As filed with the Securities and Exchange Commission on September 19, 2024

Registration No. 333-_____

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

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware	**45-2406880**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1025 Connecticut Avenue NW Suite 1000
Washington, D.C. 20036
(202) 327-5422

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Geoffrey Dow
Chief Executive Officer and President
60 Degrees Pharmaceuticals, Inc.
1025 Connecticut Avenue NW Suite 1000
Washington, D.C. 20036
(202) 327-5422

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Ross D. Carmel, Esq.
Jeffrey Hua, Esq.
Sichenzia Ross Ference Carmel LLP
1185 Avenue of the Americas, 31st Floor
New York, New York 10036
Telephone: (212) 930-9700

Approximate date of commencement of proposed sale to the public: From time to time, after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

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, other than securities offered only in connection with dividend or interest reinvestment plans, 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 filed to register additional securities for an offering pursuant to Rule 462(b) 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(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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-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 pursuant to Section 13(a) of the Exchange 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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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

Subject To Completion, Dated September 19, 2024

PROSPECTUS

Up to 8,913,044 Shares of Common Stock
underlying certain Pre-Funded Warrants,
Common Warrants and Placement Agent Warrants

This prospectus relates to the offer and sale from time to time, on a resale basis, by the selling stockholders identified herein or their permitted transferees, of up to an aggregate of 8,913,044 shares of our common stock, par value $0.0001 per share ("Common Stock"), consisting of: (i) 2,898,551 shares of Common Stock issuable upon exercise of pre-funded warrants held by certain selling stockholders (the "Pre-Funded Warrants"), (ii) 2,898,551 shares of Common Stock issuable upon exercise of Series A warrants (the "Series A Warrants"), (iii) 2,898,551 shares of Common Stock issuable upon exercise of Series B warrants (the "Series B Warrants," together with Series A Warrants, the "Common Warrants") (and collectively with the Pre-Funded Warrants and Common Warrants, the "Purchase Warrants"), and (iv) 217,391 share of Common Stock issuable upon the exercise of placement agent warrants (the "Placement Agent Warrants" and together with the Purchase Warrants, the "Warrants") that were issued to designees of H.C. Wainwright & Co., LLC ("Wainwright" or the "Placement Agent") as partial compensation for Wainwright acting as placement agent in connection with the Private Placement (as defined below). The Warrants were issued to the selling stockholders in connection with a private placement we completed on September 5, 2024 (the "Private Placement"). We refer to 8,913,044 shares of Common Stock underlying the Warrants being registered herein as the "Registered Securities."

We are not offering any shares of our Common Stock for sale by us under this prospectus. We are registering the shares of Common Stock covered by this prospectus to be sold by the selling stockholders under the terms of a registration rights agreement dated September 4, 2024, entered into with the selling stockholders in connection with the Private Placement. We will not receive any of the proceeds from the sale by the selling stockholders of the Common Stock. Upon any exercise of the Warrants for cash, however, we will receive the exercise price of the respective Warrants.

Following the effectiveness of the registration statement of which this prospectus forms a part, the selling stockholders may, from time to time, sell, transfer, or otherwise dispose of any or all of their securities on any stock exchange, market, or trading facility on which the securities are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. For more information, see "Plan of Distribution."

The selling stockholders may offer, sell or distribute all or a portion of the Registered Securities publicly or through private transactions at prevailing market prices or at negotiated prices. The selling stockholders may retain underwriters, dealers or agents from time to time. See "Plan of Distribution" for more information about how the selling stockholders may sell the Registered Securities.

We will not receive any proceeds from the sale of the Registered Securities, but we agreed to bear the expenses relating to the registration of the Registered Securities.

Our Common Stock is listed for trading on the Nasdaq Capital Market under the symbol "SXTP." On September 18, 2024, the last reported sale price of our Common Stock on the Nasdaq Capital Market was $1.41 per share.

Please be advised that on August 12, 2024, we effected a reverse stock split of our Common Stock at a ratio of 1-for-12 (the "Reverse Split"). Except as indicated otherwise, all share numbers related to our Common Stock disclosed in this prospectus have been adjusted on a post-Reverse Split basis.

Investing in our securities involves a high degree of risk. See the information contained under "Risk Factors" on page 22 of this prospectus and in the documents incorporated herein by reference. You should read this entire prospectus carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2024.

TABLE OF CONTENTS

IMPORTANT INFORMATION ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the SEC pursuant to which the selling stockholders named herein may, from time to time, offer and sell or otherwise dispose of the shares of our Common Stock, $0.0001 par value covered by this prospectus. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or shares of Common Stock are sold or otherwise disposed of on a later date. It is important for you to read and consider all information contained in this prospectus, including the documents incorporated by reference therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under "Where You Can Find More Information" and "Incorporation of Certain Documents by Reference" in this prospectus.

We have not authorized anyone to give any information or to make any representation to you other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any of our shares of Common Stock other than the shares of our Common Stock covered hereby, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy any securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such 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 the offering and the distribution of this prospectus applicable to those jurisdictions.

Unless we have indicated otherwise, or the context otherwise requires, references in this prospectus to "SXTP," the "Company," "we," "us" and "our" refer to 60 Degrees Pharmaceuticals, Inc.

CAUTIONARY 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.

PROSPECTUS SUMMARY

Our Business

We are a 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 vector-borne, fungal, and 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 beyond 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 considered for development as an antiviral product for a number of diseases.

Market Opportunity

Malaria Prevention

In 2018, the FDA approved Arakoda for malaria prevention in individuals 18 years and older. 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. Following our recent financing the Company hired a Chief Commercial Officer and commissioned IQVIA market data and a qualitative marketing demand study. That research, recently completed, suggests that prescribing for malaria prevention therapies has returned to pre-pandemic levels, and that the total U.S. market represents around 1.1 million prescriptions (one prescription per three weeks of travel). Based on consumer and HCP demand research, the Company estimates that the accessible market for Arakoda represents about one third of this volume (about 330,000 prescriptions). Barriers to entry include low brand awareness in the prescriber community and the low cost of some of the generic alternatives. In the second half of 2024 we will conduct a pilot commercialization study to confirm these barriers can be overcome (see "Strategy").

Treatment and Prevention of Tick-Borne Disease (Babesiosis)

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

- Treatment of Chronic Tick-Borne Disease (Babesiosis). *Babesia* parasites are co-transmitted by the same ticks that transmit *Borrelia*, the Lyme disease bacterium. Although Lyme in the acute phase is generally viewed by the medical community as being treatable with antibiotics, individuals who are not treated, or fail treatment, may go on to develop long term, and potentially debilitating, chronic symptoms such as fatigue, body aches, and cognitive problems.[1] This condition is defined by the Centers for Disease Control and Prevention ("CDC") as Post-Treatment Lyme Disease Syndrome ("PTLDS") or simply as Lyme in the patient community.[2] Although there are no published estimates, key opinion leaders have stated that as many as 50% of Lyme/PTLDS patients are believed to be co-infected with *Babesia* parasites, a diagnosis referred to in the Lyme community as "Chronic Babesiosis." Prescribers in the Lyme disease community utilize a number of therapeutic modalities to manage the symptoms of Chronic Babesiosis, including FDA-approved pharmaceuticals such as atovaquone and azithromycin (these are assumed to suppress the growth of *Babesia* parasites).[3]

  Recent market data shows that Tafenoquine appears to be increasingly prescribed by Lyme physicians to manage Chronic Babesiosis. This trend may follow the recent publication of several case reports demonstrating activity in immunosuppressed patients with acute babesiosis, and animal data showing eradication of *Babesia* parasites, Tafenoquine (primarily as Arakoda).[4] The Company believes the recent increases in sales of Arakoda have been driven by organic growth of these activities. There are no formal epidemiological publications articulating the incidence or prevalence of Chronic Babesiosis, so these metrics must be inferred based on data for PTLDS and the rate of coinfection with *Babesia* parasites. Thus, the cumulative case load of Chronic Babesiosis may be as high as1.01 million patients in the United States.[5] We believe, based on our market research that at least 37% of this market, or 375,000 cases, may be addressable with Tafenoquine during the remainder of its market exclusivity window for malaria. We are undertaking additional research to determine how much additional market capture might be feasible.

  Acute infection with many different organisms (e.g. Borrelia, SARS-Cov-2, Epstein Barr virus) trigger "Long Syndromes" in a minority of cases, characterized by cognitive dysfunction, fatigue and post-exertional malaise.[6] For many years, such conditions have been confusing to the mainstream medical community because there may not be formal diagnostic criteria or an established theory of disease. This is changing with the advent of Long COVID, and a recent prominent paper outlined the pathophysiological mechanisms for the first time.[7] Although there is not yet supporting evidence in the medical literature, some key opinion leaders in the Lyme community have postulated, using the veterinary literature as an analog, that life-long infection by sequestering forms of *Babesia* (e.g., *B. odocoilei*) may be a significant driver of chronic fatigue symptoms.[8] If this is true, the addressable market for antibabesial drugs may be substantially larger than stated above, since the prevalence of chronic fatigue syndrome in the U.S. is at least 3.3 million cases (excluding Long COVID and PTLDS).[9]

1 See https://www.cdc.gov/lyme/signs-symptoms/chronic-symptoms-and-lyme-disease.html.
2 See https://www.cdc.gov/lyme/signs-symptoms/chronic-symptoms-and-lyme-disease.html.
3 Conclusions from Company-commissioned market research.
4 Conclusions from Company-commissioned market research.
5 Maximum prevalence determined by multiplying the rate of Babesia coinfection in PTLDS patients (52%, from Parveen & Bhanot, Pathogens 2019;8(3):117) by the highest estimate of the cumulative prevalence of PTLDS (1,994,189, from Delong et al. BMC Public Health 2019;19(1):352). Maximum new cases determined by multiplying the number of new Lyme cases per year (476,000, from Krugeler et al (Emerg Infect Dis 2021;27:616-61) by the number of new cases that subsequently become chronic cases (up to 10%, from Delong et al. BMC Public Health 2019;19(1):352) by the proportion of such patients coinfected with Babesia (52%, from Parveen & Bhanot, Pathogens 2019;8(3):117).
6 See https://www.cdc.gov/lyme/signs-symptoms/chronic-symptoms-and-lyme-disease.html.
7 Walitt et al Nature Communications 2024;15:907.
8 Lindner HH. 2022. Chronic babesiosis caused by B. odocoilei: Diagnosis, pathophysiology & treatment. Presentation at the 2022 ILADS scientific meeting, Orlando Florida.
9 See https://www.cdc.gov/nchs/data/databriefs/db488.pdf.

Separately from the clinical indication, based on estimates from industry experts, there may be somewhere between several hundred and several thousand cases of canine babesiosis each year in the United States, and thousands more globally. Currently, standard of care treatment for babesiosis in dogs is a ten-day course of atovaquone and azithromycin, which costs about $1,350 out of pocket. A treatment course of Tafenoquine mirroring the human prophylactic dose in dogs might cost < $300, offering a compelling alternative to standard of care. The additional resources required to generate enabling data for veterinary uses are much less expensive than human clinical trials and we are already funding a pilot study at North Carolina State University related to this indication.

- Treatment of Acute Babesiosis. There are up to 38,000 cases of potentially treatable acute symptomatic babesiosis (red blood cell infections caused by deer tick bites) in the United States each year.[10] Approximately 650 of these cases are hospitalizations, a smaller fraction of which represents immunosuppressed individuals.[11] Symptomatic babesiosis is usually treated with a minimum ten day course of atovaquone and azithromycin which is extended to six weeks in the immunosuppressed, who may also experience relapses requiring multiple hospitalizations.[12] This is much longer than equivalent serious parasitic diseases such as malaria where the goal is a three-day regimen. In a recently published case series Tafenoquine in combination with standard of care cured 80% of immunosuppressed patients with relapsing babesiosis and the investigators stated in a press release that "Tafenoquine is going to make a huge difference, I think, in people who are severely immunocompromised." [13]

- Prevention of Tick-Borne Diseases. Post-exposure prophylaxis or early treatment with, respectively, a single dose or several week regimen of doxycycline following a tick-bite is a recognized indication to prevent the complications of Lyme disease. There may be more than 400,000 such 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; however, this calculation represents only about 12% of actual treated tick bites based on observations from comparable ex-U.S health systems.[14] Unlike Lyme disease, there is no characteristic rash associated with early infection and no reliable diagnostic tests. Thus, an individual bitten by a tick cannot know whether they have also been infected with babesiosis. It is likely that a drug proven to be effective for this indication for babesiosis would also be used in conjunction with Lyme prophylaxis.

Treatment and Prevention of Fungal Infections

We are evaluating Tafenoquine for potential utility in the following fungal diseases:

- Treatment of *Candida* infections. According to the CDC, there are 50,000 reported 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.[15] Since it has broad-spectrum activity against drug-resistant *Candida* spp in culture, Tafenoquine, 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.[16]

---

10 This estimate is based on the observations of Krugeler et al (*Emerg Infect Dis* 2021;27:616-61) who reported that 476,000 cases of Lyme disease occur in U.S. states where babesiosis is endemic and Krause et. al. (JAMA 1996;275:1657-16602) who reported that 10% of Lyme disease patients are co-infected with babesiosis and that according to Krause et al (AJTMH 2003;6:431-436) fact that about 80% of cases are symptomatic (thus 476,000*10%*80% = 38,000 cases of babesiosis per year).

11 Bloch et al *Open Forum Infect Dis* 2022;9(11):ofac597.

12 According to IDSA guidelines.

13 See Krause et al *Clin Infect Dis* 2024; doi:10.1093/cid/ciae238 and https://ysph.yale.edu/news-article/antimalarial-drug-is-effective-against-tick-borne-infection-babesiosis/.

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

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

16 Dow and Smith *New Microb New Infect* 2022;45:100964.

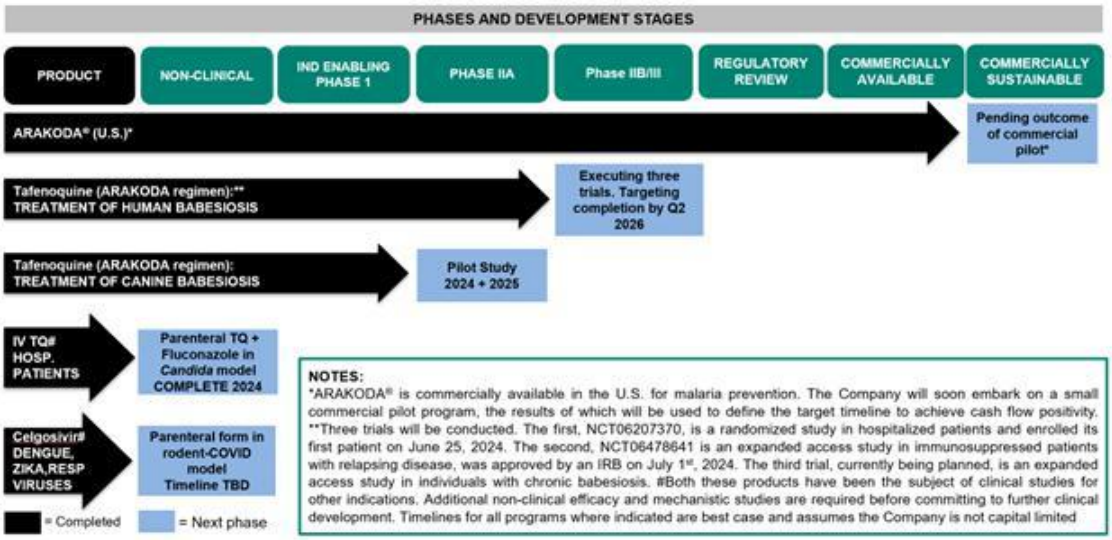
- Prevention of fungal pneumonias. There are up to ~ 91-92,000 new patient cases each year in the United States for which antifungal prophylaxis is recommended, including acute lymphoblastic leukemia (up to 6,540 cases) and large B-cell lymphoma (up to 18,000 cases) patients receiving CAR-T therapy, solid organ transplant patients (up to 42,887 cases), allogeneic (~ 9,000 cases) and autologous (~ 15,000 cases) hematopoietic stem cell transplant patients.[17] 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.[18] Since it has broad spectrum antifungal effects in cell culture, and activity against *Pneumocystis* in animal models, Tafenoquine has the potential to be added to existing standard of care regimens for the prevention of fungal pneumonias.[19]

Viral Diseases

Celgosivir, a potential clinical candidate of 60P's, has activity in a number of animal models of important viral diseases such as Dengue and RSV. According to the European CDC, Dengue is associated with at least 4.1 million cases globally. [20] And, according to the U.S. CDC, RSV is responsible for up to 240,000 hospitalizations in children less than five years of age and adults greater than 65 years of age in the United States each year.[21] As outlined in the "*Strategy*" section below, we expect to evaluate Celgosivir in additional non-clinical disease models before making a decision regarding clinical development.

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.

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.[22] 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.[23]

---

17 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.

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

19 Queener et al *JID* 1997;165:764-768; Dow and Smith *New Microb New Infect* 2022;45:100964

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

21 https://www.cdc.gov/rsv/php/surveillance/index.html#cdc_survey_profile_surveys_used-rsv-burden-estimates.

22 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.

23 Zottig et al Military Medicine 2020; 185 (S1): 687.

The FDA and Australia's medicinal regulatory agency, the Therapeutic Goods Administration, subsequently approved Arakoda (brand name in the U.S.) 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, 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.[24] Tafenoquine entered the commercial supply chains in the U.S. and Australia in the third quarter of 2019.

The only limitation of Arakoda is the requirement for a G6PD test prior to administration.[25] 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.[26] 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 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.[27] Our work followed Legacy Studies that show Tafenoquine is effective for treatment and prevention of *Pneumocystis* pneumonia in animal models.[28] 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 monotherapy, or use in combination with other antibabesial medications, clears and eradicates *Babesia* infections, respectively, in both immunocompetent and immunocompromised animal models of babesiosis (tick borne red blood cell infections).[29] In up to 80% of cases Tafenoquine administered in combination with antibabesial drugs after prior failure of conventional antibiotics in immunosuppressed babesiosis patients resulted in cures.[30] Tafenoquine is also increasingly being utilized by Lyme disease prescribers to manage symptoms of Chronic Babesiosis. Consequently, we believe that (i) if combined with standard of care products, Tafenoquine has the potential to accelerate parasite clearance and reduce the duration of illness and treatment with antibiotic therapy in immunosuppressed patients hospitalized with severe illness, (ii) 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 (iii) Tafenoquine could become the leading treatment for Chronic Babesiosis. 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.

---

24 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.

25 See prescribing information at www.arakoda.com.

26 See prescribing information at www.arakoda.com.

27 Dow and Smith, New Microbe and New Infect 2022; 45: 100964.

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

29 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.

30 Krause et al *Clin Infect Dis* 2024; doi:10.1093/cid/ciae238.

Celgosivir

Celgosivir is a host targeted glucosidase inhibitor that was developed separately by other sponsors for HIV then for hepatitis C.[31] 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, 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.[32] Celgosivir (as with other Dengue antivirals) exhibits greater capacity to cure Dengue infections in animal models when administered prior to symptom onset when compared to administration post-symptom onset. In animal models, this problem can be addressed 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).[33] 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. Unfortunately, we 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 that 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

Following our initial public offering in July 2023, our initial strategic priority was to conduct a Phase IIB that would have evaluated the potential of the Arakoda regimen of Tafenoquine to accelerate disease recovery in COVID-19 patients with low risk of disease progression. In October 2023, we made a decision to suspend this study. This was a consequence of advice previously received from the FDA, which we interpreted to mean that the Agency would not have granted clearance for the study to proceed unless we redesigned it to (i) enroll a patient population in which receipt of Paxlovid or Lagevrio would be medically contraindicated, or (ii) compare Tafenoquine to placebo in patients taking a "standard of care" regimen (defined by the FDA as Lagevrio or Paxlovid). The FDA's position was somewhat surprising given that neither Paxlovid nor Lagevrio is indicated for treatment of COVID-19 in low-risk patients. We determined that conducting our study in an alternate population in the United States would be unfeasible, and that conducting an add-on-to standard of care study might not be Phase III enabling. Accordingly, the Company made a decision to pivot back to continue commercialization of Arakoda for malaria, and further evaluation of the Arakoda regimen of Tafenoquine for babesiosis and other diseases. We believe such an approach is both less risky and less expensive.

Moving forward, our general strategy to achieve profitability and grow shareholder value has three facets: (i) increase sales of Arakoda; (ii) conduct clinical trials to expand the number of patients who can use Tafenoquine for new indications in the future; and (iii) reposition small molecule therapeutics with good clinical safety profiles for new indications.

31 Sorbera et al, Drugs of the Future 2005; 30:545-552.
32 Low et. al., Lancet ID 2014; 14:706-715.
33 Watanabe et al, Antiviral Research 2016; 10:e19.

Expansion of U.S. Arakoda Sales

Hiring of Chief Commercial Officer. In February, 2024, we hired Kristen Landon to lead our commercial efforts to reintroduce Arakoda for malaria prevention and conduct new product planning initiatives in tick-borne disease for babesiosis. We spent the first quarter analyzing the current landscape in the malaria prevention market, conducting primary market research among providers and consumers, and assessing agency partners for a virtual/digital marketing pilot program. Additionally, we kicked off a market assessment on the babesiosis space including desk top research and qualitative interviews with Key Opinion Leaders in the Infectious Disease and Lyme Community.

P&L Contract Review. We will conduct a review of all of our supply chain and formulary contracts to determine whether it is possible to increase our margin on Arakoda without increasing prices, or to compensate for any price adjustments which may be necessary to support repositioning efforts (see below).

Repositioning of Arakoda Relative to Malarone and Generic Equivalent Atovaquone-Proguanil. A malaria demand study was conducted to assess the attractiveness and acceptability of the Arakoda product profile and current pricing among health care providers and consumers. The product profile was well received among both stakeholders; however, price sensitivity on out-of-pocket costs was noted among both groups. Generic atovaquone-proguanil, our primary competitor is substantially cheaper than Arakoda for the average trip length (three weeks) and has superior formulary positioning (Tier 1 vs. Tier 3). However, generic-atovaquone proguanil does not provide the same level of confidence a traveler may experience from taking a product with a convenient weekly dosing regimen during travel, that works everywhere in the world against all malaria species and drug resistant strains, and which requires only a single dose for post-exposure prophylaxis upon return from a malarious area. The value those advantages confer needs to be communicated with key stakeholders.

Market Segment Definition and Targeting. We purchased market data to understand the malaria market landscape over the past decade and identified the current prescribers of Malarone and the generic equivalent atovaquone-proguanil, the main generic competitor to Arakoda for malaria prophylaxis. Beginning in the third quarter of 2024, we plan to reach out to prescribers covering the top 80% of atovaquone-proguanil prescribers in order to educate them about the value proposition of Arakoda. We will also compile a list of the top institutions/organizations that have ex-U.S. deployed workforces and internal occupational health and safety programs, and target these organizations with messaging regarding the convenience and global effectiveness of Arakoda. We do not initially plan to target U.S. government agencies as these organizations, such as the Department of Defense, are expected to be extremely price sensitive until operational considerations justify the use of superior products – for example, the DOD used inexpensive doxycycline for malaria prevention in the low malaria risk setting of Afghanistan, but chose superior weekly mefloquine, despite safety concerns, for the Ebola mission to west Africa in 2014, where malaria rates were extremely high.

Digital Revamp and Collateral: We will work with an agency of record to develop a marketing strategy for the proposed pilot and develop marketing assets that we believe best highlight the features and benefits of Arakoda, namely the convenience of the travel and post-travel regimen, and global effectiveness. We are currently assessing a co-pay or point of sale offer for travelers to offset out-of-pocket costs. We launched our Arakoda product website, which went live in April 2024.

Revised Forecast. We have developed an internal forecast for the malaria and Babesiosis indications and have contracted a third party vendor to validate our analyses.

Development of the Arakoda Regimen of Tafenoquine for Babesiosis

In animal models, Tafenoquine monotherapy has been shown to suppress acute babesiosis infections to the point where the immune system can control them following single or multiple doses similar to those effective against malaria parasites, and longer regimens alone or in combination with atovaquone leads to complete radical cure and to the conference of sterile immunity.[34] In three case studies in individuals with immunosuppression and/or refractory parasites, Tafenoquine alone or in combination with various standard of care antimalarials and antibiotics successfully cleared parasites, leading to three consecutive negative PCR tests, and prevention of further relapses in two of three individuals.[35] Our market research has revealed that recent sales growth for Arakoda is primarily attributable to organic growth in prescribing by Lyme community prescribers for Chronic Babesiosis. Collectively these data suggest Tafenoquine might have utility alone or in combination as treatment or post-exposure prophylaxis of babesiosis (both acute and chronic).

The Company is planning three clinical trials to aid further development and commercialization of a Babesiosis indication for Tafenoquine. Trial 1 is a randomized, placebo-controlled, evaluation of Tafenoquine (200 mg per day for a total of 800 mg) in patients hospitalized with babesiosis who are also taking standard of care treatment (10 days of atovaquone-azithromycin). The primary endpoint will be time to clinical recovery of 11 common babesiosis symptoms as reported by patients. The key secondary endpoint will be time to molecular cure as assessed by an FDA-approved Babesia nucleic acid test that is used for blood donation screening. The study will enroll a minimum of 24 and up to 33 patients before an interim analysis is conducted, which will include both a test of significance and a sample size re-estimation in case this is required. The study design was reviewed by the FDA. We have signed clinical trial agreements with Tufts Medical Group, Yale, and Rhode Island Hospital. The first patient was randomized on June 25, 2024. The earliest possible date that date would be available from the interim analysis would be January 31, 2026, assuming a minimum of 24 patients are enrolled prior to September 30, 2025. Further details are available on the clinicaltrials.gov website.[36]

Trial 2 will be an expanded use study utilizing commercially available Arakoda. The Company, if approved by an Institutional Review Board ("IRB," also known as an ethics committee), plans to offer up to one year of Arakoda at no cost to about 10 patients per year (i.e., immunocompromised patients who have previously failed standard of care treatment). Informed consent will be obtained from patients to collect a blood sample for PCR testing at the end of treatment, and patients will be asked to complete a babesiosis symptom questionnaire. The goal of the study is to generate additional prospective data to confirm the observation by Krause et al in a recent publication that an extended regimen of Tafenoquine cured 80% of immunocompromised patients with relapsing babesiosis. This study will commence utilizing proceeds from the current offering. More details about the study can be found on the clinicaltrials.gov website.[37]

34 Liu et al. Antimicrobial Agents Chemo 2021;65:e00204-21. Vydyam et al. J Infect Dis. 2024 Jan 3:jiad315. doi:10.1093/infdis/jiad315.
35 Marcos et al. IDCases 2022;27:e01460; Rogers et al. Clin Infect Dis. 2022 Jun 10:ciac473, Prasad and Wormsner. Pathogens 2022;11:1015.
36 See: https://classic.clinicaltrials.gov/ct2/show/NCT06207370.
37 See: https://clinicaltrials.gov/study/NCT06478641.

Trial 3 will be a Phase II open label study utilizing commercially available Arakoda. The Company, if approved by an IRB, plans to offer an approximately two-month supply of Arakoda at no cost to patients who have a clinical diagnosis, are willing to submit biological samples for testing, and answer babesiosis and standardized fatigue inventories before and after treatment. The goal of this study will be to ascertain whether Arakoda treatment improves patient-reported fatigue symptoms in individuals who symptoms of severe fatigue lasting more than six months and a diagnosis of chronic babesiosis. This trial will be gated by the outcome of an epidemiology study we have financed at North Carolina State University (see below).

In May 2024, we signed a research and collaboration agreement with North Carolina State University in which the College of Veterinary Medicine will screen 300 archived blood samples from patients exhibiting symptoms consistent with chronic fatigue symptoms by PCR for the presence of Babesia spp. In a second phase of the study, positive samples will be sequenced to determine which *Babesia* spp are present. The data from this study will help define whether the incidence of Chronic Babesiosis may be more widespread than amongst PTLDS patients.

In March 2024, we initiated, in collaboration with the North Carolina State University College of Veterinary Medicine, a pilot study of Tafenoquine for treatment of canine babesiosis in the United States under a sponsored research program. Should this potential collaboration be successful, we believe that the data from that study may provide supportive data for the clinical babesiosis development program, and could provide proof of concept for an expanded study to prove utility for veterinary indications.

We believe, if the Company does not become capital-limited, that the results of the above studies will come to fruition in the first quarter of 2026, potentially facilitating submission of a supplementary new drug application (or other appropriate regulatory filing) to FDA, with the goal of obtaining marketing approval of Arakoda for treatment of Babesiosis. If successful, this will allow the Company to actively market Arakoda for Babesiosis.

Parenteral Tafenoquine for Fungal Infections

We plan to support a series of studies in animal models to determine whether single dose parenteral administration of Tafenoquine exhibits efficacy against *Candida* spp including *C. auris*. These studies are being conducted under a sponsored research agreement with Monash University in Melbourne, Australia.

Combination Partner for Tafenoquine for Malaria

Most new antimalarial treatment products are developed as drug combinations to proactively combat drug resistance. We believe that Tafenoquine, due to its long half-life and activity against all parasite species and strains, would be an ideal partner in a drug combination. Recently, Kentucky Technology Inc. (“KTI”), completed Phase IIA studies in *P. vivax* malaria, in which they evaluated the safety and efficacy of SJ733, their ATP4 inhibitor in combination with Tafenoquine as the combination partner drug. It was recently announced that the SJ733 development program would be partially supported by a grant from the Global Health Innovative Technology Fund (“GHIT”). As part of its shares for services agreement with KTI, the Company recently received a detailed feasibility assessment and business plan for the project, including an assessment of potential PRV eligibility, and is considering next steps in relation to potential involvement in this project.

Celgosivir for Antiviral Diseases

Reviewing prior studies of Celgosivir for Zika, Dengue and RSV, it is evident that the drug protects against the pathological effects of viruses through a combination of anti-inflammatory and antiviral effects. These properties suggest it might have a beneficial effect in several viral diseases. Celgosivir is synthesized from Castanospermine, which is obtained from botanical sources in low yield, making its inherent cost of goods potentially high. Castanospermine is also quite water soluble, making it amenable to intravenous formulation. We plan to conduct a proof-of-concept study in a hamster-COVID-19 model to evaluate whether parenterally administered Castanospermine can ameliorate the pathological effects of SARS CoV-2 via modulation of cytokine response to infection. Following this offering this project will be added to our statement of work for our services agreement with Florida State University Research Foundation (“FSURF”), and will commence when there are sufficient proceeds from the sale of FSURF’s 60P shares to support this research. The data generated from the study will allow us to assess whether to move forward with IND enabling studies of parenteral Castanospermine (or Celgosivir) for viral indications.

Post-Marketing Requirements

We have an FDA 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.[38] The FDA has asked us to propose an alternate design, for which we submitted a concept protocol in the fourth quarter of 2022, and submitted a full protocol in July, 2024. 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 first quarter of 2026.

Capitalization and Future Financing

We previously filed Registration Statement on S-3 on July 12, 2024 enabling us to raise up to $15,000,000, of which approximately $2.0 million was already raised under the At the Market Issuance Sales Agreement with WallachBeth Capital LLC. We anticipate that those funds, and the funds from the current offering if consummated in full (exercise of all Pre-Funded and Series A and B Warrants in this offering) should be sufficient to execute the commercial and research and development activities described herein.

38 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") issued our first COVID-19 patent for Tafenoquine in 2023. 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 pending 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	Granted		2013203400[+]	10-April-2033*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	2014228035	Australia	Granted		2014228035	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	MY-170991-A	Malaysia	Granted		PI2015002372	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	378015	Mexico	Granted		MX/a/2015/013115	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11201507254V	Singapore	Granted		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	Issued	9/19/2017	14/772,873	14-Mar-2034^
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	10517854	US	Issued	12/31/2019	15/706,845	14-Mar-2034^
Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11219616	US	Issued	1/11/2022	16/725,387	14-Mar-2034^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	2015358566	Australia	Granted		2015358566	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	2968694	Canada	Granted		2968694	02-Dec-2035*

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	10342791	US	Issued	7/9/2019	15/532,280	02-Dec-2035^
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	10888558	US	Issued	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	11,744,828	US	Issued	9/5/2023	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*
Regimens of Tafenoquine for Prevention of Malaria in Malaria-Naive Subjects	Pending	US	Pending		18/240,049	02-Dec-2035^
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	2016368580	Australia	Granted		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	Issued	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*

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
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	Hong Kong	Pending		62023078645.6	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	11,633,391	US	Issued	4/25/2023	17/189,544	05-May-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		18/300,805	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	01-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	01-Mar-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	11369592	US	Issued	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 To Treat Respiratory Infection Utilizing Castanospermine Analogs	Pending	*PCT*	Pending		PCT/US23/26884	05-Jul-2043*
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	Pending	US	Pending		18/218,202	05-Jul-2043^

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Methods For The Treatment And Prevention Of Diseases Or Infections With MCP-1 Involvement By Administration Of Tafenoquine	Pending	*PCT*	Pending		PCT/US23/34169	30-Sep-2043*
Methods For The Treatment And Prevention Of Diseases Or Infections With MCP-1 Involvement By Administration Of Tafenoquine	Pending	US	Pending		18/375,070	30-Sep-2043^
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,328,061+	US	Issued		15/584,952+	2-May-2037^
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,561,642+	US	Issued		15/856,377+	2-May-2037^
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	*PCT*	Pending		PCT/US24/25436	19-Apr-2044*
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	*PCT*	Pending		PCT/US24/25458	19-Apr-2044*
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	*PCT*	Pending		PCT/US24/25472	19-Apr-2044*
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	US	Pending		18/640,611	19-Apr-2044^
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof Of Treating Babesiosis	Pending	US	Pending		18/640,657	19-Apr-2044^
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof Of Treating Babesiosis	Pending	US	Pending		18/640,695	19-Apr-2044^

* = 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	UK00915508872	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	01/03/2024		0081716-000069	16-Aug-23	Abandoned
United States of America	KODATEF	Pending	98363219	24-Jan-18	01/18/2024		0081716-000074		

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 royalties 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 (as defined in the U.S. Army Agreement) 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 fees upon the achievement of certain milestones, including a sales-based milestone fee of $75,000 once cumulative net sales from all sources exceeds $6 million (which milestone was achieved during the year ended December 31, 2023), $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 February 15, 2021, we entered into the Inter-Institutional Agreement with FSURF (the "FSURF Agreement") 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, and again on March 25, 2024, that collectively granted an option, effective through March 24, 2025, 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, and again on March 25, 2024, that collectively granted an option, effective through March 24, 2025, to us to license a patent relating to the use of alpha glucosidase inhibitors (including Castanospermine and Celgosivir) for treatment of Zika infections.

Ending upon July 12, 2033 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 the U.S. Army Agreement. 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.

On February 13, 2024, our majority-owned Australian subsidiary, 60P Australia Pty Ltd, and Monash University entered into the Research Services Agreement (the "Agreement") in which Monash University agreed to provide research services, including among other things, testing the efficacy of Tafenoquine against candidemia, confirming suitable fungal infection dosage and determining the pharmacokinetics of Tafenoquine following intraperitoneal drug administration (collectively, the "Services"). The commencement date of the Agreement was effective as of February 5, 2024, and the commencement of experiments was May 2024 and the anticipated completion date is on November 30, 2024. The Company agreed to pay Monash University $90,167 AUD on April 1, 2024 and $90,167 AUD upon the completion of the Services.

On March 20, 2024, we signed a sponsored research agreement with North Carolina State University to conduct a pilot study to evaluate the efficacy of Tafenoquine in canine babesiosis. The research is expected to be completed by March 30, 2026. The Company will retain ownership of all data and inventions related to the study, subject to retained right of North Carolina State University to utilize study data or research use and publications. For a six-month period following notification by the University, the Company retains first right of refusal to negotiate a license to utilize any inventions or data generated by the University relevant to Tafenoquine but not occurring as a direct result of performing the planned studies. The Company agreed to pay North Carolina State University $12,000 upon contract execution, $8,000 around October 1st, 2024, then $3,869 around April 1st, 2025 when work is expected to be completed.

On May 10, 2024, we entered into a sponsored research agreement with North Carolina State University to conduct a study to evaluate the incidence of Babesia infection amongst archived blood samples from patients with chronic fatigue and neurocognitive problems. The research will be completed by May 31, 2025. The Company retains the right to use all study data, joint and University-owned inventions for non-commercial purposes and first right of refusal to negotiate a royalty bearing license for commercial purposes for any university own intellectual property or ownership interest in jointly-owned intellectual property. The Company agreed to pay North Carolina State University $37,620 upon contract execution, $22,572 after six months, then $15,048 upon completion of the contract at twelve months.

On May 29, 2024, we signed a clinical trial agreement with Tufts Medicine, Inc, which specifies the terms on which Tufts will act as a clinical trial site for our Tafenoquine-Babesiosis study. The Company retains the first right to negotiate an exclusive license to any intellectual property owned by Tufts Medicine, Inc, arising from the study.

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.

Information Regarding our Capitalization

As of September 18, 2024, we had 1,861,914 shares of Common Stock issued and outstanding. Additional information regarding our issued and outstanding securities may be found under "*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.

Recent Developments

Reverse Split

On August 12, 2024, we effected a reverse stock split of our Common Stock at a ratio of 1-for-12. Beginning on August 12, 2024, the Company's Common Stock trades on The Nasdaq Capital Market on a split adjusted basis. Upon effectiveness of the reverse stock split, every 12 shares of the Company's issued and outstanding Common Stock were automatically converted into one share of Common Stock. No fractional shares were issued. Instead, any fractional shares that would have resulted from the split was rounded up to the next whole number. Trading in the Common Stock continues on the Nasdaq Capital Market under the symbol "SXTP". The new CUSIP number for the Common Stock following the reverse stock split is 83006G203. The reverse stock split was intended to increase the per share trading price of the Company's Common Stock to satisfy the $1.00 minimum bid price requirement for continued listing of the Common Stock on The Nasdaq Stock Market LLC ("Nasdaq"). The reverse stock split did not affect the number of total authorized shares of Common Stock of the Company.

ATM Offering

On July 22, 2024, we entered into an At the Market Issuance Sales Agreement (the "Sales Agreement") with WallachBeth Capital LLC ("WallachBeth") to sell shares of Common Stock having an aggregate offering price of up to $1,197,073.32 from time to time, through an "at the market offering" program (the "ATM Offering"). On July 24, 2024, we filed an amendment to the prospectus supplement with the SEC to increase the amount of Common Stock that may be offered and sold in the ATM Offering, as amended under the Sales Agreement to $1,890,705 in the aggregate, inclusive of the up to $1,197,073.32 in shares of Common Stock previously sold in the ATM Offering. On July 26, 2024, we filed a second amendment to the prospectus supplement with the SEC to further increase the amount of Common Stock that may be offered and sold in the ATM Offering, as amended under the 2021 Sales Agreement to $2,190,416 in the aggregate, inclusive of the up to $1,890,705 in shares of Common Stock previously sold in the ATM Offering. On August 2, 2024, we filed a third amendment to the prospectus supplement with the SEC to further increase the amount of Common Stock that may be offered and sold in the ATM Offering, as amended under the Sales Agreement to $2,295,192 in the aggregate, inclusive of the up to $2,190,416 in shares of Common Stock previously sold in the ATM Offering. The offer and sale of shares of Common Stock from the ATM Offering was made pursuant to our effective "shelf" registration statement on Form S-3 and an accompanying base prospectus contained therein (Registration Statement No. 333-280796) which became effective on January 20, 2021. As of the date of this prospectus, we have sold a total of 8,133,821 shares of our Common Stock pursuant to the Sales Agreement for an aggregate gross sales price of $1,994,583.43.

Tafenoquine Babesiosis Clinical Trial

In April 2024, the FDA provided some questions and recommendations related to the planned clinical trial that will study the use of Tafenoquine in treating babesiosis. The Company opened its first clinical site on June 13, 2024, following execution of a clinical agreement with Tufts Medical, Inc on May 29, 2024, and similar agreements with Yale University Island Hospital in July 2023. The first patient in the trial was enrolled on June 25, 2024.

Nasdaq Notice of Failure to Comply with Continued Listing Standards

Nasdaq stating that for the 30 consecutive business day period between January 11, 2024 and February 27, 2024, our Common Stock had not maintained a minimum closing bid price of $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until August 26, 2024 (the "Compliance Period"), to regain compliance with the Bid Price Rule.

To regain compliance, the closing bid price of our Common Stock must meet or exceed $1.00 per share for a minimum of 10 consecutive trading days, unless extended by Nasdaq under Nasdaq Rule 5810(c)(3)(H), prior to August 26, 2024. As discussed in "Prospectus Summary - Recent Developments – Reverse Stock Split," the Company effectuated a 1-for-12 reverse stock split of its Common Stock on August 12, 2024. Beginning on August 12, 2024, the Company's Common Stock traded on The Nasdaq Capital Market on a split adjusted basis.

On August 26, 2024, the Company received a formal notification from Nasdaq Listing Qualifications of Nasdaq confirming that the Company had regained compliance with bid price requirement required for continued listing on the Nasdaq as set forth in Listing Rule 5550(a)(2).

Monash University

On February 13, 2024, our majority-owned Australian subsidiary, 60P Australia Pty Ltd, and Monash University entered into the Research Services Agreement (the "Agreement") in which Monash University agreed to provide research services, including among other things, testing the efficacy of Tafenoquine against candidemia, confirming suitable fungal infection dosage and determining the pharmacokinetics of Tafenoquine following intraperitoneal drug administration (collectively, the "Services"). The commencement date of the Agreement was effective as of February 5, 2024, and the anticipated commencement of experiments and the completion date is in May 2024 and on November 30, 2024, respectively. The Company agreed to pay Monash University $90,167 AUD on April 1, 2024 and $90,167 AUD upon the completion of the Services.

North Carolina State University

On March 20, 2024, we signed a sponsored research agreement with North Carolina State University to conduct a pilot study to evaluate the efficacy of Tafenoquine in canine babesiosis. The research is expected to be completed by March 30, 2026. The Company will retain ownership of all data and inventions related to the study, subject to retained right of North Carolina State University to utilize study data or research use and publications. For a six-month period following notification by the University, the Company retains first right of refusal to negotiate a license to utilize any inventions or data generated by the University relevant to Tafenoquine but not occurring as a direct result of performing the planned studies.

On May 10, 2024, we entered into a sponsored research agreement with North Carolina State University to conduct a study to evaluate the incidence of Babesia infection amongst archived blood samples from patients with chronic fatigue and neurocognitive problems. The research will be completed by May 31, 2025. The Company retains the right to use all study data, joint and University-owned inventions for non-commercial purposes and first right of refusal to negotiate a royalty bearing license for commercial purposes for any university own intellectual property or ownership interest in jointly-owned intellectual property.

Clinical Trial Agreement

On May 29, 2024, we signed a clinical trial agreement with Tufts Medicine, Inc, which specifies the terms on which Tufts will act as a clinical trial site for our Tafenoquine-Babesiosis study. On July 15, we signed clinical trial agreements with Yale University and Rhode Island Hospital which specifies the terms on which they will act as clinical trial sites for our Tafenoquine-Babesiosis study. The Company retains the first right to negotiate an exclusive license to any intellectual property owned by the three institutions arising from the study.

January 2024 Offering

On January 29, 2024, the Company entered into an Underwriting Agreement with WallachBeth Capital LLC, as representative of the underwriters listed on Schedule I thereto, relating to the Company's public offering (the "Offering") of 5,260,901 units (the "Units") at an offering price of $0.385 per Unit and 999,076 pre-funded units (the "Pre-Funded Units") at an offering price of $0.375 per Pre-Funded Unit. Each Unit consists of one share of Common Stock and one warrant exercisable for one share of Common Stock (the "Warrant"). Each Warrant has an exercise price of $0.4235 per share, is exercisable immediately upon issuance and expires five years from the date of issuance. Each Pre-Funded Unit consists of one pre-funded warrant exercisable for one share of Common Stock (the "Pre-Funded Warrant") and one warrant identical to the Warrants included in the Units. The purchase price of each Pre-Funded Unit is equal to the price per Unit sold to the public in the offering, minus $0.01, and the exercise price of each Pre-Funded Warrant is $0.01 per share. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. WallachBeth Capital LLC partially exercised its over-allotment option with respect to 818,177 Warrants on January 31, 2024, and purchased an additional 50 shares of Common Stock at a purchase price of $0.3750 and 50 Warrants at a purchase price of $0.01 on February 14, 2024.

The Company also issued to WallachBeth Capital LLC warrants (the "Representative Warrants") to purchase 375,599 shares of the Company's Common Stock, which is equal to 6% of the Common Stock sold that were part of the Units and the pre-funded warrants sold that were part of the Pre-Funded Units in the Offering, at an exercise price of $0.4235 per share (110% of the offering price per Unit). The Representative Warrants may be exercised beginning on January 31, 2024 until January 31, 2029.

The net proceeds to the Company from the Offering were approximately $1.9 million, after deducting underwriting discounts and commissions and the payment of other offering expenses associated with the Offering that were payable by the Company. The Company paid the Underwriter an underwriting discount equal to 8.0% of the gross proceeds of the Offering and a non-accountable expense fee equal to 1.5% of the gross proceeds of the Offering.

September 2024 Private Placement

On September 4, 2024, we entered into a securities purchase agreement (the "Purchase Agreement") with a single institutional investor. The Purchase Agreement provided for the sale and issuance by us of an aggregate of: (i) Pre-Funded Warrants to purchase up to 2,898,551 Shares of our Common Stock, (ii) 2,898,551 shares of Common Stock issuable upon exercise of Series A Warrants, and (iii) 2,898,551 shares of Common Stock issuable upon exercise of Series B Warrants.

The Pre-Funded Warrants are exercisable immediately upon issuance and expire when exercised in full at an exercise price of $0.001 per share. The Series A Warrants and Series B Warrants have an exercise price of $1.38 per share and will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares of Common Stock (the "Stockholder Approval") upon exercise of the Common Warrants. The Series A Warrants will expire five years from Stockholder Approval and the Series B Warrants will expire eighteen (18) months from Stockholder Approval.

H.C. Wainwright & Co., LLC acted as the exclusive placement agent in connection with the Private Placement. In connection with the Private Placement, we issued to Wainwright the Placement Agent Warrants to purchase 217,391 shares of Common. The Placement Agent Warrants have an exercise price equal to $1.725 per share and are exercisable beginning on the effective date of the Stockholder Approval for five years from Stockholder Approval.

We agreed to register the Registered Securities.

THE OFFERING

Common Stock Offered by the Selling Stockholders[(1)]:	We are registering the resale by the selling stockholders named in this prospectus, or their permitted transferees, up to an aggregate of 8,913,044 shares of our Common Stock, par value $0.0001, consisting of: ● 2,898,551 shares of Common Stock issuable upon exercise of Pre-Funded warrants at an exercise price of $0.0001 per share; ● 2,898,551 shares of Common Stock issuable upon exercise of Series A Warrants at an exercise price of $1.38 per share; ● 2,898,551 shares of Common Stock issuable upon exercise of Series B Warrants at an exercise price of $1.38 per share; and ● 217,391 shares of Common Stock issuable upon the excise of the Placement Agent Warrants at an exercise price of $1.725 per share.
Plan of Distribution:	The selling stockholders will determine when and how it will sell the Common Stock offered in this prospectus, as described in "Plan of Distribution" on page 28 of this prospectus.
Use of Proceeds:	We will not receive any proceeds from the sale of shares of our Common Stock by the selling stockholders.
Risk Factors:	Investing in our Common Stock involves significant risks. See "Risk Factors" on page 9 of this prospectus and under similar headings in the documents incorporated by reference into this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our Common Stock.
Nasdaq symbol:	"SXTP" and "SXTPW."

(1) Throughout this prospectus, when we refer to the shares of our Common Stock being registered on behalf of the selling stockholders for offer and resale, we are referring to the shares of Common Stock issued or issuable to the selling stockholders in connection with the Private Placement, including the shares issued or issuable upon exercise of the Warrants. When we refer to the selling stockholders in this prospectus, we are referring to the selling stockholders identified in this prospectus and, as applicable, its permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties described under this section and the section titled "*Risk Factors*" contained in the applicable prospectus supplement, and discussed under the section titled "*Risk Factors*" contained in our most recent Annual Report on Form 10-K and in our most recent Quarterly Report on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus in their entirety, together with other information in this prospectus, and the documents incorporated by reference that we may authorize for use in connection with a specific offering. The risks described in this section and in these documents are not the only ones we face, but those that we consider being material. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be harmed. This could cause the trading price of our securities to decline, resulting in a loss of all or part of your investment. Please also read carefully the section above titled "*Cautionary Note Regarding Forward-Looking Statements*."

USE OF PROCEEDS

We will not receive any proceeds from the sale of the Registered Securities by the selling stockholders. We will bear all other costs, fees and expenses incurred by us, or by the selling stockholders, in effecting the registration of the Registered Securities. The selling stockholders, however, will pay any other expenses incurred in selling their Registered Securities, including any brokerage commissions or costs of sale.

SELLING STOCKHOLDERS

This prospectus relates to the offer and sale from time to time, on a resale basis, by the selling stockholders or their permitted transferees, of up to an aggregate of 8,913,044 shares of our Common Stock consisting of: (i) 2,898,551 shares of Common Stock issuable upon exercise of Pre-Funded Warrants held by certain selling stockholders, (ii) 2,898,551 shares of Common Stock issuable upon exercise of Series A Warrants (iii) 2,898,551 shares of Common Stock issuable upon exercise of Series B Warrants, and (iv) 217,391 share of Common Stock issuable upon the excise of the Placement Agent Warrants owned by certain holders. The shares of Common Stock being registered for resale hereby consist of the shares that have been issued or are issuable upon exercise of outstanding Warrants that were issued in connection with the Private Placement.

We will pay the expenses relating to such registration other than brokerage commissions in connection with the sale of the Common Stock under this prospectus by the respective selling stockholders.

All information with respect to share ownership has been furnished by the selling stockholders. The Common Stock being offered is being registered to permit secondary trading of the shares and the selling stockholders may offer all or part of the Common Stock owned for resale from time to time. Other than as described in the footnotes below, the selling stockholders do not have any family relationships with our officers, directors or controlling shareholders.

The term "selling stockholder" also includes any transferees, pledges, donees, or other successors in interest to the selling stockholders named in the table below. To our knowledge, each person named in the table has sole voting and investment power with respect to the Common Stock set forth opposite such person's name. We will file a supplement to this prospectus (or a post-effective amendment hereto, if necessary) to name successors to any named selling stockholder who is able to use this prospectus to resell the securities registered hereby.

The shares of Common Stock being offered by the selling stockholders are those issuable to the selling stockholders, upon exercise of the Warrants. For additional information regarding the issuances of those shares of Purchase Warrants and Placement Agent Warrants, see "Business - Recent Developments" above. We are registering the shares of Purchase Warrants and Placement Agent Warrants in order to permit the selling stockholders to offer the shares for resale from time to time. Except for the ownership of the shares of the Purchase Warrants and Placement Agent Warrants, the selling stockholders have not had any material relationship with us within the past three years.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the selling stockholders. The second column lists the number of shares of Common Stock beneficially owned by each selling stockholder, based on its ownership of the shares of Private Placement Common Stock and Warrants, as of September 19, 2024, assuming exercise of the Warrants held by the selling stockholders on that date, without regard to any limitations on exercises.

The third column lists the shares of Common Stock being offered by this prospectus by the selling stockholders.

In accordance with the terms of a registration rights agreement with the selling stockholders, this prospectus generally covers the resale of the sum of (i) the number of shares of Private Placement Common Stock issued to the selling stockholders in the "Business - Recent Developments" described above and (ii) the maximum number of shares of Common Stock issuable upon exercise of the related Warrants, determined as if the outstanding Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the registration right agreement, without regard to any limitations on the exercise of the warrants. The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

Under the terms of the Warrants, a selling stockholder may not exercise the Warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of such Warrants which have not been exercised. The number of shares in the second and fourth columns do not reflect this limitation, if any. The selling stockholders may sell all, some or none of their shares in this offering. See "Plan of Distribution."

The following table sets forth certain information concerning the selling stockholders and the shares of Common Stock beneficially owned by them and offered by them in this prospectus. The percentage of ownership of the selling stockholders in the following table is based upon 1,861,914 shares of Common Stock outstanding as of September 18, 2024.

Name of Selling Stockholder	Number of Shares Owned Prior to Offering[(1)]	Maximum Number of Shares to be Sold Pursuant to this Prospectus[(1)]	Number of Shares Owned After Offering[(2)]	Percentage of Shares Owned After Offering[(2)]
Armistice Capital LLC.[(3)]	8,695,653	8,695,653	0	0
Craig Schwabe [(4)]	7,337	7,337	0	0
Charles Worthman [(4)]	2,174	2,174	0	0
Michael Vasinkevich[(4)]	139,402	139,402	0	0
Noam Rubinstein[(4)]	68,478	68,478	0	0

(1) For each selling stockholder, includes shares of Common Stock known by us to be held by such selling stockholder as of the date of the prospectus plus any shares of Common Stock that are issuable upon exercise of warrants that are being registered hereunder without giving effect to any beneficial ownership limitations that may exist on such warrants. This column does not include any other securities that a selling stockholder may hold, including any other warrants that such selling stockholder may hold, that are not applicable to this prospectus.

(2) Assumes the sale of all shares of Common Stock offered pursuant to this prospectus.

(3) The securities to be sold pursuant to this prospectus consist of up to 8,694,653 (subject to adjustments) shares of Common Stock, consisting of 2,898,551 shares of Common Stock issued or issuable upon exercise of Pre-Funded Warrants, 2,898,551 shares of Common Stock issuable upon exercise of Series A Warrants and 2,898,551 shares of Common Stock issuable upon exercise of Series B Warrants, all of which are directly held by Armistice Capital Master Fund Ltd. (the "Master Fund"), a Cayman Islands exempted company, and may be deemed to be indirectly beneficially owned by Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the managing member of Armistice Capital. The Pre-Funded Warrants are subject to a 9.99% beneficial ownership limitation and the Common Warrants are subject to a 4.99% beneficial ownership limitations, which limitations prohibit the Selling Stockholder and its affiliates owning, after exercise, a number of shares of Common Stock in excess of the beneficial ownership limitation. The address of the Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(4) The selling stockholder is affiliated with H.C. Wainwright & Co., LLC, a registered broker dealer with a registered address of H.C. Wainwright & Co., LLC, 430 Park Ave, 3rd Floor, New York, NY 10022, and has sole voting and dispositive power over the securities held. The number of shares beneficially owned consists of shares of Common Stock issuable upon exercise of Placement Agent Warrants, which were received as compensation in connection with our Private Placement. The selling stockholder acquired the Placement Agent Warrants in the ordinary course of business and, at the time the Placement Agent Warrants were acquired, the selling stockholder had no agreement or understanding, directly or indirectly, with any person to distribute such securities.

PLAN OF DISTRIBUTION

We are registering the Registered Securities on behalf of the selling stockholders. The selling stockholders and any of their pledgees, assignees, distributees, and successors-in-interest in the Registered Securities received after the date of this prospectus from the selling stockholders as a partnership distribution, gift, pledge, or other transfer, may, from time to time, sell, transfer, or otherwise dispose of any or all of the shares of our Common Stock covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which the Common Stock is traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. The selling stockholders may use any one or more of the following methods when selling Common Stock:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the Common Stock 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;
- exchange distributions in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such Common Stock at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the Registered Securities owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Registered Securities, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act 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 Registered Securities 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.

In connection with the sale of the Registered Securities, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the Registered Securities in the course of hedging the positions they assume. To the extent permitted by applicable securities laws, the selling stockholders may also sell the Registered Securities short and deliver these securities to close out their short positions, or loan or pledge the Registered Securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of the Registered Securities offered by this prospectus, which Registered Securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the Registered Securities offered by them will be the purchase price of the Registered Securities less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of the Registered Securities to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholders also may resell all or a portion of the Registered Securities in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the Registered Securities or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the Registered Securities covered by this prospectus may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the Registered Securities to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the Registered Securities may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the Registered Securities 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.

DESCRIPTION OF SECURITIES

Description of Capital Stock

General

The following description summarizes some of the terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you and is subject to and qualified in its entirety by reference to our certificate of incorporation, as corrected ("Certificate of Incorporation") and amended and restated bylaws ("Bylaws"), which are filed as exhibits to our most recent Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Certificate of Incorporation and Bylaws for additional information.

As of September 19, 2024, our authorized capital stock presently consists of 150,000,000 shares of Common Stock, par value $0.00001 per share, and 1,000,000 shares of "blank check" preferred stock, par value $0.00001 per share, of which 80,965 shares of preferred stock have been designated as "Series A Non-Voting Convertible Preferred Stock" ("Series A Preferred Stock").

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. We have currently 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 the IPO 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%. As of September 19, 2024, there are 80,965 shares of Series A Preferred Stock issued and outstanding.

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.

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

Our Common Stock and Tradeable Warrants have been approved for listing on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively.

Description of Warrants

September 2024 Warrants

On September 5, 2024, in connection with the Private Placement, we issued (i) Pre-Funded Warrants to purchase up to an aggregate of 2,898.551 shares at an exercise price of $0.001 per share; (ii) Series A Common Stock Warrants to purchase up to an aggregate of 2,898.551 shares of Common Stock at an exercise price of $1.38 per share; and (iii) Series B Common Stock Warrants to purchase up to an aggregate of 2,898.551 shares of Common Stock at an exercise price of $1.38 per share.

The Pre-Funded Warrants are exercisable immediately upon issuance and expire when exercised in full at an exercise price of $0.001 per share. The Series A Warrants and Series B Warrants will be exercisable beginning on the effective date of Stockholder Approval of the issuance of the shares of Common Stock upon exercise of the Common Warrants. The Series A Warrants will expire five years from Stockholder Approval and the Series B Warrants will expire eighteen (18) months from Stockholder Approval.

The Pre-Funded Warrants and the Series A Common Stock Warrants and Series B Common Stock Warrants provide that a holder of Pre-Funded Warrants and the Series A Common Stock Warrants and Series B Common Stock Warrants, as applicable, will not have the right to exercise any portion of its Pre-Funded Warrants and the Series A Common Stock Warrants and Series B Common Stock Warrants if such holder, together with its affiliates, would beneficially own in excess of 4.99% or 9.99% of the number of shares of the Company's Common Stock outstanding immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that each holder may increase or decrease the Beneficial Ownership Limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 9.99%. If there is no effective registration statement at the time of exercise, the Pre-Funded Warrants and the Series A Common Stock Warrants and Series B Common Stock Warrants may be exercised on a cashless basis.

The Company also issued to H.C. Wainwright or its designees warrants the Placement Agent Warrants to purchase up to an aggregate of 217,391 shares of Common Stock at an exercise price equal to $1.725 per share. The Placement Agent Warrants are exercisable beginning on the effective date of the Stockholder Approval for five years from Stockholder Approval.

January 2024 Warrants

On January 29, 2024, we entered into an Underwriting Agreement with WallachBeth Capital LLC, as representative of the underwriters listed on Schedule I thereto (the "Underwriting Agreement"), relating to the Company's public offering (the "Offering") of 5,260,901 units (the "Units") at an offering price of $0.385 per Unit and 999,076 pre-funded units (the "Pre-Funded Units") at an offering price of $0.375 per Pre-Funded Unit. Each Unit consists of one share of Common Stock and one warrant exercisable for one share of Common Stock (the "Warrant"). Each Warrant has an exercise price of $0.4235 per share, is exercisable immediately upon issuance and expires five years from the date of issuance. Each Pre-Funded Unit consists of one pre-funded warrant exercisable for one share of Common Stock (the "January 2024 Pre-Funded Warrant") and one warrant identical to the Warrants included in the Units. The purchase price of each January 2024 Pre-Funded Unit is equal to the price per Unit sold to the public in the offering, minus $0.01, and the exercise price of each January 2024 Pre-Funded Warrant is $0.01 per share. The January 2024 Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the January 2024 Pre-Funded Warrants are exercised in full.

DIVIDEND POLICY

We have never declared or paid any dividends. We currently intend to retain earnings, if any, for use in our business. We do not anticipate paying dividends in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Sichenzia Ross Ference Carmel LLP, located in New York, New York.

EXPERTS

The financial statements of 60 Degrees Pharmaceuticals, Inc. as of December 31, 2023 and 2022 and for the years then ended incorporated in this registration statement and prospectus by reference to our Annual Report on Form 10-K, for the year ended December 31, 2023, have been audited by RBSM LLP, an independent registered public accounting firm, as stated in their report thereon, incorporated herein by reference, and have been incorporated in this registration statement and prospectus in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of the registration statement on Form S-3 that we filed with the Commission under the Securities Act and does not contain all of the information set forth in the registration statement. Whenever a reference is made in this prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are part of the registration statement or the exhibits to the reports or other document incorporated into this prospectus for a copy of such contract agreement or other document. Because we are subject to the information and reporting requirements under the Exchange Act, we file annual, quarterly and current reports, proxy statements and other information with the Commission. Our filings with the Commission are available to the public over the Commission's website at *www.sec.gov*. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, including any amendments to those reports, and other information that we file with or furnish to the Commission pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge on our website. You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Washington, D.C., 20549, on official business days during the hours of 10 a.m. to 3 p.m. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C., 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facility. In addition, you can find more information about us on our website at *https://60degreespharma.com*. Information contained on or accessible through our website is not a part of this prospectus and is not incorporated by reference herein, and the inclusion of our website address in this prospectus is an inactive textual reference only.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with it into this prospectus, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. The information incorporated by reference into this prospectus is deemed to be part of this prospectus, and any information filed with the SEC after the date of this prospectus will automatically be deemed to update and supersede information contained in this prospectus and any accompanying prospectus supplement.

The following documents previously filed with the SEC are incorporated by reference in this prospectus:

- The Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on April 1, 2024;
- The Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2024, filed with the SEC on May 15, 2024;
- The Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2024, filed with the SEC on August 14, 2024;
- The Registrant's Preliminary Schedule 14A, filed with the SEC on May 3, 2024, and the Registrant's Definitive Schedule 14A, filed with the SEC on May 30, 2024;
- The Registrant's Current Reports on Form 8-K filed with the SEC on January 16, 2024, February 2, 2024, February 20, 2024, February 28, 2024, July 16, 2024, July 26, 2024, August 12, 2024, August 14, 2024, August 28, 2024 and September 06, 2024 to the extent the information in such report is filed and not furnished; and
- The description of the Registrant's Common Stock, which is contained in a registration statement on Form 8-A12B filed with the SEC on June 27, 2023, under the Exchange Act, including any amendment or report filed for the purpose of updating such description.

All filings filed by us pursuant to the Exchange Act after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of the registration statement shall be deemed to be incorporated by reference into this prospectus.

We also incorporate by reference all additional documents that we file with the Securities and Exchange Commission under the terms of Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the date of the initial registration statement but prior to effectiveness of the registration statement and after the date of this prospectus but prior to the termination of the offering of the securities covered by this prospectus. We are not, however, incorporating, in each case, any documents or information that we are deemed to furnish and not file in accordance with Securities and Exchange Commission rules.

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information appearing in this prospectus is accurate only as of the date of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained herein, or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein, modifies or supersedes that statement. The modifying or superseding statement need not state it has modified or superseded a prior statement or include any other information set forth in the document that it modifies or supersedes. The making of a modifying or superseding statement is not an admission for any purposes that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that is required to be stated or that is necessary to make a statement not misleading in light of the circumstances in which it was made. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request, and we will provide you with, a copy of these filings, at no cost, by calling us at (202) 327-5422 or by writing to us at the following address:

60 Degrees Pharmaceuticals, Inc.
1025 Connecticut Avenue NW Suite 1000
Washington, D.C. 20036
Attn: Geoffrey Dow, Chief Executive Officer and President

60 Degrees Pharmaceuticals, Inc.

8,913,044 Shares of Common Stock underlying certain Pre-Funded Warrants, Common Warrants and Placement Agent Warrants

---

PROSPECTUS

, 2024

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

	Amount to Be Paid
U.S. Securities and Exchange Commission registration fee	$ 1,858.24
Legal fees and expenses	65,000*
Accounting fees and expenses	5,000*
Miscellaneous	5,000*
Total	76,858.24*

* These fee and expense amounts are estimated.

Item 15. Indemnification of Directors and Officers

Under the General Corporation Law of the State of Delaware ("DGCL"), a corporation may include provisions in its certificate of incorporation that will relieve its directors of monetary liability for breaches of their fiduciary duty to the corporation, except under certain circumstances, including a breach of the director's duty of loyalty, acts or omissions of the director not in good faith or which involve intentional misconduct or a knowing violation of law, the approval of an improper payment of a dividend or an improper purchase by the corporation of stock or any transaction from which the director derived an improper personal benefit. The Company's Amended and Restated Certificate of Incorporation eliminates the personal liability of directors to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director with certain limited exceptions set forth in the DGCL.

Section 145 of the DGCL grants to corporations the power to indemnify each officer and director against liabilities and expenses incurred by reason of the fact that he or she is or was an officer or director of the corporation if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The Company's Amended and Restated Certificate of Incorporation and Bylaws provide for indemnification of each officer and director of the Company to the fullest extent permitted by the DGCL. Section 145 of the DGCL also empowers corporations to purchase and maintain insurance on behalf of any person who is or was an officer or director of the corporation against liability asserted against or incurred by him in any such capacity, whether or not the corporation would have the power to indemnify such officer or director against such liability under the provisions of Section 145 of the DGCL.

Item 16. Exhibits and Financial Statement Schedules

The exhibits to the Registration Statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

Item 17. Undertakings

(a) 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;

(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 Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(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) of this section 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 SEC 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 of 1933, 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 of 1933 to any purchaser:

(i) 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

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. 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 effective date, 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 effective date.

5. That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the 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.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefits plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

(c) The undersigned registrant hereby undertakes to supplement the prospectus, after the expiration of the subscription period, to set forth the results of the subscription offer, the transactions by the underwriters during the subscription period, the amount of unsubscribed securities to be purchased by the underwriters, and the terms of any subsequent reoffering thereof. If any public offering by the underwriters is to be made on terms differing from those set forth on the cover page of the prospectus, a post-effective amendment will be filed to set forth the terms of such offering.

(d) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, 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 of 1933, as amended, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the 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 of whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, 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 September 19, 2024.

60 DEGREES PHARMACEUTICALS, INC.

By: */s/ Geoffrey Dow*
Geoffrey Dow
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Geoffrey Dow and Tyrone Miller, and each of them (with full power to each of them to act alone), his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this registration statement, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their substitutes, may lawfully do or cause to be done by virtue hereof.

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)	September 19, 2024
/s/ Tyrone Miller Tyrone Miller	Chief Financial Officer (Principal Financial and Accounting Officer)	September 19, 2024
/s/ Charles Allen Charles Allen	Director	September 19, 2024
/s/ Cheryl Xu Cheryl Xu	Director	September 19, 2024
/s/ Stephen Toovey Stephen Toovey	Director	September 19, 2024
**/s/ Paul Field* Paul Field	Director	September 19, 2024

* By: */s/ Geoffrey Dow*
Geoffrey Dow
Attorney-in-Fact

EXHIBIT INDEX

Exhibit No.	Description
4.1	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed with the SEC on September 6, 2024).
4.2	Form of Series A Warrant (incorporated herein by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed with the SEC on September 6, 2024).
4.3	Form of Series B Warrant (incorporated herein by reference to Exhibit 10.5 to the registrant's Current Report on Form 8-K filed with the SEC on September 6, 2024).
4.4	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 10.6 to the registrant's Current Report on Form 8-K filed with the SEC on September 6, 2024).
5.1*	Opinion of Sichenzia Ross Ference Carmel LLP
10.1	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the SEC on September 6, 2024).
10.2*	Clinical Trial Agreement, dated July 15, 2024, between 60 Degrees Pharmaceuticals, Inc. and Yale University
10.3*	Clinical Trial Agreement, dated July 15, 2024, between 60 Degrees Pharmaceuticals, Inc. and Rhode Island Hospital
23.1*	Consent of RBSM LLP dated as of September 19, 2024.
23.3*	Consent of Sichenzia Ross Ference Carmel LLP (to be included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).
107*	Filing Fee Table

* Filed herewith

Exhibit 5.1

September 19, 2024
60 Degrees Pharmaceuticals, Inc.
1025 Connecticut Avenue NW Suite 1000
Washington, D.C.

Re: Registration Statement on Form S-3

To Whom It May Concern,

We are counsel to 60 Degrees Pharmaceuticals, Inc., a Delaware corporation (the "Company"), in connection with the filing and preparing of a registration statement on Form S-3, and as may be further amended or supplemented (the "Registration Statement"), to be filed with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Act"), relating to the registration of up to an aggregate of 8,913,044 shares (the "Resale Shares") of common stock, par value $0.0001 per share (the "Common Stock"), consisting of: (i) 2,898,551 shares of Common Stock issuable upon exercise of pre-funded warrants (the "Pre-Funded Warrants"), (ii) 2,898,551 shares of Common Stock issuable upon exercise of Series A warrants (the "Series A Warrants"), and (iii) 2,898,551 shares of Common Stock issuable upon exercise of Series B warrants (the "Series B Warrants") and (iv) 217,391 share of Common Stock issuable upon the exercise of placement agent warrants (the "Placement Agent Warrants", and together with the Pre-Funded Warrants, Series A Warrants and Series B Warrants, the "Warrants"). The Warrants were issued to the selling stockholders in connection with a private placement the Company completed on September 5, 2024.

In rendering the opinion set forth herein, we have examined originals or copies, certified or otherwise identified to our satisfaction, of such documents, corporate records, certificates of public officials and other instruments as we have deemed necessary or advisable. In such examination, we have assumed without verification the genuineness of all signatures, the legal capacity of natural persons, the authenticity of all documents submitted to us as originals, the conformity to the originals of all documents submitted to us as copies and the authenticity of the originals of such copies. As to questions of fact material to this opinion, we have relied on certificates or comparable documents of public officials and of officers and representatives of the Company.

We express no opinions other than as specifically set forth herein. We are opining solely on as to the General Corporation Law of the State of Delaware and we express no opinion as to whether the laws of any jurisdiction are applicable to the subject matter hereof. We are not rendering any opinion as to compliance with any federal or state law, rule or regulation relating to securities, or to the sale or issuance thereof. This opinion letter deals only with the specified legal issues expressly addressed herein, and you should not infer any opinion that is not explicitly stated herein from any matter addressed in this opinion letter.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that:

upon exercise of the Warrants against payment of the exercise price therefor and in accordance with the terms of Warrants, the shares of Common Stock underlying the Warrants will be validly issued, fully paid and nonassessable.

In rendering the foregoing opinion, we have assumed that at or prior to the time of the delivery of any Resale Shares, that the Registration Statement will have been declared effective under the Act and that the registration will apply to all of the Resale Shares and will not have been modified or rescinded and that there will not have occurred any change in law affecting the validity of the issuance of such Resale Shares.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the references to our firm therein under the caption "Legal Matters." In giving our consent, we do not thereby admit that we are experts with respect to any part of the Registration Statement within the meaning of the term "expert," as used in Section 11 of the Securities Act or the rules and regulations promulgated thereunder by the Commission, nor do we admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

This opinion is furnished to you in connection with the filing of the Registration Statement and is not to be used, circulated, quoted or otherwise relied upon for any other purpose.

Very truly yours,

/s/ Sichenzia Ross Ference Carmel LLP

Sichenzia Ross Ference Carmel LLP

Exhibit 10.2

Specific information contained in this agreement has been excluded due to its non-material nature and because such information is considered private or confidential. Upon the request by Commission or its staff, the Company will quickly provide an unredacted copy of this agreement, along with analyses supporting its decisions on materiality and confidentiality.

CLINICAL TRIAL AGREEMENT

PROTOCOL NUMBER: TQ-BA-2024-1 (NCT06207370)
PROTOCOL TITLE: "Double-blind Placebo-controlled Study to Assess the Safety and Efficacy of Oral Tafenoquine plus Standard of Care versus Placebo plus Standard of Care in Patients Hospitalized for Babesiosis"

YALE UNIVERSITY
25 Science Park – 3rd Floor
150 Munson Street
New Haven, CT 06511 (**"INSTITUTION"**)

and

60 Degrees Pharmaceuticals, Inc
1025 Connecticut Ave NW, Suite 1000
Washington DC, United States, 20036
("**SPONSOR"**)

Table of Contents

This Clinical Trial Agreement (this "Agreement") is effective as of July 15, 2024(the "Effective Date") and sets forth certain agreements by and between **60 DEGREES PHARMACEUTICALS, INC** , having its principal place of business at 1025 Connecticut Ave NW, Washington DC, 20036 ("Sponsor"), and **YALE UNIVERSITY**, a non profit corporation organized and existing under and by virtue of a special charter granted by the General Assembly of the Colony and State of Connecticut, with offices located at 25 Science Park – 3rd Floor, 150 Munson Street, New Haven, CT 06511 (hereinafter referred to as "Institution"). Subsequent reference to Institution hereinafter shall imply the inclusion of Staff (defined in Section 1.3). The persons executing this Agreement hereby represent that they are authorized to do so for and on behalf of the above-named companies and organizations.

WHEREAS, Sponsor and Institution are hereinafter referred to individually as "Party" and collectively as "Parties;"

WHEREAS, Sponsor is arranging to use Institution as a clinical trial site to clinically conduct the study pursuant to the Protocol (as defined in Article 1 below) (the "Study");

WHEREAS, the Study contemplated by this Agreement is of mutual interest and benefit to Institution and Sponsor, and will further the instructional and research objectives of Institution in a manner consistent with its status as a nonprofit educational, research and health care institution;

WHEREAS, Institution will enroll subjects, collect clinical trial data and execute specific clinical trial activities required by the Study; and

WHEREAS, Sponsor has contracted with **Fast Track Drugs and Biologics LLC.**, a Maryland corporation with offices located at 20010 Fisher Avenue Suite G, Poolesville, MD, 20837 ("CRO") to coordinate and/or perform certain activities as its clinical research organization including, but not limited to, regulatory activities, monitoring, site initiation and close-out visits, data analysis and audits required for the conduct of the Study.

NOW, THEREFORE, the Parties, in consideration of the mutual covenants and promises contained herein, have entered into this Agreement and do specifically agree as follows:

1. Performance of Study

1.1 Study Protocol. The scope and nature of the clinical trial to be performed will be in strict accordance with the Study, including Protocol Number TQ-BA-2024-1 (NCT06207370) entitled, "Double-blind Placebo-controlled Study to Assess the Safety and Efficacy of Oral Tafenoquine plus Standard of Care versus Placebo plus Standard of Care in Patients Hospitalized for Babesiosis", and any subsequent amendments thereto, referenced and incorporated herein (the "Protocol"). The Protocol fully details the clinical research activities and responsibilities to be undertaken, pursued, and followed with all due diligence by Investigator. The Protocol will be considered final after it is signed by the Sponsor and approved by the pertinent Institutional Review Board ("IRB"). Thereafter, the Protocol may be amended only by the Sponsor and subsequent approval by the IRB. A copy of the signed Statement of Investigator (FDA Form 1572), the Protocol and any Protocol amendments will be maintained in the Investigator's Study files. The Study will be conducted by the Institution under the direction of [____] ("Investigator"), an employee/faculty member of Institution.

1.2 Conduct of Study. Institution agree to conduct the Study in strict compliance with the Protocol, this Agreement and any amendments thereto, any and all applicable federal, state, and local laws, regulations, good clinical practices as adopted by current FDA regulations and statutes and regulations of the U.S., all reasonable written instructions of the Sponsor or its designee (e.g. CRO) and any other applicable professional standards. Institution also agrees specifically to conduct the Study in accordance with the Statement of Investigator, FDA Form 1572, which Investigator has completed, signed, and delivered to Sponsor prior to the commencement of the Study at Institution. The Institution further agrees that in the performance of the Study, it shall:

(a) Require the Investigator to exercise independent medical judgment as to the compatibility of each Study participant with Protocol requirements;

(b) Obtain a signed informed consent form (in a form approved by Sponsor) from each Study participant or his/her legally authorized representative and his/her caregiver in accordance with the Protocol, which has been approved by the IRB and Sponsor in accordance with 21 CFR §56, et. seq., or any successor thereto;

(c) Properly perform and direct or administer the Study in accordance with the Protocol, the applicable laws and regulations, the guideline published by the U.S. Food and Drug Administration ("FDA") entitled, "Good Clinical Practices, Consolidated Guideline" as amended from time to time, and the other requirements as set forth therein;

(d) Review all Study participant case report forms (hereinafter "CRFs") to assure their accuracy and completeness, and assist Sponsor's representatives and clinical monitors upon request in promptly resolving any discrepancies or errors on CRFs and in performing random audits of original patient records, laboratory reports, or other raw data sources underlying data recorded on the CRFs;

(e) Submit all data and information, and undertake all activities, so that the timeline as defined in the schedule of assessments set forth in the Protocol and this Agreement are strictly met;

(f) Notify Sponsor and the IRB immediately upon becoming aware of any failures to comply with the Protocol;

(g) Maintain records of Study participant identification, clinical observations, laboratory tests, and drug receipt, storage, return and disposition as specified in the Protocol;

(h) Provide all reasonable cooperation with Sponsor and its designee in all of their efforts to monitor the Study;

(i) Pursuant to 21 CFR §312.66, assure that the IRB will comply with the requirements of 21 CFR §56, et. Seq.;

(j) Perform the services in relation to the Study with reasonable care, diligence and skill and ensure that personnel engaged by it in the provision of such Study services are competent and have appropriate professional qualifications, training and experience; and

(k) Upon request from Sponsor, Investigator will update his/her financial disclosure form in a timely matter one (1) year after Study completion.

1.3 Participating Staff. The Study shall be conducted under the immediate direction of the Investigator. Institution shall ensure that all Study Staff, including Investigator, personally perform their assigned Study tasks, as indicated in the Protocol and in accordance with this Agreement. Investigator shall qualify such personnel and oversee the work of other Study Staff. Investigator may have one or more sub-investigator(s) work on the Study; provided, however, that Investigator is responsible for all work conducted by sub-investigator. Any such sub-investigator shall be subject to all of the terms and conditions of this Agreement, including all obligations of Investigator. No sub-investigator may work on the Study unless he or she is qualified through experience and training to conduct clinical studies and agrees to be involved through completion of the Study. The sub-investigator's name shall appear in the appropriate space on the FDA Form 1572. Notwithstanding the foregoing, Sponsor may disapprove any proposed sub-investigator within five (5) days of submission of FDA Form 1572. For purposes of this Agreement, "Staff" shall mean all Institution personnel including, but not limited to, faculty, researchers, investigators, sub-investigators, study coordinators and any other person performing services related to the Study on behalf of Institution, or to whom Institution provides access to Study materials or study drug ("Study Drug").

1.4 Third Parties Staff. Institution shall ensure that any third-party personnel working, directly or indirectly, on the Study shall be competent, have appropriate professional qualifications, training and experience, and are bound by obligations of confidentiality and non-use with respect to Confidential Information (as defined by this Agreement) that are at least as restrictive as the obligations of confidentiality and non-use imposed by this Agreement. Institution shall ensure that such third-party are qualified and oversee their work.

1.5 Replacement of Investigator. In addition to any other remedy which may be available to Sponsor, in the event Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Institution shall immediately notify Sponsor of such circumstance. In addition, upon request by Sponsor, Institution will cooperate, in good faith and expeditiously, to find a replacement Investigator acceptable to Sponsor. Institution's and Investigator's cooperation in finding an acceptable replacement does not negate their obligations under this Agreement or by law or regulation.

1.6 Notification of Adverse Events. Investigator shall immediately notify Sponsor and the Institution's IRB in writing of any serious adverse drug experience within twenty-four (24) hours of learning of the event. For serious adverse drug experiences, Institution and Investigator shall assist in the investigation of the medical circumstances and shall provide Sponsor with all requested information so that Sponsor can submit any required IND Safety Report to FDA within fifteen (15) days of its initial receipt of the information. For fatal or life-threatening experiences, Institution and Investigator shall provide Sponsor with all requested information so that Sponsor can submit any required Telephone and Facsimile Transmittal Safety Report to FDA within seven (7) days of its initial receipt of the information. Institution shall follow-up with any Study participant who experienced an adverse drug experience and continue to provide Sponsor with updates.

1.7 Protocol Deviation. Prospective Protocol waivers or deviations will not be granted by Sponsor under any circumstance. Deviations from the Protocol which are medically necessary for a Study participant's safety in cases of emergency are not considered failure to comply with the Protocol. If, during the course of a Study participant's post-randomization participation in the Study, it is discovered that the Study participant did not meet all eligibility criteria, s/he will be discontinued, unless the discontinuation presents an unacceptable medical risk. The justification to allow the Study participant to continue in the Study will be made by the Sponsor, with medical input from the Investigator, and will be documented. If the Study participant is allowed to remain in the Study, this will be reported as a major Protocol deviation and not a waiver. All follow-up safety assessments must be completed and documented as outlined in the Protocol. Other Protocol deviations will be tracked and corrective measures will be put in place to prevent such deviations from being repeated.

1.8 Safety Monitoring Reports. Sponsor agrees to provide Institution with any data and safety monitoring reports related to the Clinical Trial, and Institution agrees they will be submitted to the IRB as required. During the Clinical trial and for at least two (2) years following the completion of the Clinical Trial at all sites, Sponsor shall promptly provide Institution and Principal Investigator with the written report of any findings, including Clinical Trial results and any routine monitoring findings in site monitoring reports, and data safety monitoring committee reports including, but not limited to, data and safety analyses, and any Clinical Trial information that may (i) affect the safety and welfare of current or former Enrolled Participants, or (ii) influence the conduct of the Clinical Trail. Institution and/or Principal Investigator will communicate findings to the IRB and Enrolled Participants, as appropriate.

2. Study Drug, Storage and Return, and Equipment

2.1 Study Drug. Investigator shall use the Study Drug only pursuant to and in accordance with the Protocol and this Agreement, and for no other purpose. Institution shall notify Sponsor and Institution's IRB regarding any use of the Study Drug without obtaining informed consent as soon as possible, but no later than five (5) business days after becoming aware of such use.

2.2 Storage. Institution shall keep all Study Drug in a locked, secured area at all times, within the temperatures required in the Protocol for storage of the Study Drug and maintain complete, up-to-date records showing receipt of shipments of the Study Drug, dispensing and accountability of the Study Drug, and returns of the Study Drug as required by the Protocol, applicable federal, state, and local laws, regulations, and guidelines. Furthermore, Institution shall store all Study Drug in either a central pharmacy where a qualified pharmacist supervises dispensing, or in a restricted area and dispensed under the direct supervision of Investigator.

2.3 Equipment. Sponsor may provide, or arrange for a vendor to provide, certain equipment, if applicable, for use by Investigator and Staff during the conduct of the Study ("Equipment"). During the term of this Agreement, Staff, including Investigator, may use the Equipment only for purposes of this Study in accordance with the Protocol. Until the termination of this Agreement, this Equipment remains the property of Sponsor or the respective vendor that has provided the Equipment, as applicable. The Equipment shall be returned upon request by Sponsor, at Sponsor's expense, to Sponsor or the vendor, promptly upon early termination of this Agreement or at the completion of the Study. Institution agrees to return the Equipment in the manner directed by Sponsor or the vendor in substantially the same condition as when received by Institution and/or Investigator, minus reasonable wear and tear. Institution agrees to be financially responsible to cover any loss or destruction to Equipment while in Institution's care and control, which exceeds ordinary wear and tear and/or lacks a reasonable causal relationship to proper performance of the Study. Institution further agrees that unless otherwise authorized in writing by Sponsor, Institution will not alter the Equipment in any way nor install any components or software, if applicable. Any software provided to Institution may not be duplicated. Institution shall not have any liability for damages of any sort, including personal injury or property damage, resulting from the use of Equipment except to the extent that such damages were caused by the negligence or willful misconduct of Institution.

2.4 Return of Study Drug and Sponsor Property. Upon completion of the Study or earlier termination of this Agreement, all unused Study Drug, devices, Equipment, and related materials and all copies of Confidential Information, including Sponsor Technology (as defined below), that were furnished to Investigator shall be returned to Sponsor, at Sponsor's request except for record copies which the Investigator is required to retain by law or regulation. Notwithstanding the foregoing, Institution may retain a copy of the Confidential Material in its secure files to maintain its rights and obligations under this Agreement. Regarding all unused Study Drug, the Investigator shall, upon the written direction and approval of Sponsor, either (i) return all such material back to the Sponsor at Sponsor's expense; (ii) destroy, at the site where the Study is being conducted, such material in a manner that does not expose humans to risk from the compound or drug and according to applicable laws and regulations; or (iii) dispose of such materials in another method that that does not expose humans to risk from the compound or drug. In cases of (ii) or (iii), a certificate of destruction/disposition shall be sent to Sponsor upon such action.

3. Payments

3.1 In consideration for performance of the Study, Sponsor will pay the Party identified as "Payee" in accordance with the Payment Schedule attached as Appendix I ("Payment Schedule") and the Budget attached as Appendix II ("Budget"), and each made a part hereof. The Parties acknowledge that the Payee is the appropriate payee under this Agreement and that the Payee is authorized to receive all the payments for the services performed under this Agreement. The Budget may be modified only upon the prior written consent of the Parties. Investigator acknowledges and agrees that the Payment Schedule and Budget includes Sponsor's entire payment obligation for the performance of the Study pursuant to this Agreement. CRO may process payments to the Payee on behalf of the Sponsor.

3.2 Institution agrees that its judgment with respect to the advice and care of each Study participant will not be affected by the compensation it receives from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to it for the purpose of inducing them to purchase or prescribe any drugs, devices or products. If the Sponsor provides any free products or items for use in the Study, Institution agrees that it will not bill any Study participant, insurer or governmental agency, or any other third party, for such free products or items. Institution agrees that it will not bill any Study participant, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from Sponsor, or which are not part of the ordinary care they would normally provide for the Study participant.

3.3 The Payee information needs to be completed below and on an IRS Form W-9 and returned to Sponsor for the Agreement to be effective. This information will be used for preparation of Federal Form 1099 which will be issued to Payee documenting the payments made to the Payee in each calendar year.

4. Term and Termination

4.1 Term. The term of this Agreement shall begin upon the Effective Date. Unless terminated earlier, this Agreement will terminate when (a) Institution has submitted all CRFs to Sponsor, has resolved all data clarification queries, has submitted the closeout report to the IRB and Sponsor, has returned all Equipment and Study materials to Sponsor, and has met all other close-out obligations; and (b) all payments, reimbursements and refunds have been made.

4.2 Termination by Sponsor. This Agreement may be terminated by Sponsor at any time for any reason upon thirty (30) day written notice to Institution.

4.3 Termination by Institution. This Agreement may be terminated by the Institution upon prior written notice to Sponsor if any of the following conditions occur:

(a) If the authorization and approval to conduct the Study in the United States is withdrawn by the FDA; or

(b) If the emergence of any unexpected or unanticipated significant safety issue with the Study Drug and/or Study Device is of such magnitude or incidence in the reasonable opinion of the Investigator, Sponsor or the data safety monitoring board to support termination.

4.4 Effect of Termination. In the event of expiry or termination of this Agreement for any reason, Institution shall, and shall procure, the prompt return to Sponsor of all Sponsor property as detailed in Section 2.4. The Institution and Investigator may retain only the relevant Study information and data to the extent and for the duration required by applicable law or regulation or as otherwise permitted under this Agreement. Institution shall (i) use all reasonable efforts to conclude work on the Study, (ii) stop enrollment of Study participants, (iii) not incur additional expenses, or enter into any further commitments with regard to the Study after receiving or providing a notice of termination, and (iv) reasonably cooperate with the Sponsor and its designee to allow for a close-out site visit. In the event of termination, the sum payable under this Agreement shall be limited to prorated fees based on actual work performed pursuant to the Protocol as determined in accordance with the Budget. Such payment shall be paid upon satisfaction of all outstanding obligations of Institution, including, but not limited to, return of all Equipment and Study materials to Sponsor. Institution will be entitled to payment for non-cancelable and non-refundable Study participant-related expenses only if properly substantiated, reasonably incurred in accordance with the Study through the date of termination and within the Budget. Any funds not due to Institution but already paid to Institution shall be returned to CRO and Sponsor by the earlier of ninety (90) days from the Institution close-out visit or from the notice of termination.

5. Confidentiality

5.1 All information, including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions, Study Drug Sponsor Technology (as defined in Article 7 below) and Confidential Information (as defined below), provided to or made available to Institution or Investigator by Sponsor or its agents (whether verbal, written or electronic) shall be the property of Sponsor.

5.2. "Confidential Information" means all confidential information, material or data related to the Study, including Sponsor Technology, whether provided by or on behalf of Sponsor to the Institution after the Effective Date which: (a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure; or (b) if disclosed orally, is identified at the time of disclosure as confidential and is subsequently reduced to a marked writing within thirty (30) days of such disclosure. Sponsor will make reasonable efforts to mark Confidential Information as stated in (a) and (b) above. The absence of such marking will not preclude information from being treated as confidential if information disclosed (written or verbal) is such that a reasonable person knowledgeable in the field of clinical trial research would consider it to be confidential or proprietary from the context or circumstances of such disclosure., Confidential Information may include without limitation, any information and data concerning the Study Drug, Study results, reports, Study strategies, the existence or terms of the Protocol or this Agreement, exclusive of patient medical records.

5.3 Institution shall maintain in strict confidence all of the Confidential Information, including the Sponsor Technology, and not disclose or disseminate to any third party or use for any purpose other than the performance of the Study or as permitted under this Agreement any of the same. Such Confidential Information, including the Sponsor Technology, shall remain the confidential and proprietary property of Sponsor, and shall be disclosed only on a need-to-know basis and only to the Investigator and his/her Staff who have a need to know such Confidential Information for the purposes of performing the Study according to this Agreement and the Protocol, or as otherwise permitted under this Agreement, who are bound by confidentiality terms at least as strict as those herein (individually, a "Required Disclosee"). Institution will inform and advise each Required Disclosee of the obligations under this Agreement with respect to the Confidential Information and each Required Disclosee shall be bound by such obligations in a like fashion.

5.4 Institution each shall use the same degree of care to protect the Confidential Information as it uses to protect its own confidential information, but in no event less than a reasonable amount of care. Institution shall be responsible for any breach of this Agreement by its Staff to the extent permitted by applicable law. Institutionagrees to immediately notify Sponsor in the event of any loss or unauthorized disclosure of any Confidential Information.

5.5 The foregoing obligation of non-disclosure shall not apply to Confidential Information, including the Sponsor Technology, that:

(a) was generally known to the public prior to the Effective Date of this Agreement;

(b) becomes generally known to the public through no unlawful or unauthorized act or omission of Institution or any of its Staff, including Investigator, or in violation of this Agreement;

(c) was independently developed by Institution, without reliance upon or reference to Confidential Information as evidenced by its written records;

(d) was already known by Institution, as evidenced by its written records; or

(e) was disclosed to Institution or Investigator without restriction by a third party who had the apparent right to make such disclosure.

5.6 If Institution is requested to produce any of the Confidential Information pursuant to a legal or governmental proceeding, Institution shall give Sponsor adequate prior notice of such requirement, to the extent that Institution is provided wth sufficient notice to comply with this provision, and shall use its reasonable efforts to assist Sponsor in objecting to such request. If Institution is compelled to disclose any of the Confidential Information pursuant to such legal or governmental proceeding, Institution shall use its reasonable efforts to assist Sponsor in obtaining confidential treatment for such disclosed Confidential Information. Any Confidential Information so disclosed shall still be subject to the terms of this Agreement.

5.7 **Injunctive Relief.** Institution acknowledges and agrees that any violation of the terms of this Agreement relating to the disclosure or use of Confidential Information, including the Sponsor Technology, may result in irreparable injury and damage to Sponsor not adequately compensable in money damages, and for which Sponsor may have no adequate remedy at law. Institution acknowledges and agrees, therefore, that if those disclosure terms are violated, Sponsor may need to seek injunctions, orders, or decrees in order to protect the Confidential Information and the Sponsor Technology.

5.8 **Privacy Laws.** Institution agrees to take all reasonable steps to protect the confidentiality of any patient health and medical information ("PHI") that it has access to and comply with all applicable privacy laws, including, but not limited to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations. Sponsor shall collect, use, store, access, and disclose PHI collected from Study subjects only as permitted by the IRB approved informed consent form or HIPAA authorization form obtained from a Study subject.

5.9 **Existence of Agreement.** Institution may acknowledge the Sponsor's support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations. Notwithstanding anything to the contrary in this Agreement, Institution may publicly post information about the Study to appear on Institution's clinical trials directory/website. Additionally, notwithstanding anything herein to the contrary, Institution shall have the right to post Sponsor's name, the Study title, and the Study period, and funding amount, on Institution publicly accessible lists of research conducted by the Institution.

6. Publications

6.1 Institution or Investigator may publish the results of Study, relative to his/her own Study participant(s), subject to the terms of this Section 6. At least ninety (90) days prior to submitting a manuscript to a publisher or other outside persons (i.e., reviewer(s)) or prior to any public presentation, a copy of the manuscript or presentation will be provided to Sponsor by the Institution or Investigator for review and comment. Sponsor shall have forty-five (45) days to review and comment on the provided materials. If during the review period, Sponsor notifies Institution that it desires patent applications to be filed on any Inventions (as defined in Article 7 below) disclosed or contained in the manuscript or presentation, Institution will defer publication or other disclosure for a period, not to exceed an additional forty-five (45) days, sufficient to permit Sponsor or its designee to file or have filed any desired patent applications. Institution agrees, following a request from Sponsor, to delete any Confidential Information from any publication or presentation to the extent such deletion does not preclude the complete and accurate presentation and interpretation of the Study results. The Institution and Investigator each acknowledges that if the Study is part of a multi-center study, then any publication by the Institution or the Investigator of the results of the Study conducted at the Institution shall not be made before the first multi-center publication; provided, however, that if no multi-center publication is made within eighteen (18) months from completion of the Study for all sites in the Study, or if the Sponsor informs Institution or Investigator that no such multi-center publication will be forthcoming, then the Institution or Investigator may publish individually in accordance with the requirements of this Article.

6.2 Sponsor may use, refer to, and disseminate reprints of scientific, medical, and other published articles relating to the Study, which disclose the name of Investigator and Institution, consistent with U.S. copyright laws.

7. Intellectual Property

7.1 **Sponsor Technology.** For purposes of this Agreement, the term "Sponsor Technology" shall mean all data, materials, information, know-how, methods or techniques, whether or not patented or patentable, copyrighted or copyrightable, pertaining to the research, development, manufacture, or use of compounds obtained or developed by, or on behalf of, Sponsor arising outside of the research conducted under this Agreement. In the performance of this Agreement, Sponsor may disclose Sponsor Technology to Investigator. Sponsor Technology shall remain the confidential and proprietary property of Sponsor. Institution agrees that Sponsor is the sole and exclusive owner of the Sponsor Technology, whether or not patented or subject to copyright or patent protection; and that the Sponsor Technology may be commercially valuable.

7.2 **Patent Rights.** It is expressly agreed that neither Sponsor, on the one hand, or Investigator and/or Institution, on the other hand, transfers to the other, by operation of this Agreement, any patent right, copyright or other proprietary right which any such Party owns as of the Effective Date, except as specifically set forth herein.

7.3 **Inventions.** The ownership of any information, inventions, improvements, new uses, or discoveries (whether patentable, copyrightable, or not), innovations, suggestions, ideas, communications and reports (collectively "Inventions"), conceived, reduced to practice, made or developed by the Institution or Investigator and/or all individuals or entities either employed by, appointed by, or subcontracted by Institution, that incorporate or require the Study Drug or its use or that reflect any reduction to practice of any aspect of the Protocol, belong to the Sponsor, and Institution agrees to, and shall require Investigator and/or all individuals or entities either employed by, appointed by, or contracted by Institution to assign all of their interests therein without compensation from Sponsor or its nominee whenever requested to do so by Sponsor. Institution agrees to, and shall require Investigator and/or all individuals or entities either employed by, appointed by, or contracted by Institution to execute any and all applications, assignments, or other instruments and live testimony which Sponsor shall deem reasonably necessary to apply for and obtain Letter Patent of the United States or of any foreign country or to otherwise protect the Sponsor's interest therein, and Sponsor shall reimburse Institution for its employees, faculty, or subcontractors time devoted to said activities.

7.4 Further, Institution will disclose to Sponsor any and all Inventions conceived, reduced to practice, made or developed by the Investigator or Institution, as a result of conducting the Study. However, if the Institution obtains ownership of any invention arising from research conducted under the Study that is not an Invention, Sponsor shall be granted the first opportunity to acquire an exclusive license for use of the invention (an "Option") based on good faith negotiations between the Institution and Sponsor, for a period not to exceed ninety (90) days after Sponsor's exercise of such Option. Such Option must be exercised within ninety (90) days after Sponsor's receipt of an Invention disclosure from Institution.

8. Warranty

8.1 **Study Drug.** Sponsor makes no representations or warranties, expressed or implied, related to the Study Drug and/or Study Device, including without limitation, any warranty or merchantability for fitness for a particular purpose, or non-infringement.

8.2 **Appropriate Training and Licenses.** Institution certifies that Institution, Investigator and the Staff have, and will maintain throughout the conduct of the Study, all training, information, business, professional and other licenses, approvals, or certifications that are necessary for safely, adequately and lawfully performing the Study. Institution further certifies that Investigator and Staff are Institution's employees and/or faculty and are subject to Institution's direct control and supervision.

8.3 **No Conflicts.** Institution certifies that neither it, or the Investigator, has no material obligation to any third party that would prevent it from performing its duties and obligations under this Agreement. Institution will not enter into any material obligations to any third party that would prevent it from performing its duties and obligations under this Agreement. If Institution is affiliated with a third party, Institution represents that (i) Institution has complied with any and all applicable policies and procedures of such third party pertaining to proposed agreements for services, (ii) to the extent necessary or required, received approval from such third party to enter into this Agreement and be bound by the terms herein, (iii) receipt, generation and use of Confidential Information hereunder will not conflict with any agreement Institution or Investigator has with any third party to which Institution or Investigator is employed or affiliated, and (iv) no third party shall have any interest or rights in Confidential Information or any Inventions. Institution further certifies that it is not (y) currently involved in, nor is aware of, any pending litigation proceedings relating to, respectively, the Institution's or the Investigator's role in the conduct of a human clinical trial. Institution further certifies that it has a written and enforced policy and administrative process for identifying and managing financial conflicts of interest. As part of Institution's standard process, investigators are required to disclose, through a written disclosure form, significant financial interests that relate to their research and other Institution responsibilities. In accordance with Institution's policy, its Conflict of Interest Committee (or its designees) determine whether significant financial interests present a conflict of interest and by what means such conflicts should be managed or avoided.

8.4 **Criminal and Civil Liability.** INSTITUTION AND INVESTIGATOR UNDERSTAND AND ACKNOWLEDGE THAT FABRICATION, FALSIFICATION OR ALTERATION BY INSTITUTION, INVESTIGATOR OR ANY STAFF, OF ANY PATIENT DATA OR OTHER INFORMATION PROVIDED BY INSTITUTION OR INVESTIGATOR PURSUANT TO THIS AGREEMENT CAN RESULT IN CRIMINAL ACTIONS AND SANCTIONS AGAINST INSTITUTION AND INVESTIGATOR AND IN EACH SUCH PARTY HAVING CIVIL LIABILITY TO SPONSOR.

8.5 **Form 1572.** Institution certifies and represents that (i) the statements on the FDA Form 1572 are true and accurate in all respects, (ii) the Investigator is trained and qualified to conduct clinical trials within the jurisdiction in which the Investigator shall perform the Study, and (iii) Staff shall be appropriately trained in International Conference on Harmonisation-Good Clinical Practice ("ICH GCP") as adopted by the FDA, the Protocol and the Study procedures.

8.6 **Health Care Provider Payment Tracking.** Institution understands and agrees that for purposes of complying with reporting obligations under the Patient Protection and Affordable Care Act of 2010 (together with any regulations and official guidelines promulgated thereunder) and any applicable state reporting requirements, Sponsor may collect, aggregate and report any and all payments made pursuant to this Agreement.

8.7 **Business and Financial Disclosure.** Institution represent and certifies that neither it nor any of its Staff, including Investigator, are officials, agents, representatives or employees of any foreign government or political party or any international public organization where they may be in positions of official government authority able to use that position to help Sponsor obtain or maintain business or obtain a business advantage. Investigator and Institution further represent and certify that they have not and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing, for the purpose of influencing decisions or actions or where such payment would constitute violation of any law, including but not limited to applicable anti-bribery/anti-corruption laws.

8.8 **Debarment and Disqualification.** Institution represents and warrants that it, and its Staff, is not currently:

(i) an individual who has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application (a "Debarred Individual"), or an employer, employee, or partner of a Debarred Individual; or

(ii) a corporation, partnership, or association that has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) from submitting or assisting in the submission of any abbreviated drug application (a "Debarred Entity"), or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity.

(iii) an individual or corporation, partnership, or association that has been barred from participation in a "Federal Health Care Program" (as defined in 42 U.S.C. § 1320a(7b(f)), as amended from time to time or in any other governmental payment program.

Institution further represents and certifies that it, and it Staff, including Investigator, have not engaged in any conduct or activity which could lead to any of the above-mentioned disqualifications or debarment actions and that it has no notice that FDA or another regulatory authority intends to seek disqualification or debarment. Institution shall notify Sponsor within ten (10) days of any actual or threatened disqualification, debarment or other ban of the Institution, Investigator or Staff that comes to its attention during the course of the Study.

8.9 **Compliance with Laws**. Institution represents and certifies that it, and each of its Staff, including Investigator, will comply with all applicable laws, rules and regulations and guidelines relating to the conduct of clinical investigations, including, without limitation 21 CFR Parts 50, 54, 56 and 312, the IHC GCP and other good clinical and medical practice requirements, including ISO 14155:2020 for medical device studies, if applicable.

9. Study Results, Records and Audits

9.1 **Use of Study Results.** All data and information generated by Institution as a result of conducting the Study in accordance with the Protocol ("Study Results") shall be the property of Sponsor. Study Results does not include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in the Institution's ordinary course of business operations, which shall remain the sole and exclusive property of the Institution or medical provider. Sponsor shall own and have the right to use the Study Results in accordance with the signed informed consent and authorization form, applicable laws, and the terms of this Agreement. Notwithstanding any licenses or other rights granted to Sponsor herein, but in accordance with the confidentiality and publication sections herein, Institution shall retain the right to use the Study Results and results for its publication, IRB, regulatory, legal, clinical, educational, and internal research purposes.

9.2 **Records.** Institution shall maintain all records required to be maintained by all applicable laws and regulations, including, but not limited to, CRFs, safety reports, annual reports and any other documentation or materials related to the Study and Institution's Study file, which should include all Study-related correspondence. Investigator shall sign statements in each Study participant's CRF (i) attesting to Investigator's review of the data; and (ii) that the data constitutes an accurate accounting of the treatment, care, and events surrounding the Study participant's involvement in the Study. All Study records shall be complete and up to date. Institution will retain all records for the Study produced pursuant to this Agreement for the longer of: (a) five (5) years after the FDA approves a New Drug Application for the Study Drug and indication that is the subject of the Study, or (b) the record retention period mandated by all applicable laws or regulations. Institution will contact Sponsor in writing at least sixty (60) days before the planned destruction of any Study records. At Sponsor's request, Institution will deliver such records to Sponsor at Sponsor's cost. Institution shall promptly notify Sponsor of any accidental loss or destruction of Study records. Notwithstanding anything herein, Institution and Investigator shall not destroy any Study material, information, data or records without providing appropriate notice and opportunity for the Sponsor to respond.

9.3 **Study Documents.** Institution will prepare, maintain and retain complete, current, accurate, attributable, organized and legible source documents, CRFs, regulatory documents and other Study documents as required by the Protocol and ICH GCP.

9.4 **Inspection by Sponsor.** During the term of this Agreement , Institution will permit Sponsor and Sponsor's representatives to examine or audit the work performed hereunder, the use of Sponsor's funds, the facilities systems and equipment at or with which the work is conducted and records related to such work, at mutually agreeable times during regular business hours to determine that the project assignment is being conducted in accordance with the agreed requirements and that the facilities are adequate. If records pertaining to the Study are kept electronically, Institution shall provide Sponsor's representatives access to such systems for monitoring and auditing purposes. Institution shall make Investigator and other appropriate Staff available to Sponsor's representatives, as reasonably necessary, to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Sponsor or its designee, Institution and Investigator shall correct any errors or omissions in such records and reports.

9.5 **Inspection by Regulatory Authority.** Institution shall notify Sponsor immediately by telephone or facsimile if the FDA or other duly authorized authority requests permission to or does inspect Institution's facilities or research records during the term of this Agreement and will, to the extent allowed by law, provide in writing to Sponsor copies of all materials, correspondence, statements, forms, and records which Investigator or Institution receives, obtains or generates pursuant to any such inspection. Institution, to the extent allowed by law, shall allow Sponsor to be present and provide assistance with any such inspection.

10. Indemnification

10.1 Sponsor will defend, indemnify and hold harmless the Investigator, Institution and its Staff, trustees, officers, directors, employees, agents, successors, heirs and assigns (collectively, the "Institution Indemnitees") from and against all claims, demands, actions, suits and proceedings ("Claims") that may be brought or instituted against any Institution Indemnitee by a third party, and all judgments, damages, losses, liabilities, costs and expenses incurred by any of the Institution Indemnitees resulting therefrom, by reason of (i) personal injury (including death) to any person or damage to property which directly result from the performance of the Study in accordance with the Protocol, (ii) Sponsor's use of Study data and results, including PHI, and Inventions, except to the extent that such Claims arise out of or result from (i) the negligence, recklessness, criminal act or willful misconduct of any Institution Indemnitee, (ii) any failure by an Institution Indemnitee to use the Study Drug and/or Study Device and conduct the Study in accordance with this Agreement, the Protocol, other written information, instructions or warnings furnished by Sponsor, and all applicable laws, rules or regulations, or (iii) any other material breach of the Agreement by any Institution Indemnitee.

10.2 Subject to the applicable state-mandated limits, and without waiving any immunities provided under applicable law (including constitutional provisions, statutes and case law) regarding the status, powers and authority of the Institution or the Institution's principal(s), Institution shall indemnify, hold harmless and defend Sponsor and CRO, their directors, officers, employees, agents, successors, heirs, and assigns ("Sponsor's Indemnitees" and "CRO's Indemnitees") from and against any Claims alleged to be caused by or arising from INSTITUTION's negligence or willful misconduct, except to the extent that such Claims arise out of or result from Sponsor's or CRO's negligence or willful misconduct.

10.3 **Indemnification Process**. For this indemnification to apply, an indemnitee must immediately notify the indemnifying Party in writing upon receipt of notice of any Claim, but in no event later than ten (10) days after such receipt, and must permit indemnifying Party's attorneys and personnel, at indemnifying Party's discretion and cost, to handle and control the defense of such Claim, provided, however, that failure to provide such notice shall not relieve indemnifying Party of its indemnification obligations except to the extent that the indemnifying Party's ability to defend such Claim is materially, adversely affected by such failure. Indemnifying Party shall not make any settlement admitting fault or incur any liability on the part of the indemnified Party without indemnified Party's prior written consent, such consent not to be unreasonably withheld or delayed. The indemnified Party shall cooperate with indemnifying Party in all reasonable respects regarding the defense of any such Claim, at indemnifying Party's expense. The indemnified Party shall be entitled to retain counsel of its choice at its own expense. In the event a Claim falls under this indemnification clause, in no event shall the indemnified Party compromise, settle or otherwise admit any liability with respect to any Claim without the prior written consent of the indemnifying Party, and such consent not to be unreasonably withheld or delayed.

EXCEPT FOR (I) THE PARTIES' OBLIGATIONS TO INDEMNIFY EACH OTHER PURSUANT TO THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME.

10.4 **Subject Injury**. The Sponsor shall reimburse or otherwise pay for reasonable and necessary medical expenses incurred by Study participants for any medical care, including hospitalization, in the diagnosis and treatment of adverse reactions arising directly from the Study Drug following administration in connection with the Protocol or any procedure required by the Protocol that the Study participant would not have undergone but for their participation in the Study, to the extent such expenses (i) are not the result of the negligence or intentional misconduct of any Staff or Investigator or Institution, (ii) are not the result of Institution's deviation from the Protocol, or other written instructions consistent with the Protocol provided to Institution, and (iii) are not the result of the Study participant's negligence or failure to follow the Investigator or Staff's instructions. The Parties agree that natural progression of an underlying pre-existing condition does not constitute such an adverse reaction, unless such underlying pre-existing condition was exacerbated by the Study participants participation in the Study. In addition, adverse reactions resulting solely from Institution's negligence or intentional wrongful act are excluded from the Sponsor's obligation. Alleged lack of efficacy of the Study drug and/or Study Device and/or any consequences resulting therefrom shall not constitute an adverse reaction. Sponsor will not provide compensation or reimbursement for any other injury-related costs or expenses, such as lost wages, pain and suffering compensation, or any other consequential or indirect damages.

11. Insurance

11.1 Institution certifies and represents that it possesses and shall carry at its own expense from a reputable insurance company, comprehensive general liability insurance with limits of not less than $1,000,000 per occurrence and $3,000,000 annual aggregate for each Investigator performing services under this Agreement, and ensure that professional malpractice insurance (or similar errors and omissions insurance) with limits of not less than $1,000,000 per occurrence and $3,000,000 annual aggregate is maintained. Institution's insurance covers the Study, and specifically covers the actions of the Investigator, any sub-investigators and other Study personnel, and is not materially encumbered by existing claims. In addition, Institution shall secure and maintain in full force and effect workers' compensation insurance in the amount required by the laws of the state in which Institution is located. Institution shall maintain all such coverage for the duration of this Agreement and for five (5) years thereafter. Upon request, Institution shall furnish to Sponsor evidence indicating that such insurance is in force, which shall indicate any deductible and/or self-insured retention.

11.2 Sponsor has procured, and will maintain for the duration of the Study, a policy or program of insurance at levels commercially reasonable for this Study.

12. Miscellaneous

12.1 **Publicity.** No Party to this Agreement shall use the name, trade name, service names, trademarks or service marks of any other Party in connection with any press release, advertising or promotion of any product or service without the prior written permission of such Party except as required by law or regulation.

12.2 **Independent Contractors.** Each Party to this Agreement shall act as an independent contractor and shall not be construed for any purpose as the partner, agent, employee, servant, or representative of the other Parties. Accordingly, the employee(s) of one Party shall not be considered to be employee(s) of any other Parties, and no Party shall enter into any contract or agreement with a third party which purports to obligate or bind the Party to this Agreement. Sponsor shall not be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Institution or the Investigator or any of their employees or agents.

12.3 **Complete Agreement, Amendment.** The Parties agree that this Agreement, including the Appendices hereto, constitutes the sole, full, and complete Agreement by and between the Parties and supersedes all other written and oral agreements and representations between the Parties with respect to the subject matter herein. In the event of a conflict between the Protocol and this Agreement, the terms of the Agreement will govern; provided, however, that in the case of any such conflict relating to clinical matters, the terms of the Protocol shall prevail. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by authorized representatives of the Parties.

12.4 **Notices.** Any notices or communications concerning this Agreement should be in writing and shall be deemed to have been given when (i) mailed by bonded courier:

To Sponsor:
60 Degrees Pharmaceuticals, Inc
1025 Connecticut Ave NW, Suite 1000
Washington DC, 20036
Attn: [____]
Email: [____]
Phone: [____]

To CRO:
[____]
Chief Operating Officer
Fast-Track Drugs & Biologics, LLC
20010 Fisher Avenue, Suite G
Poolesville, MD, 20837
Phone: [____]
Fax: [____]
Email: [____]

To Institution:
Yale University
Attn: [____]
Office of Sponsored Projects
25 Science Park – 3rd Floor
150 Munson Street
New Haven, CT -6511
Attn: [____]
Email: [____]

With a copy to Investigator: [____]

12.5 **Binding Effect and Survival.** This Agreement shall be binding upon the Parties, their legal representatives, successors, and assigns. The obligations of the Parties contained in Articles 2, 3, 4, 5, 6, 7, 10, 11 and 12 shall survive the termination or expiration of this Agreement.

12.6 **Waiver.** Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect.

12.7 **Severability.** In the event one or more of the provisions of this Agreement should, for any reason, be held to be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining terms and provisions shall not be affected or impaired thereby and the Parties will attempt to agree upon a valid, legal and enforceable provision that is a reasonable substitute therefore, and upon so agreeing, shall incorporate such substitute provision in this Agreement.

12.8 **Assignment.** It is expressly understood by the Parties hereto that Institution may not assign, delegate, subcontract or transfer any of its rights or obligations under this Agreement to any Party without the express prior written consent of Sponsor.

12.9 **Force Majeure**. No Party shall be responsible to the others for any delay in the performance of, or failure to perform, this Agreement where such delay or failure is caused by circumstances beyond the reasonable control of the affected Party including, without limitation, strikes, lockouts or any other labor disruptions, war, civil commotion, natural disaster, pandemics or epidemics, or acts of God. In the event of any such delay or failure in performance, the affected party shall be granted an extension of time for performance that is equitable in light of the cause of the delay.

12.10 **Effective Upon Execution; Authority.** This Agreement shall not be considered accepted, approved, or otherwise effective until signed below by the appropriate Parties. Each of the Parties hereto represents and certifies that the person signing below on such Party's behalf has the authority to enter into this Agreement.

12.11 **Counterparts.** This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, shall bear the signatures of the Parties. This Agreement may be executed by wet ink or authenticated electronic signature and exchanged by facsimile or electronically via PDF copies, and in two or more counterparts, each of which will be deemed an original document, and all of which, together with this writing, will be deemed one instrument.

12.12 **Heading.** Headings used in this Agreement are for reference purposes only and shall not be used to be duly executed this Agreement as of the Effective Date above.

(Signature Page Follows)

IN TESTIMONY WHEREOF, Sponsor, Institution and Investigator have caused this Agreement to be executed as of the Effective Date.

For Sponsor:

60 DEGREES PHARMACEUTICALS INC

By: _____
Name:
Title:
Date:

For Institution

YALE UNIVERSITY

By: _____
Name:
Title:
Date:

INVESTIGATOR

By: _____
Name:
Date:

LIST OF APPENDICES

Appendix I: Payment Schedule
Appendix II: Budget

APPENDIX I – PAYMENT SCHEDULE

Payments: Payment should be made to the following:

Payee:
[____] Payee Bank Account Details: [____]

The Parties further agree that CRO and Sponsor assume no liability for incorrect payee details provided by Institution.

Invoices: Please send original, correct and itemized invoices monthly to the following:

60 Degrees Pharmaceuticals, Inc
Attention: [____]
Email: [____]

Electronic invoice submissions shall include: *Protocol number, site number, and last name of Investigator* in the subject line of the e-mail. Failure to adhere to these terms may delay the processing and payment of the electronically submitted invoice.

Invoices from Payee shall include:

- Payee name (as shown in this Appendix I)
- Protocol number
- Invoice date
- Date & itemized description of services provided
- Applicable supporting documents/third party invoices
- Total amount payable

Invoices shall be paid within forty-five (45) days of receipt by CRO.

Enrollment: Institution acknowledges that this is a Study designed to evaluate a set number of Study participants as identified in the Study Protocol. Institution will be expected to apply best efforts for enrollment as provided for under the Agreement. When enrollment of the target number of Study participants for the entire Study is complete, Institution will be notified and instructed not to continue enrolling Study participants, unless otherwise agreed to in writing.

The Study shall be payable as follows:

Cost per Subject: The amount to be paid to the Institution per completed Study participant is $ [____] and outlined on the Budget. Payments will be made on a monthly basis in US dollars and will be prorated based on completed visits entered in the Study participant electronic case report forms ("eCRFs") in the prior month.

Screen Failures: [____]. Sponsor written approval is required for any additional payment of Screen Failures. For purposes of this Agreement, a Screen Failure shall mean any Study participant, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes the screening visit but who does not randomize into the Study. Payment for Screen Failures will be payable based on data entered into the Study participant eCRF system, and upon the receipt and verification of such data by CRO.

Administrative Start-Up Fee: [____] will be payable to the Institution upon execution of this Agreement, receipt of IRB approval, completion of all regulatory documents and Site Initiation Visit ("**SIV**"), and upon the receipt, verification and processing of an undisputed invoice by CRO.

IRB Fees: Central IRB is defined as the IRB selected by the Sponsor, and to whom Sponsor is making submissions on behalf of sites using this Central IRB. Central IRB fees will be reimbursed directly to the IRB by Sponsor or its representative. In such cases, Institution's Human resources Protection Program ("HRPP") retains responsibility for administrative review of a Central IRB submission, and Sponsor therefore agrees, in accord with the terms above, to remit payment to Institution at prevailing rates for its administrative review by Institution's HRPP of the external IRB submission. If the Parties decide to submit the Study to Institution's local IRB, then local IRB Fees will be submitted by the Institution and reimbursable directly to the Institution upon the receipt of correct and itemized invoices by CRO.

Subject/Caregiver Stipends: Study participant and/or Caregiver stipends will be paid to Institution at the rate stated in the Budget based on completed visits. In the event that any Study participant stipend is paid by CRO to Institution but not actually paid to the Study participant by the Institution, Institution will promptly refund that amount to CRO.

Unscheduled Visits: An "Unscheduled Visit" means a Study participant visit which is not expressly set forth in the Protocol but is conducted for the well-being of the Study participant. Institution shall be reimbursed for actual unscheduled procedures performed in accordance with the Budget. Unscheduled Visits will be reimbursed and prorated at the rate set forth in Budget. In the event a medically necessary procedure is not included in the Budget, Institution must receive prior written approval for the compensation amount before such procedure is performed, except in cases of emergency or cases that are medically time sensitive. Payment will be made following the receipt, verification and processing of an itemized undisputed invoice by CRO.

Final Payment: The final payment will be payable upon completion of the close-out visit and the following: (i) return of all final Study documentation, samples, materials and equipment (ii) the accountability of all used and unused Study Drug, (iii) submission of all completed and correct eCRFs/queries to Sponsor and/or CRO, and (iv) submission to Sponsor and/or CRO of responses to any clarification requests made by CRO or Sponsor regarding Study data or records. All invoices for Study payments, as outlined in this payment schedule, must be submitted to Sponsor within ninety (90) days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.

No other additional funding requests will be considered without the prior written consent of Sponsor.

Exhibit 10.3

Specific information contained in this agreement has been excluded due to its non-material nature and because such information is considered private or confidential. Upon the request by Commission or its staff, the Company will quickly provide an unredacted copy of this agreement, along with analyses supporting its decisions on materiality and confidentiality.

CLINICAL TRIAL AGREEMENT

PROTOCOL NUMBER: TQ-BA-2024-1 (NCT06207370)
PROTOCOL TITLE: "Double-blind Placebo-controlled Study to Assess the Safety and Efficacy of Oral Tafenoquine plus Standard of Care versus Placebo plus Standard of Care in Patients Hospitalized for Babesiosis"

Rhode Island Hospital
593 Eddy Street

Providence, RI 02903
USA
(**"INSTITUTION"**)

and

60 Degrees Pharmaceuticals, Inc
1025 Connecticut Ave NW, Suite 1000
Washington DC, United States, 20036
("**SPONSOR"**)

Table of Contents

This Clinical Trial Agreement (this "Agreement") is effective as of the last date of signature (the "Effective Date") and sets forth certain agreements by and between **60 DEGREES PHARMACEUTICALS, INC** , having its principal place of business at 1025 Connecticut Ave NW, Washington DC, 20036 ("Sponsor"), and **Rhode Island Hospital** with a principal place of business at **593 Eddy Street, Providence RI 02903** (hereinafter referred to as "Institution"), The persons executing this Agreement hereby represent that they are authorized to do so for and on behalf of the above-named companies and organizations.

WHEREAS, Sponsor and Institution are hereinafter referred to individually as "Party" and collectively as "Parties;"

WHEREAS, [____], an agent of the institution, shall serve as the Principal Investigator of the Study ("Investigator");

WHEREAS, Sponsor is arranging to use Institution as a clinical trial site to clinically conduct the study pursuant to the Protocol (as defined in Article 1 below) (the "Study");

WHEREAS, the Investigator acknowledges having read and understood the Protocol and any documents appended to the Protocol, as well as this Agreement.

WHEREAS, Institution will enroll subjects, collect clinical trial data and execute specific clinical trial activities required by the Study.

WHEREAS, Sponsor has contracted with **Fast Track Drugs and Biologics LLC.**, a Maryland corporation with offices located at 20010 Fisher Avenue Suite G, Poolesville, MD, 20837 ("CRO") to coordinate and/or perform certain activities as its clinical research organization including, but not limited to, regulatory activities, monitoring, site initiation and close-out visits, data analysis and audits required for the conduct of the Study.

NOW, THEREFORE, the Parties, in consideration of the mutual covenants and promises contained herein, have entered into this Agreement and do specifically agree as follows:

1. Performance of Study

1.1 Study Protocol. The scope and nature of the clinical trial to be performed will be in strict accordance with the Study, including Protocol Number TQ-BA-2024-1 (NCT06207370) entitled, "Double-blind Placebo-controlled Study to Assess the Safety and Efficacy of Oral Tafenoquine plus Standard of Care versus Placebo plus Standard of Care in Patients Hospitalized for Babesiosis", and any subsequent amendments thereto, referenced and incorporated herein (the "Protocol"). The Protocol fully details the clinical research activities and responsibilities to be undertaken, pursued, and followed with all due diligence by Investigator. The Protocol will be considered final after it is signed by the Sponsor and approved by the pertinent Institutional Review Board ("IRB"). Thereafter, the Protocol may be amended only by the Sponsor and subsequent approval by the IRB. A copy of the signed Statement of Investigator (FDA Form 1572) or Investigator Agreement for medical device studies, the Protocol and any Protocol amendments will be maintained in the Investigator's Study files.

1.2 Conduct of Study. Institution agrees, and Investigator acknowledges that each shall conduct the Study in strict compliance with the Protocol, this Agreement and any amendments thereto, any and all applicable federal, state, and local laws, regulations, good clinical practices, all reasonable written instructions of the Sponsor or its designee (e.g. CRO) and any other relevant professional standards. Investigator shall also conduct the Study in accordance with the Statement of Investigator, FDA Form 1572 (or Investigator Agreement for medical device studies), which Investigator has completed, signed, and delivered to Sponsor prior to the commencement of the Study at the Investigator's site. Further, the Institution agrees, and Investigator acknowledges that in the performance of the Study, each shall:

(a) Exercise independent medical judgment as to the compatibility of each Study participant with Protocol requirements (applicable to Investigator only);

(b) Obtain a signed informed consent form (in a form approved by Sponsor) from each Study participant or his/her legally authorized representative and his/her caregiver in accordance with the Protocol, which has been approved by the IRB and Sponsor in accordance with 21 CFR §56, et. seq., or any successor thereto;

(c) Properly perform and direct or administer the Study in accordance with the Protocol, the applicable laws and regulations, the guideline published by the U.S. Food and Drug Administration ("FDA") entitled, "Good Clinical Practices, Consolidated Guideline" as amended from time to time, and the other requirements as set forth therein, including ISO 14155:2020 for medical device studies, if applicable;

(d) Review all Study participant case report forms (hereinafter "CRFs") to assure their accuracy and completeness, and assist Sponsor's representatives and clinical monitors upon request in promptly resolving any discrepancies or errors on CRFs and in performing random audits of original patient records, laboratory reports, or other raw data sources underlying data recorded on the CRFs;

(e) Submit all data and information, and undertake all activities, so that the timeline as defined in the schedule of assessments set forth in the Protocol and this Agreement are strictly met;

(f) Notify Sponsor and the IRB promptly of any failures to comply with the Protocol;

(g) Maintain records of Study participant identification, clinical observations, laboratory tests, and drug receipt, storage, return and disposition as specified in the Protocol;

(h) Provide all reasonable cooperation with Sponsor and its designee in all of their efforts to monitor the Study;

(i) Pursuant to 21 CFR §312.66, assure that the IRB will comply with the requirements of 21 CFR §56, et. Seq.;

(j) Perform the services in relation to the Study with reasonable care, diligence and skill and ensure that personnel engaged by it in the provision of such Study services are competent and have appropriate professional qualifications, training and experience (Only applicable to Institution); and

(k) Upon request from Sponsor, Investigator will update his/her financial disclosure form in a timely matter one (1) year after Study completion.

1.3 Participating Staff. The Study shall be conducted under the immediate direction of the Investigator. Institution and Investigator shall ensure that all Staff personally perform their assigned Study tasks, as indicated in the Protocol and in accordance with this Agreement. Investigator shall qualify such personnel and oversee their work. Investigator may have one or more sub-investigator(s) work on the Study; provided, however, that Investigator is responsible for all work conducted by sub-investigator. Any such sub-investigator shall be subject to all of the terms and conditions of this Agreement, including all obligations of Investigator. No sub-investigator may work on the Study unless he or she is qualified through experience and training to conduct clinical studies and agrees to be involved through completion of the Study. The sub-investigator's name shall appear in the appropriate space on the FDA Form 1572 or Investigator Agreement for medical device studies. Notwithstanding the foregoing, Sponsor may disapprove any proposed sub-investigator within five (5) days of submission of FDA Form 1572 or Investigator Agreement for medical device studies. For purposes of this Agreement, "Staff" shall mean all Institution personnel including, but not limited to, researchers, investigators, sub-investigators, study coordinators and any other person performing services related to the Study on behalf of Institution, or to whom Institution provides access to Study materials or study drug ("Study Drug").

1.4 Third Parties Staff. Institution shall ensure that any third-party personnel working, directly or indirectly, on the Study shall be competent, have appropriate professional qualifications, training and experience, and are bound by obligations of confidentiality and non-use with respect to Confidential Information (as defined by this Agreement) that are at least as restrictive as the obligations of confidentiality and non-use imposed by this Agreement. Investigator shall qualify such personnel and oversee their work.

1.5 Replacement of Investigator. In addition to any other remedy which may be available to Sponsor, in the event Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Institution shall promptly notify Sponsor of such circumstance. In addition, upon request by Sponsor, Institution will cooperate, in good faith and expeditiously, to find a replacement Investigator acceptable to Sponsor. Institution's and Investigator's cooperation in finding an acceptable replacement does not negate their obligations under this Agreement or by law or regulation.

1.6 Notification of Adverse Events. Investigator shall promtly notify Sponsor and the Institution's IRB in writing of any serious adverse drug experience within twenty-four (24) hours of learning of the event. For serious adverse drug experiences, Institution and Investigator shall assist in the investigation of the medical circumstances and shall provide Sponsor with all requested information so that Sponsor can submit any required IND Safety Report to FDA within fifteen (15) days of its initial receipt of the information. For fatal or life-threatening experiences, Institution and Investigator shall provide Sponsor with all requested information so that Sponsor can submit any required Telephone and Facsimile Transmittal Safety Report to FDA within seven (7) days of its initial receipt of the information. Investigator shall follow-up with any Study participant who experienced an adverse drug experience and continue to provide Sponsor with updates.

1.7 Protocol Deviation. Prospective Protocol waivers or deviations will not be granted by Sponsor under any circumstance. deviations from the Protocol which are medically necessary for a Study participant's safety in cases of emergency are not considered failure to comply with the Protocol. If, during the course of a Study participant's post-randomization participation in the Study, it is discovered that the Study participant did not meet all eligibility criteria, s/he will be discontinued, unless the discontinuation presents an unacceptable medical risk. The justification to allow the Study participant to continue in the Study will be made by the Sponsor and Investigator, with medical input from the Investigator, and will be documented. If the Study participant is allowed to remain in the Study, this will be reported as a major Protocol deviation and not a waiver. All follow-up safety assessments must be completed and documented as outlined in the Protocol. Other Protocol deviations will be tracked and corrective measures will be put in place to prevent such deviations from being repeated.

2. Study Drug, Storage and Return, and Equipment

2.1 Study Drug. Investigator shall use the Study Drug and/or Study Device only pursuant to and in accordance with the Protocol and this Agreement, and for no other purpose. Institution and Investigator shall notify Sponsor and Institution's IRB regarding any use of the Study Drug and/or Study Device without obtaining informed consent as soon as possible, but no later than five (5) business days after such use. Any use of the Study Drug and/or Study Device other than as specified in the Protocol shall constitute a material breach of this Agreement.

2.2 Storage. Institution and Investigator shall keep all Study Drug and/or Study Device in a locked, secured area at all times, within the temperatures required in the Protocol for storage of the Study Drug and maintain complete, up-to-date records showing receipt of shipments of the Study Drug, dispensing and accountability of the Study Drug and/or Study Device, and returns of the Study Drug as required by the Protocol, applicable federal, state, and local laws, regulations, and guidelines. Furthermore, Institution shall store all Study Drug and/or Study Device in either a central pharmacy where a qualified pharmacist supervises dispensing, or in a restricted area and dispensed under the direct supervision of Investigator.

2.3 Equipment. Sponsor may provide, or arrange for a vendor to provide, certain equipment, if applicable, for use by Investigator and Staff during the conduct of the Study ("Equipment"). During the term of this Agreement, Investigator and Staff may use the Equipment only for purposes of this Study in accordance with the Protocol. Until the termination of this Agreement, this Equipment remains the property of Sponsor or the respective vendor that has provided the Equipment, as applicable. The Equipment shall be returned upon request by Sponsor, to Sponsor or the vendor, promptly upon early termination of this Agreement or at the completion of the Study, at the expense of the Sponsor. Institution agrees to return the Equipment in the reasonable manner directed by Sponsor or the vendor in substantially the same condition as when received by Institution and/or Investigator, minus reasonable wear and tear. Institution agrees to be financially responsible to cover any loss or destruction to Equipment while in Institution's and Investigator's care, which exceeds ordinary wear and tear and/or lacks a reasonable causal relationship to proper performance of the Study. Institution further agrees that unless otherwise authorized in writing by Sponsor, Institution and Investigator will not alter the Equipment in any way nor install any components or software, if applicable. Any software provided to Institution and/or Investigator may not be duplicated. Sponsor shall not have any liability for damages of any sort, including personal injury or property damage, resulting from the use of Equipment except to the extent that such damages were caused by the gross negligence or willful misconduct of Sponsor.

2.4 Return of Study Drug and Sponsor Property. Upon completion of the Study or earlier termination of this Agreement, all unused Study Drug, devices, Equipment, and related materials and all copies of Confidential Information, including Sponsor Technology (as defined below), that were furnished to Investigator shall be returned to Sponsor, at the expense of the Sponsor, except for record copies which the Investigator is required to retain by law or regulation. Notwithstanding the foregoing, nothing shall require the deletion or destruction of Confidential Information stored in the ordinary course of business on Receiving Party's IT system, provided that the Confidential Information is stored in a manner that prevents unauthorized access or use of Confidential Information. Regarding all unused Study Drug, the Investigator shall, upon the written direction and approval of Sponsor, either (i) return all such material back to the Sponsor at Sponsor's expense; (ii) destroy, at the site where the Study is being conducted, such material in a manner that does not expose humans to risk from the compound or drug and according to applicable laws and regulations; or (iii) dispose of such materials in another method that that does not expose humans to risk from the compound or drug. In cases of (ii) or (iii), a certificate of destruction/disposition shall be sent to Sponsor upon such action.

3. Payments

3.1 In consideration for performance of the Study, Sponsor will pay the Party identified as "Payee" in accordance with the Payment Schedule attached as Appendix I ("Payment Schedule") and the Budget attached as Appendix II ("Budget"), and each made a part hereof. The Parties acknowledge that the Payee is the appropriate payee under this Agreement and that the Payee is authorized to receive all the payments for the services performed under this Agreement. If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator will be determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by Sponsor to the Payee. Investigator acknowledges that if Investigator is not the Payee, Sponsor will not pay Investigator even if the Payee fails to reimburse Investigator. The Budget may be modified only upon the prior written consent of the Parties. Institution agrees and Investigator acknowledges that the Payment Schedule and Budget includes Sponsor's entire payment obligation for the performance of the Study pursuant to this Agreement. CRO may process payments to the Payee on behalf of the Sponsor.

3.2 Institution agrees and Investigator acknowledges that their judgment with respect to the advice and care of each Study participant will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products. If the Sponsor provides any free products or items for use in the Study, Institution agrees that it will not bill any Study participant, insurer or governmental agency, or any other third party, for such free products or items. Institution agrees that it will not bill any Study participant, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from Sponsor, or which are not part of the ordinary care they would normally provide for the Study participant.

3.3 Institution acknowledges that it has advised Payee that Payee is accepting tax liability for the work performed under this Agreement. The Payee information needs to be completed below and on an IRS Form W-9 and returned to Sponsor for the Agreement to be effective. This information will be used for preparation of Federal Form 1099 which will be issued to Payee documenting the payments made to the Payee in each calendar year.

3.4 If any invoice or payment is disputed, Sponsor will notify Institution within (15) fifteen business days of receipt of invoice or payment due date. In the event parties are in dispute over whether payment for any item or service is due, all non-disputed amounts shall be paid in accordance with the regularly scheduled payment as detailed in the [budget/payment schedule] attached herein. The parties shall use good faith efforts to reach agreement on the disputed portion of the invoice or payment as soon as practical, but no later than (30) days of dispute notification.

Institution reserves the right to suspend the Study if there are undisputed amounts more than 90 days past due per the terms of the [budget/payment schedule], if Institution determines that Sponsor is unreasonably withholding payments and reimbursement of expenses in breach of this Agreement, or if Sponsor does not notify Institution of disputed amounts within (15) fifteen days of receipt of invoice or due date of payment. Institution shall ensure that such suspension does not affect the health or safety of currently enrolled subjects.

Notwithstanding the foregoing, in the event Sponsor notifies Institution of a fee dispute in accordance with this section 3.4 and Sponsor pays the undisputed portion of the payment or invoice, Institution will take no action to suspend the Study for non-payment of such disputed fees, unless the parties fail to reach resolution using good faith efforts.

If such good faith efforts do not solve the dispute either party may choose to pursue legal action in a court of law or equity to assert or enforce a claim it has against the other party in this agreement. The right to pursue legal action is in addition to any and all other rights and remedies available under this Agreement.

4. Term and Termination

4.1 Term. The term of this Agreement shall begin upon the Effective Date. Unless terminated earlier, this Agreement will terminate when (a) Institution has submitted all CRFs to Sponsor, has resolved all data clarification queries, has submitted the closeout report to the IRB and Sponsor, has returned all Equipment and Study materials to Sponsor, and has met all other close-out obligations; and (b) all payments, reimbursements and refunds have been made.

4.2 Termination by Sponsor. This Agreement may be terminated by Sponsor at any time for any reason upon 30 days written notice to Institution and Investigator. The Sponsor may terminate the Study without 30 days notice if any of the following conditions occur:

(a) If the authorization and approval to conduct the Study in the United States is withdrawn by the FDA; or

(b) If the emergence of any unexpected or unanticipated significant safety issue with the Study Drug and/or Study Device is of such magnitude or incidence in the reasonable opinion of the Investigator, Sponsor or the data safety monitoring board to support termination.

4.3 Termination by Institution. This Agreement may be terminated by the Institution at any time for any reason upon 30 days prior written notice to Sponsor. The Institution may terminate the Study without 30 days notice if any of the following conditions occur::

(c) If the authorization and approval to conduct the Study in the United States is withdrawn by the FDA; or

(d) If the emergence of any unexpected or unanticipated significant safety issue with the Study Drug and/or Study Device is of such magnitude or incidence in the reasonable opinion of the Investigator, Sponsor or the data safety monitoring board to support termination.

4.4 Effect of Termination. In the event of expiry or termination of this Agreement for any reason, Institution and Investigator shall, and shall procure, the prompt return to Sponsor of all Confidential Information, Equipment and Inventions (as defined herein) provided to Institution or Investigator or generated by Institution or Investigator in connection with the provision of the Study services. The Institution and Investigator may retain only the relevant Study information and data to the extent and for the duration required by applicable law or regulation. Investigator shall (i) use all reasonable efforts to conclude work on the Study, (ii) stop enrollment of Study participants, (iii) not incur additional expenses, or enter into any further commitments with regard to the Study after receiving or providing a notice of termination, and (iv) reasonably cooperate with the Sponsor and its designee to allow for a close-out site visit. In the event of termination, the sum payable under this Agreement shall be limited to prorated fees based on actual work performed pursuant to the Protocol as determined in accordance with the Budget. Such payment shall be paid upon satisfaction of all outstanding obligations of Investigator and Institution, including, but not limited to, return of all Equipment and Study materials to Sponsor, at the expense of the Sponsor. Institution will be entitled to payment for non-cancelable Study participant-related expenses only if properly substantiated, reasonably incurred in accordance with the Study through the date of termination and within the Budget. Any funds not due to Institution but already paid to Institution shall be returned to CRO and Sponsor by the earlier of thirty (30) days from the Institution close-out visit or from the notice of termination.

5. Confidentiality

5.1 All information, including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions, Study Drug and/or Study Device, materials and patient specimens, Sponsor Technology (as defined in Article 7 below) and Confidential Information (as defined below), provided to or made available to Institution or Investigator by Sponsor or its agents (whether verbal, written or electronic) or generated by Institution, Investigator or their respective Staff shall be the property of Sponsor.

5.2. “Confidential Information” means all information, material or data related to the Study, including Sponsor Technology, whether provided by or on behalf of Sponsor (either before or after execution of this Agreement), or developed for Sponsor, or generated by Institution and/or Investigator in accordance with this Agreement, whether in writing, electronic, oral or visual transmission, including without limitation, any information and data concerning the Study Drug and/or Study Device, Study results, reports, Study strategies, the existence or terms of the Protocol or this Agreement, exclusive of patient medical records.

5.3 Investigator and Institution shall maintain in strict confidence all of the Confidential Information, including the Sponsor Technology, and not disclose or disseminate to any third party or use for any purpose other than the performance of the Study any of the same. Such Confidential Information, including the Sponsor Technology, shall remain the confidential and proprietary property of Sponsor, and shall be disclosed only on a need-to-know basis and only to the Investigator and his/her Staff who have a need to know such Confidential Information for the purposes of performing the Study according to this Agreement and the Protocol who are bound by confidentiality terms at least as strict as those herein (individually, a “Required Disclosee”). Institution will inform and advise each Required Disclosee of the obligations under this Agreement with respect to the Confidential Information and each Required Disclosee shall be bound by such obligations in a like fashion.

5.4 Investigator and Institution each shall use the same degree of care to protect the Confidential Information as it uses to protect its own confidential information, but in no event less than a reasonable amount of care. Institution shall be responsible for any breach of this Agreement by its Investigator, agents and Staff to the extent permitted by applicable law. Institution agrees to promptly notify Sponsor in the event of any loss or unauthorized disclosure of any Confidential Information.

5.5 The foregoing obligation of non-disclosure shall not apply to Confidential Information, including the Sponsor Technology, that Institution or Investigator is able to demonstrate by written evidence:

(a) was generally known to the public prior to the Effective Date of this Agreement;

(b) becomes generally known to the public through no unlawful or unauthorized act or omission of Institution or Investigator or any of the Institution's agents or Staff, or in violation of this Agreement;

(c) was independently developed by Institution, without reliance upon or reference to Confidential Information as evidence by its written records; or

(d) was disclosed to Institution or Investigator without restriction by a third party who had the right to make such disclosure.

5.6 If Institution or Investigator is requested to produce any of the Confidential Information pursuant to a legal or governmental proceeding, Institution shall, as allowable by law, give Sponsor prior notice of such requirement. If Institution is compelled to disclose any of the Confidential Information pursuant to such legal or governmental proceeding, Institution shall furnish only that portion of the Confidential Information which it is legally required to disclose. Any Confidential Information so disclosed shall still be subject to the terms of this Agreement.

5.7 **Injunctive Relief.** Institution acknowledges and agrees that any violation of the terms of this Agreement relating to the disclosure or use of Confidential Information, including the Sponsor Technology, may result in irreparable injury and damage to Sponsor not adequately compensable in money damages, and for which Sponsor may have no adequate remedy at law. Institution acknowledges and agrees, therefore, that if those disclosure terms are violated, Sponsor may need to seek injunctions, orders, or decrees in order to protect the Confidential Information and the Sponsor Technology.

5.8 **Privacy Laws.** Institution agrees, on behalf of itself and its Investigator to take all reasonable steps to protect the confidentiality of any patient health and medical information that it has access to and comply with all applicable privacy laws, including, but not limited to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations. Institution consents to the sharing of their personal data, as defined under any applicable privacy laws, with Sponsor.

5.9 **Existence of Agreement.** Investigator and Institution shall not disclose the existence of this Agreement, except to the extent required by academic policies, law or regulation.

6. Publications

6.1 Institution and Investigator may publish the results of Study, relative to his/her own Study participant(s. At least thirty (30) days prior to submitting a manuscript to a publisher or other outside persons (i.e., reviewer(s)) or prior to any public presentation, a copy of the manuscript or presentation will be provided to Sponsor by the Institution or Investigator for review and comment. Sponsor shall have thirty (30) days to review and comment on the provided materials. If, within the 30-day period, Sponsor requests that any Confidential Information be removed or provides any comments, Institution shall remove all such Confidential Information and Institution will consider any such comments in good faith but is under no obligation to incorporate such comments. If during the review period, Sponsor notifies Institution that it desires patent applications to be filed on any Inventions (as defined in Article 7 below) disclosed or contained in the manuscript or presentation, Institution will defer publication or other disclosure for a period, not to exceed an additional sixty (60) days, sufficient to permit Sponsor or its designee to file or have filed any desired patent applications. . The Institution and Investigator each understands that if the Study is part of a multi-center study, then any publication by the Institution or the Investigator of the results of the Study conducted at the Institution shall not be made before the first multi-center publication; provided, however, that if no multi-center publication is made within eighteen (18) months from completion of the Study for all sites in the Study, then the Institution or Investigator may publish individually in accordance with the requirements of this Article.

6.2 Subject to the rights of any third- party publisher, Sponsor may use, refer to, and disseminate reprints of scientific, medical, and other published articles relating to the Study, which disclose the name of Investigator and Institution, consistent with U.S. copyright laws.

7. Intellectual Property

7.1 **Sponsor Technology.** For purposes of this Agreement, the term "Sponsor Technology" shall mean all data, materials, information, know-how, methods or techniques, whether or not patented or patentable, copyrighted or copyrightable, pertaining to the research, development, manufacture, or use of compounds obtained or developed by, or on behalf of, Sponsor. In the performance of this Agreement, Sponsor may disclose Sponsor Technology to Investigator. Sponsor Technology shall remain the confidential and proprietary property of Sponsor. Institution agrees and Investigator acknowledges that Sponsor is the sole and exclusive owner of the Sponsor Technology, whether or not patented or subject to copyright or patent protection; and that the Sponsor Technology is commercially valuable.

7.2 **Patent Rights.** It is expressly agreed that neither Sponsor, on the one hand, or Institution, on the other hand, transfers to the other, by operation of this Agreement, any patent right, copyright or other proprietary right which any such Party owns as of the Effective Date, except as specifically set forth herein.

7.3 **Inventions.** The ownership of any information, inventions, improvements, new uses, or discoveries (whether patentable, copyrightable, or not), innovations, suggestions, ideas, communications and reports (collectively "Inventions"), conceived, reduced to practice, made or developed by the Institution or Investigator and/or all individuals or entities either employed by or subcontracted by Institution, as a result of or relating to the conduct of the Study or Study Drug and/or Study Device, belong to the Sponsor and Institution agrees to assign all of its interests therein without compensation from Sponsor or its nominee whenever requested to do so by Sponsor. Institution agrees it will execute any and all applications, assignments, or other instruments and live testimony which Sponsor shall deem necessary to apply for and obtain Letter Patent of the United States or of any foreign country or to otherwise protect the Sponsor's interest therein, and Sponsor shall reimburse Institution for its time devoted to said activities.

7.4 Further, Institution will disclose to Sponsor any and all Inventions conceived, reduced to practice, made or developed by the Investigator or Institution, as a result of conducting the Study. However, if the Institution obtains ownership of any invention arising from research conducted under the Study, Sponsor shall be granted the first opportunity to acquire an exclusive license for use of the invention based on good faith negotiations between the Institution and Sponsor.

8. Warranty

8.1 **Study Drug and/or Study Device.** Sponsor makes no representations or warranties, expressed or implied, related to the Study Drug and/or Study Device, including without limitation, any warranty or merchantability for fitness for a particular purpose, or non-infringement.

8.2 **Appropriate Training and Licenses.** Institution warrants that Institution, Investigator and the Staff have, and will maintain throughout the conduct of the Study, all training, information, business, professional and other licenses, approvals, or certifications that are necessary for safely, adequately and lawfully performing the Study. . Institution considers Investigator to be its agent for purposes of research conducted pursuant to the Protocol, and, as such, Investigator is legally bound to follow Institution's policies and procedures and to act under Institution's direction with respect to the conduct of the research.

8.3 **No Conflicts.** Institution warrants that it is not a Party to any existing agreements that would prevent it from entering into and performing this Agreement. Institution will not enter into any other agreement that is in conflict with their obligations under this Agreement. If Institution is affiliated with a university or other third party, Institution represents that (i) Institution has complied with any and all applicable policies and procedures of such university or other third party pertaining to proposed agreements for services, (ii) to the extent necessary or required, received approval from such university or other third party to enter into this Agreement and be bound by the terms herein, (iii) receipt, generation and use of Confidential Information hereunder will not conflict with any agreement Institution or Investigator has with any university or third party to which Institution or Investigator is employed or affiliated, and (iv) no university or third party shall have any interest or rights in Confidential Information or any Inventions. Institution further warrants that it is not subject to (x) any conflicting obligations or legal impediment that might interfere with the performance of the Study or that might impair the acceptance of the resulting data by the FDA or (y) is currently involved in, nor is aware of, any pending litigation proceedings relating to, respectively, the Institution's or the Investigator's role in the conduct of a human clinical trial. Institution will notify Sponsor promptly of any conflicting obligations or legal impediments that may occur during the term of this Agreement.

8.4 **Criminal and Civil Liability.** INSTITUTION AND INVESTIGATOR UNDERSTAND AND ACKNOWLEDGE THAT FABRICATION, FALSIFICATION OR ALTERATION BY INSTITUTION, INVESTIGATOR OR ANY STAFF, OF ANY PATIENT DATA OR OTHER INFORMATION PROVIDED BY INSTITUTION OR INVESTIGATOR PURSUANT TO THIS AGREEMENT CAN RESULT IN CRIMINAL ACTIONS AND SANCTIONS AGAINST INSTITUTION AND INVESTIGATOR AND IN EACH SUCH PARTY HAVING CIVIL LIABILITY TO SPONSOR.

8.5 **Form 1572 or Investigator Agreement for Medical Device Studies.** Institution warrants and represents, on behalf of its Investigator, that (i) the statements on his/her FDA Form 1572 or Investigator Agreement for medical device studies are true and accurate in all respects, (ii) he/she is trained and qualified to conduct clinical trials within the jurisdiction in which the Investigator shall perform the Study, and (iii) Staff shall be appropriately trained in International Conference on Harmonisation-Good Clinical Practice ("ICH GCP"), the Protocol and the Study procedures.

8.6 **Health Care Provider Payment Tracking.** Institution understands and agrees that for purposes of complying with reporting obligations under the Patient Protection and Affordable Care Act of 2010 (together with any regulations and official guidelines promulgated thereunder) and any applicable state reporting requirements, Sponsor may collect, aggregate and report any and all payments made pursuant to this Agreement.

8.7 **Business and Financial Disclosure.** Institution represents and warrants that neither it nor any of its Investigator, agents or Staff are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in positions of official government authority able to use that position to help Sponsor obtain or maintain business or obtain a business advantage. Institution further represents and warrants that both it and its Investigator have not and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing, for the purpose of influencing decisions or actions or where such payment would constitute violation of any law, including but not limited to applicable anti-bribery/anti-corruption laws.

8.8 **Debarment and Disqualification.** Institution and Sponsor each represent and warrant that it, and each of its Staff, agents and representatives, have never been and are not currently:

(i) an individual who has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application (a "Debarred Individual"), or an employer, employee, or partner of a Debarred Individual; or

(ii) a corporation, partnership, or association that has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) from submitting or assisting in the submission of any abbreviated drug application (a "Debarred Entity"), or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity.

(iii) an individual or corporation, partnership, or association that has been barred from participation in a "Federal Health Care Program" (as defined in 42 U.S.C. § 1320a(7b(f)), as amended from time to time or in any other governmental payment program.

Institution further represents and warrants, to the best of its knowledge, that it/he/she, and each of its Investigator and Staff, have not engaged in any conduct or activity which could lead to any of the above-mentioned disqualifications or debarment actions and that it has no notice that FDA or another regulatory authority intends to seek disqualification or debarment. Institution shall notify Sponsor within ten (10) days of any actual or threatened disqualification, debarment or other ban or investigation of the Institution, Investigator or Staff that comes to its attention during the course of the Study and for five (5) years thereafter.

8.9 **Compliance with Laws**. Institution represents and warrants that it/he/she, and each of its Investigator and Staff, will comply with all applicable laws, rules and regulations and guidelines relating to the conduct of clinical investigations, including, without limitation 21 CFR Parts 50, 54, 56 and 312, the IHC GCP and other good clinical and medical practice requirements, including ISO 14155:2020 for medical device studies, if applicable.

9. Study Results, Records and Audits

9.1 **Use of Study Results.** Sponsor shall have the unrestricted access and right to use all information resulting from the Study for any and all lawful purposes. Institution and Investigator shall have no right to use any information, data or results relating to the Study, except for patient care or in a publication subject to Article 6.

9.2 **Records.** Institution shall maintain all records required to be maintained by all applicable laws and regulations, including, but not limited to, CRFs, safety reports, annual reports and any other documentation or materials related to the Study and Institution's Study file, which should include all Study-related correspondence. Investigator shall sign statements in each Study participant's CRF (i) attesting to Investigator's review of the data; and (ii) that the data constitutes an accurate accounting of the treatment, care, and events surrounding the Study participant's involvement in the Study. All Study records shall be complete and up to date. Institution will retain all records for the Study produced pursuant to this Agreement for the longer of: (a) five (5) years after the FDA approves a New Drug Application for the Study Drug and indication that is the subject of the Study, or (b) the record retention period mandated by all applicable laws or regulations. Institution will contact Sponsor in writing at least sixty (60) days before the planned destruction of any Study records. At Sponsor's request, Institution will deliver such records to Sponsor at Sponsor's cost. Institution shall promptly notify Sponsor of any accidental loss or destruction of Study records. Notwithstanding anything herein, Institution and Investigator shall not destroy any Study material, information, data or records without the prior written consent by Sponsor. Any extension of the length of record retention requested by the Sponsor beyond what is described above shall be at the expense of the Sponsor.

9.3 **Study Documents.** Institution will prepare, maintain and retain complete, current, accurate, attributable, organized and legible source documents, CRFs, regulatory documents and other Study documents as required by the Protocol and ICH GCP.

9.4 **Inspection by Sponsor.** During the term of this Agreement, Institution will permit Sponsor and Sponsor's representatives to examine or audit the work performed hereunder, the use of Sponsor's funds, the facilities systems and equipment at or with which the work is conducted and records related to such work, upon reasonable advance notice during regular business hours to determine that the project assignment is being conducted in accordance with the agreed requirements and that the facilities being used directly for the performance of the protocol are adequate. If records pertaining to the Study are kept electronically, Institution shall provide Sponsor's representatives access to such systems for monitoring and auditing purposes. Institution shall make Investigator and other appropriate Staff available to Sponsor's representatives to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Sponsor or its designee, Institution and Investigator shall correct any errors or omissions in such records and reports.

9.5 **Inspection by Regulatory Authority.** Unless prohibited by law or regulatory authority, Investigator and Institution shall notify Sponsor promptly by telephone or facsimile if the FDA or other duly authorized authority requests permission to or does inspect Institution's facilities or research records directly related to the Protocol during the term of this Agreement and will, to the extent allowed by law, provide in writing to Sponsor copies of all materials, correspondence, statements, forms, and records which Investigator or Institution receives, obtains or generates pursuant to any such inspection. Institution, to the extent allowed by law, shall allow Sponsor to be present and provide assistance with any such inspection.

10. Indemnification

10.1 Sponsor will defend, indemnify and hold harmless the Investigator, Institution and its Staff (collectively, the "Institution Indemnitees") from and against all claims, demands, actions, suits and proceedings ("Claims") that may be brought or instituted against any Institution Indemnitee by a third party, and all judgments, damages, losses, liabilities, costs and expenses incurred by any of the Institution Indemnitees resulting therefrom, by reason of personal injury (including death) to any person or damage to property which directly result from the performance of the Study in accordance with the Protocol, Sponsor's use of data provided to it under this Agreement, Sponsor's negligence, willful misconduct, and breach of the Agreement and applicable laws, and claims of patent infringement and unfair competition except to the extent that such Claims arise out of or result from (i) the negligence, recklessness, criminal act or willful misconduct of any Institution Indemnitee, (ii) any failure by an Institution Indemnitee to use the Study Drug and/or Study Device and conduct the Study in accordance with this Agreement, the Protocol, other written information, instructions or warnings furnished by Sponsor, and all applicable laws, rules or regulations, or (iii) any other breach of the Agreement by any Institution Indemnitee. A deviation from the protocol which is deemed medically necessary for the protection of subject safety shall not relieve the Sponsor of its obligations of indemnification.

10.2 Subject to the applicable state-mandated limits, and without waiving any immunities provided under applicable law (including constitutional provisions, statutes and case law) regarding the status, powers and authority of the Institution or the Institution's principal(s), Institution shall indemnify, hold harmless and defend Sponsor and CRO, their directors, officers, employees, agents, successors, heirs, and assigns ("Sponsor's Indemnitees" and "CRO's Indemnitees") from and against any Claims alleged to be caused by or arising from INSTITUTION's Indemnified Actions.

10.3 **Indemnification Process**. For this indemnification to apply, an indemnitee must promptly notify the indemnifying Party in writing upon receipt of notice of any Claim, but in no event later than ten (10) days after such receipt, and must permit indemnifying Party's attorneys and personnel, at indemnifying Party's discretion and cost, to handle and control the defense of such Claim, provided, however, that failure to provide such notice shall not relieve indemnifying Party of its indemnification obligations except to the extent that the indemnifying Party's ability to defend such Claim is materially, adversely affected by such failure. Indemnifying Party shall not make any settlement admitting fault or incur any liability on the part of the indemnified Party without indemnified Party's prior written consent, such consent not to be unreasonably withheld or delayed. The indemnified Party shall cooperate with indemnifying Party in all reasonable respects regarding the defense of any such Claim, at indemnifying Party's expense. The indemnified Party shall be entitled to retain counsel of its choice at its own expense. In the event a Claim falls under this indemnification clause, in no event shall the indemnified Party compromise, settle or otherwise admit any liability with respect to any Claim without the prior written consent of the indemnifying Party, and such consent not to be unreasonably withheld or delayed.

EXCEPT FOR (I) A PARTY'S INTENTIONAL MISCONDUCT, OR (II) THE PARTIES' OBLIGATIONS TO INDEMNIFY EACH OTHER PURSUANT TO THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME.

10.4 **Subject Injury**. The Sponsor shall reimburse for reasonable and necessary medical expenses incurred by Study participants for any medical care, including hospitalization, in the diagnosis and treatment of injuries arising directly from the Study Drug and/or Study Device following administration in connection with the Protocol, or the proper performance of procedures which are specifically required by protocol and not part of the usual standard of care to the extent such expenses (ii) are not the result of the negligence or intentional misconduct of any Staff or Investigator or Institution, (iii) are not the result of a deviation from the Protocol, or other written instructions consistent with the Protocol provided to Institution, except for deviations deemed medically necessary for the protection of subject safety and (iv) are not the result of the Study participant's negligence or failure to follow the Investigator or Staff's instructions. The Parties agree that natural progression of an underlying pre-existing condition does not constitute such an injury. In addition, injuries resulting solely from Institution's negligence or intentional wrongful act are excluded from the Sponsor's obligation. Alleged lack of efficacy of the Study drug and/or Study Device and/or any consequences resulting therefrom shall not constitute an injury. Sponsor will not provide compensation or reimbursement for any other injury-related costs or expenses, such as lost wages, pain and suffering compensation, or any other consequential or indirect damages.

11. Insurance

11.1 Institution warrants and represents that it possesses and shall carry at its own expense, comprehensive general liability insurance with limits of not less than $1,000,000 per occurrence and $3,000,000 annual aggregate for each Investigator performing services under this Agreement, and professional malpractice insurance (or similar errors and omissions insurance) with limits of not less than $8,000,000 per occurrence. Institution's insurance covers the Study, and specifically covers the actions of the Investigator, any sub-investigators and other Study personnel, and is not materially encumbered by existing claims. In addition, Institution shall secure and maintain in full force and effect workers' compensation insurance in the amount required by the laws of the state in which Institution is located. Institution shall maintain all such coverage for the duration of this Agreement and for five (5) years thereafter. Upon request, Institution shall furnish to Sponsor a certificate indicating that such insurance is in force, which shall indicate any deductible and/or self-insured retention. Institution shall provide Sponsor with at least thirty (30) days prior written notice of cancellation or any material change in the policy or policies of insurance required.

11.2 Sponsor has procured, and will maintain for the duration of the Study, a policy or program of insurance at levels commercially reasonable for this Study.

12. Miscellaneous

12.1 **Publicity.** No Party to this Agreement shall use the name, trade name, service names, trademarks or service marks of any other Party in connection with any press release, advertising or promotion of any product or service without the prior written permission of such Party except as required by law or regulation. Institution may, without prior consent, disclose in Institution's confidential internal reports or governmental reports and grant applications, its participation in the Study, not to exceed the information available at clinicaltrials.gov.

12.2 **Independent Contractors.** Each Party to this Agreement shall act as an independent contractor and shall not be construed for any purpose as the partner, agent, employee, servant, or representative of the other Parties. Accordingly, the employee(s) of one Party shall not be considered to be employee(s) of any other Parties, and no Party shall enter into any contract or agreement with a third party which purports to obligate or bind the Party to this Agreement. Sponsor shall not be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Institution or the Investigator or any of their employees or agents.

12.3 **Complete Agreement, Amendment.** The Parties agree that this Agreement, including the Appendices hereto, constitutes the sole, full, and complete Agreement by and between the Parties and supersedes all other written and oral agreements and representations between the Parties with respect to the subject matter herein. In the event of a conflict between the Protocol and this Agreement, the terms of the Agreement will govern; provided, however, that in the case of any such conflict relating to clinical matters, the terms of the Protocol shall prevail. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties.

12.4 **Notices.** Any notices or communications concerning this Agreement should be in writing and shall be deemed to have been given when (i) mailed by U.S. Mail postage prepaid or bonded courier or (ii) delivered via facsimile with confirmed transmission report and forwarded to the following:

To Sponsor:
60 Degrees Pharmaceuticals, Inc
1025 Connecticut Ave NW, Suite 1000
Washington DC, 20036
Attn: [____]
Email: [____]
Phone: [____]

To CRO:
[____]
Chief Operating Officer
Fast-Track Drugs & Biologics, LLC
20010 Fisher Avenue, Suite G
Poolesville, MD, 20837
Phone: [____]
Fax: [____]
Email: [____]

To Institution:
Rhode Island Hospital
Lifespan Office of Research
Coro East, Suite 1A, Room 170
167 Point Street, Box 42
Providence, Rhode Island 02903
Fax: [____]

To Investigator:
[____]
Brown Medicine
180 Corliss Street, 3rd Floor, Providence, RI 02904-2602
Fax: [____]

12.5 **Binding Effect and Survival.** This Agreement shall be binding upon the Parties, their legal representatives, successors, and assigns. The obligations of the Parties contained in Articles 2, 3, 5, 6, 7, 10, 11 and 12 shall survive the termination or expiration of this Agreement.

12.6 **Waiver.** Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect.

12.7 **Severability.** In the event one or more of the provisions of this Agreement should, for any reason, be held to be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining terms and provisions shall not be affected or impaired thereby and the Parties will attempt to agree upon a valid, legal and enforceable provision that is a reasonable substitute therefore, and upon so agreeing, shall incorporate such substitute provision in this Agreement.

12.8 **Assignment.** It is expressly understood by the Parties hereto that Institution may not assign, delegate, subcontract or transfer any of its rights or obligations under this Agreement to any Party without the express prior written consent of Sponsor.

12.9 **Force Majeure**. No Party shall be responsible to the others for any delay in the performance of, or failure to perform, this Agreement where such delay or failure is caused by circumstances beyond the reasonable control of the affected Party including, without limitation, strikes, lockouts or any other labor disruptions, war, civil commotion, natural disaster, pandemics or epidemics, or acts of God. In the event of any such delay or failure in performance, the affected party shall be granted an extension of time for performance that is equitable in light of the cause of the delay. Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) days, then the parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

12.10 **Effective Upon Execution; Authority.** This Agreement shall not be considered accepted, approved, or otherwise effective until signed below by the appropriate Parties. Each of the Parties hereto represents and warrants that the person signing below on such Party's behalf has the authority to enter into this Agreement.

12.11 **Counterparts.** This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, shall bear the signatures of the Parties. This Agreement may be executed by wet ink or authenticated electronic signature and exchanged by facsimile or electronically via PDF copies, and in two or more counterparts, each of which will be deemed an original document, and all of which, together with this writing, will be deemed one instrument.

12.12 **Heading.** Headings used in this Agreement are for reference purposes only and shall not be used to be duly executed this Agreement as of the Effective Date above.

12.13 **Patient Safety.** During and for a period of at least two (2) years after the completion of the study, Sponsor shall promptly (or in a timely manner appropriate to the level of risk involved,) report to the Institution and Investigator any information that could directly affect the health or safety of past or current study subjects or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee reports as required by the protocol. In each case, the Institution and Principal Investigator shall be free to communicate these findings to each study subject and the IRB.

(Signature Page Follows)

IN TESTIMONY WHEREOF, Sponsor, Institution and Investigator have caused this Agreement to be executed as of the Effective Date.

For Sponsor:

60 DEGREES PHARMACEUTICALS INC

By: _____
Name:
Title:
Date:

For Institution:

Rhode Island Hospital

By: _____
Name:
Title:
Date:

READ AND ACKNOWLEDGED:

By: _____
Name:
Date:

LIST OF APPENDICES

Appendix I: Payment Schedule
Appendix II: Budget

APPENDIX I – PAYMENT SCHEDULE

Payments: Sponsor agrees that all payment remittances for electronic payments will include PI Name, Protocol number, and Invoice number**.** Payment should be made to the following:

Payee:
[____] Tax ID Number: [____] Payee Bank Account Details: [____]:

Invoices: Please send original, correct and itemized invoices monthly to the following:

60 Degrees Pharmaceuticals, Inc
[____]

Electronic invoice submissions shall include: *Protocol number, site number, and last name of Investigator* in the subject line of the e-mail. Failure to adhere to these terms may delay the processing and payment of the electronically submitted invoice.

Invoices from Payee shall include:

- Payee name (as shown in this Appendix I)
- Protocol number
- Invoice date
- Date & itemized description of services provided
- Applicable supporting documents/third party invoices
- Total amount payable

Invoices shall be paid within forty-five (45) days of receipt by CRO.

Enrollment: Institution acknowledges that this is a Study designed to evaluate a set number of Study participants as identified in the Study Protocol. Institution will be expected to apply best efforts for enrollment as provided for under the Agreement. When enrollment of the target number of Study participants for the entire Study is complete, Institution will be notified and instructed not to continue enrolling Study participants, unless otherwise agreed to in writing.

The Study shall be payable as follows:

Cost per Subject: The amount to be paid to the Institution per completed Study participant is $[____] and outlined on the Budget, less ten percent (10%) withholding. Payments will be made on a monthly basis in US dollars and will be prorated based on completed visits entered in the Study participant electronic case report forms ("eCRFs") in the prior month. (Please see the Final Payment section below regarding payment of the 10% withheld.)

Screen Failures: Institution will be reimbursed a flat rate of $[____] for a maximum of [____] Screen Failures. Sponsor written approval is required for any additional payment of Screen Failures. For purposes of this Agreement, a Screen Failure shall mean any Study participant, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes the screening visit but who does not randomize into the Study. Payment for Screen Failures will be payable based on data entered into the Study participant eCRF system, and upon the receipt and verification of such data by CRO.

Administrative Start-Up Fee: [____] will be payable to the Institution upon execution of this Agreement, and upon the receipt, verification and processing of an undisputed invoice by CRO.

IRB Fees: Central IRB is defined as the IRB selected by the Sponsor, and to whom Sponsor is making submissions on behalf of sites using this Central IRB. Central IRB fees will be reimbursed directly to the IRB by Sponsor or its representative. Local IRB Fees will be submitted by the Institution and reimbursable directly to the Institution upon the receipt of correct and itemized invoices by CRO.

Subject/Caregiver Stipends: Study participant and/or Caregiver stipends will be paid to Institution at the rate stated in the Budget based on completed visits. In the event that any Study participant stipend is paid by CRO to Institution but not actually paid to the Study participant by the Institution, Institution will promptly refund that amount to CRO.

Unscheduled Visits: [____]. Institution shall be reimbursed for actual unscheduled procedures performed in accordance with . Unscheduled Visits will be reimbursed and prorated at the rate set forth in Budget. In the event a medically necessary procedure is not included in the Budget, Institution must receive prior written approval for the compensation amount before such procedure is performed, except in cases of emergency or cases that are medically time sensitive. Payment will be made following the receipt, verification and processing of an itemized undisputed invoice by CRO.

Final Payment: The final payment to include the ten percent (10%) withholding will be payable upon completion of the close-out visit and the following: (i) return of all final Study documentation, samples, materials and equipment (ii) the accountability of all used and unused Study Drug, (iii) submission of all completed and correct eCRFs/queries to Sponsor and/or CRO, and (iv) submission to Sponsor and/or CRO of responses to any clarification requests made by CRO or Sponsor regarding Study data or records. All invoices for Study payments, as outlined in this payment schedule, must be submitted to Sponsor within ninety (90) days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.

No other additional funding requests will be considered without the prior written consent of Sponsor.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement of 60 Degrees Pharmaceuticals, Inc. on Form S-3 of our reports dated April 1, 2024 relating to the financial statements of 60 Degrees Pharmaceuticals, Inc., as of December 31, 2023 and 2022 and for each of the years in the two-year period ended December 31, 2023 (which report includes an explanatory paragraph regarding the Company's ability to continue as a going concern).

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
September 19, 2024

Exhibit 107

Calculation of Filing Fee Table

Form S-3
(Form Type)

60 Degrees Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Fees to be paid	Equity	Common Stock, par value $0.0001 per share	457(c)	8,913,044(1)	$ 1.41(2)	$12,589,674.65	$ 0.00014760	$ 1,858.24
		Total Offering Amounts				$12,589,674.65		$ 1,858.24
		Total Fee Offsets				—		—
		Net Fee Due				$12,589,674.65		$ 1,858.24

(1) Consists of an aggregate of 8,913,044 shares of Common Stock registered for sale by certain of the selling stockholders named in this registration statement including (i) 2,898,551 shares of Common Stock issuable upon exercise of pre-funded warrants held by certain selling stockholders, (ii) 2,898,551 shares of Common Stock issuable upon exercise of Series A warrants, (iii) 2,898,551 shares of Common Stock issuable upon exercise of Series B warrants and (iv) 217,391 share of Common Stock issuable upon the exercise of placement agent warrants that were issued to designees of H.C. Wainwright & Co., LLC.

(2) Determined pursuant to Rule 457(c) under the Securities Act of 1933, as amended, solely for the purpose of calculating the registration fee. The price shown is the average of the high and low selling price of the Common Stock on September 17, 2024, which is a date within 5 business days prior to the date of filing of this Registration Statement, as reported on the Nasdaq Capital Market.

Table 2: Fee Offset Claims and Sources
N/A

Table 3: Combined Prospectuses
N/A