for, any Intellectual Property Rights of others. The Company has not received any notice alleging any such infringement, fee or conflict with asserted Intellectual Property Rights of others. Except as would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Effect (A) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any of the Intellectual Property Rights owned by the Company; (B) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the rights of the Company in or to any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim, that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii), reasonably be expected to result in a Material Adverse Effect; (C) the Intellectual Property Rights owned by the Company and, to the knowledge of the Company, the Intellectual Property Rights licensed to the Company have not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, and there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii) reasonably be expected to result in a Material Adverse Effect; (D) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes, misappropriates or otherwise violates any Intellectual Property Rights or other proprietary rights of others, the Company has not received any written notice of such claim and the Company is unaware of any other facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii), reasonably be expected to result in a Material Adverse Effect; and (E) to the Company's knowledge, no employee of the Company is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company, or actions undertaken by the employee while employed with the Company and could reasonably be expected to result, individually or in the aggregate, in a Material Adverse Effect. To the Company's knowledge, all material technical information developed by and belonging to the Company which has not been patented has been kept confidential. The Company is not a party to or bound by any options, licenses or agreements with respect to the Intellectual Property Rights of any other person or entity that are required to be set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus and are not described therein. The Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus contain in all material respects the same description of the matters set forth in the preceding sentence. None of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or, to the Company's knowledge, any of its officers, directors or employees, or otherwise in violation of the rights of any persons. To the Company's knowledge, there is no prior art or public or commercial activity that may render any patent included in the Intellectual Property Rights invalid or that would preclude the issuance of any patent on any patent application included in the Intellectual Property which has not been disclosed to the U.S. Patent and Trademark Office or the relevant foreign patent authority, as the case may be. The Company has not, and to the Company's knowledge, no third party has, committed any act or omitted to undertake any act the effect of such commission or omission would reasonably be expected to result in a legal determination that any item of Intellectual Property Rights thereby was rendered invalid or unenforceable in whole or in part. The manufacture, use and sale of the products or product candidates described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus as under development by the Company fall within the scope of one or more claims of the patents or patent applications included in the Intellectual Property Rights. Other than information disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, no government funding, facilities or resources of a university, college, other educational institution or research center was used in the development of any Intellectual Property Rights that are owned or purported to be owned by the Company that would confer upon any governmental agency or body, university, college, other educational institution or research center any claim or right in or to any such Intellectual Property Rights.

(xiii) **Employment Matters**. There is (A) no unfair labor practice complaint pending against the Company, nor to the Company's knowledge, threatened against it, before the National Labor Relations Board, any state or local labor relation board or any foreign labor relations board, and no grievance or arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company, or, to the Company's knowledge, threatened against it and (B) no labor disturbance by the employees of the Company exists or, to the Company's knowledge, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers, customers or contractors, that could reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company.

(xiv) **ERISA Compliance**. No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "Code")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur with respect to any employee benefit plan of the Company which would reasonably be expected to, singularly or in the aggregate, have a Material Adverse Effect. Each employee benefit plan of the Company is in compliance in all material respects with applicable law, including ERISA and the Code. The Company has not incurred and could not reasonably be expected to incur liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified, and, to the Company's knowledge, nothing has occurred, whether by action or by failure to act, which could, singularly or in the aggregate, cause the loss of such qualification.

(xv) **Environmental Matters**. The Company is in compliance with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to their businesses, except where the failure to comply has not had and would not reasonably be expected to have, singularly or in the aggregate, a Material Adverse Effect. There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability, except for any violation or liability which has not had and would not reasonably be expected to have, singularly or in the aggregate, a Material Adverse Effect; and there has been no disposal, discharge, emission or other release of any kind onto such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances with respect to which the Company has knowledge.

(xvi) **SOX Compliance**. The Company has taken all actions it deems reasonably necessary or advisable to take on or prior to the date of this Agreement to assure that, upon and at all times after the Effective Date, it will be in compliance in all material respects with all applicable provisions of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof (the "Sarbanes-Oxley Act") that are then in effect and will take all action it deems reasonably necessary or advisable to assure that it will be in compliance in all material respects with other applicable provisions of the Sarbanes-Oxley Act not currently in effect upon it and at all times after the effectiveness of such provisions.

(xvii) **Money Laundering Laws**. The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "Money Laundering Laws"); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xviii) **Foreign Corrupt Practices Act**. Neither the Company nor, to the knowledge of the Company, any director, officer, employee, representative, agent, affiliate of the Company or any other person acting on behalf of the Company, is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(xix) **OFAC**. Neither the Company nor, to the knowledge of the Company, any director, officer, employee, representative, agent or affiliate of the Company or any other person acting on behalf of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering of the Securities contemplated hereby, or lend, contribute or otherwise make available such proceeds to any person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(xx) **Insurance**. Following the consummation of the offering contemplated hereby, the Company will carry insurance in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses in similar industries.

(xxi) **Books and Records**. The minute books of the Company have been made available to the Underwriters and counsel for the Underwriters, and such books (A) contain a complete summary of all meetings and actions of the board of directors (including each board committee) and stockholders of the Company (or analogous governing bodies and interest holders, as applicable), since the time of its incorporation or organization through the date of the latest meeting and action, and (B) accurately in all material respects reflect all transactions referred to in such minutes.

(xxii) **No Violation**. Neither the Company nor, to its knowledge, any other party is in violation, breach or default of any Contract that has resulted in or could reasonably be expected to result in a Material Adverse Effect.

(xxiii) **Continued Business**. No supplier, customer, distributor or sales agent of the Company has notified the Company that it intends to discontinue or decrease the rate of business done with the Company, except where such discontinuation or decrease has not resulted in and could not reasonably be expected to result in a Material Adverse Effect.

(xxiv) **No Finder's Fee**. There are no claims, payments, issuances, arrangements or understandings for services in the nature of a finder's, consulting or origination fee with respect to the introduction of the Company to any Underwriter or the sale of the Securities hereunder or any other arrangements, agreements, understandings, payments or issuances with respect to the Company that may affect the Underwriters' compensation, as determined by FINRA.

(xxv) **No Fees**. Except as disclosed to the Representative in writing, the Company has not made any direct or indirect payments (in cash, securities or otherwise) to (A) any person, as a finder's fee, investing fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who provided capital to the Company, (B) any FINRA member, or (C) any person or entity that has any direct or indirect affiliation or association with any FINRA member within the twelve (12) month period prior to the date on which the Registration Statement was filed with the Commission ("Filing Date") or thereafter.

(xxvi) **Proceeds**. None of the net proceeds of the offering will be paid by the Company to any participating FINRA member or any affiliate or associate of any participating FINRA member, except as specifically authorized herein.

(xxvii) **No FINRA Affiliations**. To the Company's knowledge and except as disclosed to the Representative in writing, no (A) officer or director of the Company or (B) owner of 5% or more of any class of the Company's securities or (C) owner of any amount of the Company's unregistered securities acquired within the 180-day period prior to the Filing Date, has any direct or indirect affiliation or association with any FINRA member. The Company will advise the Representative and counsel to the Underwriter if it becomes aware that any officer, director of the Company or any owner of 5% or more of any class of the Company's securities is or becomes an affiliate or associated person of a FINRA member participating in the offering.

(xxviii) **No Financial Advisor**. Other than the Underwriters, no person has the right to act as an underwriter or as a financial advisor to the Company in connection with the transactions contemplated hereby.

(xxix) **Data Privacy and Security Laws**. The Company is, and at all prior times was, in material compliance with all applicable state and federal data privacy and security laws and regulations in the United States, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act, and all applicable provincial and federal data privacy and security laws and regulations in Canada, including without limitation the Personal Information Protection and Electronic Documents Act (S.C. 2000, c. 5) ("PIPEDA"); and the Company has taken commercially reasonable actions to prepare to comply with, and have been and currently are in compliance with, the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (collectively, the "Privacy Laws"). To ensure compliance with the Privacy Laws, the Company has in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data. "Personal Data" means (A) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (B) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (C) Protected Health Information as defined by HIPAA; (D) "personal information," "personal health information" and "business contact information" as defined by PIPEDA; (E) "personal data" as defined by GDPR; and (F) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. The Company has at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies it has not received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice.

(xxx) **No Registration Rights**. Except as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, there are no contracts, agreements or understandings between the Company and any person granting such person the right (other than rights which have been waived in writing or otherwise satisfied) to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person or to require the Company to include such securities in the securities registered pursuant to the Registration Statement or in any securities being registered pursuant to any other registration statement filed by the Company under the Securities Act.

(xxxi) **Prior Sales of Securities**. Except as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the Company has not sold or issued any shares of Common Stock during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulations D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, stock option plans or other employee compensation plans, pursuant to outstanding preferred stock, options, rights or warrants or other outstanding convertible securities or in connection with the vesting of any outstanding stock grants.

(xxxii) **Compliance with Laws**. The Company: (A) is and at all times has been in compliance with all statutes, rules, or regulations applicable to the Company, including, without limitation, all statutes, rules, or regulations relating to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company and, without limiting the foregoing, include (I) the Federal Food, Drug, and Cosmetic Act, (II) the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act and Laws applicable to hazardous or regulated substances and radioactive or biologic materials, (III) the federal Anti-Kickback Statute, (IV) the False Claims Act, (V) the Civil Monetary Penalties Law, (VI) the Physician Payments Sunshine Act, (VII) the criminal False Claims Law, (VIII) HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act and (IX) licensing and certification laws covering any aspect of the business of the Company ("Applicable Laws"), except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; (B) has not received any warning letter, untitled letter or other correspondence or notice from any other governmental authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws and/or to carry on its business as now conducted ("Applicable Authorizations"); (C) possesses all material Application Authorizations and such Applicable Authorizations are valid and in full force and effect and are not in material violation of any term of any such Applicable Authorizations; (D) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product operation or activity is in violation of any Applicable Laws or Applicable Authorizations and has no knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding nor, to the Company's knowledge, has there been any material noncompliance with or violation of any Applicable Laws by the Company that could reasonably be expected to require the issuance of any such communication or result in an investigation, corrective action, or enforcement action by any Governmental Entity; (E) has not received notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Applicable Authorizations and has no knowledge that any such Governmental Entity has threatened or is considering such action; (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Applicable Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (G) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(xxxiii) **Clinical and Preclinical Studies**. The studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company were and, if still ongoing, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all authorizations and applicable laws and the rules and regulations promulgated thereunder and any applicable rules, regulations and policies of the jurisdiction in which such trials and studies are being conducted; the descriptions of the results of such studies, tests and trials contained in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus are, to the Company's knowledge, accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; except to the extent disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the Company is not aware of any studies, tests or trials, the results of which the Company believes reasonably call into question the study, test, or trial results described or referred to in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus when viewed in the context in which such results are described and the clinical state of development; and, except to the extent disclosed in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus, the Company has not received any notices or correspondence from the U.S. Food and Drug Administration or any governmental entity requiring the termination or suspension of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company.

4. Purchase, Sale and Delivery of Shares.

(a) On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell the Firm Units to the several Underwriters, and the several Underwriters agree, severally and not jointly, to purchase the Firm Units set forth opposite the names of the Underwriters in **Schedule I** hereto. The purchase price for each Firm Unit shall be $[●] per Firm Unit (92% of the public offering price for each Firm Unit) which purchase price will be allocated as $[●] per Firm Share, $0.01 per Firm Tradeable Warrant and $0.01 per Firm Non-tradeable Warrant.

(b) The Company hereby grants to the Underwriters the option to purchase some or all of the Option Securities and, upon the basis of the warranties and representations and subject to the terms and conditions herein set forth, the Underwriter shall have the right, severally and not jointly, to purchase all or any portion of the Option Shares and/or the Option Warrants as may be necessary to cover over-allotments made in connection with the transactions contemplated hereby. The purchase price to be paid per Option Share shall be equal to $[●]. The purchase price to be paid per Option Tradeable Warrant shall be equal to $0.01. The purchase price to be paid per Option Non-tradeable Warrant shall be equal to $0.01. The Underwriters shall not be under any obligation to purchase any of the Option Securities prior to the exercise of the Over-allotment Option. This Over-Allotment Option may be exercised by the Underwriters at any time and from time to time on or before the forty-fifth (45^{th}) day following the date hereof, by written notice to the Company (the "Option Notice"). The Option Notice shall set forth the aggregate number of Option Shares and/or Option Warrants as to which the option is being exercised, and the date and time when the Option Shares and/or the Option Warrants are to be delivered (such date and time being herein referred to as the "Option Closing Date"); *provided, however*, that the Option Closing Date shall not be earlier than the Closing Date (as defined below) nor earlier than the first (1^{st}) business day after the date on which the option shall have been exercised nor later than the fifth (5^{th}) business day after the date on which the option shall have been exercised unless the Company and the Representative otherwise agree. Upon exercise of the Over-allotment Option with respect to all or any portion of the Option Securities subject to the terms and conditions set forth herein, (i) the Company shall become obligated to sell to the Underwriters the number of Option Securities specified in such notice; (ii) each of the Underwriters, acting severally and not jointly, shall purchase that portion of the total number of Option Securities then being purchased as set forth in **Schedule I** opposite the name of such Underwriter, subject to such adjustments as the Representative, in their sole discretion, shall determine and (iii) each of the Underwriters, acting severally and not jointly, shall purchase that portion of the total number of Option Warrants then being purchased that the number of Option Warrants as set forth in **Schedule I** opposite the name of such Underwriter bears to the total number of Option Warrants, subject, in each case, to such adjustments as the Representative, in their sole discretion, shall determine. The Representative may cancel the Over-Allotment Option at any time prior to the expiration of the Over-Allotment Option by written notice to the Company (except to the extent the Representative has exercised the Over-Allotment Option in accordance herewith).

(c) Payment of the purchase price for and delivery of the Option Shares and/or the Option Warrants shall be made on an Option Closing Date in the same manner and at the same office as the payment for the Firm Securities as set forth in subparagraph (d) below.

(d) The Firm Securities will be delivered by the Company to the Representative, for the respective accounts of the several Underwriters against payment of the purchase price therefor by wire transfer of same day funds payable to the order of the Company at the offices of WallachBeth Capital LLC, Harborside Financial Center Plaza 5, 185 Hudson Street, Suite 1410, Jersey City, NJ 07311, or such other location as may be mutually acceptable, at 9:00 a.m. Eastern Time, on the second (2^{nd}) (or if the Firm Securities are priced, as contemplated by Rule 15c6-1(c) under the Exchange Act, after 4:30 p.m. Eastern time, the third (3^{rd})) full business day following the date hereof, or at such other time and date as the Representative and the Company determine pursuant to Rule 15c6-1(a) under the Exchange Act, or, in the case of the Option Securities, at such date and time set forth in the Option Notice. The time and date of delivery of the Firm Shares is referred to herein as the "Closing Date." On the Closing Date, the Company shall deliver the Firm Securities which shall be registered in the name or names and shall be in such denominations as the Representative may request on behalf of the Underwriters at least one (1) business day before the Closing Date, to the respective accounts of the several Underwriters, which delivery shall with respect to the Firm Securities, be made through the facilities of the Depository Trust Company's Deposit or Withdrawal at Custodian system.

(e) It is understood that WallachBeth Capital LLC, has been authorized, for its own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Securities and any Option Securities the Underwriters have agreed to purchase. WallachBeth Capital LLC, individually and not as the Representative of the Underwriters, may (but shall not be obligated to) make payment for any Securities to be purchased by any Underwriter whose funds shall not have been received by the Representative by the Closing Date or any Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

5. Covenants.

(a) The Company covenants and agrees with the Underwriters as follows:

(i) The Company shall prepare the Final Prospectus in a form approved by the Representative and file such Final Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement, or, if applicable, such earlier time as may be required by the Rules and Regulations.

(ii) During the period beginning on the date hereof and ending on the later of the Closing Date or such date as determined by the Representative the Final Prospectus is no longer required by law to be delivered in connection with sales by an underwriter or dealer (the "Prospectus Delivery Period"), prior to amending or supplementing the Registration Statement, including any Rule 462 Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, the Company shall furnish to the Representative for review and comment a copy of each such proposed amendment or supplement, and the Company shall not file any such proposed amendment or supplement to which the Representative reasonably objects.

(iii) From the date of this Agreement until the end of the Prospectus Delivery Period, the Company shall promptly advise the Representative in writing (A) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission, (B) of the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to the Time of Sale Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus, (C) of the time and date that any post-effective amendment to the Registration Statement becomes effective and (D) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending its use or the use of the Time of Sale Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Stock from any securities exchange upon which it is listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time during the Prospectus Delivery Period, the Company will use its reasonable efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with the provisions of Rules 424(b), 430A, 430B or 430C as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission (without reliance on Rule 424(b)(8) or 164(b) of the Securities Act).

(iv) (A) During the Prospectus Delivery Period, the Company will comply with all requirements imposed upon it by the Securities Act, as now and hereafter amended, and by the Rules and Regulations, as from time to time in force, and by the Exchange Act, as now and hereafter amended, so far as necessary to permit the continuance of sales of or dealings in the Securities as contemplated by the provisions hereof, the Time of Sale Disclosure Package, the Registration Statement and the Final Prospectus. If during the Prospectus Delivery Period any event occurs the result of which would cause the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) to include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances then existing, not misleading, or if during such period it is necessary or appropriate in the opinion of the Company or its counsel or the Representative or counsel to the Underwriters to amend the Registration Statement or supplement the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) to comply with the Securities Act, the Company will promptly notify the Representative, allow the Representative the opportunity to provide reasonable comments on such amendment, prospectus supplement or document, and will amend the Registration Statement or supplement the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) or file such document (at the expense of the Company) so as to correct such statement or omission or effect such compliance. (B) If at any time during the Prospectus Delivery Period there occurred or occurs an event or development the result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement or any Prospectus or included or would include, when taken together with the Time of Sale Disclosure Package, an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in light of the circumstances prevailing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(v) The Company shall take or cause to be taken all necessary action to qualify the Securities for sale under the securities laws of such jurisdictions as the Representative reasonably designate and to continue such qualifications in effect so long as required, except that the Company shall not be required in connection therewith to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified, to execute a general consent to service of process in any state or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise subject.

(vi) The Company will furnish to the Underwriters and counsel to the Underwriters copies of the Registration Statement, each Prospectus, any Issuer Free Writing Prospectus, and all amendments and supplements to such documents, in each case as soon as available and in such quantities as the Underwriters may from time to time reasonably request.

(vii) The Company will make generally available to its security holders as soon as practicable, but in any event not later than fifteen (15) months after the end of the Company's current fiscal quarter, an earnings statement (which need not be audited) covering a twelve (12)-month period that shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 of the Rules and Regulations.

(viii) The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, will pay or cause to be paid all expenses relating to the Offering, including, without limitation, (A) all filing fees and communication expenses relating to the registration of the Securities with the Commission; (B) all filing fees associated with the review of the public offering of the Securities by FINRA; (C) all fees and expenses relating to the listing of such Offered Securities on Nasdaq; (D) fees relating to background checks by the Representative; (E) all fees, expenses and disbursements relating to the registration, qualification or exemption of such Securities under the securities laws of such foreign jurisdictions as the Representative may reasonably designate; (F) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, Selected Dealers' Agreement, Underwriters' Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (G) the costs and expenses of a public relations firm for the Company mutually agreed upon by the Representative and the Company; (H) the costs of preparing, printing and delivering certificates representing the Securities; (I) fees and expenses of the transfer agent for the Securities of the Company; (J) the fees and expenses of the Company's legal counsel and other agents and Representative; (K) fees and expenses of legal counsel for the Underwriters not to exceed $145,000 and (l) all reasonable road show expenses for the Offering.

(ix) The Company intends to apply the net proceeds from the sale of the Securities to be sold by it hereunder for the purposes set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus under the heading "Use of Proceeds."

(x) The Company has not taken and will not take, directly or indirectly, during the Prospectus Delivery Period, any action designed to, or which might reasonably be expected to cause or result in, or that has constituted, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(xi) The Company represents and agrees that, unless it obtains the prior written consent of the Representative, and each Underwriter, severally, and not jointly, represents and agrees that, unless it obtains the prior written consent of the Company, it has not made and will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus; *provided* that the prior written consent of the parties hereto shall be deemed to have been given in respect of the free writing prospectuses included in **Schedule III**, if any. Any such free writing prospectus consented to by the Company and the Representative is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company represents that it has treated or agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as defined in Rule 433, and has complied or will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely Commission filing where required, legending and record-keeping.

(xii) The Company hereby agrees that, without the prior written consent of the Representative, it and any successors will not, during the period ending sixteen (16) months after the date hereof, (A) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock or the Company, (B) file or caused to be filed any registration statement with the Commission relating to the offering or resale of any shares of capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock or (C) enter into any swap or other arrangement that transfers to another in whole or in part, any of the economic consequences of ownership of capital stock of the Company, whether any such transaction described in clause (A), (B) or (C) above is to be settled by delivery of shares of capital stock of the Company or any successors or such other securities, in cash or otherwise, other than in the case of a Variable Rate Transaction (as defined below). The restrictions contained in the preceding sentence shall not apply to (I) the Securities to be sold hereunder, (II) the issuance by the Company of shares of Common Stock upon the exercise of a stock option or warrant or the conversion of a security outstanding on the date hereof, which is disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the terms of which option, warrant or other outstanding convertible security are not thereafter amended, (III) the issuance by the Company of shares of Common Stock upon the vesting of outstanding stock grants, (IV) grants of stock options, stock awards, restricted stock, restricted stock units or other equity awards and the issuance of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock (whether upon the exercise of stock options or otherwise) to the Company's employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the Closing Date and described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus *provided* the grantee of any such equity award set forth in this Section enters into a Lock-Up Agreement (as defined below) in the form attached hereto as **Exhibit A** in connection with any such grant *provided further* that any such grant to advisors or consultants are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith within one hundred eighty (180) days following the date hereof; and (V) the filing by the Company of any registration statement on Form S-8 or a successor form thereto relating to an equity compensation plan described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus.

(xiii) From the date hereof until sixteen (16) months after the Closing Date, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of Common Stock or any securities of the Company or any subsidiary which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock (or a combination of units thereof) involving a Variable Rate Transaction. "Variable Rate Transaction" means a transaction in which the Company (A) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (I) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (II) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (B) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. Any Underwriter shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages.

(xiv) To engage and maintain, at its expense, a registrar and transfer agent for the Common Stock (if other than the Company).

(xv) To use its reasonable best efforts to maintain the listing of the Common Stock on Nasdaq.

(xvi) To not take, directly or indirectly, any action designed to cause or result in, or that has constituted or might reasonably be expected to constitute, under the Exchange Act or otherwise, the stabilization or manipulation of the price of any securities of the Company to facilitate the sale or resale of the Securities.

(xvii) The Company further agrees that, in addition to the expenses payable pursuant to Section 5(a)(viii), on the Closing Date it shall pay to the Representative, by deduction from the net proceeds of the Offering contemplated herein, a non-accountable expense allowance equal to one and one-half percent (1.5%) of the gross proceeds received by the Company from the sale of the Securities; *provided, however*, that in the event that the Offering is terminated, the Company agrees to reimburse the Underwriters pursuant to Section 7 hereof. Notwithstanding the foregoing, any advance previously paid by the Company to WallachBeth Capital LLC against the Representative's non-accountable expense allowance actually anticipated to be incurred, shall be applied towards the accountable expenses set forth herein; *provided* that the Representative will reimburse the Company for any remaining portion of the Advance to the extent amount of the Advance was not used for accountable expenses actually incurred by the Representative in the offering.

(xviii) As of the Closing Date, the Company shall have retained an investor relations advisory firm reasonably acceptable to the Representative and the Company and shall retain such firm or another firm reasonably acceptable to the Representative for a period of not less than six (6) months after the Closing Date.

(xix) On or prior to the Closing Date, the Company will have appropriate Directors' & Officers' and Errors & Omissions insurance with appropriate liability levels as reasonably determined by the Company.

6. Conditions of the Underwriter's Obligations. The respective obligations of the several Underwriters hereunder to purchase the Shares are subject to the accuracy, as of the date hereof and at all times through the Closing Date, and on each Option Closing Date (as if made on the Closing Date or such Option Closing Date, as applicable), of and compliance with all representations, warranties and agreements of the Company contained herein, the performance by the Company of its obligations hereunder and the following additional conditions:

(a) If filing of the Final Prospectus, or any amendment or supplement thereto, or any Issuer Free Writing Prospectus, is required under the Securities Act or the Rules and Regulations, the Company shall have filed the Final Prospectus (or such amendment or supplement) or such Issuer Free Writing Prospectus with the Commission in the manner and within the time period so required (without reliance on Rule 424(b)(8) or 164(b) under the Securities Act); the Registration Statement shall remain effective; no stop order suspending the effectiveness of the Registration Statement or any part thereof, any Rule 462 Registration Statement, or any amendment thereof, nor suspending or preventing the use of the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus or any Issuer Free Writing Prospectus shall have been issued; no proceedings for the issuance of such an order shall have been initiated or threatened by the Commission; any request of the Commission or the Representative for additional information (to be included in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, any Issuer Free Writing Prospectus or otherwise) shall have been complied with to the satisfaction of the Representative.

(b) The Common Stock and tradeable warrants shall be approved for listing on The Nasdaq Capital Market, and satisfactory evidence thereof shall have been provided to the Representative and its counsel.

(c) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(d) The Representative shall not have reasonably determined, and advised the Company, that the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment thereof or supplement thereto, or any Issuer Free Writing Prospectus, contains an untrue statement of fact which, in the reasonable opinion of the Representative, is material, or omits to state a fact which, in the reasonable opinion of the Representative, is material and is required to be stated therein or necessary to make the statements therein not misleading.

(e) Intentionally Omitted.

(f) On the Closing Date and on each Option Closing Date, there shall have been furnished to the Representative on behalf of the Underwriters the opinion and negative assurance letters of Carmel, Milazzo & Feil LLP, corporate counsel to the Company, dated the Closing Date or the Option Closing Date, as applicable, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representative.

(g) Intentionally Omitted.

(h) The Underwriters shall have received a letter of RBSM LLP, on the date hereof and on the Closing Date and on each Option Closing Date, addressed to the Underwriters, confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualifications of accountants under Rule 2-01 of Regulation S-X of the Commission, and confirming, as of the date of each such letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, as of a date not prior to the date hereof or more than five (5) days prior to the date of such letter), the conclusions and findings of said firm with respect to the financial information and other matters required by the Underwriters.

(i) Intentionally Omitted.

(j) On the Closing Date and on each Option Closing Date, there shall have been furnished to the Underwriters a certificate, dated the Closing Date and on each Option Closing Date and addressed to the Underwriters, signed by the Chief Executive Officer and the Chief Financial Officer of the Company, in their capacity as officers of the Company, to the effect that:

(i) The representations and warranties of the Company in this Agreement that are qualified by materiality or by reference to any Material Adverse Effect are true and correct in all respects, and all other representations and warranties of the Company in this Agreement are true and correct, in all material respects, as if made at and as of the Closing Date and on the Option Closing Date, and the Company has complied in all material respects with all the agreements and satisfied all the conditions on its part required to be performed or satisfied at or prior to the Closing Date or on the Option Closing Date, as applicable;

(ii) No stop order or other order (A) suspending the effectiveness of the Registration Statement or any part thereof or any amendment thereof, (B) suspending the qualification of the Securities for offering or sale, or (C) suspending or preventing the use of the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus or any Issuer Free Writing Prospectus, has been issued, and no proceeding for that purpose has been instituted or, to their knowledge, is contemplated by the Commission or any state or regulatory body; and

(iii) There has been no occurrence of any event resulting or reasonably likely to result in a Material Adverse Effect during the period from and after the date of this Agreement and prior to the Closing Date or on the Option Closing Date, as applicable.

(k) On or before the date hereof, the Representative shall have received duly executed lock-up agreement, substantially in the form of **Exhibit A** attached hereto (each a "Lock-Up Agreement"), by and between the Representative and each of the parties specified in **Schedule IV** hereto.

(l) On the Closing Date, the Company shall have delivered to the Representative executed copies of the Warrant Agreement.

(m) The Company shall have furnished to the Representative and its counsel such additional documents, certificates and evidence as the Representative and its counsel may have reasonably requested.

If any condition specified in this Section 6 shall not have been fulfilled when and as required to be fulfilled, this Agreement may be terminated by the Representative by notice to the Company at any time at or prior to the Closing Date or on the Option Closing Date, as applicable, and such termination shall be without liability of any party to any other party, except that Section 5(a)(viii), Section 7 and Section 8 shall survive any such termination and remain in full force and effect.

7. Indemnification and Contribution.

(a) The Company agrees to indemnify, defend and hold harmless each Underwriter, its affiliates, directors and officers and employees, and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities to which such Underwriter or such person may become subject, under the Securities Act or otherwise (including in settlement of any litigation if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon (i) an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including the information deemed to be a part of the Registration Statement at the time of effectiveness and at any subsequent time pursuant to Rules 430A and 430B of the Rules and Regulations, or arise out of or are based upon the omission from the Registration Statement, or alleged omission to state therein, a material fact required to be stated therein or necessary to make the statements therein not misleading (ii) an untrue statement or alleged untrue statement of a material fact contained in the Time of Sale Disclosure Package, any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act ("Written Testing-the-Waters Communications"), any Prospectus, the Final Prospectus, or any amendment or supplement thereto, any Issuer Free Writing Prospectus, or the Marketing Materials or in any other materials used in connection with the offering of the Securities, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, (iii) in whole or in part, any inaccuracy in the representations and warranties of the Company contained herein, or (iv) in whole or in part, any failure of the Company to perform its obligations hereunder or under law, and will reimburse each Underwriter for any legal or other expenses reasonably incurred by it in connection with evaluating, investigating or defending against such loss, claim, damage, liability or action; *provided*, *however*, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Time of Sale Disclosure Package, any Written Testing-the-Waters Communications, any Prospectus, the Final Prospectus, or any amendment or supplement thereto or any Issuer Free Writing Prospectus, in reliance upon and in conformity with written information furnished to the Company by such Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f).

(b) Each Underwriter, severally and not jointly, will indemnify, defend and hold harmless the Company, its affiliates, directors, officers and employees, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities to which the Company may become subject, under the Securities Act or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment or supplement thereto or any Issuer Free Writing Prospectus, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment or supplement thereto or any Issuer Free Writing Prospectus in reliance upon and in conformity with written information furnished to the Company by such Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f), and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with evaluating, investigating, and defending against any such loss, claim, damage, liability or action. The obligation of each Underwriter to indemnify the Company (including any controlling person, director or officer thereof) shall be limited to the amount of the underwriting discount applicable to the Shares to be purchased by such Underwriter hereunder actually received by such Underwriter.

(c) Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof, but the failure to notify the indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party except to the extent such indemnifying party has been materially prejudiced by such failure. In case any such action shall be brought against any indemnified party, and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of the indemnifying party's election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof; *provided*, *however*, that if (i) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (ii) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party), or (iii) the indemnifying party has not in fact employed counsel reasonably satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, the indemnified party shall have the right to employ a single counsel to represent it in any claim in respect of which indemnity may be sought under subsection (a) or (b) of this Section 7, in which event the reasonable fees and expenses of such separate counsel shall be borne by the indemnifying party or parties and reimbursed to the indemnified party as incurred.

The indemnifying party under this Section 7 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is a party or could be named and indemnity was or would be sought hereunder by such indemnified party, unless such settlement, compromise or consent (A) includes an unconditional release of such indemnified party from all liability for claims that are the subject matter of such action, suit or proceeding and (B) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) If the indemnification provided for in this Section 7 is unavailable or insufficient to hold harmless an indemnified party under subsection (a) or (b) above, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in subsection (a) or (b) above, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering and sale of the Securities or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discount received by the Underwriters, in each case as set forth in the table on the cover page of the Final Prospectus. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters and the parties' relevant intent, knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this subsection (d) were to be determined by pro rata allocation or by any other method of allocation that does not take account of the equitable considerations referred to in the first sentence of this subsection (d). The amount paid by an indemnified party as a result of the losses, claims, damages or liabilities referred to in the first sentence of this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending against any action or claim that is the subject of this subsection (d). Notwithstanding the provisions of this subsection (d), no Underwriter shall be required to contribute any amount in excess of the amount of the underwriting discount applicable to the Shares to be purchased by such Underwriter hereunder actually received by such Underwriter. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' respective obligations to contribute as provided in this Section 7 are several in proportion to their respective underwriting commitments and not joint.

(e) The obligations of the Company under this Section 7 shall be in addition to any liability that the Company may otherwise have and the benefits of such obligations shall extend, upon the same terms and conditions, to each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act; and the obligations of each Underwriter under this Section 7 shall be in addition to any liability that each Underwriter may otherwise have and the benefits of such obligations shall extend, upon the same terms and conditions, to the Company and its officers, directors and each person who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act.

(f) For purposes of this Agreement, each Underwriter severally confirms, and the Company acknowledges, that there is no information concerning such Underwriter furnished in writing to the Company by such Underwriter specifically for preparation of or inclusion in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus or any Issuer Free Writing Prospectus, other than the statement set forth in the last paragraph on the cover page of the Prospectus, the marketing and legal names of each Underwriter, and the statements set forth in the "Underwriting" section of the Registration Statement, the Time of Sale Disclosure Package, and the Final Prospectus only insofar as such statements relate to the amount of selling concession and re-allowance, if any, or to over-allotment, stabilization and related activities that may be undertaken by such Underwriter.

8. Representations and Agreements to Survive Delivery. All representations, warranties, and agreements of the Company contained herein or in certificates delivered pursuant hereto, including, but not limited to, the agreements of the several Underwriters and the Company contained in Section 5(a)(viii) and Section 7 hereof, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of the several Underwriters or any controlling person thereof, or the Company or any of its officers, directors, or controlling persons, and shall survive delivery of, and payment for, the Shares to and by the Underwriters hereunder.

9. Termination of this Agreement.

(a) The Representative shall have the right to terminate this Agreement by giving notice to the Company as hereinafter specified at any time at or prior to the Closing Date or any Option Closing Date (as to the Option Shares to be purchased on such Option Closing Date only), if in the discretion of the Representative, (i) there has occurred any material adverse change in the securities markets or any event, act or occurrence that has materially disrupted, or in the opinion of the Representative, will in the future materially disrupt, the securities markets or there shall be such a material adverse change in general financial, political or economic conditions or the effect of international conditions on the financial markets in the United States is such as to make it, in the judgment of the Representative, inadvisable or impracticable to market the Shares or enforce contracts for the sale of the Shares (ii) trading in the Company's Common Stock shall have been suspended by the Commission or Nasdaq or trading in securities generally on Nasdaq, the NYSE or the NYSE American shall have been suspended, (iii) minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required, on Nasdaq, the NYSE or NYSE American, by such exchange or by order of the Commission or any other governmental authority having jurisdiction, (iv) a banking moratorium shall have been declared by federal or state authorities, (v) there shall have occurred any attack on, outbreak or escalation of hostilities or act of terrorism involving the United States any declaration by the United States of a national emergency or war, any substantial change or development involving a prospective substantial change in United States or other international political, financial or economic conditions or any other calamity or crisis, or (vi) the Company suffers any loss by strike, fire, flood, earthquake, accident or other calamity, whether or not covered by insurance, or (vii) in the judgment of the Representative, there has been, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company, whether or not arising in the ordinary course of business. Any such termination shall be without liability of any party to any other party except that the provisions of Section 5(a)(viii) and Section 7 hereof shall at all times be effective and shall survive such termination.

(b) If the Representative elect to terminate this Agreement as provided in this Section 9, the Company and the other Underwriters shall be notified promptly by the Representative by telephone, confirmed by letter.

(c) If this Agreement is terminated pursuant to any of its provisions, the Company shall not be under any liability to any Underwriter, and no Underwriter shall be under any liability to the Company, except that (y) subject to a maximum reimbursement of $145,000, the Company will reimburse the Representative only for all actual, accountable out-of-pocket expenses (including the reasonable fees and disbursements of its counsel) reasonably incurred by the Representative in connection with the proposed purchase and sale of the Securities or in contemplation of performing their obligations hereunder and (z) no Underwriter who shall have failed or refused to purchase the Securities agreed to be purchased by it under this Agreement, without some reason sufficient hereunder to justify cancellation or termination of its obligations under this Agreement, shall be relieved of liability to the Company, or to the other Underwriters for damages occasioned by its failure or refusal.

10. Substitution of Underwriters. If any Underwriter or Underwriters shall default in its or their obligations to purchase Securities hereunder on the Closing Date or any Option Closing Date and the aggregate number of Securities which such defaulting Underwriter or Underwriters agreed but failed to purchase does not exceed five percent (5%) of the total number of Securities to be purchased by all Underwriters on such Closing Date or Option Closing Date, the other Underwriters shall be obligated severally, in proportion to their respective commitments hereunder, to purchase the Securities which such defaulting Underwriter or Underwriters agreed but failed to purchase on such Closing Date or Option Closing Date. If any Underwriter or Underwriters shall so default and the aggregate number of Securities with respect to which such default or defaults occur is more than ten percent (10%) of the total number of Securities to be purchased by all Underwriters on such Closing Date or Option Closing Date and arrangements satisfactory to the remaining Underwriters and the Company for the purchase of such Securities by other persons are not made within forty-eight (48) hours after such default, this Agreement shall terminate.

If the remaining Underwriters or substituted Underwriters are required hereby or agree to take up all or part of the Securities of a defaulting Underwriter or Underwriters on such Closing Date or Option Closing Date as provided in this Section 10, (i) the Company shall have the right to postpone such Closing Date or Option Closing Date for a period of not more than five (5) full business days in order to permit the Company to effect whatever changes in the Registration Statement, the Final Prospectus, or in any other documents or arrangements, which may thereby be made necessary, and the Company agrees to promptly file any amendments to the Registration Statement or the Final Prospectus which may thereby be made necessary, and (ii) the respective numbers of Securities to be purchased by the remaining Underwriters or substituted Underwriters shall be taken as the basis of their underwriting obligation for all purposes of this Agreement. Nothing herein contained shall relieve any defaulting Underwriter of its liability to the Company or any other Underwriter for damages occasioned by its default hereunder. Any termination of this Agreement pursuant to this Section 10 shall be without liability on the part of any non-defaulting Underwriters or the Company, except that the obligations with respect to expenses to be paid or reimbursed pursuant to Section 5(a)(viii) and Section 7 and Sections 9 through 17, inclusive, shall not terminate and shall remain in full force and effect.

11. **[Intentionally Omitted]**.

12. Notices. All notices and communications hereunder shall be in writing and mailed or delivered or by telephone, electronic mail or telegraph if subsequently confirmed in writing, (a) if to the Representative, WallachBeth Capital LLC, Harborside Financial Center Plaza 5, 185 Hudson Street, Ste 1410, Jersey City, NJ 07311, with a copy (which shall not constitute notice) to David Ficksman, Esq., TroyGould PC, 1801 Century Park East, Suite 1600, Los Angeles, CA 90067 and (b) if to the Company, to the Company's agent for service as such agent's address appears on the cover page of the Registration Statement with a copy (which shall not constitute notice) to Carmel, Milazzo & Feil LLP, 55 West 39th Street, 4th Floor, New York, NY 10018, Attention: Ross Carmel, Esq.

13. Persons Entitled to Benefit of Agreement. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and assigns and the controlling persons, officers and directors referred to in Section 7. Nothing in this Agreement is intended or shall be construed to give to any other person, firm or corporation any legal or equitable remedy or claim under or in respect of this Agreement or any provision herein contained. The term "successors and assigns" as herein used shall not include any purchaser, as such purchaser, of any of the Shares from any Underwriters.

14. Absence of Fiduciary Relationship. The Company acknowledges and agrees that: (a) each Underwriter has been retained solely to act as underwriter in connection with the sale of the Securities and that no fiduciary, advisory or agency relationship between the Company and any Underwriter has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Underwriter has advised or is advising the Company on other matters; (b) the price and other terms of the Securities set forth in this Agreement were established by the Company following discussions and arms-length negotiations with the Underwriters and the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement; (c) it has been advised that the Underwriters and their affiliates are engaged in a broad range of transactions that may involve interests that differ from those of the Company and that no Underwriter has any obligation to disclose such interest and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and (d) it has been advised that each Underwriter is acting, in respect of the transactions contemplated by this Agreement, solely for the benefit of such Underwriter, and not on behalf of the Company.

15. Amendments and Waivers. No supplement, modification or waiver of this Agreement shall be binding unless executed in writing by the party to be bound thereby. The failure of a party to exercise any right or remedy shall not be deemed or constitute a waiver of such right or remedy in the future. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision hereof (regardless of whether similar), nor shall any such waiver be deemed or constitute a continuing waiver unless otherwise expressly provided.

16. Partial Unenforceability. The invalidity or unenforceability of any section, paragraph, clause or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph, clause or provision.

17. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

18. Submission to Jurisdiction. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Agreement shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. EACH OF THE COMPANY (ON BEHALF OF ITSELF AND, TO THE FULLEST EXTENT PERMITTED BY LAW, ON BEHALF OF ITS RESPECTIVE EQUITY HOLDERS AND CREDITORS) AND THE UNDERWRITER HEREBY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY CLAIM BASED UPON, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, THE REGISTRATION STATEMENT, THE TIME OF SALE DISCLOSURE PACKAGE, ANY PROSPECTUS AND THE FINAL PROSPECTUS.

19. Counterparts. This Agreement may be executed and delivered (including by facsimile transmission or electronic mail) in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original and all such counterparts shall together constitute one and the same instrument.

[*Signature Page Follows*]

Please sign and return to the Company the enclosed duplicates of this letter whereupon this letter will become a binding agreement between the Company and the several Underwriters in accordance with its terms.

Very truly yours,

60 DEGREES PHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

Confirmed as of the date first above-mentioned by the Representative of the several Underwriters.

WALLACHBETH CAPITAL LLC

By: _____
Name: _____
Title: _____

[Signature page to Underwriting Agreement]

SCHEDULE I

Schedule of Underwriters

Underwriter	*Number of Firm Securities to be Purchased*	*Total Number of Option Securities to be Purchased*	
	Number of Firm Units	Number of Option Shares	Number of Option Warrants
WallachBeth Capital LLC			
Total			

SCHEDULE II

Pricing Information

Number of Firm Units:

Number of Option Shares:

Number of Option Tradeable Warrants:

Number of Option Non-tradeable Warrants:

Public Offering Price per Firm Unit: $[●]

Public Offering Price per Option Share: $[●]

Public Offering Price per Option Tradeable Warrant: $0.15

Public Offering Price per Option Non-tradeable Warrant: $0.15

Underwriting Discount per Firm Unit: (8% per Firm Unit)

Underwriting non-accountable expense allowance per Firm Unit: (1.5% per Firm Unit)

SCHEDULE III

Free Writing Prospectus

None.

SCHEDULE IV

Lock-Up Parties

- Geoffrey Dow
- Tyrone Miller
- Bryan Smith
- Charles Allen
- Cheryl Xu
- Stephen Toovey
- Paul Field

EXHIBIT A
Form of Lock-Up Agreement
(*See attached*.)

Exhibit 5.1

June 1, 2023

60 Degrees Pharmaceuticals, Inc.
1025 Connecticut Avenue NW
Suite 1000
Washington, DC 20036

Attn: Board of Directors

RE: 60 Degrees Pharmaceuticals, Inc.
Registration Statement on Form S-1 (File No.: 333-269483)

Ladies and Gentlemen:

We have acted as counsel to 60 Degrees Pharmaceuticals, Inc., a Delaware corporation (the "Company"), in connection with the preparation and filing with the Securities and Exchange Commission (the "Commission") of the above-caption registration under the Securities Act of 1933, as amended (the "Securities Act"), initially filed with the Commission on January 31, 2023, and as amended on April 3, 2023, April 28, 2023 and May 19, 2023 (the "Registration Statement"). The Company filed the Registration Statement in connection with the proposed registration of up to an aggregate of: (i) 1,415,095 units (the "Units"), with each Unit consisting of (A) one share of common stock, par value $0.0001 per share ("Common Stock"), (B) one tradeable warrant to purchase one share of Common Stock ("Tradeable Warrant") and (C) one non-tradeable warrant to purchase one share of Common Stock ("Non-tradeable Warrant"), to be issued and sold by the Company in its initial public offering (the 1,415,095 shares of Common Stock underlying the Units, the "Unit Shares," the 1,415,095 shares of Common Stock issuable upon the exercise of the Tradeable Warrants underlying the Units, the "Unit Tradeable Warrant Shares" and the 1,415,095 shares of Common Stock issuable upon the exercise of the Non-tradeable Warrants underlying the Units, the "Unit Non-tradeable Warrant Shares"); (ii) 1,992,846 shares of Common Stock on behalf of the selling stockholders of the Company named in the Registration Statement (the "Selling Stockholders"), consisting of (A) 10,482 shares of common stock to be issued upon conversion of a convertible note immediately prior to the consummation of the initial public offering (the "Note Shares"), (B) 373,426 shares of common stock to be issued in conjunction with the conversion or extinguishment of interim financing notes on the date of effectiveness of the Registration Statement (together with the Note Shares, the "Selling Stockholders' Shares") and (C) 1,608,938 shares of common stock held by certain of the Selling Stockholders (the "Selling Stockholders' Outstanding Shares"); (iii) (A) 212,265 shares of Common Stock (the "Over-Allotment Option Shares") issuable upon the exercise of an over-allotment option granted by the Company to the underwriters (the "Over-Allotment Option"), (B) 212,265 Tradeable Warrants issuable upon the exercise of the Over-Allotment Option (the "Over-Allotment Option Tradeable Warrants"), including 212,265 shares of Common Stock issuable upon the exercise of the Over-Allotment Option Tradeable Warrants (the "Over-Allotment Option Tradeable Warrant Shares") and (C) 212,265 Non-tradeable Warrants issuable upon the exercise of the Over-Allotment Option (the "Over-Allotment Option Non-tradeable Warrants"), including 212,265 shares of Common Stock issuable upon the exercise of the Over-Allotment Option Non-tradeable Warrants (the "Over-Allotment Option Non-tradeable Warrant Shares"); (iv) 84,906 warrants to be issued to the representative of the underwriters as compensation for their services pursuant to the underwriting agreement to be entered into by and between the Company and the underwriters (the "Representative Warrants"), including the 84,906 shares of Common Stock issuable upon the exercise of the Representative Warrants (the "Representative Warrant Shares "); and (v) 231,917 shares of Common Stock issuable upon the exercise of the warrants to be issued to the investors in the May 2022 and 2023 interim financings on the effective date of the Registration Statement (the "Interim Investors' Warrant Shares"). This opinion is being furnished in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act.

In rendering these opinions, we have examined the Company's certificate of incorporation, as corrected, and amended and restated bylaws, both as currently in effect, the Registration Statement, and the exhibits thereto, and such other records, instruments and documents as we have deemed advisable in order to render these opinions. In such examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, conformed or photostatic copies and the authenticity of the originals of such latter documents. In providing these opinions, we have further relied as to certain matters on information obtained from officers of the Company.

Based upon the foregoing and in reliance thereon, and subject to the qualifications, limitations, exceptions and assumptions set forth herein, we are of the opinion that, having been issued and sold in exchange for payment in full to the Company of all consideration required therefor as applicable, including with regard to the Units, the Unit Shares, the Tradeable Warrants underlying the Units, the Unit Tradeable Warrant Shares, the Non-tradeable Warrants underlying the Units, the Unit Non-tradeable Warrant Shares, the Over-Allotment Option Tradeable Warrants, the Over-Allotment Option Tradeable Warrant Shares, the Over-Allotment Option Non-tradeable Warrants, the Over-Allotment Option Non-tradeable Warrant Shares, the Representative Warrants, the Representative Warrant Shares and the Interim Investor Warrant Shares, and as described in the Registration Statement:

(i) The Units, when delivered in accordance with the Underwriting Agreement upon payment of the agreed upon consideration therefor, will constitute valid and binding obligations of the Company, enforceable against the Company in accordance with its terms;

(ii) The Unit Shares, when issued against payment therefor, will be validly issued, fully paid and non-assessable shares of Common Stock of the Company;

(iii) The Tradeable Warrants underlying the Units, when issued against payment therefor, will constitute the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with their terms, except that (a) such enforceability may be limited by bankruptcy, insolvency or other similar laws affecting the enforcement of creditors' rights in general and (b) the remedies of specific performance and injunctive and other forms of injunctive relief may be subject to equitable defenses;

(iv) The Unit Tradeable Warrant Shares have been duly authorized by all necessary corporate action on the part of the Company and, when issued, sold and delivered by the Company pursuant to the exercise of the Tradeable Warrants underlying the Units against payment therefor, will be validly issued, fully paid and non-assessable shares of Common Stock of the Company;

(v) The Non-tradeable Warrants underlying the Units, when issued against payment therefor, will constitute the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with their terms, except that (a) such enforceability may be limited by bankruptcy, insolvency or other similar laws affecting the enforcement of creditors' rights in general and (b) the remedies of specific performance and injunctive and other forms of injunctive relief may be subject to equitable defenses;

(vi) The Unit Non-tradeable Warrant Shares have been duly authorized by all necessary corporate action on the part of the Company and, when issued, sold and delivered by the Company pursuant to the exercise of the Non-tradeable Warrants underlying the Units against payment therefor, will be validly issued, fully paid and non-assessable shares of Common Stock of the Company;

(vii) The Selling Stockholders' Shares, when issued to certain of the Selling Stockholders, will be deemed to be validly issued, fully paid and non-assessable shares of Common Stock of the Company;

(viii) The Selling Stockholders' Outstanding Shares are validly issued, fully paid and nonassessable shares of Common Stock;

(ix) The Over-Allotment Option Shares, when issued pursuant to the exercise of the Over-Allotment Option, will be validly issued, fully paid, and non-assessable;

(x) The Over-Allotment Option Tradeable Warrants, when issued against payment therefor, will constitute the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with their terms, except that (a) such enforceability may be limited by bankruptcy, insolvency or other similar laws affecting the enforcement of creditors' rights in general and (b) the remedies of specific performance and injunctive and other forms of injunctive relief may be subject to equitable defenses;

(xi) The Over-Allotment Option Tradeable Warrant Shares have been duly authorized by all necessary corporate action on the part of the Company and, when issued, sold and delivered by the Company pursuant to the exercise of the Over-Allotment Option Tradeable Warrants against payment therefor, will be validly issued, fully paid and non-assessable shares of Common Stock of the Company.

(xii) The Over-Allotment Option Non-tradeable Warrants, when issued against payment therefor, will constitute the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with their terms, except that (a) such enforceability may be limited by bankruptcy, insolvency or other similar laws affecting the enforcement of creditors' rights in general and (b) the remedies of specific performance and injunctive and other forms of injunctive relief may be subject to equitable defenses;

(xiii) The Over-Allotment Option Non-tradeable Warrant Shares have been duly authorized by all necessary corporate action on the part of the Company and, when issued, sold and delivered by the Company pursuant to the exercise of the Over-Allotment Option Non-tradeable Warrants against payment therefor, will be validly issued, fully paid and non-assessable shares of Common Stock of the Company;

(xiv) The Representative Warrants, when issued against payment therefor, will constitute the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with their terms, except that (a) such enforceability may be limited by bankruptcy, insolvency or other similar laws affecting the enforcement of creditors' rights in general and (b) the remedies of specific performance and injunctive and other forms of injunctive relief may be subject to equitable defenses;

(xv) The Representative's Warrant Shares have been duly authorized by all necessary corporate action on the part of the Company and, when issued, sold and delivered by the Company pursuant to the Representative's Warrants against payment therefor, will be validly issued, fully paid and non-assessable shares of Common Stock of the Company; and

(xvi) The Interim Investors' Warrant Shares have been duly authorized by all necessary corporate action on the part of the Company and, when issued, sold and delivered by the Company pursuant to the Interim Investors' Warrants against payment therefor, will be validly issued, fully paid and non-assessable shares of Common Stock of the Company.

Our opinion is limited to the federal laws of the United States and the Delaware General Corporation Law and, with respect to the opinions set forth in paragraphs (iv), (vi), (xi), (xiii), (xv) and (xvi) above, the internal laws of the State of New York. We express no opinion as to the effect of the law of any other jurisdiction. Our opinion is rendered as of the date hereof, and we assume no obligation to advise you of changes in law or fact (or the effect thereof on the opinions expressed herein) that hereafter may come to our attention. This opinion letter is limited to the laws in effect as of the date the Registration Statement is declared effective by the Commission and is provided exclusively in connection with the public offering and resale offering contemplated by the Registration Statement.

This opinion letter speaks only as of the date hereof and we assume no obligation to update or supplement this opinion letter if any applicable laws change after the date of this opinion letter or if we become aware after the date of this opinion letter of any facts, whether existing before or arising after the date hereof, that might change the opinions expressed above.

This opinion letter is furnished in connection with the filing of the Registration Statement and may not be relied upon for any other purpose without our prior written consent in each instance. Further, no portion of this letter may be quoted, circulated or referred to in any other document for any other purpose without our prior written consent.

We consent to the use of this opinion as Exhibit 5.1 to the Registration Statement and further consent to all references to us, if any, in the Registration Statement, and in the prospectus forming a part thereof. We do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder. This opinion is rendered on, and speaks only as of, the date of this letter first written above, and does not address any potential change in facts or law that may occur after the date of this opinion letter. We assume no obligation to advise you of any fact, circumstance, event or change in the law or the facts that may hereafter be brought to our attention, whether or not such occurrence would affect or modify any of the opinions expressed herein.

Very truly yours,

/s/ Carmel, Milazzo & Feil LLP

Carmel, Milazzo & Feil LLP

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933 (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

COMMON STOCK PURCHASE WARRANT

Warrant Shares: <Number of Warrant Shares>[1]

Initial Exercise Date: May 8, 2023

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, <HOLDER>., or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") and on or prior to the close of business on the fifth year anniversary of the date of the IPO (the "Termination Date") but not thereafter, to subscribe for and purchase from 60° Pharmaceuticals, Inc. (the "Company"), up to <WARRANT SHARES> shares of Common Stock (subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one Warrant Share under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant issued pursuant to a Securities Purchase Agreement (the "Purchase Agreement") entered into as of the Initial Exercise Date between the Company and the initial Holder.

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Securities Purchase Agreement (the "Purchase Agreement"), dated April [*], 2023 among the Company and the Purchasers.

Section 2. Exercise.

(a) Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed copy of the Notice of Exercise Form annexed hereto. Within two Trading Days following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank, unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary (although the Holder may surrender the Warrant to, and receive a replacement Warrant from, the Company), the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise Form within one Trading Day of delivery of such notice. The Holder by acceptance of this Warrant or any transferee, acknowledges and agrees that, by reason of the provisions of this Section 2(a), following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.

(b) Exercise Price. The initial exercise price per share of the Common Stock under this Warrant shall be equal to either 110% of the IPO (as defined in the Purchase Agreement) price (the "Exercise Price") or, if the Company does not complete the IPO, the price calculated using a $27 million pre-money valuation for the Company and the number of the Company's shares outstanding on the Maturity Date.

1 The number of Warrant Shares shall equal 50% of the number of shares of common stock issuable upon conversion of that certain Promissory Note dated as of May 8, 2023, issued by the Company to the Holder.

(c) Cashless Exercise. Other than as provided for in Section 2(f), if at any time after the six month anniversary of the Initial Exercise Date, there is no effective Registration Statement covering the resale of the Warrant Shares by the Holder (or the prospectus does not meet the requirements of Section 10 of the Securities Act), then this Warrant may also be exercised at the Holder's election, in whole or in part and in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the number obtained by dividing [(A - B) times (C)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. ("Bloomberg") as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder, at the time of such exercise; and

(C) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise;

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies:
(a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)) (or a similar organization or agency succeeding to its functions of reporting prices), (b) if no volume weighted average price of the Common Stock is reported for the Trading Market, the most recent reported bid price per share of the Common Stock, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, if on the Termination Date (unless the Holder notifies the Company otherwise) if there is no effective Registration Statement covering the resale of the Warrant Shares by the Holder, then this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

(d) Mechanics of Exercise.

(i) Delivery of Certificates Upon Exercise. Certificates for the shares of Common Stock purchased hereunder shall be transmitted to the Holder by the Transfer Agent by crediting the account of the Holder's prime broker with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise and Rule 144 is available, or otherwise by physical delivery to the address specified by the Holder in the Notice of Exercise by the date that is the latest of (A) two Trading Days after the delivery to the Company of the Notice of Exercise and (B) the date that of payment of the aggregate Exercise Price as set forth above (unless by cashless exercise, if permitted) (such date, the "Warrant Share Delivery Date"). The Warrant Shares shall be deemed to have been issued, and Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date the Warrant has been exercised, subject only to payment to the Company of the Exercise Price (unless by cashless exercise, if permitted). The Company understands that a delay in the delivery of the Warrant Shares after the Warrant Share Delivery Date could result in economic loss to the Holder. As compensation to the Holder for such loss, the Company agrees to pay (as liquidated damages and not as a penalty) to the Holder for late issuance of Warrant Shares upon exercise of this Warrant the proportionate amount of $10 per Trading Day (increasing to $20 per Trading Day after the fifth Trading Day) after the Warrant Share Delivery Date for each $1,000 of the value of the Warrant Shares for which this Warrant is exercised (based on the Exercise Price) which are not timely delivered. Furthermore, in addition to any other remedies which may be available to the Holder, in the event that the Company fails for any reason to effect delivery of the Warrant Shares by the Warrant Share Delivery Date, the Holder may revoke all or part of the relevant Warrant exercise by delivery of a notice to such effect to the Company, whereupon the Company and the Holder shall each be restored to their respective positions immediately prior to the exercise of the relevant portion of this Warrant, except that the liquidated damages described above shall be payable through the date notice of revocation or rescission is given to the Company or the date the Warrant Shares are delivered to the Holder, whichever date is earlier.

(ii) Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant, at the time of delivery of the certificate or certificates representing Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical to this Warrant. Unless the Warrant has been fully exercised, the Holders shall not be required to surrender this Warrant as a condition of exercise.

(iii) Rescission Rights. If the Company fails to deliver the Warrant Shares or cause the Transfer Agent to transmit to the Holder a certificate or the certificates representing the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right, at any time prior to issuance of such Warrant Shares, to rescind such exercise.

(iv) Compensation for Buy-In on Failure to Timely Deliver Certificates Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to deliver the Warrant Shares, or cause the Transfer Agent to transmit to the Holder the certificate or certificates representing the Warrant Shares pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall pay in cash to the Holder the amount as provided under Section 4.1(e) of the Purchase Agreement. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

(v) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

(vi) Charges, Taxes and Expenses. Issuance of certificates for Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such certificate including any charges of any clearing firm, all of which taxes and expenses shall be paid by the Company, and such certificates shall be issued in the name of the Holder or in such name or names as may be directed by the Holder. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise. The Company shall cause its attorneys to promptly provide any reliance opinion to the Transfer Agent, and, if required, pay the Holder the sums required under Section 2(d)(iv).

(vii) Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon not less than 61 days' prior notice to the Company, may increase the Beneficial Ownership Limitation provisions of this Section 2(e) solely with respect to the Holder's Warrant, provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any such increase will not be effective until the 61st day after such notice is delivered to the Company. The Holder may also decrease the Beneficial Ownership Limitation provisions of this Section 2(e) solely with respect to the Holder's Warrant at any time, which decrease shall be effectively immediately upon delivery of notice to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant or pursuant to any of the other Transaction Documents), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Subsequent Equity Sales. If and whenever on or after the Initial Exercise Date, the Company issues or sells, or in accordance with this Section 3 is deemed to have issued or sold, any shares of Common Stock (including the issuance or sale of shares of Common Stock owned or held by or for the account of the Company, issued or sold or deemed to have been issued or sold) for a consideration per share (the "Base Share Price") less than a price equal to the Exercise Price in effect immediately prior to such issuance or sale or deemed issuance or sale (such Exercise Price then in effect is referred to herein as the "Applicable Price") (the foregoing a "Dilutive Issuance"), then immediately after such Dilutive Issuance, the Exercise Price then in effect shall be reduced to an amount equal to the Base Share Price. For all purposes of the foregoing (including, without limitation, determining the adjusted Exercise Price and the Base Share Price under this Section 3(b)), the following shall be applicable:

(i) Issuance of Options. If the Company in any manner grants or sells any Options and the lowest price per share for which one share of Common Stock is at any time issuable upon the exercise of any such Option or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the granting or sale of such Option for such price per share. For purposes of this Section 3(b)(i), the "lowest price per share for which one share of Common Stock is issuable upon the exercise of any such Options or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof" shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to any one share of Common Stock upon the granting or sale of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option or otherwise pursuant to the terms thereof and (y) the lowest exercise price set forth in such Option for which one share of Common Stock is issuable upon the exercise of any such Options or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Option (or any other Person) upon the granting or sale of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option or otherwise pursuant to the terms thereof plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Option (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock or of such Convertible Securities upon the exercise of such Options or otherwise pursuant to the terms of or upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Convertible Securities.

(ii) Issuance of Convertible Securities. If the Company in any manner issues or sells any Convertible Securities and the lowest price per share for which one share of Common Stock is at any time issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the issuance or sale of such Convertible Securities for such price per share. For the purposes of this Section 3(b)(ii), the "lowest price per share for which one share of Common Stock is issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof" shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to one share of Common Stock upon the issuance or sale of the Convertible Security and upon conversion, exercise or exchange of such Convertible Security or otherwise pursuant to the terms thereof and (y) the lowest conversion price set forth in such Convertible Security for which one share of Common Stock is issuable upon conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Convertible Security (or any other Person) upon the issuance or sale of such Convertible Security plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Convertible Security (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Convertible Securities or otherwise pursuant to the terms thereof, and if any such issuance or sale of such Convertible Securities is made upon exercise of any Options for which adjustment of this Warrant has been or is to be made pursuant to other provisions of this Section 3(b), except as contemplated below, no further adjustment of the Exercise Price shall be made by reason of such issuance or sale.

(iii) Change in Option Price or Rate of Conversion. "Convertible Securities" means any stock or other security (other than Options) that is at any time and under any circumstances, directly or indirectly, convertible into, exercisable or exchangeable for, or which otherwise entitles the holder thereof to acquire, any shares of Common Stock. If the purchase or exercise price provided for in any Options, the additional consideration, if any, payable upon the issue, conversion, exercise or exchange of any Convertible Securities, or the rate at which any Convertible Securities are convertible into or exercisable or exchangeable for shares of Common Stock increases or decreases at any time (other than proportional changes in conversion or exercise prices, as applicable, in connection with an event referred to in Section 3(a)), the Exercise Price in effect at the time of such increase or decrease shall be adjusted to the Exercise Price which would have been in effect at such time had such Options or Convertible Securities provided for such increased or decreased purchase price, additional consideration or increased or decreased conversion rate, as the case may be, at the time initially granted, issued or sold. For purposes of this Section 3(b)(iii), if the terms of any Option or Convertible Security that was outstanding as of the Closing Date are increased or decreased in the manner described in the immediately preceding sentence, then such Option or Convertible Security and the shares of Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such increase or decrease. No adjustment pursuant to this Section 3(b) shall be made if such adjustment would result in an increase of the Exercise Price then in effect.

(iv) Calculation of Consideration Received. If any Option is issued in connection with the issuance or sale of any other securities of the Company together comprising one integrated transaction in which no specific consideration is allocated to such Option by the parties thereto, the Options will be deemed to have been issued for a consideration of par value of the Company's Common Stock. If any shares of Common Stock, Options or Convertible Securities are issued or sold or deemed to have been issued or sold for cash, the consideration received therefor will be deemed to be the net amount of consideration received by the Company therefor. If any shares of Common Stock, Options or Convertible Securities are issued or sold for a consideration other than cash, the amount of such consideration received by the Company will be the fair value of such consideration, except where such consideration consists of publicly traded securities, in which case the amount of consideration received by the Company for such securities will be the arithmetic average of the VWAPs of such security for each of the five Trading Days immediately preceding the date of receipt. If any shares of Common Stock, Options or Convertible Securities are issued to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving entity, the amount of consideration therefor will be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such shares of Common Stock, Options or Convertible Securities. The fair value of any consideration other than cash or publicly traded securities will be determined jointly by the Company and the Holder. If such parties are unable to reach agreement within 10 days after the occurrence of an event requiring valuation (the "Valuation Event"), the fair value of such consideration will be determined within five Trading Days after the 10th day following such Valuation Event by an independent, reputable appraiser jointly selected by the Company and the Holder. The determination of such appraiser shall be final and binding upon all parties absent manifest error. If such appraiser's valuation differs by less than 5% from the Company's proposed valuation, the fees and expenses of such appraiser shall be borne by the Holder, and if such appraiser's valuation differs by more than 5% from the Company's proposed valuation, the fees and expenses of such appraiser shall be borne by the Company.

(v) Record Date. If the Company takes a record of the holders of shares of Common Stock for the purpose of entitling them (A) to receive a dividend or other distribution payable in shares of Common Stock, Options or in Convertible Securities or (B) to subscribe for or purchase shares of Common Stock, Options or Convertible Securities, then such record date will be deemed to be the date of the issuance or sale of the shares of Common Stock deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase (as the case may be).

(vi) Notwithstanding the foregoing, this Section 3(b) shall not apply to any Exempt Issuances.

(c) Full Ratchet Increase in Warrant Shares. Until the Notes are no longer outstanding, whenever the Exercise Price is adjusted under Section 3(b), the number of Warrant Shares shall be increased on a full ratchet basis to the number of shares of Common Stock determined by multiplying the Exercise Price then in effect immediately prior to such adjustment by the number of Warrant Shares issuable upon exercise of this Warrant immediately prior to such adjustment and dividing the product thereof by the Exercise Price resulting from such adjustment. By way of example, if E is the total number of Warrant Shares in effect immediately prior to such Dilutive Issuance, F is the Exercise Price in effect immediately prior to such Dilutive Issuance, and G is the Dilutive Issuance Price, the adjustment to the number of Warrant Shares can be expressed in the following formula: Total number of Warrant Shares after such Dilutive Issuance = the number obtained from dividing [E x F] by G.

(d) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

(e) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, shall distribute to all holders of Common Stock (and not to the Holder) evidences of its indebtedness or assets (including cash and cash dividends) or rights or warrants to subscribe for or purchase any security other than the Common Stock (which shall be subject to Section 3(d)), then in each such case the Exercise Price shall be adjusted by multiplying the Exercise Price in effect immediately prior to the record date fixed for determination of stockholders entitled to receive such distribution by a fraction of which the denominator shall be the VWAP determined as of the record date mentioned above, and of which the numerator shall be such VWAP on such record date less the then per share fair market value at such record date of the portion of such assets or evidence of indebtedness so distributed applicable to one outstanding share of the Common Stock as determined by the Board of Directors in good faith. In either case the adjustments shall be described in a statement provided to the Holder of the portion of assets or evidences of indebtedness so distributed or such subscription rights applicable to one share of Common Stock. Such adjustment shall be made whenever any such distribution is made and shall become effective immediately after the record date mentioned above.

(f) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (or any Subsidiary), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires 50% or more of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity of the Company (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, the Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of (1) the 30 day volatility, (2) the 100 day volatility or (3) the 365 day volatility, each of clauses (1)-(3) as obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to this Section 3(e) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within the later of (i) five Business Days of the Holder's election and (ii) the date of consummation of the Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant and the other Transaction Documents with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(e) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

(g) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(h) Notice to Holder.

(i) Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly email to the Holder a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment. The Holder may supply an email address to the Company and change such address.

(ii) Notice to Allow Exercise by the Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall deliver to the Holder at its last address as it shall appear upon the Warrant Register of the Company, at least 5 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to email such notice or any defect therein or in the emailing thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries (as determined in good faith by the Company), the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

(a) Transferability. Subject to compliance with any applicable securities laws and the provisions of the Purchase Agreement, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney. Upon such surrender, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. The Warrant, if properly assigned in accordance herewith, may be exercised by a new Holder for the purchase of Warrant Shares without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

(a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof other than as explicitly set forth in Section 3.

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it, and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate. In no event shall the Holder be required to deliver a bond or other security.

(c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Trading Day.

(d) Authorized Shares.

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its Articles of Incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use best efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Purchase Agreement.

(f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered or if not exercised on a cashless basis when Rule 144 (or any successor law or rule) is available, may have restrictions upon resale imposed by state and federal securities laws.

(g) Non-waiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of the Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant or the Purchase Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

(h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Purchase Agreement.

(i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate or that there is no irreparable harm and not to require the posting of a bond or other security.

(k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder of Warrant Shares.

(l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

(m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

(n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

60° PHARMACEUTICALS, INC.

By: */s/ Geoffrey Dow*
Name: Geoffrey Dow
Title: Chief Executive Officer

NOTICE OF EXERCISE

TO: **60 Degrees Pharmaceuticals, Inc.**

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue a certificate or certificates representing said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

(4) After giving effect to this Notice of Exercise, the undersigned will not have exceeded the Beneficial Ownership Limitation.

The Warrant Shares shall be delivered to the following DWAC Account Number or by physical delivery of a certificate to:

_____

_____

_____

SIGNATURE OF HOLDER

Name of Investing Entity:

_____

Signature of Authorized Signatory of Investing Entity:

_____

Name of Authorized Signatory:

_____

Title of Authorized Signatory:

_____

Date:

ASSIGNMENT FORM

(To assign the foregoing warrant, execute this
form and supply required information. Do not use
this form to exercise the warrant.)

60 Degrees Pharmaceuticals, Inc.

FOR VALUE RECEIVED,_____all of or_____shares of the foregoing Warrant and all rights evidenced thereby are hereby assigned to _____

_____whose address is

_____

Dated:_____, _____

Holder's Signature:_____

Holder's Address:_____

Signature Guaranteed:_____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank or trust company. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933 (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

COMMON STOCK PURCHASE WARRANT

Warrant Shares: <Number of Warrant Shares>

Initial Exercise Date: May 8, 2023

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, <HOLDER>., or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date that is one hundred eighty days (180) days after the date hereof (the "Initial Exercise Date") and on or prior to the close of business on the fifth year anniversary of the date of the IPO (the "Termination Date") but not thereafter, to subscribe for and purchase from 60° Pharmaceuticals, Inc. (the "Company"), up to <WARRANT SHARES> shares of Common Stock (subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one Warrant Share under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant issued pursuant to a Securities Purchase Agreement (the "Purchase Agreement") entered into as of the Initial Exercise Date between the Company and the initial Holder. The Holder agrees that the Holder shall not, during the period ending 180 days after the pricing of the IPO: (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Warrant Shares or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Warrant Shares.

Section 1. [Reserved.]

Section 2. Exercise.

(a) Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed copy of the Notice of Exercise Form annexed hereto. Within two Trading Days following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank, unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary (although the Holder may surrender the Warrant to, and receive a replacement Warrant from, the Company), the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise Form within one Trading Day of delivery of such notice. The Holder by acceptance of this Warrant or any transferee, acknowledges and agrees that, by reason of the provisions of this Section 2(a), following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.

(b) Exercise Price. The initial exercise price per share of the Common Stock under this Warrant shall be equal to either 110% of the IPO (as defined in the Purchase Agreement) price (the "Exercise Price") or, if the Company does not complete the IPO, the price calculated using a $27 million pre-money valuation for the Company and the number of the Company's shares outstanding on the Maturity Date.

(c) Cashless Exercise. Other than as provided for in Section 2(f), if at any time after the six month anniversary of the Initial Exercise Date, there is no effective Registration Statement covering the resale of the Warrant Shares by the Holder (or the prospectus does not meet the requirements of Section 10 of the Securities Act), then this Warrant may also be exercised at the Holder's election, in whole or in part and in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the number obtained by dividing [(A - B) times (C)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. ("Bloomberg") as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder, at the time of such exercise; and

(C) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise;

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)) (or a similar organization or agency succeeding to its functions of reporting prices), (b) if no volume weighted average price of the Common Stock is reported for the Trading Market, the most recent reported bid price per share of the Common Stock, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, if on the Termination Date (unless the Holder notifies the Company otherwise) if there is no effective Registration Statement covering the resale of the Warrant Shares by the Holder, then this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

(d) Mechanics of Exercise.

(i) Delivery of Certificates Upon Exercise. Certificates for the shares of Common Stock purchased hereunder shall be transmitted to the Holder by the Transfer Agent by crediting the account of the Holder's prime broker with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise and Rule 144 is available, or otherwise by physical delivery to the address specified by the Holder in the Notice of Exercise by the date that is the latest of (A) two Trading Days after the delivery to the Company of the Notice of Exercise and (B) the date that of payment of the aggregate Exercise Price as set forth above (unless by cashless exercise, if permitted) (such date, the "Warrant Share Delivery Date"). The Warrant Shares shall be deemed to have been issued, and Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date the Warrant has been exercised, subject only to payment to the Company of the Exercise Price (unless by cashless exercise, if permitted). The Company understands that a delay in the delivery of the Warrant Shares after the Warrant Share Delivery Date could result in economic loss to the Holder. As compensation to the Holder for such loss, the Company agrees to pay (as liquidated damages and not as a penalty) to the Holder for late issuance of Warrant Shares upon exercise of this Warrant the proportionate amount of $10 per Trading Day (increasing to $20 per Trading Day after the fifth Trading Day) after the Warrant Share Delivery Date for each $1,000 of the value of the Warrant Shares for which this Warrant is exercised (based on the Exercise Price) which are not timely delivered. Furthermore, in addition to any other remedies which may be available to the Holder, in the event that the Company fails for any reason to effect delivery of the Warrant Shares by the Warrant Share Delivery Date, the Holder may revoke all or part of the relevant Warrant exercise by delivery of a notice to such effect to the Company, whereupon the Company and the Holder shall each be restored to their respective positions immediately prior to the exercise of the relevant portion of this Warrant, except that the liquidated damages described above shall be payable through the date notice of revocation or rescission is given to the Company or the date the Warrant Shares are delivered to the Holder, whichever date is earlier.

(ii) Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant, at the time of delivery of the certificate or certificates representing Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical to this Warrant. Unless the Warrant has been fully exercised, the Holders shall not be required to surrender this Warrant as a condition of exercise.

(iii) Rescission Rights. If the Company fails to deliver the Warrant Shares or cause the Transfer Agent to transmit to the Holder a certificate or the certificates representing the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right, at any time prior to issuance of such Warrant Shares, to rescind such exercise.

(iv) Compensation for Buy-In on Failure to Timely Deliver Certificates Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to deliver the Warrant Shares, or cause the Transfer Agent to transmit to the Holder the certificate or certificates representing the Warrant Shares pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall pay in cash to the Holder the amount as provided under Section 4.1(e) of the Purchase Agreement. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

(v) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

(vi) Charges, Taxes and Expenses. Issuance of certificates for Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such certificate including any charges of any clearing firm, all of which taxes and expenses shall be paid by the Company, and such certificates shall be issued in the name of the Holder or in such name or names as may be directed by the Holder. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise. The Company shall cause its attorneys to promptly provide any reliance opinion to the Transfer Agent, and, if required, pay the Holder the sums required under Section 2(d)(iv).

(vii) Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon not less than 61 days' prior notice to the Company, may increase the Beneficial Ownership Limitation provisions of this Section 2(e) solely with respect to the Holder's Warrant, provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any such increase will not be effective until the 61st day after such notice is delivered to the Company. The Holder may also decrease the Beneficial Ownership Limitation provisions of this Section 2(e) solely with respect to the Holder's Warrant at any time, which decrease shall be effectively immediately upon delivery of notice to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant or pursuant to any of the other Transaction Documents), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Subsequent Equity Sales. If and whenever on or after the Initial Exercise Date, the Company issues or sells, or in accordance with this Section 3 is deemed to have issued or sold, any shares of Common Stock (including the issuance or sale of shares of Common Stock owned or held by or for the account of the Company, issued or sold or deemed to have been issued or sold) for a consideration per share (the "Base Share Price") less than a price equal to the Exercise Price in effect immediately prior to such issuance or sale or deemed issuance or sale (such Exercise Price then in effect is referred to herein as the "Applicable Price") (the foregoing a "Dilutive Issuance"), then immediately after such Dilutive Issuance, the Exercise Price then in effect shall be reduced to an amount equal to the Base Share Price. For all purposes of the foregoing (including, without limitation, determining the adjusted Exercise Price and the Base Share Price under this Section 3(b)), the following shall be applicable:

(i) Issuance of Options. If the Company in any manner grants or sells any Options and the lowest price per share for which one share of Common Stock is at any time issuable upon the exercise of any such Option or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the granting or sale of such Option for such price per share. For purposes of this Section 3(b)(i), the "lowest price per share for which one share of Common Stock is issuable upon the exercise of any such Options or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof" shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to any one share of Common Stock upon the granting or sale of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option or otherwise pursuant to the terms thereof and (y) the lowest exercise price set forth in such Option for which one share of Common Stock is issuable upon the exercise of any such Options or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Option (or any other Person) upon the granting or sale of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option or otherwise pursuant to the terms thereof plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Option (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock or of such Convertible Securities upon the exercise of such Options or otherwise pursuant to the terms of or upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Convertible Securities.

(ii) Issuance of Convertible Securities. If the Company in any manner issues or sells any Convertible Securities and the lowest price per share for which one share of Common Stock is at any time issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the issuance or sale of such Convertible Securities for such price per share. For the purposes of this Section 3(b)(ii), the "lowest price per share for which one share of Common Stock is issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof" shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to one share of Common Stock upon the issuance or sale of the Convertible Security and upon conversion, exercise or exchange of such Convertible Security or otherwise pursuant to the terms thereof and (y) the lowest conversion price set forth in such Convertible Security for which one share of Common Stock is issuable upon conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Convertible Security (or any other Person) upon the issuance or sale of such Convertible Security plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Convertible Security (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Convertible Securities or otherwise pursuant to the terms thereof, and if any such issuance or sale of such Convertible Securities is made upon exercise of any Options for which adjustment of this Warrant has been or is to be made pursuant to other provisions of this Section 3(b), except as contemplated below, no further adjustment of the Exercise Price shall be made by reason of such issuance or sale.

(iii) Change in Option Price or Rate of Conversion. "Convertible Securities" means any stock or other security (other than Options) that is at any time and under any circumstances, directly or indirectly, convertible into, exercisable or exchangeable for, or which otherwise entitles the holder thereof to acquire, any shares of Common Stock. If the purchase or exercise price provided for in any Options, the additional consideration, if any, payable upon the issue, conversion, exercise or exchange of any Convertible Securities, or the rate at which any Convertible Securities are convertible into or exercisable or exchangeable for shares of Common Stock increases or decreases at any time (other than proportional changes in conversion or exercise prices, as applicable, in connection with an event referred to in Section 3(a)), the Exercise Price in effect at the time of such increase or decrease shall be adjusted to the Exercise Price which would have been in effect at such time had such Options or Convertible Securities provided for such increased or decreased purchase price, additional consideration or increased or decreased conversion rate, as the case may be, at the time initially granted, issued or sold. For purposes of this Section 3(b)(iii), if the terms of any Option or Convertible Security that was outstanding as of the Closing Date are increased or decreased in the manner described in the immediately preceding sentence, then such Option or Convertible Security and the shares of Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such increase or decrease. No adjustment pursuant to this Section 3(b) shall be made if such adjustment would result in an increase of the Exercise Price then in effect.

(iv) Calculation of Consideration Received. If any Option is issued in connection with the issuance or sale of any other securities of the Company together comprising one integrated transaction in which no specific consideration is allocated to such Option by the parties thereto, the Options will be deemed to have been issued for a consideration of par value of the Company's Common Stock. If any shares of Common Stock, Options or Convertible Securities are issued or sold or deemed to have been issued or sold for cash, the consideration received therefor will be deemed to be the net amount of consideration received by the Company therefor. If any shares of Common Stock, Options or Convertible Securities are issued or sold for a consideration other than cash, the amount of such consideration received by the Company will be the fair value of such consideration, except where such consideration consists of publicly traded securities, in which case the amount of consideration received by the Company for such securities will be the arithmetic average of the VWAPs of such security for each of the five Trading Days immediately preceding the date of receipt. If any shares of Common Stock, Options or Convertible Securities are issued to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving entity, the amount of consideration therefor will be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such shares of Common Stock, Options or Convertible Securities. The fair value of any consideration other than cash or publicly traded securities will be determined jointly by the Company and the Holder. If such parties are unable to reach agreement within 10 days after the occurrence of an event requiring valuation (the "Valuation Event"), the fair value of such consideration will be determined within five Trading Days after the 10^{th} day following such Valuation Event by an independent, reputable appraiser jointly selected by the Company and the Holder. The determination of such appraiser shall be final and binding upon all parties absent manifest error. If such appraiser's valuation differs by less than 5% from the Company's proposed valuation, the fees and expenses of such appraiser shall be borne by the Holder, and if such appraiser's valuation differs by more than 5% from the Company's proposed valuation, the fees and expenses of such appraiser shall be borne by the Company.

(v) Record Date. If the Company takes a record of the holders of shares of Common Stock for the purpose of entitling them (A) to receive a dividend or other distribution payable in shares of Common Stock, Options or in Convertible Securities or (B) to subscribe for or purchase shares of Common Stock, Options or Convertible Securities, then such record date will be deemed to be the date of the issuance or sale of the shares of Common Stock deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase (as the case may be).

(vi) Notwithstanding the foregoing, this Section 3(b) shall not apply to any Exempt Issuances.

(c) Full Ratchet Increase in Warrant Shares. Until the Notes are no longer outstanding, whenever the Exercise Price is adjusted under Section 3(b), the number of Warrant Shares shall be increased on a full ratchet basis to the number of shares of Common Stock determined by multiplying the Exercise Price then in effect immediately prior to such adjustment by the number of Warrant Shares issuable upon exercise of this Warrant immediately prior to such adjustment and dividing the product thereof by the Exercise Price resulting from such adjustment. By way of example, if E is the total number of Warrant Shares in effect immediately prior to such Dilutive Issuance, F is the Exercise Price in effect immediately prior to such Dilutive Issuance, and G is the Dilutive Issuance Price, the adjustment to the number of Warrant Shares can be expressed in the following formula: Total number of Warrant Shares after such Dilutive Issuance = the number obtained from dividing [E x F] by G.

(d) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

(e) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, shall distribute to all holders of Common Stock (and not to the Holder) evidences of its indebtedness or assets (including cash and cash dividends) or rights or warrants to subscribe for or purchase any security other than the Common Stock (which shall be subject to Section 3(d)), then in each such case the Exercise Price shall be adjusted by multiplying the Exercise Price in effect immediately prior to the record date fixed for determination of stockholders entitled to receive such distribution by a fraction of which the denominator shall be the VWAP determined as of the record date mentioned above, and of which the numerator shall be such VWAP on such record date less the then per share fair market value at such record date of the portion of such assets or evidence of indebtedness so distributed applicable to one outstanding share of the Common Stock as determined by the Board of Directors in good faith. In either case the adjustments shall be described in a statement provided to the Holder of the portion of assets or evidences of indebtedness so distributed or such subscription rights applicable to one share of Common Stock. Such adjustment shall be made whenever any such distribution is made and shall become effective immediately after the record date mentioned above.

(f) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (or any Subsidiary), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires 50% or more of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity of the Company (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, the Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of (1) the 30 day volatility, (2) the 100 day volatility or (3) the 365 day volatility, each of clauses (1)-(3) as obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to this Section 3(e) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within the later of (i) five Business Days of the Holder's election and (ii) the date of consummation of the Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant and the other Transaction Documents with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(e) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

(g) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(h) Notice to Holder.

(i) Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly email to the Holder a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment. The Holder may supply an email address to the Company and change such address.

(ii) Notice to Allow Exercise by the Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall deliver to the Holder at its last address as it shall appear upon the Warrant Register of the Company, at least 5 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to email such notice or any defect therein or in the emailing thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries (as determined in good faith by the Company), the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

(a) Transferability. Subject to compliance with any applicable securities laws and the provisions of the Purchase Agreement, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney. Upon such surrender, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. The Warrant, if properly assigned in accordance herewith, may be exercised by a new Holder for the purchase of Warrant Shares without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

(a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof other than as explicitly set forth in Section 3.

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it, and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate. In no event shall the Holder be required to deliver a bond or other security.

(c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Trading Day.

(d) Authorized Shares.Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its Articles of Incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use best efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Purchase Agreement.

(f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered or if not exercised on a cashless basis when Rule 144 (or any successor law or rule) is available, may have restrictions upon resale imposed by state and federal securities laws.

(g) Non-waiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of the Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant or the Purchase Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

(h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Purchase Agreement.

(i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate or that there is no irreparable harm and not to require the posting of a bond or other security.

(k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder of Warrant Shares.

(l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

(m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

(n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

60 DEGREES PHARMACEUTICALS, INC.

By: _____
Name: Geoffrey Dow
Title: Chief Executive Officer

NOTICE OF EXERCISE

TO: **60 Degrees Pharmaceuticals, Inc.**

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue a certificate or certificates representing said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

(4) After giving effect to this Notice of Exercise, the undersigned will not have exceeded the Beneficial Ownership Limitation.

The Warrant Shares shall be delivered to the following DWAC Account Number or by physical delivery of a certificate to:

_____

_____

SIGNATURE OF HOLDER

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing warrant, execute
this form and supply required information.
Do not use this form to exercise the warrant.)

60 Degrees Pharmaceuticals, Inc.

FOR VALUE RECEIVED, ____ all of or _____ shares of the foregoing Warrant and all rights evidenced thereby are hereby assigned to

_____ whose address is

_____

_____

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

_____

Signature Guaranteed: _____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank or trust company. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

Exhibit 10.52

NOTE EXTENSION AGREEMENT

THIS NOTE EXTENSION AGREEMENT (this "Agreement") is entered into and made effective as of May 22, 2023, by and between 60 DEGREES PHARMACEUTICALS, INC., a Delaware corporation (the "Maker") and BIGGER CAPITAL FUND, L.P. (the "Holder").

WHEREAS, the Maker and the Holder entered into that certain Promissory Note dated as of May 24, 2022 for the amount of Three Hundred Thirty-Three Thousand Three Hundred Thirty-Three Dollars and Thirty Cents ($333,333.30) (the "Note"). The Note is due and payable on May 24, 2023 (the "Maturity Date").

WHEREAS, the Maker and the Holder desire to enter into this Agreement in order to extend the Maturity Date in exchange for a cash payment of Eight Thousand Three Hundred Thirty-Three Dollars and Thirty-Three Cents ($8,333.33) (the "Cash Payment").

NOW, THEREFORE, this Agreement is duly agreed by both the Maker and the Holder to extend the Maturity Date to the earlier of (i) July 23, 2023, (ii) the date of the Maker's initial public offering, and (iii) such earlier date as the Note is required or permitted to be repaid as provided thereunder, in exchange for the Cash Payment, with all other terms and conditions of the Note remaining in full force and effect.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned have duly executed this Agreement as of the day and year first written above.

MAKER

60 DEGREES PHARMACEUTICALS, INC.,
a Delaware corporation

By: */s/ Geoffrey Dow*
Name: Geoffrey Dow
Title: President and CEO

PAYEE

BIGGER CAPITAL FUND, L.P.

By: */s/ Michael Bigger*
Name: Michael Bigger
Title: Managing Member of the GP

Signature Page to Note Extension Agreement (Bigger Capital Fund, L.P.)

Exhibit 10.53

NOTE EXTENSION AGREEMENT

THIS NOTE EXTENSION AGREEMENT (this "Agreement") is entered into and made effective as of May 22, 2023, by and between 60 DEGREES PHARMACEUTICALS, INC., a Delaware corporation (the "Maker") and CAVALRY INVESTMENT FUND, L.P. (the "Holder").

WHEREAS, the Maker and the Holder entered into that certain Promissory Note dated as of May 24, 2022 for the amount of Two Hundred Seventy-Seven Thousand Seven Hundred Seventy-Seven Dollars and Seventy-Eight Cents ($277,777.78) (the "Note"). The Note is due and payable on May 24, 2023 (the "Maturity Date").

WHEREAS, the Maker and the Holder desire to enter into this Agreement in order to extend the Maturity Date in exchange for a cash payment of Six Thousand Nine Hundred Forty-Four Dollars and Forty-Four Cents ($6,944.44) (the "Cash Payment").

NOW, THEREFORE, this Agreement is duly agreed by both the Maker and the Holder to extend the Maturity Date to the earlier of (i) July 23, 2023, (ii) the date of the Maker's initial public offering, and (iii) such earlier date as the Note is required or permitted to be repaid as provided thereunder, in exchange for the Cash Payment, with all other terms and conditions of the Note remaining in full force and effect.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned have duly executed this Agreement as of the day and year first written above.

MAKER

60 DEGREES PHARMACEUTICALS, INC.,
a Delaware corporation

By: */s/ Geoffrey Dow*
Name: Geoffrey Dow
Title: President and CEO

PAYEE

CAVALRY INVESTMENT FUND, L.P.

By: */s/ Thomas Walsh*
Name: Thomas Walsh
Title: Managing Partner

Exhibit 10.54

NOTE EXTENSION AGREEMENT

THIS NOTE EXTENSION AGREEMENT (this "Agreement") is entered into and made effective as of May 22, 2023, by and between 60 DEGREES PHARMACEUTICALS, INC., a Delaware corporation (the "Maker") and WALLEYE OPPORTUNITIES MASTER FUND LTD. (the "Holder").

WHEREAS, the Maker and the Holder entered into that certain Promissory Note dated as of May 24, 2022 for the amount of Two Hundred Seventy-Seven Thousand Seven Hundred Seventy-Seven Dollars and Seventy-Eight Cents ($277,777.78) (the "Note"). The Note is due and payable on May 24, 2023 (the "Maturity Date").

WHEREAS, the Maker and the Holder desire to enter into this Agreement in order to extend the Maturity Date in exchange for a cash payment of Six Thousand Nine Hundred Forty-Four Dollars and Forty-Four Cents ($6,944.44) (the "Cash Payment").

NOW, THEREFORE, this Agreement is duly agreed by both the Maker and the Holder to extend the Maturity Date to the earlier of (i) July 23, 2023, (ii) the date of the Maker's initial public offering, and (iii) such earlier date as the Note is required or permitted to be repaid as provided thereunder, in exchange for the Cash Payment, with all other terms and conditions of the Note remaining in full force and effect.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned have duly executed this Agreement as of the day and year first written above.

MAKER

60 DEGREES PHARMACEUTICALS, INC.,
a Delaware corporation

By: */s/ Geoffrey Dow*
Name: Geoffrey Dow
Title: President and CEO

PAYEE

WALLEYE OPPORTUNITIES MASTER FUND LTD.

By: */s/ William England*
Name: William England
Title: CEO of the Manager

Exhibit 10.55

NOTE EXTENSION AGREEMENT

THIS NOTE EXTENSION AGREEMENT (this "Agreement") is entered into and made effective as of May 18, 2023, by and between 60 DEGREES PHARMACEUTICALS, INC., a Delaware corporation (the "Maker") and GEOFFREY S. DOW REVOCABLE TRUST (the "Holder").

WHEREAS, the Maker and the Holder entered into that certain Promissory Note dated as of May 19, 2022 for the amount of Forty-Four Thousand Four-Hundred Forty-Four Dollars and Forty-Four Cents ($44,444.44) (the "Note"). The Note is due and payable on May 19, 2023 (the "Maturity Date").

WHEREAS, the Maker and the Holder desire to enter into this Agreement in order to extend the Maturity Date in exchange for a cash payment of One Thousand One Hundred Eleven Dollars and Eleven Cents ($1,111.11) (the "Cash Payment").

NOW, THEREFORE, this Agreement is duly agreed by both the Maker and the Holder to extend the Maturity Date to the earlier of (i) July 18, 2023, (ii) the date of the Maker's initial public offering, and (iii) such earlier date as the Note is required or permitted to be repaid as provided thereunder, in exchange for the Cash Payment, with all other terms and conditions of the Note remaining in full force and effect.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned have duly executed this Agreement as of the day and year first written above.

MAKER

60 DEGREES PHARMACEUTICALS, INC.,
a Delaware corporation

By: */s/ Geoffrey Dow*
Name: Geoffrey Dow
Title: President and CEO

PAYEE

GEOFFREY S. DOW REVOCABLE TRUST

By: */s/ Geoffrey Dow*
Name: Geoffrey Dow
Title: Trustee

Exhibit 10.56

NOTE EXTENSION AGREEMENT

THIS NOTE EXTENSION AGREEMENT (this "Agreement") is entered into and made effective as of May 18, 2023, by and between 60 DEGREES PHARMACEUTICALS, INC., a Delaware corporation (the "Maker") and MOUNTJOY TRUST (the "Holder").

WHEREAS, the Maker and the Holder entered into that certain Promissory Note dated as of May 19, 2022 for the amount of Two Hundred Ninety-Four Thousand Four Hundred Forty-Four Dollars and Forty-Four Cents ($294,444.44) (the "Note"). The Note is due and payable on May 19, 2023 (the "Maturity Date").

WHEREAS, the Maker and the Holder desire to enter into this Agreement in order to extend the Maturity Date in exchange for a cash payment of Seven Thousand Three Hundred Sixty-One Dollars and Eleven Cents ($7,361.11) (the "Cash Payment").

NOW, THEREFORE, this Agreement is duly agreed by both the Maker and the Holder to extend the Maturity Date to the earlier of (i) July 18, 2023, (ii) the date of the Maker's initial public offering, and (iii) such earlier date as the Note is required or permitted to be repaid as provided thereunder, in exchange for the Cash Payment, with all other terms and conditions of the Note remaining in full force and effect.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned have duly executed this Agreement as of the day and year first written above.

MAKER

60 DEGREES PHARMACEUTICALS, INC.,
a Delaware corporation

By: */s/ Geoffrey Dow*
Name: Geoffrey Dow
Title: President and CEO

PAYEE

MOUNTJOY TRUST

By: */s/ John Dow*
Name: John Dow
Title: Trustee

Signature Page to Note Extension Agreement (Mountjoy Trust)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation in the Registration Statement of 60 Degrees Pharmaceuticals, Inc. (F/K/A 60 Degrees Pharmaceuticals, LLC) on Form S-1 Amendment No. 4 of our report dated April 3, 2023 which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the financial statements of 60 Degrees Pharmaceuticals, Inc. as of December 31, 2022 and 2021, and for the each of the two years in the period ended December 31, 2022.

We also consent to the reference to us under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ RBSM LLP

Las Vegas, Nevada
June 1, 2023