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

FORM 10-K

☒ ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2025

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ until _____

Commission File Number: 001-41719

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 No.)
1025 Connecticut Avenue NW Suite 1000 Washington, D.C.	**20036**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (202) 327-5422

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	SXTP	The Nasdaq Stock Market LLC
Warrants, each warrant to purchase one share of Common Stock	SXTPW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit post such files).

Yes ☒ No ☐

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 the definitions 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. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The aggregate market value of the Registrant's common stock, held by non-affiliates of the Registrant on June 30, 2025 (which is the last business day of Registrant's most recently completed second fiscal quarter) based upon checking the closing market price of such stock on The Nasdaq Capital Market on June 30, 2025 was approximately $3.34 million.

As of March 30, 2026 the Registrant had 2,636,788 shares of common stock, par value $0.0001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

TABLE OF CONTENTS

In this Annual Report on Form 10-K, unless otherwise stated or as the context otherwise requires, references to "60 Degrees Pharmaceuticals, Inc.," "60 Degrees Pharmaceuticals," "60P," the "Company," "we," "us," "our" and similar references refer to 60 Degrees Pharmaceuticals, Inc., a Delaware corporation. Our logo and other trademarks or service marks of the Company appearing in this Annual Report on Form 10-K are the property of 60 Degrees Pharmaceuticals, Inc. This Annual Report on Form 10-K also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this Annual Report on Form 10-K are the property of their respective holders.

Cautionary Note Regarding Forward-Looking Statements and Industry Data

This Annual Report on Form 10-K, in particular, Part II Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements represent our expectations, beliefs, intentions or strategies concerning future events, including, but not limited to, any statements regarding our assumptions about financial performance; the continuation of historical trends; the sufficiency of our cash balances for future liquidity and capital resource needs; the expected impact of changes in accounting policies on our results of operations, financial condition or cash flows; anticipated problems and our plans for future operations; and the economy in general or the future of the industry in which we operate, all of which were subject to various risks and uncertainties.

When used in this Annual Report on Form 10-K and other reports, statements and information we have filed with the Securities and Exchange Commission ("SEC"), in our press releases, presentations to securities analysts or investors, in oral statements made by or with the approval of an executive officer, the words or phrases "believes," "may," "will," "expects," "should," "continue," "anticipates," "intends," "will likely result," "estimates," "projects" or similar expressions and variations thereof are intended to identify such forward-looking statements. However, any statements contained in this Annual Report on Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and particular markets, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, general publications, government data and similar sources.

PART I

Item 1. Description of Business.

Overview

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 and/or botanical extracts from Australian Chestnut Trees.

Corporate History

60 Degrees Pharmaceuticals, Inc. is a Delaware corporation that was incorporated on June 1, 2022. On June 1, 2022, 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company ("60P LLC"), entered into the Agreement and Plan of Merger with 60 Degrees Pharmaceuticals, Inc., pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. The value of each outstanding 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 $1,200.00 per share.

We also operate one subsidiary. A summary of our majority-owned subsidiary is below.

We own 97% equity in 60P Australia Pty Ltd, a Sydney, Australia-based subsidiary ("60P Australia"). 60P Australia holds sub-licensing rights for several ex-U.S. territories for our product.

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

Recent Developments

Reverse Stock Splits

On October 8, 2025, a majority of the stockholders of the Company approved the proposed reverse stock split of our Common Stock at a split ratio ranging between 1:3 and 1:10, as to be determined by the Board in its sole discretion. On December 17, 2025, our Board approved a 1-for-4 reverse split ratio. On January 20, 2026, we effectuated a 1-for-4 reverse stock split of our common stock (the "1:4 Reverse Stock Split" and together, with the 1:5 Reverse Stock Split and the 1:12 Reverse Stock Split, each as defined below, the "Reverse Stock Splits"). Beginning January 20, 2026, our common stock traded on The Nasdaq Capital Market on a split adjusted basis.

On November 6, 2024, our Board approved a reverse stock split of our Common Stock at a split ratio ranging between 1:3 and 1:5, as determined by the Board in its sole discretion. On November 6, 2024, a majority of the stockholders of the Company approved the proposed reverse stock split. On February 10, 2025, the Board approved a 1-for-5 reverse split ratio. On February 24, 2025, we effectuated a 1-for-5 reverse stock split of our common stock (the "1:5 Reverse Stock Split"). Beginning February 24, 2025, our common stock traded on The Nasdaq Capital Market on a split adjusted basis.

Previously, at the 2024 Annual Meeting of Stockholders in July 2024, our stockholders approved an amendment to our Certificate of Incorporation to effect reverse stock split of our common stock at a range of ratios between 1:5 to 1:12, and on July 19, 2024, our Board approved the implementation of the reverse stock split at a ratio of 1:12 (the "1:12 Reverse Stock Split"). On August 12, 2024, we effectuated a 1-for-12 reverse stock split of our common stock. Beginning August 12, 2024, our common stock began trading on The Nasdaq Capital Market on a split adjusted basis.

The Reverse Stock Splits did not change the authorized number of shares of common stock or preferred stock. Proportional adjustments were made to the number of shares of common stock issuable upon exercise or conversion of our equity awards, warrants, and other equity instruments convertible into common stock, as well as the respective exercise prices, if applicable in accordance with the terms of the instruments. No fractional shares of common stock were issued in connection with the Reverse Stock Splits and all fractional shares were rounded up to the nearest whole share with respect to outstanding shares of common stock.

Unless otherwise noted, all references to numbers of shares of our common stock and per share information presented in this Annual Report on Form 10-K have been retroactively restated, as appropriate, to reflect the effect of the Reverse Stock Splits.

2025 Annual Meeting of Stockholders

On October 8, 2025, we conducted our virtual 2025 Annual Meeting of Stockholders (the "2025 Annual Meeting"). Our stockholders of record at the close of business on August 29, 2025, the record date for the determination of stockholders entitled to vote at the 2025 Annual Meeting, approved the proposals to (1) elect five directors to serve until the 2026 Annual Meeting of Stockholders and until their respective successors are duly elected and qualified; (2) approve an amendment to the 2022 Plan to increase the number of shares of common stock available for issuance by 62,500 shares; (3) approve an amendment to the Company's Certificate of Incorporation, to effect a reverse stock split of the common stock at a reverse stock split ratio ranging from 1:3 to 1:10 inclusive, as may be determined at the appropriate time by the Board of Directors, in its sole discretion; and (4) ratify the selection of RBSM LLP by the Board of Directors as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2025.

2025 ATM Agreement

On September 5, 2025, we entered into an At-The-Market Sales Agreement (the "2025 ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") pursuant to which we may, from time to time, offer and sell shares of our common stock, having aggregate gross sales proceeds of up to $1,397,532 (the "2025 ATM Offering"). As compensation for acting as the sales agent for the 2025 ATM Offering, Wainwright was entitled to a commission of 3.0% of the gross proceeds from sales of shares in the 2025 ATM Offering.

The common stock sold under the 2025 ATM Agreement was issued and sold pursuant to our shelf registration statement on Form S-3 and accompanying base prospectus (Registration Statement No. 333-280796), which was declared effective by the SEC on July 18, 2024, and our prospectus supplement dated September 5, 2025 relating to the offer and sale of the shares pursuant to the 2025 ATM Agreement.

Between October 16, 2025 and January 22, 2026, we sold an aggregate of 555,593 shares at a weighted average price per share of $2.51, generating net proceeds of $1,239,819, after deducting commissions and other offering expenses.

2026 ATM Offering

On March 2, 2026, we filed a prospectus supplement pursuant to Rule 424(b)(5) (the "2026 ATM Prospectus Supplement") in connection with our At-The-Market Offering Agreement, with H.C. Wainwright & Co., LLC, pursuant to which we may, from time to time, offer and sell additional shares of our common stock having aggregate sales proceeds of up to $1,308,000 (the "2026 ATM Prospectus Supplement"). The 2026 ATM Prospectus Supplement was subsequently amended on March 11, 2026, to increase the maximum aggregate offering price under the 2026 ATM Offering by $981,000 (the "2026 ATM Prospectus Supplement Amendment," and together with the 2026 ATM Prospectus Supplement the "2026 ATM Offering").

As compensation for acting as the sales agent for the 2026 ATM Offering, Wainwright is entitled to a commission of 3.0% of the gross proceeds from the sales of shares in the 2026 ATM Offering.

The common stock that may be sold pursuant to the 2026 ATM Prospectus Supplement will be issued and sold pursuant to our shelf registration statement on Form S-3 and accompanying base prospectus (Registration Statement No. 333-280796), which was declared effective by the SEC on July 18, 2024, and the 2026 ATM Prospectus Supplement relating to the offer and sale of the shares pursuant to the 2025 ATM Agreement.

Between March 2, 2026 and March 25, 2026, we sold an aggregate of 1,055,106 shares at a weighted average price per share of $2.49, generating net proceeds of $2,545,297, after deducting commissions and other offering expenses.

July 2025 Offering

On July 15, 2025, we entered into a securities purchase agreement with certain institutional investors pursuant to which we sold, in a registered direct offering (the "July 2025 Offering"), 438,332 units at an offering price of $7.60 per unit and 219,569 pre-funded units at an offering price of $7.596 per pre-funded unit. Each unit consisted of (i) one share of common stock, (ii) one series A-1 warrant exercisable for one share of common stock (the "July 2025 A-1 Warrants"), and (iii) one series A-2 warrant exercisable for one share of common stock (the "July 2025 A-2 Warrants" and together with the July 2025 A-1 Warrants, the "July 2025 Warrants"). Each pre-funded unit consists of one pre-funded warrant exercisable for one share of common stock (the "July 2025 Pre-Funded Warrants") and warrants identical to the July 2025 Warrants included in the units. The July 2025 Pre-Funded Warrants have an exercise price of $0.004 per share, and were immediately exercisable beginning on July 16, 2025 until exercised in full. The July 2025 A-1 Warrants have an exercise price of $7.60 per share and are exercisable beginning on July 16, 2025 until July 15, 2030. The July 2025 A-2 Warrants have an exercise price of $7.60 per share and are exercisable beginning on July 16, 2025 until January 15, 2027.

As compensation for acting as the placement agent for the July 2025 Offering, we also issued to H.C. Wainwright & Co., LLC warrants (the "July 2025 Placement Agent Warrants") to purchase up to 49,342 shares of common stock. The July 2025 Placement Agent Warrants have an exercise price equal to $9.50 per share and are exercisable upon issuance, or July 16, 2025, and expire five years from the date of issuance, or July 15, 2030. The July 2025 Offering was made pursuant to our registration statement on Form S-1 (File No. 333-288550), which was declared effective by the Securities and Exchange Commission (the "SEC") on July 15, 2025, and the final prospectus, which we filed with the SEC on July 16, 2025. The Offering closed on July 16, 2025, resulting in net proceeds of approximately $4,281,300, after deducting placement agent fees and other offering expenses paid by us.

February 2025 Offering

On February 5, 2025, we entered into a securities purchase agreement (the "February 2025 Securities Purchase Agreement") with certain institutional investors (the "February 2025 Purchasers") pursuant to which the Company sold an aggregate of 75,176 shares (the "February 2025 Shares") of common stock at a purchase price of $14.30 per share in a registered direct offering priced at-the-market under the rules of Nasdaq (the "February 2025 Offering").

The February 2025 Shares were offered pursuant to a "shelf" registration statement on Form S-3 (Registration No. 333-280796), which was declared effective by the Securities and Exchange Commission (the "SEC") on July 18, 2024 as supplemented by a prospectus supplement dated February 5, 2025, filed with the SEC on February 6, 2025 and accompanying base prospectus, pursuant to Rule 424(b)(5) promulgated under the Securities Act.

In a concurrent private placement, the Company also issued to the February 2025 Purchasers unregistered warrants (the "February 2025 Warrants") to purchase up to an aggregate of 75,176 shares of common stock at an exercise price of $11.80 per share. The February 2025 Warrants are exercisable upon issuance and expire twenty-four months from the date of issuance.

Pursuant to the February 2025 Securities Purchase Agreement, we were required to file a registration statement with the SEC within 45 days after the date of the February 2025 Securities Purchase Agreement to register the shares underlying the February 2025 Warrants under the Securities Act. We agreed to use commercially reasonable efforts to cause such registration statement to become effective within 75 days following the closing date of the February 2025 Offering, and to keep such registration statement effective at all times until no February 2025 Purchaser owns any February 2025 Warrants or shares underlying the February 2025 Warrants issuable upon exercise thereof. Subsequently on February 14, 2025, we filed a registration statement covering the resale of the shares issuable upon exercise of the February 2025 Warrants and the February 2025 Placement Agent Warrants (as defined below) on Form S-1 (File No. 333-284983), which was declared effective by the Securities and Exchange Commission on April 2, 2025.

Any holder will not have the right to exercise any portion of the February 2025 Warrants if the holder (together with its affiliates) would beneficially own more than 4.99% (or, upon the election of the holder, 9.99%) of the number of shares of the common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the February 2025 Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

The exercise price of the February 2025 Warrants is subject to customary adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock and also upon any distributions of assets, including cash, stock or other property to the stockholders of the Company.

The issuance of the February 2025 Warrants pursuant to the February 2025 Securities Purchase Agreement and issuance of the February 2025 Placement Agent Warrants (defined below) were made pursuant to the exemption from the registration requirements under the Securities Act, available to the Company under Section 4(a)(2) promulgated thereunder and Rule 506 of Regulation D promulgated under the Securities Act due to the fact the offering of the February 2025 Common Warrants and the February 2025 Placement Agent Warrants thereunder did not involve a public offering of securities.

The February 2025 Securities Purchase Agreement contained customary representations and warranties. The February 2025 Offering closed on February 6, 2025.

Pursuant to the Engagement Agreement, the Placement Agent acted as the Company's exclusive placement agent in connection with the offering.

Pursuant to the terms of the Engagement Agreement, the Company paid the Placement Agent a cash transaction fee equal to 7.5% of the aggregate gross cash proceeds in the offering and a management fee equal to 1.0% of the aggregate gross cash proceeds in the offering. In addition, the Company paid for certain non-accountable expenses in the amount of $15,000 and a clearing fee in the amount of $10,000. The Company also issued to the Placement Agent (or its designees) warrants to purchase up to 5,640 shares of Common Stock (the "February 2025 Placement Agent Warrants"). The February 2025 Placement Agent Warrants have an exercise price equal to $17.88 per share and are exercisable upon issuance and expire twenty-four months from the date of issuance.

The Company received net proceeds of $908,627 from the offering, after deducting estimated offering expenses paid by the Company, including the Placement Agent fees. The Company intends to use the net proceeds from the offering for general corporate purposes, including working capital.

January 2025 Offering

On January 28, 2025, we entered into a securities purchase agreement (the "January 2025 Securities Purchase Agreement") with certain institutional investors (the "January 2025 Purchasers") pursuant to which the Company sold, in a registered direct offering an aggregate of 51,079 shares (the "January 2025 Shares") of common stock at a purchase price of $20.42 per share in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market LLC ("Nasdaq").

The January 2025 Shares were offered pursuant to a "shelf" registration statement on Form S-3 (Registration No. 333-280796), which was declared effective by the Securities and Exchange Commission (the "SEC") on July 18, 2024 as supplemented by a prospectus supplement dated January 28, 2025, filed with the SEC on January 30, 2025, and accompanying base prospectus, pursuant to Rule 424(b)(5) promulgated under the Securities Act of 1933, as amended (the "Securities Act").

In a concurrent private placement, the Company also issued to the January 2025 Purchasers unregistered warrants (the "January 2025 Warrants") to purchase up to an aggregate of 102,158 shares of common stock at an exercise price of $15.42 per share. The January 2025 Warrants are exercisable upon issuance and expire twenty-four months from the date of issuance.

Pursuant to the January 2025 Securities Purchase Agreement, we were required to file a registration statement with the SEC within 45 days after the date of the January 2025 Securities Purchase Agreement to register the shares underlying the January 2025 Warrants under the Securities Act. We agreed to use commercially reasonable efforts to cause such registration statement to become effective within 75 days following the closing date of the January 2025 Offering, and to keep such registration statement effective at all times until no January 2025 Purchaser owns any January 2025 Warrants or shares underlying the January 2025 Warrants issuable upon exercise thereof. Subsequently on February 14, 2025, we filed a registration statement covering the resale of the shares issuable upon exercise of the January 2025 Warrants and the January 2025 Placement Agent Warrants (as defined below) on Form S-1 (File No. 333-284983), which was declared effective by the Securities and Exchange Commission on April 2, 2025.

Any holder will not have the right to exercise any portion of the January 2025 Warrants if the holder (together with its affiliates) would beneficially own more than 4.99% (or, upon the election of the holder, 9.99%) of the number of shares of the common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the January 2025 Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

The exercise price of the January 2025 Warrants is subject to customary adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock and also upon any distributions of assets, including cash, stock or other property to the stockholders of the Company.

The issuance of the January 2025 Warrants pursuant to the January 2025 Securities Purchase Agreement and issuance of the January 2025 Placement Agent Warrants (defined below) were made pursuant to the exemption from the registration requirements under the Securities Act of 1933, as amended, available to the Company under Section 4(a)(2) promulgated thereunder and Rule 506 of Regulation D promulgated under the Securities Act due to the fact the offering of the January 2025 Warrants and the January 2025 Placement Agent Warrants thereunder did not involve a public offering of securities.

The January 2025 Securities Purchase Agreement contained customary representations and warranties. The January 2025 Offering closed on January 30, 2025.

Pursuant to an engagement letter agreement between and H.C. Wainwright & Co., LLC dated August 30, 2024, as amended on September 3, 2024 and January 24, 2025, the Placement Agent acted as the Company's exclusive placement agent in connection with the offering.

Pursuant to the terms of the Engagement Agreement, the Company paid the Placement Agent a cash transaction fee equal to 7.5% of the aggregate gross cash proceeds in the offering and a management fee equal to 1.0% of the aggregate gross cash proceeds in the offering. In addition, the Company paid for certain non-accountable expenses in the amount of $15,000 and a clearing fee in the amount of $10,000. The Company also issued to the Placement Agent (or its designees) warrants to purchase up to 3,833 shares of common stock (the "January 2025 Placement Agent Warrants"). The January 2025 Placement Agent Warrants have an exercise price equal to $ 25.53 per share and are exercisable upon issuance, or January 30, 2025, for twenty-four months from the date of issuance, or January 30, 2027.

The Company received net proceeds of approximately $804,346 from the offering, after deducting estimated offering expenses paid by the Company, including the Placement Agent fees. The Company intends to use the net proceeds from the offering for general corporate purposes, including working capital.

Supply Chain Updates

In February 2025, the FDA authorized the importation of Kodatef from Australia, to cover any future disruption of Arakoda in the U.S. market. Kodatef is the branded version of tafenoquine for malaria prevention approved by the TGA for use in Australia. The Company made this request of the FDA due to robust demand for Arakoda in late 2024/early 2025, and the potential for delays in the completion of new lots of Arakoda currently being commercially

validated at the time by our key supplier, PCI. We have recently supplied new commercial lots, and do not anticipate further disruptions in the foreseeable future.

IRB Approval of Phase II Study to Evaluate Tafenoquine for Chronic Babesiosis

On January 8, 2025, we announced that the approval of an Investigational Review Board (IRB) sanctioned Phase II clinical study. The study (NCT06656351) will evaluate the efficacy and safety of the ARAKODA® regimen (tafenoquine) over 90 days for treating patients with a presumptive diagnosis of chronic babesiosis who have experienced severe fatigue with significant functional impairment for at least six months upon enrollment. The first patient was enrolled in Q4 2025.

First Patient in Tafenoquine Expanded Access Clinical Study for Persistent (B. microti) Babesiosis

On January 8, 2025, we announced that the first patient had been enrolled in NCT06478641, an expanded access clinical study intended to confirm the activity of tafenoquine in treating patients with persistent babesiosis who have failed standard of care treatment and are at high risk of experiencing a relapse.

Patent License Agreement

On December 23, 2024, we and Tufts Medical Center announced signing of a Patent License Agreement to jointly advance the development and commercialization of tafenoquine for the treatment and prevention of babesiosis. Tafenoquine is not currently approved by the U.S. Food and Drug Administration ("FDA") for the treatment and prevention of babesiosis. The agreement follows initiation of collaboration between researchers from both organizations to study the activity of tafenoquine against babesiosis, a serious tick-borne disease caused by microscopic parasites that infect red blood cells. The study formed the basis of U.S. Provisional Patent Application No. 63/461,060, and related U.S. utility and PCT applications, granting the parties shared intellectual property rights to tafenoquine's potential future use for babesiosis.

Expansion of Tafenoquine Clinical Trial for Babesiosis to Brigham and Women's Hospital

On December 11, 2024, we entered into a clinical trial agreement with Brigham and Women's Hospital (BWH) in Boston to conduct a double-blind, placebo-controlled study evaluating the safety and efficacy of tafenoquine in combination with standard of care treatment for hospitalized babesiosis patients. The trial (NCT06207370) evaluates tafenoquine combined with standard treatment for babesiosis, addressing a critical unmet medical need. The double-blind, placebo-controlled trial will examine outcomes for hospitalized patients with severe babesiosis, a tick-borne illness often found as a co-infection of Lyme disease.

ARAKODA® Promotional Pilot in Advance of Expanded U.S. Launch

On October 3, 2024, we announced that we have commenced a nine-month promotional pilot to bring greater awareness of ARAKODA® (tafenoquine) and its benefits to patients and healthcare providers who prescribe it. The pilot program includes inside, or virtual, sales representatives who will conduct outreach to prospective and current ARAKODA customers to promote the co-pay program and increase sales. The status of this program is outlined in the "Strategy" section.

Amendments to 2022 Equity Incentive Plan

On July 16, 2024, November 6, 2024, and October 8, 2025, our stockholders approved an amendment to the 60 Degrees Pharmaceuticals, Inc. 2022 Equity Incentive Plan (the "2022 Plan") to increase the number of shares of Common Stock authorized for issuance by 20,834 shares, 25,000 shares, and 62,500 shares, respectively, which were previously approved by the Board. The total number of shares that remain available for issuance under the 2022 Plan is 115,284 shares effective as of March 30, 2026, which additional reservation of shares provides us with flexibility to address future equity compensation needs. These increases are essential to attract and retain qualified employees, directors and consultants, and to align their interests with those of our stockholders.

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 144,928 Shares of our Common Stock, (ii) 144,928 shares of Common Stock issuable upon exercise of Series A Warrants, and (iii) 144,928 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 $0.02 per share. The Series A Warrants and Series B Warrants have an exercise price of $27.60 per share and were exercisable beginning on the effective date of stockholder approval of the issuance of the shares of Common Stock upon exercise of the Common Warrants and the Placement Agent Warrants (discussed below), which was received November 6, 2024 (the "Stockholder Approval"). 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 10,870 shares of our Common Stock. The Placement Agent Warrants have an exercise price equal to $34.50 per share and are exercisable beginning on the effective date of Stockholder Approval for five years from Stockholder Approval.

The Registered Securities were subsequently registered pursuant to a registration statement on Form S-3 (File No. 333-282221) that was originally filed with the Securities and Exchange Commission on September 19, 2024, and which was declared effective on September 30, 2024.

2024 ATM Offering

On July 12, 2024, we entered into an At-the-Market Issuance Sales Agreement (the "ATM Agreement") with WallachBeth Capital LLC ("WallachBeth") to sell shares of Common Stock having an aggregate offering price of up to $1,253,603 from time to time, through an "at the market offering" program (the "ATM Offering"). The offer and sale of shares of Common Stock from the ATM Offering were 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 July 18, 2024. We subsequently amended our prospectus supplement four times to increase the maximum aggregate offering price under the ATM Agreement. From July 19, 2024 to August 2, 2024, we sold a total of 33,897 shares in the ATM Offering for gross proceeds of $1,994,583. We entered into a Waiver and Termination Agreement with WallachBeth Capital LLC, agreeing to terminate the 2024 ATM Agreement effective September 3, 2025.

Mission

Our mission is to address the unmet medical need associated with vector-borne 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 have submitted a 75-day notification to FDA for Australian Chestnut Extract as a new dietary ingredient, and may seek to develop and license other molecules in the future.

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 financing in January 2024, 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 conducted a pilot commercialization study which suggested a lift in prescribing amongst physicians familiar with the product when exposed to promotional materials for Arakoda for malaria prevention. New initiatives are underway in 2026 to further overcome these barriers (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.[1] 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).[2]

Recent market data shows that Tafenoquine (primarily as Arakoda) 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 with Tafenoquine.[3] 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, we previously estimated the cumulative case load of Chronic Babesiosis may be as high as 1.01 million patients in the United States, but believe that, based on several new lines of evidence, the ceiling is 2-3 million. [4]

We have recently completed initial market research involving interviews with 300 prescribing physicians, a survey of 6,000 U.S. adults, and an administrative claims dataset. Collectively this research suggests that the minimum number of persistent cases of babesiosis subject to insurance claims each year is approximately 7,900.[5] However, prescribing intent and consumer survey data suggest that following a sustained diseases and product awareness campaign, assuming FDA labeling for babesiosis, and the commercial availability of sensitive molecular tests, the number of individuals diagnosed with persistent babesiosis with chronic fatigue treatable with Tafenoquine each year could be up to 380,000 individuals, representing approximately $245 million in sales (based on the Arakoda wholesale acquisition cost) and cumulatively 1.71 million patients treated with $1.1 billion in sales through patent expiry in 2035.[6,7] While this difference between the status quo is and future potential is large, it mirrors the shift in disease burden in Lyme disease which was once believed to be < 30,000, and is now thought to number > 475,000 based on administrative claims data.[8] Additional market research and diagnostic screening data will be needed to anchor the upper and lower bounds of this potential opportunity with more precision.

Treatment of Acute Babesiosis. There are up to 119,000 cases of potentially treatable acute symptomatic babesiosis (red blood cell infections caused by deer tick bites) in the United States each year.[9] Approximately 650 of these cases are hospitalizations, a smaller fraction of which represents immunosuppressed individuals.[10] 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.[11] 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." [12]

1 See https://www.cdc.gov/lyme/signs-symptoms/chronic-symptoms-and-lyme-disease.html.

2 Conclusions from Company-commissioned market research.

3 Conclusions from Company-commissioned market research.

4 Previously, we had estimated the maximum prevalence of chronic babesiosis to be 1.01 million 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). However, since it was recently determined that only 41% of hospitalized babesiosis patients have Lyme as a coinfection (Ssentongo et al Open Forum Infect Dis 2024 Oct 8;11(10)) total prevalence might be as high as 2.46 million (divide 1.01 million by 41%). Our recent survey of 6,000 U.S. consumers suggested that 3 million U.S. adults have experience babesiosis based on 1.26% of responders reporting have received such a medical diagnosis from a healthcare provider. Based on molecular epidemiology studies we have sponsored, we have made the operational assumption that up to 20% of individuals with chronic fatigue lasting more than six months may be infected with Babesia parasites, and our recent consumer survey and claims studies indicated that the prevalence of chronic fatigue in the U.S. is approximately 10 million (thus there maybe 2 million individuals with persistent babesiosis).

5 Company-commissioned market research indicates there are medical insurance claims data representing approximately 40% of U.S. lives indicated a total of 9,520 cases of chronic babesiosis of at least 30 days duration over three years. Annual incidence is 9,520/3/40% = 7,933.

6 Represents the maximum potential incidence of tafenoquine-treated persistent babesiosis cases ten years after commencing a full product and disease awareness program, based on combined data from a 6,000-patient and a 300-prescriber survey conducted by an independent market research agency assuming regulatory labeling for Arakoda has been expanded to include babesiosis.

7 Same as Note 6, but inclusive of the effect of sensitive molecular tests like the Grifols or Roche blood donation screening tests becoming commercially available for patient care.

8 For example, official Lyme cases were zero before the first case description in 1975, in 2010 the official Lyme case count was 30,158, but CDC now reports 476,000 cases per year based on insurance claims according to the Centers for Disease Control and Prevention.

9 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 Ssentongo et al (*Open Forum Infect Dis* 2024 Oct 8;11(10):ofae504.doi:10.1093), approximately 40% of acute babesiosis patients are coinfected with Lyme disease (thus 476,000*10%/40% = 119,000 cases of babesiosis per year).

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

11 According to IDSA guidelines.

12 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/.

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.[13] 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.

Veterinary Indications. 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. Separately, the Company is exploring the potential utility of Tafenoquine to manage equine Theileria (a tick-borne disease related to babesiosis). Horses entering the United States are required to be tested prior to quarantine release and treated if positive.

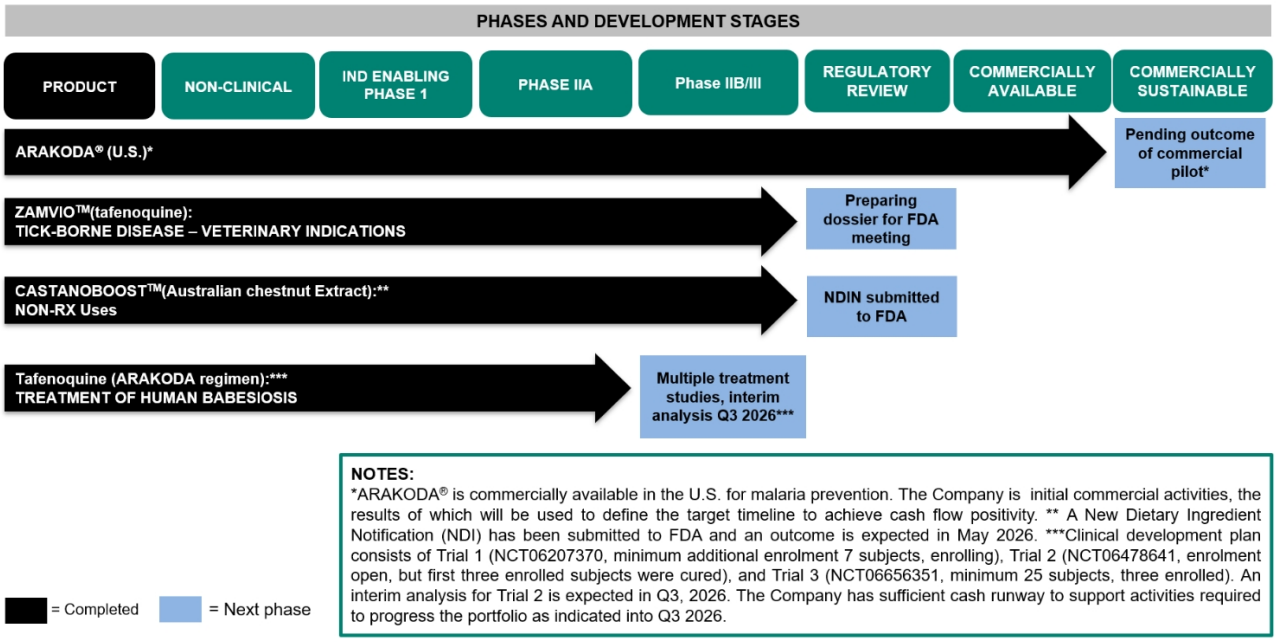
Viral Diseases

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.[14] 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.[15] As outlined in the "*Strategy*" section below, we plan to make any development decisions regarding Celgosivir after the potential commercialization opportunity for Australian Chestnut Extract comes into view.

13 Marx et. al., MMWR 2021;70:612-616.
14 According to the European Center for Disease Control.
15 According to the U.S. Centers for Disease Control.

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.[16] 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.[17]

16 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.
17 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.[18] 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.[19] 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.[20] 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.[21] Our work followed Legacy Studies that show Tafenoquine is effective for treatment and prevention of *Pneumocystis* pneumonia in animal models.[22] In 2025 we tested the hypothesis in animal models that Tafenoquine might act synergistically with fluconazole against *Candida auris*. Those data are currently being prepared for publication but suggest that Tafenoquine might only be applicable for adjunctive use, and thus a formal clinical development program is not warranted.

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).[23] In up to 100% of cases, Tafenoquine (at a higher weekly dose than the Arakoda regimen) administered in combination with antibabesial drugs with treatment sustained until consecutive negative PCRs were observed, following prior failure of conventional antibiotics in immunosuppressed babesiosis patients, resulted in cure.[24] In our expanded access trial (see "*Strategy*" section), we have observed that the Arakoda regimen of Tafenoquine administered concurrently with a combination of existing drugs including atovaquone cured all three relapsing immunosuppressed patients enrolled in the study. 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.

18 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.

19 According to literature cited in Footnote 18.

20 According to literature cited in Footnote 18.

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

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

23 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.

24 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.[25] 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.[26] 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).[27] 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.

Australian Chestnut Extract

Celgosivir is derived synthetically in a single chemical step from the naturally occurring alkaloid, castanospermine, isolated from extracts of the Australian Chestnut Tree (*Castanospermum australe*). When administered to humans or animals, celgosivir is almost completely metabolized to castanopsermine, which is the dominant metabolite. Abundant scientific literature has confirmed the antiviral, metabolic, and immunomodulatory properties of castanospermine. In March 2026, we submitted a 75-Day Notification to FDA that we intend to market a capsule formulation of Australian Chestnut Extract. We plan to commercialize this product under the trade name Castanoboost™.

Competitive Strengths

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

Strategy

Our general strategy 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.

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 of 2024 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. In 2025 we conducted quantitative research with Healthcare Providers and consumers to assess the market opportunity for the Chronic Babesiosis development program. We included a patient survey to measure self-reported prevalence of babesiosis and other relevant conditions across geographic regions and assessed claims data to support our findings. We have developed and cultivated key relationships with the tick-borne disease community including professional associations such as ILADS and Global Lyme Alliance and advocacy groups to help us understand the unmet needs in this currently under recognized, under diagnosed and misunderstood therapeutic area.

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

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). We introduced an 8-count bottle of ARAKODA NCD # 71475-257-02 into the supply chain in Q2 of 2025.

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, Targeting, and Commercial Update. 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. The ARAKODA commercial pilot program commenced in Q1 2025, with three main objectives: 1. Increase ARAKODA awareness and communicate ARAKODA's value proposition; 2. Drive ARAKODA trial and usage; and 3. Facilitate access and affordability. The pilot includes a three-pronged approach utilizing Virtual Sales Representatives (VSRs), a programmatic email campaign, and a co-pay offering for commercially insured patients. Based on the results of the pilot, we expanded our VSR team, optimized our omnichannel outreach, and partnered with GoodRx to expand our Point of Sale (POS) discount. We announced a partnership with Runway Health, an asynchronous travel medicine platform to engage travelers that are actively seeking malaria prophylaxis treatment. We plan to launch the ARAKODA landing page on the Runway platform in Q1 of 2026. Additionally, we conducted an ATU (Awareness, Trial, and Usage) with study with HCPs in Q1 2026 and were encouraged by the findings. Our overall awareness is relatively low, however the receptivity to the ARAKODA messaging in our new promotional materials greatly increased the level of interest and intended use of the product which substantiates our commercial expansion with the added VSRs and increased medical congress presence. We do not initially plan to target U.S. government agencies as these organizations are either contracting their ex-U.S footprints or, as in the case of 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: Our marketing strategy and objectives for our commercial outreach include 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 and a co-pay benefit to reduce the out-of-pocket expense for individuals with commercial insurance. We will launch new marketing assets including HCP promotions, a patient brochure and ARAKODA dosing cards based on feedback from our pilot. All marketing assets will be distributed by our VSRs and available at medical congresses and will also reside on ARAKODA.com.

Revised Forecast. We have developed an internal forecast for malaria indication and will do the same for the Babesiosis indication after completion of market research studies.

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.[28] In a case series of five immunosuppressed patients in whom prior standard of care treatments failed, weekly Tafenoquine at a higher weekly dose than the Arakoda regimen combined with standard of care treatments resulted in sustained clinical resolution (symptom clearance and at least two negative consecutive PCRs) in four (80%) of individuals.[29] In the fifth patient in that case series treatment was discontinued for unstated reasons prior to the observation of consecutive negative PCRs, meaning that the overall cure rate may actually approach 100% in treatment compliant individuals. 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 an approximately one-month treatment course of Tafenoquine (Arakoda regimen) 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 and the secondary endpoint is the time to molecular cure (using a commercial PCR assay). 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. We have signed clinical trial agreements with Tufts Medical Group, Yale, Rhode Island Hospital, and Brigham & Women's Hospital, and will attempt to initiate two additional sites prior to the 2026 tick season. The first patient was randomized on June

25, 2024, and 19 patients have completed the study. The earliest possible date that date would be available from the interim analysis would be around September 30, 2026, assuming a minimum of 24 patients are enrolled prior to July 31, 2026. Further details are available on the clinicaltrials.gov website.[30]

28 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.
29 Krause et al *Clin Infect Dis* 2024; doi:10.1093/cid/ciae238.
30 See entry for NCT06207370 on the clinicaltrials.gov website

Trial 2 is an expanded use study utilizing commercially available Arakoda. The Company is offering up to one year of Arakoda at no cost to up to 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 combined with standard of care regimens cured up to 100% of treatment-compliant immunocompromised patients with relapsing babesiosis. The main difference is that the study will evaluate the weekly Arakoda dose of Tafenoquine (200 mg) whereas Krause evaluated a 300 mg weekly dose, although simulations suggest both regimens maintain drug levels above protective thresholds. As of the date of this filing, three patients have completed the study and all were cured. More details about the study can be found on the clinicaltrials.gov website.[31]

Trial 3 is a Phase II open label study utilizing commercially available Arakoda. The Company is offering an approximately three-month supply of Arakoda at no cost to patients who have a clinical diagnosis of Chronic Babesiosis, 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 have symptoms of severe fatigue lasting more than six months and a diagnosis of chronic babesiosis. Secondary objectives include assessing confirmable *Babesia* infection rates in these populations using validated molecular assays, and assessing the safety and tolerability profile of Arakoda in this patient population. As of the date of this filing, three patients were enrolled. The study will be concluded upon the earlier of (i) 16 patients with a diagnosis of babesiosis confirmed using a FDA-licensed blood bank screening test complete the study or (ii) a maximum of 100 patients are enrolled and complete the study. More details about the study can be found on the clinicaltrials.gov website.[32]

In May 2024, we signed a research and collaboration agreement with North Carolina State University in which the College of Veterinary Medicine will screen archived blood samples from 50 patients exhibiting symptoms consistent with chronic fatigue by PCR for the presence of Babesia spp by digital PCR and DNA sequencing. This work was recently published. A key finding of the study was that *Babesia* infection was confirmed in 24% of patients.[33] These data were used to set the sample size for Trial 3.

We believe, if the Company does not become capital-limited, and no recruitment issues are encountered, that the results of one or more of the above studies will come to fruition in the third 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.

Tafenoquine for Veterinary Indications

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. That study is now complete. Collectively, the data suggest a two dose oral treatment for acute canine babesiosis may be possible. The product has been assigned the tradename Zamvio™. We believe there may be sufficient data to apply to the FDA for a Minor Use/Minor Species (MUMS) designation and conditional marketing approval for Zamvio™. We have been granted fee waivers on our INAD, and plan to submit a meeting request to FDA soon.

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. The Company has provided KTI with a right of reference to its Arakoda IND, in order to assist with regulatory approvals of forthcoming clinical trials.

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. As of the date of this report, we are pausing development of celgosivir until the potential commercial utility of Castanoboost™ for non-Rx applications becomes clearer.

Australian Chestnut Extract

Extensive scientific literature suggests that main molecular component of extracts of the seeds of the Australian Chestnut Tree, castanospermine, has broad antiviral, metabolic, and immunomodulatory effects by virtue of its inhibition of glucosidases (enzymes that break down glucose containing polymers). These properties suggest that Australian Chestnut Extract may provide support to patients suffering numerous conditions. The Company has submitted a 75-day notification to the FDA that it intends to market a capsule formulation of Australian Chestnut Extract.

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.[34] 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. In 2025, FDA agreed to our proposal to defer completion of this study to December 2030. We estimate the cost of conducting this study to be approximately $2 million.

31 See entry for NCT06478641 on the clinicaltrials.gov website
32 See entry for NCT06656351 on the clinicaltrials.gov website
33 Breitschwerdt et al. Pathogens 2025 Dec 19;15(1):2. doi: 10.3390/pathogens15010002.
34 Velez et al 2021 - Lancet Child Adolesc Health 2022; 6: 86–95.

Intellectual Property

We are co-owners, with the U.S. Army, of patents in the United States and certain foreign jurisdictions directed toward use of Tafenoquine for malaria and have obtained an exclusive worldwide license from the U.S. Army to practice these inventions. We also have an exclusive worldwide license to use manufacturing information and non-clinical and clinical data that the U.S. Army possesses relating to use of Tafenoquine for all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. We have submitted patent applications in the United States and certain foreign jurisdictions for use of Tafenoquine for COVID-19, fungal lung infections, tick-borne diseases, and other infectious and non-infectious diseases in which induction of host cytokines/inflammation is a component of the disease process. The United States Patent and Trademark Office ("USPTO") recently allowed our first COVID-19 patent for Tafenoquine. We have optioned or licensed patents involving Celgosivir for the treatment and prevention of Dengue (from the National University of Singapore), COVID-19 & Zika (Florida State University), and have 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			2013203400+	10-Apr-2033*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	2014228035	Australia			2014228035	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	MY-170991-A	Malaysia			PI2015002372	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	378015	Mexico			MX/a/2015/013115	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11201507254V	Singapore			11201507254V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	Pending	Singapore	Pending		10201908089V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	9763921	US		9/19/2017	14/772,873	14-Mar-2034**
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	10517854	US		12/31/2019	15/706,845	14-Mar-2034**
Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11219616	US		1/11/2022	16/725,387	14-Mar-2034**
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	2015358566	Australia			2015358566	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	2968694	Canada			2968694	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	10342791	US		7/9/2019	15/532,280	02-Dec-2035**
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	10888558	US		1/12/2021	16/504,533	02-Dec-2035**
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	10201904908Q	Singapore			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*

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Regimens Of Tafenoquine For Prevention Of Malaria In Mal2aria-Naive Subjects	11,744,828	US		9/5/2023	17/145,530	02-Dec-2035**
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	731813	New Zealand			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			2016368580	09-Dec-2036*
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	Pending	Singapore	Pending		10201912141Y	09-Dec-2036*
Dosing Regimens Of Celgosivir For The Prevention Of Dengue	11000516	US		5/11/2021	16/060,945	09-Dec-2036**
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	EP	Pending		21764438.4	02-Mar-2041*
Methods For Treating And Preventing Pulmonary Infections By Administering Tafenoquine	Pending	China	Pending		202180029643.7	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	2021231743	Australia			2021231743	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused	Pending	Hong Kong	Pending		62023078645.6	02-Mar-2041*

By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine						
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		4/25/2023	17/189,544	31-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	12383546	US		8/12/2025	17/683,679	02-Mar-2041**
Methods For The Treatment And Prevention Of Lung Infections Caused By Sars-Cov-2 Virus By Administration Of Tafenoquine	Pending	US	Pending		17/683,718	02-Mar-2041**
Methods For The Treatment And Prevention Of Lung Infections Caused By Fungus By Administration Of Tafenoquine	Pending	US	Pending		19/294531	02-Mar-2041**

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	11369592	US		6/28/2022	17/180,140#	19-Feb-2041**
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	US	Pending		17/664,693#	19-Feb-2041**
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	EP	Pending		2021757552#	19-Feb-2041*
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	Pending	Australia	Pending		2023304186	05-Jul-2043*
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	12,569,473	US		3/10/2026	18/218,202	05-Jul-2043**
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	Pending	*China*	Pending		202380053343.1	05-Jul-2043*
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	Pending	EP	Pending		23836044.4	05-Jul-2043*
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	Pending	*Canada*	Pending		3261048	05-Jul-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**
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	Pending	Canada	Pending		3289679	19-Apr-2044*
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	China	Pending		202480041674.8	19-Apr-2044*
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	EP	Pending		24793579.4	19-Apr-2044*
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	Japan	Pending		2025-561977	19-Apr-2044*
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	US	Pending		18/640,657	19-Apr-2044**
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	Canada	Pending		3289735	19-Apr-2044*

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	China	Pending		National Phase of PCT/24/025458	19-Apr-2044*
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	EP	Pending		24793592.7	19-Apr-2044*
Methods For The Treatment And	Pending	Japan	Pending		2025-561995	19-Apr-2044*

Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof						
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	US	Pending		18/640,695	19-Apr-2044**
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	Canada	Pending		3289731	19-Apr-2044*
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	*China*	Pending		202480041665.9	19-Apr-2044*
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	EP	Pending		24793598.4	19-Apr-2044*
Methods For The Treatment And Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	*Japan*	Pending		2025-561996	19-Apr-2044*
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,328,061+	US		6-25-2019	15/584,952+	02-May-2037
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,561,642+	US		2-18-2020	15/856,377+	02-May-2037

* = 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.

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

Trademarks

Country	Mark	Status	Application Number	Date Filed	Registration Date	Registration Number	BIR Ref Number	Due Date	Due Date Description
Australia	KODATEF	Registered	1774631	2-Jun-16	6/2/2016	1774631	0081716-000029	2-Jun-26	Renewal Due
Canada	KODATEF	Registered	1785098	1-Jun-16	11/26/2019	TMA1,064,371	0081716-000028	26-Nov-29	Renewal Due
Canada	ARAKODA	Registered	1899317	15-May-18	8/20/2020	TMA1,081,180	0081716-000053	20-Aug-30	Renewal Due
China	KODATEF	Registered	20842242	2-Aug-16	9/28/2017	20842242	0081716-000035	27-Sep-27	Renewal Due
European Union	KODATEF	Registered	15508872	3-Jun-16	9/21/2016	15508872	0081716-000034	3-Jun-26	Renewal Due
European Union	ARAKODA	Registered	17900852	16-May-18	9/20/2018	17900852	0081716-000054	16-May-28	Renewal Due
Israel	KODATEF	Registered	285476	6-Jun-16	6/6/2016	285476	0081716-000033	6-Jun-26	Renewal Due
New Zealand	KODATEF	Registered	1044407	7-Jun-16	12/8/2016	1044407	0081716-000031	6-May-26	Renewal Due
Russian Federation	KODATEF	Registered	2016720181	6-Jun-16	7/10/2017	623174	0081716-000032	6-Jun-26	Renewal Due
Singapore	KODATEF	Registered	40201707950V	2-May-17	11/8/2017	40201707950V	0081716-000040	2-May-27	Renewal Due
United Kingdom	ARAKODA	Registered	17900852	16-May-18	9/20/2018	UK00917900852	0081716-000054	16-May-28	Renewal Due
United Kingdom	KODATEF	Registered	15508872	3-Jun-16	9/21/2016	UK009015508872	0081716-000072	3-Jun-26	Renewal Due
United States of America	TQ 100 & TABLET DESIGN	Registered	87608493	14-Sep-17	9/11/2018	5562900	0081716-000037	11-Sep-24	Section 8 & 15 Due
United States of America	ARAKODA	Registered	87688137	16-Nov-17	12/31/2019	5950691	0081716-000050	31-Dec-25	Section 8 & 15 Due
United States of America	KODATEF	Abandoned-	90072885	24-Jul-20			0081716-000069	16-Aug-23	Statement of Use/3rd Extension of Time Due
United States of America	KODATEF	Allowed	98/363,219	18-Jan-24			0081716-000074	12-May-25	Statement of Use/1st Extension of Time Due

Key Relationships & Licenses

On May 30, 2014, we entered into the Exclusive License Agreement (the "2014 NUS-SHS Agreement") with National University of Singapore ("NUS") and Singapore Health Services Pte Ltd ("SHS") in which we were granted a license from NUS and SHS with respect to their share of patent rights regarding "Dosing Regimen for Use of Celgosivir as an Antiviral Therapeutic for Dengue Virus Infection" to develop, market and sell licensed products. The 2014 NUS-SHS Agreement continues in force until the expiration of the last to expire of any patents under the patent rights unless terminated earlier in accordance with the 2014 NUS-SHS Agreement. We are obligated to pay 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"), pursuant to which we obtained a license to develop and commercialize the licensed technology with respect to all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. This exclusion does not impact our ability to market Arakoda for the FDA-approved use, which is the prevention of malaria utilizing the indicated dose in asymptomatic individuals traveling to malarious areas (whereas the license exclusion relates to its use to treat symptomatic vivax malaria in a patient already presenting with that disease). The term of the U.S. Army Agreement will continue until the expiration of the last to expire of the patent application or valid claim of the licensed technology, or 20 years from the start date of the U.S. Army Agreement, unless terminated earlier by the parties. We must make a minimum annual royalty payment of 3% of Net Sales (as defined in the U.S. Army Agreement) for Net Sales less than $35 million, and 5% of Net Sales greater than $35 million, with US government sales excluded from the definition of Net Sales. The U.S. Army Agreement requires us to make a change of control payment of $100,000 if we are acquired or merge with another company, and regulatory approval milestone payments once marketing authorizations are achieved in Canada ($5,000) and Europe ($5,000). In addition, we were required to pay a sales-based milestone fee of $75,000 once cumulative net sales from all sources exceeded $6 million, which sales-based milestone target was achieved in 2023 and settled in full in June 2024.

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

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

On February 15, 2021, we entered into the Inter-Institutional Agreement with FSURF (the "FSURF Agreement") in which FSURF 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 effective on March 24, 2025, that collectively granted an option, effective through March 23, 2026, 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 effective on March 24, 2025, that collectively granted an option, effective through March 23, 2026, to us to license a patent relating to the use of alpha glucosidase inhibitors (including castanospermine and Celgosivir) for treatment of Zika infections.

On January 9, 2023, and subsequently amended, we entered into a Debt Conversion Agreement with Knight Therapeutics, Inc. ("Knight"). Among other things, this agreement requires us to pay Knight a quarterly royalty equal to 3.5% of Net Sales, where Net Sales has the same meaning as in the U.S. Army Agreement described above. Royalties due to Knight commenced upon the closing of our IPO in July 2023 and will end on the earlier of (i) July 12, 2033 or (ii) the conversion or redemption in full of all of the shares of Series A Preferred Stock held by Knight.

On December 20, 2024, we entered into a Patent License Agreement with Tufts Medical Center ("Tufts MC"), pursuant to which Tufts MC granted us a license to research and commercialize certain patent applications covering jointly developed inventions related to the use of tafenoquine for treatment and/or prevention of babesiosis. The term of the agreement will continue until the expiration or final abandonment of the last patent application or issued patent for the use of tafenoquine for treatment and/or prevention of babesiosis, unless terminated earlier by the parties. On the earlier of (x) the date of patent issuance or (y) the date of regulatory approval for the use of tafenoquine product in treatment of babesiosis, we must make royalty payments equal to 4% of net sales of tafenoquine products sold in a format labeled for use in the treatment of babesiosis or 2% of net sales of tafenoquine products that are sold in a format not labeled for use in the treatment of babesiosis. In addition, for all sublicense revenue received by us from sales of sublicensed products, we must make payments equal to 20% of the revenue we receive for sales of tafenoquine products sold in a format labeled for use in the treatment of babesiosis or 10% of the revenue we receive for sales of tafenoquine that are sold in a format not labeled for use in the treatment of babesiosis.

On April 3, 2025, we entered into an Agreement with Yale University ("Yale") pursuant to which Yale has granted us an exclusive, worldwide license to make, have made, use, sell, have sold, import, or practice certain patents and patent applications covering jointly developed inventions related to the treatment of babesiosis using Tafenoquine within the field of using Tafenoquine to treat babesiosis. Yale retains the right to use the inventions for research, clinical, teaching, or other non-commercial purposes. In exchange for the license granted to Yale to us, we agreed to pay Yale a royalty of 2% on net sales of licensed products covering the licensed patents if the licensed produce it branded for treatment of babesiosis and a royalty of 1% on net sales if licensed products covering the licensed product is not specifically branded for treatment of babesiosis.

On April 4, 2025, we entered into an Option Agreement with FSURF, pursuant to which FSURF granted us a 12-month option to exclusively license certain patent and technology rights held by FSURF relating to large scale purification of castanospermine, including U.S. Patent No 11,518,762, while we assess the potential feasibility of commercializing Australian Chestnut Tree extracts. We exercised the option in February 2026, and are now negotiating a full license.

Manufacturing

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

Australian Research Tax Credit and Overseas Finding Process

Under Section 27 of the Industry Research and Development Act 1986[38], the Australian government offers a research tax credit of 43.5% on registered research and development activities executed in Australia by eligible Australian domiciled entities. Companies are eligible to receive tax credits if they meet the following criteria: (i) are domiciled in Australia, (ii) have incurred at least $20,000 in eligible research and development expenses, (iii) have conducted at least one eligible research and development activity, (iv) beneficial owner(s) with > 40 % beneficial ownership when considered together do

not have > $20 million AUD aggregated turnover on an annual basis. 60P Australia Pty Ltd. meets all these criteria, and will continue to do so in the future unless, considered together with any of our shareholders who have > 40% beneficial ownership, have > $20 million AUD in aggregate annual turnover.

Under Section 28D of the Industry Research and Development Act 1986[39], research and development activities conducted outside Australia are also potentially eligible if they meet the following criteria: (i) they are approved in advance, (ii) they are linked to a core research and development activity conducted in Australia, (iii) cannot be conducted in Australia for various reasons and (iv) the value of activities conducted overseas is less than the value of activities conducted in Australia.

38 See Industry Research and Development Act 1986 (legislation.gov.au).
39 See Australian Government R&D Tax Incentive - Overseas R&D: Information Sheet.

Government Regulation and Product Approvals

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

Review and Approval of Drugs in the United States

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

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

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

Preclinical Studies

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

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

The IND and IRB Processes

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

At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

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

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

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

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

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

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

Human Clinical Studies in Support of an NDA

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

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

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

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

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

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

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

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

Submission of an NDA to the FDA

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

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

of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

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

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

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

Fast-Track, Breakthrough Therapy and Priority Review Designations

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

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

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

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

Tropical Disease PRVs

The Tropical Disease Priority Review Voucher ("PRV") program was created by Congress under the Food and Drug Administration Amendments Act of 2007 ("FDAAA") in order to encourage innovation and public access to new medicines. Pursuant to Section 1102 of FDAAA, which amended section 524 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), along with later amendments, the FDA must award a PRV to certain applicants that obtain an approved NDA to treat certain tropical diseases. Congress later expanded the scope of diseases that were eligible for a PRV (e.g., a PRV for obtaining approval for a drug to treat rare pediatric diseases). A PRV entitles the holder of the voucher to designate a different drug application as qualifying for priority review from FDA. When a drug application is designated for priority review through use of a priority review voucher, that application must be reviewed by FDA no later than 6 months after receipt.[40] This guarantees a much more rapid review by FDA compared to the standard review time.

Tropical disease PRVs were created under the FDAAA to encourage pharmaceutical companies to develop treatments for specific neglected tropical diseases. As defined by the statute, tropical diseases refer to certain "infectious disease[s] for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations."[41] Because tropical diseases occur rarely in the United States, obtaining approval from the FDA for treating these diseases would normally be unprofitable for pharmaceutical companies due to the limited domestic market and the scope and significant financial costs of the post-marketing requirements imposed by FDA. Congress intended to incentivize companies to turn their attentions to tropical diseases by providing a PRV to those companies that obtained approval from FDA for a tropical disease drug product, and the granted PRV could then be sold to another company for money.

A PRV is an extremely valuable property interest. For example, Rhythm Pharmaceutical, Inc. announced in 2021 that it had sold a PRV for $100,000,000.[42]

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical

benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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

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

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

40 21 U.S.C. § 360n(a)(1).

41 21 U.S.C. § 360n(a)(3).

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

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, the FDA's regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of

Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), and its implementation regulations, as well as the Drug Supply Chain Security Act ("DSCSA"), which regulates the distribution of and tracing of prescription drugs and prescription drug samples at the federal level, and sets minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an ANDA to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug..."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity ("NCE"), is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

Under FDARA, a priority review track will be established for certain generic drugs, requiring the FDA to review a drug application within eight months for a drug that has three or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The new legislation also authorizes the FDA to expedite review of "competitor generic therapies" or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

the required patent information has not been filed;

the listed patent has expired;

the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Safety and Innovation Act ("FDASIA"), in 2012, sponsors

must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. For drugs intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments.

In addition, FDARA requires the FDA to meet early in the development process to discuss pediatric study plans with drug sponsors. The legislation requires the FDA to meet with drug sponsors no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly responds to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. With regard to patents, the six-month pediatric exclusivity period will not attach to any patents for which a generic (ANDA or 505(b)(2) NDA) applicant submitted a paragraph IV patent certification, unless the NDA sponsor or patent owner first obtains a court determination that the patent is valid and infringed by a proposed generic product.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Those circumstances include instances in which another sponsor's application for the same drug product and indication is shown to be "clinically superior" to the previously approved drug. In this context, clinically superior means that the drug provides a significant therapeutic advantage over and above the already approved drug in terms of greater efficacy, greater safety or by providing a major contribution to patient care. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Under FDARA, orphan exclusivity will not bar approval of another orphan drug under certain circumstances, including if a subsequent product with the same drug for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Medical Devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FDCA, a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. If not, it is generally a medical device.

Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices have the lowest level or risk associated with them, and are subject to general controls, including labeling, premarket notification and adherence to the Quality System Regulation ("QSR"). Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are subject to most of the aforementioned requirements as well as to premarket approval.

A 510(k) must demonstrate that the proposed device is substantially equivalent to another legally marketed device, or predicate device, which did not require premarket approval. In evaluating a 510(k), the FDA will determine whether the device has the same intended use as the predicate device, and (a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics, and (i) the data supporting substantial equivalence contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as a legally marketed device, and (ii) does not raise different questions of safety and effectiveness than the predicate device. Most 510(k)s do not require clinical data for clearance, but the FDA may request such data. The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA concludes that a new device is not

substantially equivalent to a predicate device, the new device will be classified in Class III and the manufacturer will be most likely required to submit a PMA to market the product.

Under the PMA application process, the applicant must demonstrate that the device is safe and effective for its intended use. This PMA approval process applies to most Class III devices, and generally requires clinical data to support the safety and effectiveness of the device, obtained in conformance with Investigational Device Exemption regulations. The FDA will approve a PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose, and that the proposed manufacturing is in compliance with the QSRs. For novel technologies, the FDA will seek input from an advisory panel of medical experts regarding the safety and effectiveness of, and their benefit-risk analysis for the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process, though both processes can be expensive and lengthy, and require payment of significant user fees, unless an exemption is available.

Modifications to a 510(k)-cleared medical device may require the submission of another 510(k) or a PMA if the changes could significantly affect safety or effectiveness or constitute a major change in the intended use of the device. Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Procedures Governing Approval of Drug Products in the European Union

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an E.U. member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent Ethics Committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a product under European Union regulatory systems, an applicant must submit a marketing authorization application ("MAA"), either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all E.U. member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (the "CHMP"), established at the European Medicines Agency ("EMA"), is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various E.U. member states where such a product has not previously received marketing approval in any E.U. member states. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including Good Clinical Practice, are set forth in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the E.U. member states. Under this system, approval must be obtained from the competent national authority of each E.U. member state in which a study is planned to be conducted. To this end, a clinical trial application is submitted, which must be supported by an investigational medicinal product dossier ("IMPD"), and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent Ethics Committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the European Union passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new E.U. clinical trials legislation was passed as a regulation that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of EMA, the new Clinical Trials Regulation will become applicable in 2019. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old system.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the E.U. portal; a single set of documents to be prepared and submitted for

the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states; a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts-Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned; strictly defined deadlines for the assessment of clinical trial applications; and the involvement of the Ethics Committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Clinical Trials Regulation.

Data and Market Exclusivity in the European Union

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company can complete a full MAA with a complete database of pharmaceutical tests, preclinical tests and clinical trials and obtain marketing approval of its product.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Periods of Authorization and Renewals

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the European Union market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Orphan Drug Designation and Exclusivity

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the European Union. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

Regulatory Framework in Australia

The Therapeutic Goods Administration, through the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations is responsible for the efficacy, quality, safety and timely availability of drugs and medical devices in Australia. The mission statement of the TGA is "To ensure the safety, quality and efficacy of therapeutic goods available in Australia at a standard equal to that of comparable countries, and that premarket assessment of therapeutic goods is conducted within a reasonable time."

The drug regulation process in Australia is complex and resource intensive. It must be accountable in terms of the quality, safety and efficacy of drugs made available in Australia. This accountability includes an acceptance of a balance between safety and efficacy. The approval process is a detailed evaluation of the data supplied by the company sponsoring an application.

A drug may first come to the attention of the TGA when an application for marketing is received or when an Australian clinical trial is being planned. For clinical trials, the sponsoring company may submit preliminary data for evaluation to the TGA or notify the TGA that the trial has been approved by an institutional Ethics Committee.

The drug evaluation process for new chemical entities is as follows:

Application

Check to see data complies with Australian guidelines.

Invoice sponsor for 75% of evaluation fee.

Evaluation

Evaluate pharmaceutical and chemical data.

Evaluate animal pharmacology and toxicology data.

Evaluate clinical data.

Evaluation Unit reviews reports (coordinates external evaluations if used), prepares a summary and makes an initial recommendation.

Pre ADEC consultation with sponsor.

Prepare approved product information and consider consumer product information.

Submit final package of summaries and recommendations to the ADEC (six meetings per year).

Approval

ADEC review and advice to the TGA.

Final decision by the TGA.

Finalize conditions of registration.

Advice to sponsor, invoice final 25% of evaluation fee.

For new chemical entity, advise drug information centers, forensic laboratories, etc.

Registration

Sponsor applies to register the product on the Australian Register of Therapeutic Goods.

Supply is permitted once the applicable number is allocated.

The drug's chemistry, toxicology and clinical use are evaluated using data submitted by the sponsoring company. Most of the evaluations are done within the TGA, but external evaluations can be used. When all the data have been evaluated, the application is considered by the Australian Drug Evaluation Committee ("ADEC"). This committee is a group of doctors appointed by the Minister to advise on the suitability of drugs for marketing in Australia. The TGA takes into consideration the advice received from the ADEC when making a final recommendation.

The evaluation process relates to pre-marketing activity, but the TGA is also responsible for drugs after they are marketed.

Other activities under the control of the TGA include:

maintenance of the Australian Register of Therapeutic Goods for the registration and listing of products;

control of drug and device exports from Australia;

inspection and licensing of manufacturing premises;

post marketing surveillance;

adverse drug reaction monitoring;

reports were received by the Adverse Drug Reactions Advisory Committee;

medical device complaint reporting;

drug and device recalls;

laboratory testing, sample testing;

complaint reporting and follow up; and

drug and device advertising controls

The performance of the TGA is monitored in quarterly performance reports which are reviewed by the Industry/Government Consultative Committee. This committee has membership from the TGA, the Department of Finance, the Department of Industry, Science and Technology, and the peak industry organizations representing the manufacturers of prescription drugs, non-prescription drugs, medical devices and herbal and nutritional products.

If the TGA does not meet the statutory timelines in approving a drug, then it forgoes 25% of the evaluation fee as a penalty. The sponsor concerned can also consider the outcome as a "deemed refusal" and appeal to the Administrative Appeals Tribunal for a resolution. For variations to the registration of a drug, the TGA must raise an objection within 45 working days, otherwise the application is deemed to be approved.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for our product candidates will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities and their business associates that associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act (collectively the "ACA"), which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS"), within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians and teaching hospitals and information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the Affordable Care Act (the "ACA"), which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. The reductions have been suspended temporarily through December 2021 in response to the COVID-19 pandemic. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures were passed by the U.S. Senate. The ACA has also been challenged numerous times in various court cases, including challenges before the U.S. Supreme Court. In the most recent case (decided in June 2021) the Supreme Court held that the individual plaintiffs and states lacked standing to challenge the constitutionality of the ACA.

Previously in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, President Trump signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction ("CSR"), payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA.

For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, in June 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in Affordable Care Act risk corridor payments to third-party payors who argued the payments were owed to them. In April 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula.

A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures have been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

Most recently, on August 16, 2022, the Inflation Reduction Act of 2022 was signed into law which provides for (i) the government to set or negotiate prices for select high-cost Medicare Part D (beginning in 2026) and Medicare Part B drugs (beginning in 2028) that are more than nine years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval, (ii) manufacturers to pay a rebate for Medicare Part B and Part D drugs when prices increase faster than inflation beginning in 2022 for Medicare Part D and 2023 for Medicare Part B drugs, and (iii) Medicare Part D redesign which replaces the current coverage gap provisions and establishes a $2,000 cap for out-of-pocket limits costs for Medicare beneficiaries beginning in 2025, with manufacturers being responsible for 10% of costs up to the $2,000 cap and 20% after that cap is reached.

Future indications for Arakoda may justify higher pricing in principle, but cumulative health-care reforms inclusive of the IRA limit price increases and/or indication-based pricing without financial penalties if manufacturers' products have Medicare coverage. The impact of these reforms on the pharmaceutical industry generally is in its infancy, and will depend on how or if they are implemented by regulators. We will monitor this issue to determine the effects of this legislation on our business – full implementation of the reforms may have a negative impact on maximizing the profitability, but the actual impact at this juncture is uncertain.

Human Capital Resources

As of December 31, 2025, we had a total of three employees, all of whom are full-time. We also utilize the services of two part-time contractors.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Available Information

Our website address is *https://60degreespharma.com*. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, any amendments to those reports, proxy and registration statements filed or furnished with the SEC, are available free of charge through our website. We make these materials available through our website as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the SEC. The reports filed with the SEC by our executive officers and directors pursuant to Section 16 under the Exchange Act are also made available, free of charge on our website, as soon as reasonably practicable after copies of those filings are provided to us by those persons. These materials can be accessed through the "Investor Relations" section of our website. The information contained in, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

Item 1A. Risk Factors.

As a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, we are not required to provide the information in this Item.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We acknowledge the increasing importance of cybersecurity in today's digital and interconnected world. Cybersecurity threats pose significant risks to the integrity of our systems and data, potentially impacting our business operations, financial condition and reputation.

As a smaller reporting company, we currently do not have formalized cybersecurity measures, a dedicated cybersecurity team or specific protocols in place to manage cybersecurity risks. Our approach to cybersecurity is in the developmental stage, and we have not yet conducted comprehensive risk assessments, established an incident response plan or engaged with external cybersecurity consultants for assessments or services.

Given our current stage of cybersecurity development, we have not experienced any significant cybersecurity incidents to date. However, we recognize that the absence of a formalized cybersecurity framework may leave us vulnerable to cyberattacks, data breaches and other cybersecurity incidents. Such events could potentially lead to unauthorized access to, or disclosure of, sensitive information, disrupt our business operations, result in regulatory fines or litigation costs and negatively impact our reputation among customers and partners. In addition, cybersecurity incidents could have material adverse effects on our business strategy, financial condition, and results of operations (e.g., a significant breach could result in direct financial losses due to fraud, system downtime impacting revenue generation, increased compliance costs or contractual liabilities with third-party vendors and customers).

We are in the process of evaluating our cybersecurity needs and developing appropriate measures to enhance our cybersecurity posture. This includes considering the engagement of external cybersecurity experts to advise on best practices, conducting vulnerability assessments and developing an incident response strategy. Our goal is to establish a cybersecurity framework that is commensurate with our size, complexity and the nature of our operations, thereby reducing our exposure to cybersecurity risks.

In addition, the Board will oversee any cybersecurity risk management framework and a dedicated committee of the Board or an officer appointed by the Board will review and approve any cybersecurity policies, strategies and risk management practices. The Board (or designated committee or officer) will receive periodic updates on cybersecurity risks, including emerging threats, mitigation efforts and incident response activities. The updates will be provided at least annually, or more frequently as needed, to ensure cybersecurity risks are appropriately managed and integrated into our broader risk oversight strategy.

Despite our efforts to improve our cybersecurity measures, there can be no assurance that our initiatives will fully mitigate the risks posed by cyber threats. The landscape of cybersecurity risks is constantly evolving, and we will continue to assess and update our cybersecurity measures in response to emerging threats

For a discussion of potential cybersecurity risks affecting us, please refer to the "Risk Factors" section of our Registration Statement on Form S-1 filed with the Securities and Exchange Commission on February 14, 2025 titled "*Cybersecurity risks could adversely affect our business and disrupt our operations*."

Item 2. Properties.

Our corporate headquarters are located at 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036. We do not own any physical property, plant or labs. We currently lease one office at the above address, which lease was recently renewed for an additional one-year term expiring on March 31, 2027.

Item 3. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "SXTP," and warrants under the symbol "SXTPW." Trading in our common stock has historically lacked consistent volume, and the market price has been volatile.

On March 27, 2026, the closing price for our common stock and warrants as reported on The Nasdaq Capital Market was $1.50 per share and $0.08, respectively.

Holders of Common Stock

On March 30, 2026, there were 21 holders of record of our common stock.

Reverse Stock Split

On October 8, 2025, a majority of the stockholders of the Company approved the proposed reverse stock split of our Common Stock at a split ratio ranging between 1:3 and 1:10, as to be determined by the Board in its sole discretion. On December 17, 2025, our Board approved a 1-for-4 reverse split ratio. On January 20, 2026, the Company effectuated a 1-for-4 reverse stock split of our common stock (the "1:4 Reverse Stock Split" and together, with the 1:5 Reverse Stock Split and the 1:12 Reverse Stock Split, each as defined below, the "Reverse Stock Splits"). Beginning January 20, 2026, our common stock traded on The Nasdaq Capital Market on a split adjusted basis.

On November 6, 2024, our Board approved a reverse stock split of our Common Stock at a split ratio ranging between 1:3 and 1:5, as determined by the Board in its sole discretion. On November 6, 2024, a majority of the stockholders of the Company approved the proposed reverse stock split. On February 10, 2025, the Board approved a 1-for-5 reverse split ratio. On February 24, 2025, the Company effectuated a 1-for-5 reverse stock split of our common stock (the "1:5 Reverse Stock Split"). Beginning February 24, 2025, our common stock traded on The Nasdaq Capital Market on a split adjusted basis.

In July 2024, our Board approved a reverse stock split of our Common Stock at a split ratio ranging between 1:5 and 1:12, as determined by the Board in its sole discretion. On July 16, 2024, a majority of the stockholders of the Company approved the proposed reverse stock split. On July 19, 2024, our Board approved a 1-for-12 reverse split ratio. On August 12, 2024, the Company effectuated a 1-for-12 reverse stock split of our common stock (the "1:12 Reverse Stock Split" and together, with the 1:5 Reverse Stock Split, the "Reverse Stock Splits"). Beginning August 12, 2024, our common stock traded on The Nasdaq Capital Market on a split adjusted basis.

All common share and applicable per share amounts in this Annual Report on Form 10-K have been retroactively restated to reflect the effect of the Reverse Stock Splits.

Transfer Agent

The transfer agent for our common stock is 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*.

Dividend Policy

We have never paid any cash dividends on our common stock. We anticipate that we will retain funds and future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board and will depend on our financial condition, results of operations, capital requirements, and other factors that our Board deems relevant. In addition, the terms of any future debt or credit financings may preclude us from paying dividends.

Unregistered Sales of Equity Securities

Common Stock

On July 22, 2024 and July 26, 2024, we issued 2,000 and 1,667 shares of common stock to Knight, respectively, upon conversion of 1,291 and 1,032 shares of Series A Preferred Stock, respectively, at the conversion price detailed in Note 6 to the accompanying consolidated financial statements.

From October 2024 to January 2025, we issued an aggregate of 144,928 shares of common stock upon the exercise of pre-funded warrants issued to investors in the September 2024 private placement.

In July 2025, we issued an aggregate of 219,569 shares of common stock upon the exercise of pre-funded warrants issued to investors in the July 2025 private placement.

The issuances of shares of common stock listed above were deemed exempt from registration under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder in that the issuance of securities did not involve a public offering.

Warrants

On September 4, 2024, we issued 144,928 pre-funded warrants, 144,928 Series A Warrants and 144,928 Series B Warrants to investors in a private offering. The Pre-Funded Warrants are exercisable immediately upon issuance and expire when exercised in full at an exercise price of $0.02 per share. The Series A Warrants and Series B Warrants have an exercise price of $27.60 per share and were exercisable beginning on the effective date of stockholder approval of the issuance of the shares of Common Stock (the "Stockholder Approval"), which was received on November 6, 2024. 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 10,870 shares of Common Stock. The Placement Agent Warrants have an exercise price equal to $34.50 per share and are exercisable beginning on the effective date of the Stockholder Approval for five years from Stockholder Approval.

In January 2025, we issued warrants to purchase up to an aggregate of 102,158 shares of common stock at an exercise price of $ 15.42 per share. The January 2025 Warrants are exercisable upon issuance and expire twenty-four months from the date of issuance. We also issued to the Placement Agent (or its designees) warrants to purchase up to 3,833 shares of common stock. The January 2025 Placement Agent Warrants have an exercise price equal to $ 25.53 per share and are exercisable upon issuance, or January 30, 2025, for twenty-four months from the date of issuance, or January 30, 2027.

On February 5, 2025, we issued warrants to purchase up to an aggregate of 75,176 shares of common stock at an exercise price of $11.80 per share. The February 2025 Warrants are exercisable upon issuance and expire twenty-four months from the date of issuance. We issued to the Placement Agent (or its designees) warrants to purchase up to 5,640 shares of common stock. The February 2025 Placement Agent Warrants have an exercise price equal to $ 17.88 per share and are exercisable upon issuance, or February 6, 2025, for twenty-four months from the date of issuance, or February 8, 2027.

The warrants described above were deemed exempt from registration in reliance on Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder in that the issuance of securities were made to an accredited investor and did not involve a public offering. The recipients of such securities represented its intention to acquire the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof.

Option Grants

On July 16, 2024, the effective date of shareholder approval to increase the number of shares authorized under the 2022 Plan, we granted a total of 128 fully vested, non-qualified options to purchase shares of common stock at a per share exercise price of $1,272.00 to the following directors and in the amounts listed: (i) Stephen Toovey (32 common stock options), (ii) Charles Allen (32 common stock options), (iii) Paul Field (32 common stock options) and (iv) Cheryl Xu (32 common stock options).

On July 16, 2024, the effective date of shareholder approval to increase the number of shares authorized under the 2022 Plan, we granted a total of 3,084 options to purchase shares of common stock at a per share exercise price of $240.00 to Geoff Dow, our Chief Executive Officer, (1,250 common stock

options), Tyrone Miller, our Chief Financial Officer (1,000 common stock options), and Bryan Smith, an external consultant, (834 common stock options). These options vest in five equal tranches on the last date of each fiscal year, with the first vesting date being December 31, 2024.

On September 26, 2024, we granted 1,042 options to purchase shares of common stock at a per share exercise price of $27.40 to Kristen Landon, our Chief Commercial Officer, which vest in five equal tranches on the last date of each fiscal year, with the first vesting date being December 31, 2024.

On January 2, 2025, we granted a total of 30,000 options to purchase shares of common stock at a per share exercise price of $26.20 to Geoff Dow, our Chief Executive Officer, (26,250 common stock options) and Tyrone Miller, our Chief Financial Officer (3,750 common stock options), which vest in five equal tranches. The first tranche was fully vested on the date of grant and thereafter, the options vest on the last date of each fiscal year beginning December 31, 2025.

On October 21, 2025, we granted a total of 8,000 fully vested, non-qualified options to purchase shares of common stock at a per share exercise price of $5.84 to the following directors and in the amounts listed: (i) Stephen Toovey (2,000 common stock options), (ii) Charles Allen (2,000 common stock options), (iii) Paul Field (2,000 common stock options) and (iv) Cheryl Xu (2,000 common stock options).

2022 Equity Incentive Plan

On November 22, 2022, the Board and majority stockholder adopted the 60 Degrees Pharmaceuticals, Inc. 2022 Equity Incentive Plan (the "2022 Plan"). The 2022 Plan provides for the grant of the following types of stock awards: (i) incentive stock options, (ii) nonstatutory stock options, (iii) stock appreciation rights, (iv) restricted stock awards, (v) restricted stock unit awards and (vi) other stock awards. The 2022 Plan is intended to help us secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for our success and any of our affiliates and provide a means by which the eligible recipients may benefit from increases in value of the common stock. Initially, the Board reserved 995 shares of common stock issuable upon the grant of awards under the 2022 Plan. The 2022 Plan provides for an automatic increase in the number of shares available for issuance beginning on January 1, 2023 and each January 1 thereafter, by 4% of the number of outstanding shares of common stock on the immediately preceding December 31, or such number of shares as determined by the Board of Directors.

On July 16, 2024, November 6, 2024, and October 8, 2025, our stockholders approved an increase to the number of shares available under the 2022 Plan by 20,834 shares, 25,000 shares, and 62,500 shares respectively, which increases were previously approved by the Board. The total number of shares that remain available for issuance under the 2022 Plan as of December 31, 2025 is 68,760 shares, which additional reservation of shares provides us with flexibility to address future equity compensation needs. This increase is essential to attract and retain qualified employees, directors and consultants, and to align their interests with those of our stockholders.

EQUITY PLAN INFORMATION

Plan Category:	Number of securities to be issued upon exercise or issuance of outstanding options, units, and rights:	Weighted average exercise price of outstanding options, units and rights(1):	Number of securities remaining available for future issuance:
2022 Equity Incentive Plan:			
Equity compensation plans approved by security holders	21,940	$ 47.18	68,760
Equity compensation plans not approved by security holders	—	—	—
Total	**21,940**	**$ 47.18**	**68,760**

(1) Balances presented as of December 31, 2025, and reflect the effects of the 1:4 Reverse Stock Split on January 20, 2026.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Prospective investors should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this annual report. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements." This discussion should be read in conjunction with our audited consolidated financial statements and the notes thereto included elsewhere in this report. In this discussion, we may use certain non-generally accepted accounting principles (GAAP) financial measures. An explanation of these non-GAAP financial measures and a reconciliation to the most directly comparable GAAP financial measures are included in this "Management's Discussion and Analysis of Financial Condition and Results of Operations." Investors should not consider non-GAAP financial measures in isolation or as substitutes for financial information presented in compliance with GAAP.

1. Overview

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® ("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 and/or botanical extracts from Australian Chestnut Trees.

2. Components of Results of Operations

Product Revenues - net of Discounts and Rebates

We receive the majority of our product revenues from sales of our Arakoda product to resellers in the U.S. and abroad. Foreign sales to both Australia and Europe were further subject to profit sharing agreements for boxes sold to customers. Sales to resellers in the US are subject to considerable discounts and rebates for services provided by our third-party logistics ("3PL") partner and wholesalers and pharmacy benefit managers ("PBMs").

Cost of Revenues, Gross Profit, and Gross Margin

Cost of revenues associated with our products is primarily comprised of direct materials, shipping, manufacturing related costs incurred in the production process, serialization costs and inventory write-downs due to expiration.

Other Operating Revenues

Other operating revenues for the periods presented include research revenue earned from the Australian Tax Authority for research activities conducted in Australia. Beginning in the third quarter of 2024, we began to recognize research revenues associated with our new contract with the United States Army Medical Materiel Development Activity (USAMMDA) for Arakoda supply chain upgrade support. Research revenue under this contract is recognized when we incur the direct costs eligible for reimbursement, up to the maximum allowable amount.

Operating Expenses

Research and Development

Research and development costs for the periods presented primarily consist of contracted R&D services and costs associated with preparation for and conducting our Babesiosis trial. We expense all research and development costs in the period in which they are incurred. Payments made prior to the receipt of goods or services to be used in research and development are recognized as prepaid assets and expensed over the service period as the services are provided. We have also issued shares of our common stock to vendors in exchange for research and development services

General and Administrative Expenses

Our general and administrative expenses primarily consist of salaries, advertising and promotion expenses, professional services fees, such as consulting, audit, accounting and legal fees, general corporate costs and allocated costs, including facilities, information technology and amortization of intangibles.

Interest and Other Income (Expense), Net

We earn interest income from cash invested in interest-bearing accounts, as well as cash equivalents and short-term investments consisting of certificates of deposits with original maturities ranging from three to six months. Interest expense for the periods presented is limited to a single $150,000 SBA loan that bears interest at 3.75%. Other components of other income (expense) include changes in the fair value of derivative liabilities and other miscellaneous income or expenses.

---

3. Results of Operations

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

	For the Year Ended December 31,	
Consolidated Statements of Operations Data:	**2025**	**2024**
Product Revenues – net of Discounts and Rebates	$ 1,005,471	$ 607,574
Cost of Revenues	781,695	384,765
Gross Profit	223,776	222,809
Research Revenues	403,624	73,771
Net Revenue	627,400	296,580
Operating Expenses:		
Research and Development	2,106,156	4,986,526
General and Administrative Expenses	6,279,823	5,025,235
Total Operating Expenses	8,385,979	10,011,761
Loss from Operations	(7,758,579)	(9,715,181)
Interest Expense	(7,805)	(7,912)
Change in Fair Value of Derivative Liabilities	266,089	1,665,966
Other Income, net	131,970	101,464
Total Interest and Other Income (Expense), net	390,254	1,759,518

Loss from Operations before Provision for Income Taxes	(7,368,325)	(7,955,663)
Provision for Income Taxes (Note 9)	-	-
Net Loss including Noncontrolling Interest	(7,368,325)	(7,955,663)
Net Loss – Noncontrolling Interest	(3,167)	(8,556)
Net Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	$ (7,365,158)	$ (7,947,107)

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

	For the Year Ended December 31,	
Consolidated Statements of Operations Data:	**2025**	**2024**
Product Revenues – net of Discounts and Rebates	100.00%	100.00%
Cost of Revenues	77.74	63.33
Gross Profit	22.26	36.67
Research Revenues	40.14	12.14
Net Revenue	62.40	48.81
Operating Expenses:		
Research and Development	209.47	820.73
General and Administrative Expenses	624.57	827.10
Total Operating Expenses	834.03	1,647.83
Loss from Operations	(771.64)	(1,599.01)
Interest Expense	(0.78)	(1.30)
Change in Fair Value of Derivative Liabilities	26.46	274.20
Other Income, net	13.13	16.70
Total Interest and Other Income (Expense), net	38.81	289.60
Loss from Operations before Provision for Income Taxes	(732.82)	(1,309.41)
Provision for Income Taxes (Note 9)	-	-
Net Loss including Noncontrolling Interest	(732.82)	(1,309.41)
Net Loss – Noncontrolling Interest	(0.31)	(1.41)
Net Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	(732.51)%	(1,308.01)%

4. Comparison of the Years Ended December 31, 2025, and 2024

Product Revenues - net of Discounts and Rebates, Cost of Revenues, Gross Profit, and Gross Margin

	For the Year Ended December 31,			
Consolidated Statements of Operations Data:	**2025**	**2024**	**$ Change**	**% Change**
Product Revenues – net of Discounts and Rebates	$ 1,005,471	$ 607,574	$ 397,897	65.49%
Cost of Revenues	781,695	384,765	396,930	103.16
Gross Profit	$ 223,776	$ 222,809	$ 967	0.43%
Gross Margin %	**22.26%**	**36.67%**		

Product Revenues - net of Discounts and Rebates

Our product revenues - net of discounts and rebates were $1,005,471 for the year ended December 31, 2025, as compared to $607,574 for the year ended December 31, 2024. For the year ended December 31, 2025, our U.S. pharmaceutical distributor accounted for 92% of our total net product sales and Kodatef sales to our Australian distributor accounted for 6% of total net product sales (95% and 5% for the year ended December 31, 2024, respectively). Despite a shortage of Arakoda 16-ct boxes starting in April 2025, which resulted from a delay in completing commercial validation of a new packaging format, domestic, commercial product sales increased during the period, primarily due to the combination of rising sales, price increases and fewer returns.

We offer discounts and rebates to the civilian U.S. supply chain distribution channel. We record sales when our 3PL partner transfers boxes into their title model. Discounts and rebates offered to our 3PL partner amount to 12% (lower rates available upon reaching larger revenue tiers) along with a $5,500 fixed monthly fee. The product is then transferred usually to one of the three large U.S. pharmaceutical distributors where rebates are 10%. Lastly, we have relationships with several large pharmacy benefit managers (“PBMs”) that allow patients to purchase Arakoda at a discount. The rebate associated with PBMs ranges from 30% to 41.25% depending on the amount of coverage provided. For the year ended December 31, 2025, discounts and rebates were $476,430 compared to $476,218 for the year ended December 31, 2024.

Arakoda entered the U.S. civilian supply chain in the third quarter of 2019. Since the introduction of the new 8-ct bottle in June 2025, we will be reporting Arakoda unit sales in terms of 16-ct box equivalents. For the year ended December 31, 2024, 5,119 16-ct box equivalents were sold to pharmacies and dispensaries. Sales volume increased by 12% to 5,724 16-ct box equivalents sold to pharmacies and dispensaries for the year ended December 31, 2025.

Kodatef sales to our distributor Biocelect in Australia for the year ended December 31, 2025 were $57,058 ($30,652 for the year ended December 31, 2024). A historical portion of sales to Biocelect remained subject to a profit share distribution once the original transfer price has been recouped. As of December 31, 2025, Biocelect has no inventory left that remains subject to profit share. Biocelect, which acts as a distributor in the Australian and New Zealand markets, reported year-over-year growth of <1%, with 1,854 boxes sold for the year ended December 31, 2025, compared to 1,850 boxes for the year ended December 31, 2024. Additionally, under a new agreement executed during 2025, Biocelect began to purchase from the latest manufactured lot

of Kodatef at $49.50 AUD per box which are not subject to historical profit share. As of December 31, 2025, no receivables were due to us ($9,444 as of December 31, 2024).

Arakoda sales volume in Europe continues to grow. We first shipped Arakoda to our distributor Scandinavian Biopharma ("SB") in September 2022. For the year ended December 31, 2025, SB reported 353 boxes sold (147 for the year ended December 31, 2024). According to our distributor, this is due to greater interest in treating babesiosis. Additionally, we recorded $22,500 in European sales for the year ended December 31, 2025 ($0 for the year ended December 31, 2024).

Cost of Revenues, Gross Profit, and Gross Margin

Cost of revenues was $781,695 for the year ended December 31, 2025, as compared to $384,765 for the year ended December 31, 2024. The increase in cost of revenues was, in part, due to higher product sales during the year, as well as higher write-offs of inventory not expected to be sold prior to its expiration date. Write-offs for expiring inventory were $445,181 during the year ended December 31, 2025, as compared to $22,046 during the year ended December 31, 2024. The excess inventory resulted from our strategic decision to validate a new, larger-scale production method with then soon to be expiring raw materials (API), with the offsetting assistance from our USAMMDA grant. The development proved successful but the dating on the produced inventory is already considered in the industry to be short-dated and will have to be replaced by the beginning of the second quarter of 2026. The temporary increase in inventory write-offs was a necessary step in scaling our operations and is not expected to be recurring. Our new larger-scale production processes are expected to help keep inventory costs lower than otherwise. Due to these factors, the Gross Margin % decreased from 36.67% for the year ended December 31, 2024 to 22.26% for the year ended December 31, 2025.

Other Operating Revenues

	For the Year Ended December 31,			
Consolidated Statements of Operations Data:	**2025**	**2024**	**$ Change**	**% Change**
Research Revenues	$ 403,624	$ 73,771	$ 329,853	447.13%

The research revenues earned by us were $403,624 for the year ended December 31, 2025, as compared to $73,771 for the year ended December 31, 2024. The increase in research revenues is due to the new USAMMDA contract we were awarded in July 2024 to facilitate commercial validation of a new bottle and replacement blister packaging of Arakoda and the contract we signed with the University of
Kentucky for tafenoquine clinical trial supply. We recognized research revenues of $298,868 related to the USAMMDA grant for the year ended December 31, 2025 ($12,994 for the year ended December 31, 2024). We recognized research revenues of $89,302 from the University of Kentucky for the year ended December 31, 2025 ($0 for the year ended December 31, 2024). Other research revenues were $15,454 for the year ended December 31, 2025 ($60,777 for the year ended December 31, 2024).

Operating Expenses

	For the Year Ended December 31,			
Consolidated Statements of Operations Data:	**2025**	**2024**	**$ Change**	**% Change**
Research and Development	$ 2,106,156	$ 4,986,526	$ (2,880,370)	(57.76)%
General and Administrative Expenses	6,279,823	5,025,235	1,254,588	24.97
Total Operating Expenses	$ 8,385,979	$ 10,011,761	$ (1,625,782)	(16.24)%

Research and Development

Research and development costs decreased by $2,880,370 during the year ended December 31, 2025 when compared to the year ended December 31, 2024. The decline is primarily attributable to non-cash charges totaling $3,225,000 recognized during the year ended December 31, 2024 related to share-based payments issued to vendors in January 2023 as advance consideration, which payments were initially deferred and capitalized. Kentucky Technology, Inc. delivered us a report on the potential development of SJ733 + tafenoquine in the second quarter of 2024 and Trevally completed the synthesis of 8.8 kilograms of castanospermine in the third quarter of 2024, resulting in $2,625,000 and $600,000, respectively, of research and development expense recognized for the year ended December 31, 2024. Otherwise, research and development costs incurred during the years ended December 31, 2025 and 2024 primarily consisted of costs related to our babesiosis trial for tafenoquine. Direct trial-related costs represent 71% of the total research and development costs at $1,496,148 during the year ended December 31, 2025, compared to 27% of the costs at $1,359,532 during the year ended December 31, 2024. We also recorded $153,198 in research and development expenses related to commercial validation and packaging of Arakoda, for which a majority qualifies for reimbursement under the USAMMDA grant discussed above.

General and Administrative Expenses

For the year ended December 31, 2025, our general and administrative expenses increased by 24.97% or $1,254,588 from the year ended December 31, 2024. During the year ended December 31, 2025, we recorded lower compensation expenses including $11,791 of bonus expense and $728,829 of salaries, taxes, and benefits expense, respectively (compared to $275,114 and $662,951 for the year ended December 31, 2024, respectively) due to certain sales and performance bonuses awarded to our executives in 2024. However, during the year ended December 31, 2025, we incurred $518,150 in legal and professional fees, $1,217,826 of investor outreach expenses, and $1,401,529 of sales advisory, advertising and promotion expenses (up from $410,016, $1,019,111, and $433,884 for the year ended December 31, 2024, respectively). Additionally, we recognized higher stock-based compensation costs, from $32,767 for the year ended December 31, 2024 to $279,873 for the year ended December 31, 2025. This increase was in part due to new partially vested option grants awarded to two executives in January 2025 and certain fully vested stock-based awards granted to our directors at the end of 2025, as well as the ongoing quarterly expense recognized for additional stock options granted in the third quarter of 2024.

Interest and Other Income (Expense), Net

	For the Year Ended December

Consolidated Statements of Operations Data:	31, 2025	2024	$ Change	% Change
Interest Expense	$ (7,805)	$ (7,912)	$ 107	(1.35)%
Change in Fair Value of Derivative Liabilities	266,089	1,665,966	(1,399,877)	(84.03)
Other Income, net	131,970	101,464	30,506	30.07
Total Interest and Other Income (Expense), net	$ 390,254	$ 1,759,518	$ (1,369,264)	(77.82)%

Interest Expense

For the year ended December 31, 2025, we recognized $7,805 of interest expense ($7,912 for the year ended December 31, 2024). Our interest expense for the periods presented relates primarily to our single outstanding loan from the SBA. Cash paid for interest was $8,772 and $8,772 for the years ended December 31, 2025 and December 31, 2024, respectively.

Change in Fair Value of Derivative Liabilities

For the year ended December 31, 2025, we recognized a net gain on the change in fair value of derivative liabilities of $266,089 compared to a net gain of $1,665,966 for the year ended December 31, 2024. During the years ended December 31, 2025 and December 31, 2024, derivative liabilities include the contingent milestone payment due to Knight upon a future sale of Arakoda or a Change of Control. We use a probability-weighted expected return method to estimate the fair value of this derivative liability.

Other Income (Expense), net

For the year ended December 31, 2025, we recognized $131,970 in other income compared to $101,464 in other income for the year ended December 31, 2024. We recognized interest income of $104,360 during the year ended December 31, 2025 ($103,299 during the year ended December 31, 2024). Other income for the year ended December 31, 2024 also included $10,789 of storage revenue recognized in association with final payment under the legacy contract with the USAMMDA for storing Arakoda purchases. We did not recognize storage revenue for the year ended December 31, 2025.

5. Liquidity and Capital Resources

As of December 31, 2025, we had cash and cash equivalents of $1,510,065 ($1,659,353 as of December 31, 2024). For the year ended December 31, 2025 and 2024, our net cash used in operating activities was $6,849,022 and $5,648,088, respectively. To date, we have financed our operations primarily through the issuance of common stock, warrants to purchase common stock, and proceeds from the issuance of convertible debt and promissory notes. Based on current internal projections, taking into consideration the net proceeds of approximately $4.3 million received from the July 2025 public offering, and approximately $4.0 million in gross proceeds received through the 2025 ATM Agreement between October 15, 2026 and March 25, 2026, we estimate that we will have sufficient funds to remain viable through September 30, 2026, assuming no additional capital raises. We cannot give assurance that we can increase our cash balances or limit our cash consumption and thus maintain sufficient cash balances for our planned operations or future acquisitions. Future business demands may lead to cash utilization at levels greater than recently experienced. We may need to raise additional capital in the future. However, we cannot assure you that we will be able to raise additional capital on acceptable terms, or at all.

Going Concern

In their audit report for the fiscal year ended December 31, 2025, our auditors have expressed their concern as to our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate cash flows from operations and obtain financing. The audited consolidated financial statements for the years ended December 31, 2025, and December 31, 2024, respectively, included an explanatory note referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern.

Our future results are subject to substantial risks and uncertainties. Since our inception, we have not demonstrated the ability to generate enough revenues to date to cover operating expenses and we have accumulated losses to date. To date, we have funded our operations primarily with proceeds from sales of common stock and warrants for the purchase of common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements.

Continuation as a going concern is dependent upon our ability to meet our financial requirements, raise additional capital, and achieve gross profitability from our single marketed product. To achieve profitability, we expect we will need to raise additional capital to fund our activities relating to commercial support for our existing product and any future clinical research trials and operating activities. However, there can be no assurance that we will ever achieve or maintain profitability. These conditions, among others, raise substantial doubt about our ability to continue as a going concern for one year from the date these financial statements are issued.

We plan to fund our operations through third party and related party debt/advances, private placement of restricted securities and the issuance of stock in a subsequent offering until such a time as the business achieves profitability or a business combination may be achieved. However, there can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are favorable to us. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

As such, we have concluded that such plans do not alleviate the substantial doubt about our ability to continue as a going concern for one year from the date the accompanying financial statements are issued.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of obligations in the normal course of business, and do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2025:

		Payments Due By Period			
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 Years
Principal obligations on the debt arrangements	$ 150,000	$ 713	$ 6,566	$ 7,092	$ 135,629
Interest obligations on the debt arrangements	94,917	8,059	10,978	10,453	65,427
Accounts payable and accrued expenses	1,459,279	1,459,279	-	-	-
Total	$ 1,704,196	$ 1,468,051	$ 17,544	$ 17,545	$ 201,056

Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the achievement of certain milestones. These contingent milestones may or may not be achieved. We have not included any of these amounts in the table above as we cannot estimate or predict when, or if, these amounts will become due.

Cash Flows

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Net Cash (Used In) Provided By :				
Operating Activities	$ (6,849,022)	$ (5,648,088)	$ (1,200,934)	21.26%
Investing Activities	254,916	(1,889,114)	2,144,030	(113.49)
Financing Activities	6,437,691	7,053,571	(615,880)	(8.73)
Effect of Foreign Currency Translation on Cash Flow	7,127	499	6,628	1,328.26
Net (Decrease) Increase in Cash and Cash Equivalents	$ (149,288)	$ (483,132)	$ 333,844	(69.10)%

Cash Used in Operating Activities

Net cash used in operating activities was $6,849,022 for the year ended December 31, 2025, as compared to $5,648,088 for the year ended December 31, 2024. Our net cash used in operating activities increased, in part due to higher general and administrative expenses of $6,279,823 for the year ended December 31, 2025 ($5,025,235 for the year ended December 31, 2024) primarily due to higher cash compensation and related expenses, legal and professional fees, investor outreach expenses, and advertising and promotion expenses, as discussed above. In addition, we incurred $1,496,148 in costs related to our babesiosis trial for tafenoquine during the year ended December 31, 2025 ($1,304,183 during the year ended December 31, 2024).

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $254,916 for the year ended December 31, 2025, as compared to cash used in investing activities of $1,889,114 for the year ended December 31, 2024. The decrease in cash used in investing activities is primarily driven by purchases of short-term certificates of deposit for a total cost of $1,235,000 during the year ended December 31, 2025 ($1,708,000 during the year ended December 31, 2024), purchased for the purposes of earning interest income. Additionally, purchases of computer and lab equipment totaled $139,881 during the year ended December 31, 2025 ($103,773 during the year ended December 31, 2024), and capitalized website development costs and patent costs totaled $22,670 and $55,533, respectively, for the year ended December 31, 2025 ($25,374 and $51,967 for the year ended December 31, 2024, respectively).

Cash Provided by Financing Activities

Net cash provided by financing activities was $6,437,691 for the year ended December 31, 2025, as compared to $7,053,571 for the year ended December 31, 2024. The decrease in net cash provided by financing activities is primarily attributable to net proceeds aggregating to $7,042,608 received in connection with our common stock and warrant offering in January 2024, (ii) the sale of common stock pursuant to the At-the-Market Sales Agreement in July and August 2024, and (iii) the sale of warrants in our Private Placement offering that closed in September 2024, which exceeded the aggregate net proceeds of $6,452,887 received in connection with our common stock and warrant offerings completed in January, February, and July 2025 and the sale of common stock pursuant to the At-the-Market Sales Agreement in October and December 2025.

We also received lower proceeds from the exercise of warrants at $2,804 for the year ended December 31, 2025, compared to $10,963 for the year ended December 31, 2024. Additionally, for the year ended December 31, 2025, we withheld shares valued at $18,000 to cover tax withholdings for net share settlement of certain 2024 performance bonuses awarded to our executives ($0 for the year ended December 31, 2024).

Effect of Foreign Currency Translation on Cash Flow

Our foreign operations were small relative to U.S. operations for the years ended December 31, 2025 and December 31, 2024, thus effects of foreign currency translation have been minor.

6. Critical Accounting Policies, Significant Judgments, and Use of Estimates

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

Revenue Recognition

We recognize revenue in accordance with FASB ASC Topic No. 606, *Revenue from Contracts with Customers* ("ASC 606"). Revenues are recognized when control is transferred to customers in amounts that reflect the consideration we expect to be entitled to receive in exchange for those goods. Revenue recognition is evaluated through the following five steps: (i) identification of the contract, or contracts, with a customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the performance obligations in the contract; and (v) recognition of revenue when or as a performance obligation is satisfied. As part of the accounting for these arrangements, we may be required to make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

Revenues from product sales are recorded at the net sales price, or "transaction price," which may include estimates of variable consideration that result from product returns. We determine the amount of variable consideration by using either the expected value method or the most-likely-amount method. We include the unconstrained amount of estimated variable consideration in the transaction price, which reflects the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, we re-evaluate the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment. Reserves are established for the estimates of variable consideration based on the amounts we expect to be earned or to be claimed on the related sales.

We record U.S. commercial revenues as a receivable when our American distributor transfers shipped product to their title model for 60P. Foreign sales to both Australia and Europe are recognized as a receivable at the point product is shipped to distributor. The shipments to Australia and Europe were further subject to profit sharing agreements for boxes sold to customers.

Inventory

We report inventories at the lower of cost or net realizable value. Cost is comprised of direct materials and, where applicable, costs we incur in bringing the inventories to their present location and condition. We use the Specific Identification method per lot. A box or a bottle price is calculated per lot number and sales are recognized by their lot number.

We regularly monitor our inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value, and record write-downs for inventory that has expired, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected sales requirements. We charge any write-downs of inventories to Cost of Revenues in the Consolidated Statements of Operations and Comprehensive Loss.

Share-Based Payments

We account for share-based payments in accordance with ASC Subtopic 718, *Compensation - Stock Compensation* ("ASC 718"). We measure compensation for all share-based payment awards granted to employees, directors, and nonemployees, based on the estimated fair value of the awards on the date of grant. For awards that vest based on continued service, the service-based compensation cost is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the awards. For service vesting awards with compensation expense recognized on a straight-line basis, at no point in time does the cumulative grant date value of vested awards exceed the cumulative amount of compensation expense recognized. The grant date is determined based on the date when a mutual understanding of the key terms of the share-based awards is established. We account for forfeitures as they occur.

We estimate the fair value of all stock option awards as of the grant date by applying the Black-Scholes option pricing model. The application of this valuation model involves assumptions, including the fair value of the common stock, expected volatility, risk-free interest rate, expected dividends and the expected term of the option. Due to the lack of a public market for our common stock prior to the IPO and lack of company-specific historical implied volatility data, we base our computations of expected volatility on the historical volatility of a representative group of public companies with similar characteristics of the Company, including stage of development and industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. We generally use the simplified method as prescribed by the SEC Staff Accounting Bulletin Topic 14, *Share-Based Payment*, to estimate the expected term for stock options, whereby, the expected term equals the midpoint of the weighted average remaining time to vest, vesting period and the contractual term of the options due to our lack of historical exercise data. For certain options granted out-of-the-money, our best estimate of the expected term is the contractual term of the award. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock. The assumptions used in calculating the fair value of share-based awards represent our best estimates and involve inherent uncertainties and the application of significant judgment.

We recognize compensation expense for restricted stock units ("RSUs") with only service-based vesting conditions on a straight-line basis over the vesting period. Compensation cost for service-based RSUs is based on the grant date fair value of the award, which is the closing market price of our common stock on the grant date multiplied by the number of shares awarded.

For awards that vest upon a liquidity event or a change in control, the performance condition is not probable of being achieved until the event occurs. As a result, no compensation expense is recognized until the performance-based vesting condition is achieved, at which time the cumulative compensation expense is recognized. Compensation cost related to any remaining time-based service for share-based awards after the liquidity-based event is recognized on a straight-line basis over the remaining service period.

For fully vested, nonforfeitable equity instruments that are granted at the date we enter into an agreement for goods or services with a nonemployee, we recognize the fair value of the equity instruments on the grant date. The corresponding cost is recognized as an immediate expense or a prepaid asset and expensed over the service period depending on the specific facts and circumstances of the agreement with the nonemployee.

Derivative Liabilities

We assess the classification of our derivative financial instruments each reporting period, which formerly consisted of bridge shares, convertible notes payable, and certain warrants, and determined that such instruments initially qualified for treatment as derivative liabilities as they met the criteria for

liability classification under ASC 815. As of December 31, 2025, our derivative financial instruments consist of contingent payment arrangements.

We analyze all financial instruments with features of both liabilities and equity under the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic No. 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and FASB ASC Topic No. 815, *Derivatives and Hedging* ("ASC 815"). Derivative liabilities are adjusted to reflect fair value at each reporting period, with any increase or decrease in the fair value recorded in the results of operations, as a component of other income or expense as change in fair value of derivative liabilities. We use a Monte Carlo simulation model or a probability-weighted expected return method to determine the fair value of these instruments.

Upon conversion or repayment of a debt or equity instrument in exchange for equity shares, where the embedded conversion option has been bifurcated and accounted for as a derivative liability (generally convertible debt and warrants), we record the equity shares at fair value on the date of conversion, relieve all related debt, derivative liabilities, and unamortized debt discounts, and recognize a net gain or loss on debt extinguishment, if any.

Equity or liability instruments that become subject to reclassification under ASC Topic 815 are reclassified at the fair value of the instrument on the reclassification date.

Off-Balance Sheet Arrangements

During 2025 and 2024, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

JOBS Act Accounting Election

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

Recent Accounting Pronouncements

From time to time, the FASB issues Accounting Standards Update ("ASUs") to amend the authoritative literature in the ASC. We regularly evaluate new ASUs to determine the impact that these pronouncements may have on our consolidated financial statements. Other than the pronouncements listed below, management believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, or (iii) are not applicable to our consolidated financial statements or related disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07") which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses and segment profit or loss. ASU 2023-07 also requires entities with a single reportable segment to provide all segment disclosures under ASC 280, including the new required disclosures under the ASU. We adopted ASU 2023-07 on a retrospective basis for the 2024 annual period, and for interim periods beginning in 2025. The impact is limited to our financial statement disclosures, which are presented in Note 2 to the accompanying consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (ASC 740): Improvements to Income Tax Disclosures* ("ASU 2023-09") which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 was effective for us for our annual period ending December 31, 2025. The impact of the adoption is limited to our financial statement disclosures, which are presented on a prospective basis. See Note 9 to the accompanying consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which applies to all public business entities that file financial statements with the SEC. The amendments in this ASU require public business entities to disclose on an annual and interim basis, disaggregated information about certain income statement expense line items. The new standard is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. We are currently evaluating the impact that ASU 2024-03 will have on our financial statement disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software* ("ASU 2025-06"), which amends certain aspects of the accounting for and disclosure of software costs under ASC 350-40. The amendments modernize the recognition and disclosure framework for internal-use software costs, removing the previous "development stage" model and introducing a more judgment-based approach. The ASU is effective for all entities for interim and annual periods beginning after December 15, 2027, with early adoption permitted. We are currently evaluating the impact that ASU 2025-06 will have on our consolidated financial statements.

In September 2025, the FASB issued ASU 2025-07, *Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract* ("ASU 2025-07"). ASU 2025-07 adds a new scope exception from derivative accounting under ASC 815 for certain non-exchange-traded contracts with customers with an underlying that is based on operations or activities specific to one of the parties to the contract. Further, ASU 2025-07 clarifies that an entity should apply the guidance in ASC 606 to a contract with stock-based noncash consideration. The ASU is effective for annual periods beginning after December 15, 2026 and interim periods within those annual periods, with early adoption permitted. We are currently evaluating the impact that ASU 2025-06 will have on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We qualify as a smaller reporting company, as defined by SEC Rule 229.10(f)(1) and are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
60 Degrees Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 60 Degrees Pharmaceuticals, Inc. and subsidiary ("the Company") as of December 31, 2025 and 2024, and the related statements of operations and comprehensive loss, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2025, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has an accumulated deficit, recurring losses and expects future losses that raise substantial doubt about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RBSM LLP

PCAOB ID Number 587

We have served as the Company's auditor since 2022.

Las Vegas, Nevada

March 30, 2026

60 DEGREES PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS:		
Current Assets:		
Cash and Cash Equivalents	$ 1,510,065	$ 1,659,353

Accounts Receivable	509,644	486,748
Prepaid and Other Assets	978,131	1,068,940
Short-Term Investments	1,240,721	1,728,472
Inventory (Note 3)	656,924	442,764
Total Current Assets	**4,895,485**	**5,386,277**
Property and Equipment, net (Note 4)	246,365	149,808
Other Assets:		
Long-Term Prepaid Expense	-	66,176
Intangible Assets, net (Note 5)	224,361	157,084
Total Other Assets	**224,361**	**223,260**
Total Assets	**$ 5,366,211**	**$ 5,759,345**
LIABILITIES AND SHAREHOLDERS' EQUITY:		
Current Liabilities:		
Accounts Payable and Accrued Expenses	$ 1,459,279	$ 1,007,618
SBA EIDL (*including accrued interest*) (Note 7)	8,772	8,772
Derivative Liabilities (Note 8)	374,741	640,830
Total Current Liabilities	**1,842,792**	**1,657,220**
Long-Term Liabilities:		
SBA EIDL (*including accrued interest*) (Note 7)	144,003	147,119
Total Long-Term Liabilities	**144,003**	**147,119**
Total Liabilities	**1,986,795**	**1,804,339**
Commitments and Contingencies (Note 11)		
SHAREHOLDERS' EQUITY:		
Series A Preferred Stock, $0.0001 par value, 1,000,000 shares authorized; 76,480 and 76,480 issued and outstanding as of December 31, 2025 and December 31, 2024, respectively (Note 6)	9,567,439	9,567,439
Common Stock, $0.0001 par value, 150,000,000 shares authorized; 1,163,142 and 141,749 issued and outstanding as of December 31, 2025 and December 31, 2024, respectively[(1)] (Note 6)	116	14
Additional Paid-in Capital[(1)]	41,646,139	34,860,633
Accumulated Other Comprehensive Income	142,598	135,471
Accumulated Deficit	(47,893,115)	(40,527,957)
60P Shareholders' Equity:	3,463,177	4,035,600
Noncontrolling Interest	(83,761)	(80,594)
Total Shareholders' Equity	**3,379,416**	**3,955,006**
Total Liabilities and Shareholders' Equity	**$ 5,366,211**	**$ 5,759,345**

(1) Periods presented have been adjusted to reflect the 1:4 reverse stock split on January 20, 2026.

See accompanying notes to these consolidated financial statements which are an integral part of these consolidated financial statements.

60 DEGREES PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Years Ended December 31,	
	2025	**2024**
Product Revenues – net of Discounts and Rebates	$ 1,005,471	$ 607,574
Cost of Revenues	781,695	384,765
Gross Profit	223,776	222,809
Research Revenues	403,624	73,771
Net Revenue	627,400	296,580
Operating Expenses:		
Research and Development	2,106,156	4,986,526
General and Administrative Expenses	6,279,823	5,025,235
Total Operating Expenses	8,385,979	10,011,761
Loss from Operations	(7,758,579)	(9,715,181)
Interest Expense	(7,805)	(7,912)
Change in Fair Value of Derivative Liabilities	266,089	1,665,966
Other Income, net	131,970	101,464
Total Interest and Other Income (Expense), net	390,254	1,759,518
Loss from Operations before Provision for Income Taxes	(7,368,325)	(7,955,663)
Provision for Income Taxes (Note 9)	-	-
Net Loss including Noncontrolling Interest	(7,368,325)	(7,955,663)
Net Loss – Noncontrolling Interest	(3,167)	(8,556)
Net Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	(7,365,158)	(7,947,107)
Comprehensive Loss:		

Net Loss	(7,368,325)	(7,955,663)
Unrealized Foreign Currency Translation Gain (Loss)	7,127	(90)
Total Comprehensive Loss	(7,361,198)	(7,955,753)
Net Loss – Noncontrolling Interest	(3,167)	(8,556)
Comprehensive Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	(7,358,031)	(7,947,197)
Cumulative Dividends on Series A Preferred Stock	(501,056)	(483,301)
Net Loss - attributed to common stockholders	**$ (7,859,087)**	**$ (8,430,498)**
Net Loss per Common Share[1]		
Basic and Diluted	$ (11.73)	$ (74.17)
Weighted Average Number of Common Shares Outstanding[1]		
Basic and Diluted	670,211	113,665

(1) Periods presented have been adjusted to reflect the 1:4 reverse stock split on January 20, 2026.

See accompanying notes to these consolidated financial statements which are an integral part of these consolidated financial statements.

60 DEGREES PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

For the Year Ended December 31, 2025

	Series A Preferred Stock		Common Stock[1]		Additional Paid-In Capital[1]	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity Attributable to 60P	Noncontrolling Interest on Shareholders	Total Shareholders' Equity
	Shares	Amount	Shares	Amount						
Balance—December 31, 2024	76,480	$ 9,567,439	141,749	$ 14	$ 34,860,633	$ (40,527,957)	$ 135,471	$ 4,035,600	$ (80,594)	$ 3,955,006
Issuance of common stock and warrants pursuant to January 2025 Offering, net of offering costs paid at closing and deferred offering costs (Note 6)	-	-	51,079	5	804,341	-	-	804,346	-	804,346
Issuance of common stock and warrants pursuant to February 2025 Offering, net of offering costs paid at closing and deferred offering costs (Note 6)	-	-	75,176	8	908,619	-	-	908,627	-	908,627
Issuance of common stock upon exercise of Pre-Funded Warrants	-	-	315,869	31	2,773	-		2,804	-	2,804
Issuance of shares for annual performance bonuses, net of shares withheld for taxes	-	-	3,953	-	103,544	-	-	103,544	-	103,544
Issuance of common stock and warrants pursuant to July 2025 Offering, net of offering costs paid at closing and deferred offering costs (Note 6)	-	-	438,332	44	4,281,256	-	-	4,281,300	-	4,281,300
Issuance of common stock pursuant to ATM Offering, net of offering costs paid at closing and deferred offering costs (Note 6)	-	-	136,991	14	405,100	-	-	405,114	-	405,114
Share rounding adjustment for 1:5 Reverse Stock Split	-	-	(7)	-	-	-	-	-	-	-
Share-based compensation expense	-	-	-	-	279,873	-	-	279,873	-	279,873
Net foreign translation gain	-	-	-	-	-	-	7,127	7,127	-	7,127
Net loss	-	-	-	-	-	(7,365,158)	-	(7,365,158)	(3,167)	(7,368,325)
Balance— December 31, 2025	**76,480**	**$ 9,567,439**	**1,163,142**	**$ 116**	**$ 41,646,139**	**$ (47,893,115)**	**$ 142,598**	**$ 3,463,177**	**$ (83,761)**	**$ 3,379,416**

For the Year Ended December 31, 2024

	Series A Preferred Stock		Common Stock[1]		Additional Paid-In Capital[1]	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity Attributable to 60P	Noncontrolling Interest on Shareholders	Total Shareholders' Equity
	Shares	Amount	Shares	Amount						
Balance—December 31, 2023	**78,803**	**$ 9,858,040**	**24,226**	**$ 2**	**$ 27,457,381**	**$ (32,580,850)**	**$ 135,561**	**$ 4,870,134**	**$ (72,038)**	**$ 4,798,096**
Issuance of common stock and warrants, net of underwriting discounts and offering costs paid at closing and deferred offering costs (Note 6)	-	-	21,922	2	1,898,294	-	-	1,898,296	-	1,898,296
Issuance of common stock upon exercise of Pre-Funded Warrants	-	-	52,792	5	10,958	-	-	10,963	-	10,963
Issuance of shares for RSUs	-	-	1,070	-	-	-		-	-	-
Voluntary return of shares issued to vendor for services	-	-	(500)	-	-	-	-	-	-	-
Voluntary conversion of Series A Preferred Stock into common stock	(2,323)	(290,601)	3,667	1	290,600	-	-	-	-	-
Issuance of common stock pursuant to ATM Offering, net of offering costs paid at closing and deferred offering costs (Note 6)	-	-	33,897	3	1,729,807	-	-	1,729,810	-	1,729,810
Issuance of warrants in Private Placement, net of offering costs paid at closing and deferred offering costs (Note 6)	-	-	-	-	3,414,502	-	-	3,414,502	-	3,414,502
Issuance of common stock for fractional shares pursuant to 1:12 Reverse Stock Split rounding adjustment	-	-	4,675	1	(1)	-	-	-	-	-
Share-based compensation to vendors for services	-	-	-	-	26,325	-	-	26,325	-	26,325
Share-based compensation expense	-	-	-	-	32,767	-	-	32,767	-	32,767
Net foreign translation loss	-	-	-	-	-	-	(90)	(90)	-	(90)
Net loss	-	-	-	-	-	(7,947,107)	-	(7,947,107)	(8,556)	(7,955,663)
Balance— December 31, 2024	**76,480**	**$ 9,567,439**	**141,749**	**$ 14**	**$ 34,860,633**	**$ (40,527,957)**	**$ 135,471**	**$ 4,035,600**	**$ (80,594)**	**$ 3,955,006**

(1) Periods presented have been adjusted to reflect the 1:4 reverse stock split on January 20, 2026.

See accompanying notes to these consolidated financial statements which are an integral part of these consolidated financial statements.

60 DEGREES PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Years Ended December 31,	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (7,368,325)	$ (7,955,663)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation	43,324	11,726
Amortization	39,548	38,502
Amortization of ROU Asset	-	13,517
Amortization of Capitalized Share-Based Payments	176,471	3,575,881
Share-Based Compensation under Equity Incentive Plan	279,873	32,767
Change in Fair Value of Derivative Liabilities	(266,089)	(1,665,966)
Write-offs of Capitalized Patents	-	108,424
Change in Inventory Reserve	251,677	-
Changes in Operating Assets and Liabilities:		
Accounts Receivable	(22,896)	(255,416)
Prepaid and Other Assets	(19,486)	(39,423)
Inventory	(465,837)	23,405
Accounts Payable and Accrued Liabilities	491,083	501,412
Accrued Interest, net	11,635	(23,604)
Reduction of Lease Liability	-	(13,650)
Net Cash Used in Operating Activities	**(6,849,022)**	**(5,648,088)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Capitalization of Patents	(55,533)	(51,967)
Purchases of Fixed Assets	(139,881)	(103,773)
Acquisition of Intangibles	(22,670)	(25,374)
Purchase of Short-Term Investments	(1,235,000)	(1,708,000)
Maturities of Short-Term Investments	1,708,000	-
Net Cash Provided by (Used in) Investing Activities	**254,916**	**(1,889,114)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Net Proceeds from January 2024 Offering	-	1,898,296
Net Proceeds from January 2025 Offering	804,346	-
Net Proceeds from February 2025 Offering	908,627	-
Net Proceeds from July 2025 Offering	4,281,300	-
Shares Withheld for Net Share Settlement of Performance Bonuses	(18,000)	-
Net proceeds from ATM Offering	458,614	1,729,810
Net proceeds from Private Placement	-	3,414,502
Proceeds from Exercise of Pre-Funded Warrants	2,804	10,963
Net Cash Provided by Financing Activities	**6,437,691**	**7,053,571**
Effect of Exchange Rate Changes on Cash	7,127	499
Change in Cash and Cash Equivalents	(149,288)	(483,132)
Cash and Cash Equivalents—Beginning of Period	1,659,353	2,142,485
Cash and Cash Equivalents—End of Period	**$ 1,510,065**	**$ 1,659,353**
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid During the Year for Interest	$ 8,772	$ 8,772
Cash paid During the Year for Income Taxes	$ -	$ -
NONCASH INVESTING/FINANCING ACTIVITIES		
Conversion of Series A Preferred Stock into Common Stock	$ -	$ 290,601
Capitalized Share-Based Payments to Vendors	$ -	$ 26,325
Fair Value of Warrants Issued to Underwriters	$ -	$ 71,364
Capitalized Patent Costs included in Accounts Payable	$ 24,292	$ -
Capitalized Website Costs included in Accounts Payable	$ 4,330	$ -
ATM Offering Costs included in Accounts Payable	$ 53,500	$ -
Gross Shares Issued for Annual Performance Bonuses	$ 121,544	$ -

See accompanying notes to these consolidated financial statements which are an integral part of these consolidated financial statements.

1. NATURE OF OPERATIONS

60 Degrees Pharmaceuticals, Inc. was incorporated in Delaware on June 1, 2022 and merged on the same day with 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company organized on September 9, 2010 ("60P LLC"). 60 Degrees Pharmaceuticals, Inc. and its subsidiary (referred to collectively as the "Company", "60P", or "60 Degrees Pharmaceuticals") is a specialty pharmaceutical company that specializes in the development and marketing of new medicines for the treatment and prevention of infectious diseases. 60P achieved FDA approval of its lead product, ARAKODA® (tafenoquine), for malaria prevention, in 2018. Currently, 60P's pipeline under development covers development programs for vector-borne 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 and/or botanical extracts from Australian Chestnut Trees. The Company's headquarters are located in Washington, D.C., with a majority-owned subsidiary in Australia.

Since the Company's initial public offering in July 2023, its common stock has been listed and trades on The Nasdaq Capital Market under the symbol "SXTP," and tradeable warrants under the symbol "SXTPW."

Risks and Uncertainties

The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, the risks associated with developing product candidates and successfully launching and commercializing its drug/device combination products, the Company's ability to obtain regulatory approval of its such products in the United States and other geography markets, the uncertainty of the broad adoption of its approved products by physicians and consumers, and significant competition.

In addition, higher rates of inflation have resulted in the U.S. Federal Reserve raising interest rates. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Furthermore, if additional banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, the Company or its partners' ability to access existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on the Company's business and financial condition, including the Company's ability to access additional capital on favorable terms, or at all, which could in the future negatively affect the Company's ability to pursue its business strategy.

Going Concern

The Company's future results are subject to substantial risks and uncertainties. Since its inception, the Company has not demonstrated the ability to generate enough revenues to date to cover operating expenses and has accumulated losses to date. At December 31, 2025, the Company had cash and cash equivalents totaling $1,510,065, as compared to cash and cash equivalents totaling $1,659,353 at December 31, 2024. During the year ended December 31, 2025, the Company used cash of $6,849,022 in its operating activities ($5,648,088 during the year ended December 31, 2024). The Company's capital commitments over the next twelve months include interest and principal payments on the Company's debt arrangement of $8,772, $1,459,279 to satisfy accounts payable and accrued expenses, and $18,775 payable under its short-term lease arrangement. In addition, the Company is subject to certain royalty obligations based on future net product sales (See Note 11).

To date, the Company has funded its operations primarily with proceeds from sales of common stock and warrants for the purchase of common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements.

Continuation as a going concern is dependent upon the Company's ability to meet its financial requirements, raise additional capital, and achieve gross profitability from the Company's single marketed product. To achieve profitability, the Company expects it will need to raise additional capital to fund its activities relating to commercial support for its existing product and any future clinical research trials and operating activities. However, there can be no assurance that it will ever achieve or maintain profitability. These conditions, among others, raise substantial doubt about the ability of the Company to continue as a going concern for one year from the date these financial statements are issued.

Management plans to fund operations of the Company through third party and related party debt/advances, private placement of restricted securities and the issuance of stock in a subsequent offering until such a time as the business achieves profitability or a business combination may be achieved. However, there can be no assurance that the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are favorable to the Company. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises funds through collaborations, or other similar arrangements with third parties, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company and/or may reduce the value of its common stock. If the Company is unable to raise additional funds through equity or debt financings when needed, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market its product candidates even if the Company would otherwise prefer to develop and market such product candidates itself.

As such, management concluded that such plans do not alleviate the substantial doubt about the ability of the Company to continue as a going concern for one year from the date these financial statements are issued.

These financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of obligations in the normal course of business, and do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company be unable to continue as a going concern.

---

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The financial statements of 60P and its subsidiary are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The Company has prepared the accompanying consolidated financial statements pursuant to the instructions to Form 10-K and Article 8 of

Regulation S-X of the Securities and Exchange Commission ("SEC"). In the opinion of management, all adjustments considered necessary for a fair presentation of the Company's financial position, results of operations and cash flows have been included and are of a normal and recurring nature.

Principles of Consolidation and Noncontrolling Interest

The Company's consolidated financial statements include the financial statements of its 96.61% owned subsidiary, 60P Australia Pty Ltd. All significant intercompany accounts and transactions have been eliminated in consolidation.

For entities that are consolidated, but not 100% owned, a portion of the income or loss and corresponding equity is allocated to owners other than the Company. The aggregate of the income or loss and corresponding equity that is not owned by us is included in Noncontrolling Interest in the consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates, and those estimates may be material. Significant estimates include the reserve for inventory, the fair value of derivative liabilities, and stock-based compensation.

Reverse Stock Splits

Following stockholder approval in July 2024, the Company effected a reverse stock split at a ratio of 1:12 (the "1:12 Reverse Stock Split"), which was effective as of August 12, 2024. Following stockholder approval in November 2024, the Company effected an additional reverse stock split at a ratio of 1:5 (the "1:5 Reverse Stock Split), which was effective as of February 24, 2025. Following stockholder approval in October 2025, the Company effected an additional reverse stock split at a ratio of 1:4 (the "1:4 Reverse Stock Split" and together with the 1:12 Reverse Stock Split and the 1:5 Reverse Stock Split, the "Reverse Stock Splits"), which was effective January 20, 2026 (See Note 12 – Subsequent Events).

Proportional adjustments were made to the number of shares of common stock issuable upon exercise or conversion of the Company's equity awards, warrants, and other equity instruments convertible into common stock, as well as the respective exercise prices, if applicable, in accordance with the terms of the instruments. Unless otherwise noted, all references to numbers of shares of the Company's common stock and per share information presented in these consolidated financial statements have been retroactively adjusted, as appropriate, to reflect the Reverse Stock Splits, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

Cash and Cash Equivalents

The Company's cash consists of cash deposited in demand accounts at financial institutions, which are insured by the Federal Deposit Insurance Corporation ("FDIC"). The Company considers short-term highly liquid investments with original maturities of three months or less to be cash equivalents. The Company's cash and cash equivalents, at times, may exceed the FDIC insurable limits (currently $250,000). The Company has not experienced any losses related to amounts in excess of FDIC Limits. The Company periodically assesses the credit risk associated with these financial institutions and believes that the risk of loss is minimal.

Short-Term Investments

Short-term investments consist of certificates of deposit with original maturities of greater than three months and less than twelve months, which are classified as held-to-maturity as the Company has the intent and ability to hold these investments until they mature. The classification of short-term investments is determined at the time of purchase and is reevaluated at each balance sheet date. Short-term investments are reported at amortized cost.

Accounts Receivable and Allowance for Doubtful Accounts

The Company records accounts receivable at net realizable value. This value includes an appropriate allowance for estimated uncollectible accounts to reflect any loss anticipated on the trade accounts receivable balances and charged to the provision for doubtful accounts. Based on the Company's history there has been no need to make a recording to Allowance for Doubtful Accounts. Most of the Company's revenue has been earned via government contracts, an Australian pharmaceutical distributor and a large American pharmaceutical distributor. There was no allowance as of December 31, 2025 and December 31, 2024. As the Company continues to engage with smaller distributors, it will continue to analyze whether an allowance should be established. As of December 31, 2025, the U.S. pharmaceutical distributor accounted for 97% of the accounts receivable balance (95% as of December 31, 2024).

Inventory

Inventories are stated at the lower of cost or net realizable value. Cost is comprised of direct materials and, where applicable, costs that have been incurred in bringing the inventories to their present location and condition. The Company uses the Specific Identification method per lot. A box or a bottle price is calculated per lot number and sales are recognized by their lot number.

The Company regularly monitors its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value, and records write-downs for inventory that has expired, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected sales requirements. Any write-downs of inventories are charged to Cost of Revenues in the Consolidated Statements of Operations and Comprehensive Loss. During the year ended December 31, 2025, write-downs for expired inventory totaled $445,181 ($22,046 for the year ended December 31, 2024).

Property and Equipment

Property and equipment are stated at cost. Normal repairs and maintenance costs are charged to earnings as incurred and additions and major improvements are capitalized. The cost of assets retired or otherwise disposed of and the related depreciation are eliminated from the accounts in the period of disposal and the resulting gain or loss is credited or charged to earnings.

Depreciation is computed over the estimated useful lives of the related asset type or term of the operating lease using the straight-line method for financial statement purposes. The estimated service lives for Property and Equipment are either three (3), five (5) or seven (7) years.

Impairment of Long-lived Assets

Long-lived assets, such as property and equipment and identifiable intangibles with finite useful lives, are periodically evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company monitors for potential indicators of a trigger event for asset impairment, including whether there is an adverse change in the extent or manner in which an asset is being used or its physical condition. Assets are grouped and evaluated for impairment at the lowest level of which there are identifiable cash flows, which is generally at a location level. Assets are reviewed using factors including, but not limited to, future operating plans and projected cash flows. The determination of whether impairment has occurred is based on an estimate of undiscounted future cash flows directly related to the assets, compared to the carrying value of the assets. If the sum of the undiscounted future cash flows of the assets does not exceed the carrying value of the assets, full or partial impairment may exist. If the asset's carrying amount exceeds its fair value, an impairment charge is recognized in the amount by which the carrying amount exceeds the fair value of the asset. Fair value is determined using an income approach, which requires discounting the estimated future cash flows associated with the asset.

Intangible Assets

The Company capitalizes its patent and filing fees and legal patent and prosecution fees in connection with internally developed pending patents. When pending patents are issued, patents will be amortized over the expected period to be benefitted, not to exceed the patent lives, which may be as long as ten to fifteen years.

Website Development Costs

The Company accounts for website development costs in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Subtopic No. 350-50, *Website Development Costs*. Accordingly, all costs incurred in the planning stage are expensed as incurred, costs incurred in the website application and infrastructure development stage that meet specific criteria are capitalized and costs incurred in the day-to-day operation of the website are expensed as incurred. All costs associated with the websites are subject to straight-line amortization over a three-year period.

Derivative Liabilities

The Company assesses the classification of its derivative financial instruments each reporting period, which formerly consisted of bridge shares, convertible notes payable, and certain warrants, and determined that such instruments initially qualified for treatment as derivative liabilities as they met the criteria for liability classification under ASC 815. As of December 31, 2025, the Company's derivative financial instruments consist of contingent payment arrangements.

The Company analyzes all financial instruments with features of both liabilities and equity under FASB ASC Topic No. 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and FASB ASC Topic No. 815, *Derivatives and Hedging* ("ASC 815"). Derivative liabilities are adjusted to reflect fair value at each reporting period, with any increase or decrease in the fair value recorded in the results of operations, as a component of other income or expense as change in fair value of derivative liabilities. The Company uses a probability-weighted expected return method to determine the fair value of these instruments.

Upon conversion or repayment of a debt or equity instrument in exchange for equity shares, where the embedded conversion option has been bifurcated and accounted for as a derivative liability (generally convertible debt and warrants), the Company records the equity shares at fair value on the date of conversion, relieves all related debt, derivative liabilities, and unamortized debt discounts, and recognizes a net gain or loss on debt extinguishment, if any.

Equity or liability instruments that become subject to reclassification under ASC Topic 815 are reclassified at the fair value of the instrument on the reclassification date.

Equity-Classified Warrants

As of December 31, 2025, the Company accounts for all outstanding warrants to purchase common stock as equity-classified instruments based on an assessment of the warrants' specific terms and applicable authoritative guidance in ASC 480 and ASC 815. This assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the respective issuance dates and as of each subsequent reporting period while the warrants are outstanding.

Income Taxes

60 Degrees Pharmaceuticals, Inc. is a corporation for U.S. Federal and state income tax purposes. The tax years that remain subject to examination by major tax jurisdictions include the years ended December 31, 2022, 2023, 2024 and 2025. 60P Australia Pty Ltd. is subject to taxation by the Australian Taxation Office.

Management assesses, on a jurisdictional basis, the available means of recovering deferred tax assets, including the ability to carry-back net operating losses, the existence of reversing temporary differences, the availability of tax planning strategies and available sources of future taxable income. On the basis of this evaluation, the Company has determined that it is not more likely than not that the Company will recognize the benefits of its net deferred tax assets, and, as a result, a full valuation allowance has been recorded against its net deferred tax assets as of December 31, 2025 and December 31, 2024.

During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. The Company establishes reserves for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These reserves are established when the Company believes that certain positions might be challenged despite its belief that its tax return positions are fully supportable. The

Company adjusts these reserves in light of changes in facts and circumstances, such as the outcome of tax examinations. As of December 31, 2025 and December 31, 2024, no reserves for uncertain tax positions have been established.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the years ended December 31, 2025 and 2024, the Company did not recognize interest and penalties related to unrecognized tax benefits.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments, accounts receivable, inventory purchases, and borrowings.

Significant customers represent any customer whose business makes up 10% of receivables or revenues. At December 31, 2025, significant customers represented 97% of receivables (consisting of three customers and one significant customer) and 92% of total net product revenues (consisting of three customers and one significant customer). At December 31, 2024, significant customers represented 95% of receivables (consisting of three customers and one significant customer) and 95% of total net product revenues (consisting of three customers and one significant customer).

Currently, the Company has exclusive relationships with distributors in Australia and Europe. A failure to perform by any of our current distributors would create disruption for patients in those markets.

Since the Company first started working on tafenoquine all inventory has been acquired in a collaborative relationship from a sole vendor. Should the vendor cease to supply tafenoquine it would take significant costs and efforts to rebuild the supply chain with a new sole vendor sourcing the active pharmaceutical ingredient ("API").

Segment Information

Since its inception, the Company operates and manages its business as a single identifiable segment, focused on the development and marketing of new medicines for the treatment and prevention of infectious diseases. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM").

The Company's CODM is its Chief Executive Officer, who reviews and evaluates consolidated net income or loss for purposes of evaluating performance, making operating decisions, allocating resources, and planning and forecasting for future periods. The significant components of consolidated net income or loss regularly provided to the CODM include net product revenues and the significant expense categories presented in the accompanying Consolidated Statements of Operations and Comprehensive Loss (cost of revenues, research and development, and general and administrative expenses). These are presented at the consolidated level and used by the CODM to monitor budgeted versus actual results to make key operating decisions. The information and operating expense categories presented in the accompanying Consolidated Statements of Operations and Comprehensive Loss are fully reflective of the significant expense categories and amounts that are regularly provided to the CODM.

The measure of segment assets that is regularly reported to the CODM includes cash and cash equivalents and short-term investments, each as reported on the Consolidated Balance Sheets. Total consolidated cash and cash equivalents and short-term investments were $2,750,786 and $3,387,825 as of December 31, 2025 and December 31, 2024, respectively.

Revenue Recognition

The Company recognizes revenue in accordance with FASB ASC Topic No. 606, *Revenue from Contracts with Customers* ("ASC 606"). Revenues are recognized when control is transferred to customers in amounts that reflect the consideration the Company expects to be entitled to receive in exchange for those goods. Revenue recognition is evaluated through the following five steps: (i) identification of the contract, or contracts, with a customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the performance obligations in the contract; and (v) recognition of revenue when or as a performance obligation is satisfied. As part of the accounting for these arrangements, the Company may be required to make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

Revenues from product sales are recorded at the net sales price, or "transaction price," which may include estimates of variable consideration that result from product returns. The Company determines the amount of variable consideration by using either the expected value method or the most-likely-amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price, which reflects the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment. Reserves are established for the estimates of variable consideration based on the amounts the Company expects to be earned or to be claimed on the related sales.

The Company receives the majority of its revenues from sales of its Arakoda™ product to resellers in the US and abroad. The Company records US commercial revenues as a receivable when our American distributor transfers shipped product to their title model for 60P. Foreign sales to both Australia and Europe are recognized as a receivable at the point product is shipped to distributor. Historically, the shipments to Australia and Europe were further subject to profit sharing agreements for boxes sold to customers.

In addition to revenue from product sales, beginning in the third quarter of 2024, the Company recognizes research revenues associated with its contract with the United States Army Medical Materiel Development Activity (USAMMDA) for Arakoda supply chain upgrade support. Research revenue under this contract is recognized when the direct costs eligible for reimbursement are incurred, up to the maximum allowable amount. Other research revenues consist of sales of clinical trial supplies, which are recognized at a point in time, and research rebates earned from the Australian Tax Authority, which are recognized over time as qualifying research activities in Australia are performed.

Research and Development Costs

The Company accounts for research and development costs in accordance with FASB ASC Subtopic No. 730-10, *Research and Development* ("ASC 730-10"). Under ASC 730-10, research and development costs are expensed as incurred. Accordingly, internal research and development costs are expensed as incurred. Prepayments for research and development services are deferred and amortized over the service period as the services are provided. Advance payments for specific materials, equipment, or facilities determined to have no alternative future use are initially deferred and recognized as research and development expense when the related goods are delivered.

The Company recorded $2,106,156 in research and development costs during the year ended December 31, 2025 ($4,986,526 for the year ended December 31, 2024). The Company has also issued shares of common stock to nonemployees in exchange for research and development services. The Company recognizes prepaid research and development costs on the grant date, as defined in FASB ASC Subtopic No. 718, *Compensation – Stock Compensation*. See Note 10 for further details.

Fair Value of Financial Instruments and the Fair Value Option ("FVO")

The inputs used to measure fair value are based on a hierarchy that prioritizes observable and unobservable inputs used in valuation techniques. These levels, in order of highest to lowest priority, are described below:

Level 1 - Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities.

Level 2 - Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3 - Unobservable inputs reflecting the Company's assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The Company may choose to elect the FVO for certain eligible financial instruments, such as certain Promissory Notes, in order to simplify the accounting treatment. Items for which the FVO has been elected are presented at fair value in the Consolidated Balance Sheets and any change in fair value unrelated to credit risk is recorded in Other Expense, net in the Consolidated Statements of Operations and Comprehensive Loss. Changes in fair value related to credit risk are recognized in Other Comprehensive Loss. As a result of the completion of the IPO, all financial instruments for which the FVO was elected were extinguished. See Note 7 for more information on the extinguishment of the Promissory Notes.

The Company's financial instruments recorded at fair value on a recurring basis at December 31, 2025, and December 31, 2024 include the derivative liability associated with the contingent milestone payment due to Knight upon a future sale of Arakoda™ or a Change of Control, which is carried at fair value based on Level 3 inputs. The Company uses a probability-weighted expected return method to determine the fair value of the contingent milestone payment using significant inputs such as the timing and probability of discrete potential exit scenarios, forward interest rate curves, and discount rates based on implied and market yields. See Note 8 for more information on Derivative Liabilities.

Liabilities measured at fair value at December 31, 2025 and 2024 are as follows:

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Derivative Liabilities	$ -	$ -	$ 374,741	$ 374,741
Total	$ -	$ -	$ 374,741	$ 374,741

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Derivative Liabilities	$ -	$ -	$ 640,830	$ 640,830
Total	$ -	$ -	$ 640,830	$ 640,830

There were no transfers of financial instruments between Level 1, Level 2, and Level 3 during the periods presented. A rollforward of liabilities measured at fair value using Level 3 inputs outstanding during the years ended December 31, 2025 and 2024 is presented in Note 8 (Derivative Liabilities).

Assets and Liabilities Not Measured at Fair Value on a Recurring Basis

In addition to assets and liabilities that are measured at fair value on a recurring basis, the Company also measures certain assets and liabilities at fair value on a non-recurring basis. The Company's non-financial assets, including Intangible Assets and Property and Equipment, are measured at fair value when there is an indication of impairment and the carrying amount exceeds the asset's projected undiscounted cash flows. These assets are recorded at fair value only when an impairment charge is recognized.

As of December 31, 2025 and 2024, the carrying value of the Company's financial instruments included in current assets and current liabilities (such as cash, accounts receivable, accounts payable, and accrued expenses) approximate their fair value due to the short-term nature of such instruments. Certificates of deposit, classified as cash equivalents or short-term investments depending on the instrument's original time to maturity, are measured at amortized cost, which approximates fair value as of December 31, 2025 and 2024.

Foreign Currency Transactions and Translation

The individual financial statements of each group entity are measured and presented in the currency of the primary economic environment in which the entity operates (its functional currency). The consolidated financial statements of the Company are presented in US dollars, which is the functional currency of the Company and the presentation currency for the consolidated financial statements.

For the purpose of presenting consolidated financial statements, the assets and liabilities of the Company's foreign operations are mostly translated at exchange rates prevailing on the reporting date. Income and expense items are translated at the average exchange rates for the period, unless exchange rates

fluctuate significantly during that period, in which case the exchange rates at the dates of the transactions are used. Exchange differences arising, if any, are recognized as a component of other comprehensive income (loss) as Unrealized Foreign Currency Translation Gain or Loss.

Exchange rates along with historical rates used in these financial statements are as follows:

	Average Exchange Rate			
	Year Ended December 31,		As of	
Currency	2025	2024	December 31, 2025	December 31, 2024
1 AUD =	0.64 USD	0.66 USD	0.67 USD	0.62 USD

Reclassifications

Certain prior period amounts have been reclassified for consistency with the current period presentation. These reclassifications had no material effect on the consolidated results of operations and comprehensive loss, shareholders' equity, or cash flows.

Share-Based Payments

On November 22, 2022, the Company adopted the 2022 Equity Incentive Plan also referred to as ("2022 Plan"). The 2022 Plan and related share-based awards are discussed more fully in Note 10.

The Company accounts for share-based payments in accordance with ASC Subtopic 718, *Compensation - Stock Compensation* ("ASC 718"). The Company measures compensation for all share-based payment awards granted to employees, directors, and nonemployees, based on the estimated fair value of the awards on the date of grant. For awards that vest based on continued service, the service-based compensation cost is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the awards. For service vesting awards with compensation expense recognized on a straight-line basis, at no point in time does the cumulative grant date value of vested awards exceed the cumulative amount of compensation expense recognized. The grant date is determined based on the date when a mutual understanding of the key terms of the share-based awards is established. The Company accounts for forfeitures as they occur.

The Company estimates the fair value of all stock option awards as of the grant date by applying the Black-Scholes option pricing model. The application of this valuation model involves assumptions, including the fair value of the common stock, expected volatility, risk-free interest rate, expected dividends and the expected term of the option. Due to the lack of a public market for the Company's common stock prior to the IPO and lack of company-specific historical implied volatility data, the Company has based its computations of expected volatility on the historical volatility of a representative group of public companies with similar characteristics of the Company, including stage of development and industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company generally uses the simplified method as prescribed by the SEC Staff Accounting Bulletin Topic 14, *Share-Based Payment*, to estimate the expected term for stock options, whereby, the expected term equals the midpoint of the weighted average remaining time to vest, vesting period and the contractual term of the options due to its lack of historical exercise data. For certain options granted out-of-the-money, the Company's best estimate of the expected term is the contractual term of the award. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The assumptions used in calculating the fair value of share-based awards represent management's best estimates and involve inherent uncertainties and the application of significant judgment.

Compensation expense for restricted stock units ("RSUs") with only service-based vesting conditions is recognized on a straight-line basis over the vesting period. Compensation cost for service-based RSUs is based on the grant date fair value of the award, which is the closing market price of the Company's common stock on the grant date multiplied by the number of shares awarded.

For awards that vest upon a liquidity event or a change in control, the performance condition is not probable of being achieved until the event occurs. As a result, no compensation expense is recognized until the performance-based vesting condition is achieved, at which time the cumulative compensation expense is recognized. Compensation cost related to any remaining time-based service for share-based awards after the liquidity-based event is recognized on a straight-line basis over the remaining service period.

For fully vested, nonforfeitable equity instruments that are granted at the date the Company and a nonemployee enter into an agreement for goods or services, the Company recognizes the fair value of the equity instruments on the grant date. The corresponding cost is recognized as an immediate expense or a prepaid asset and expensed over the service period depending on the specific facts and circumstances of the agreement with the nonemployee. See Note 10 for further details.

Net Loss per Common Share

Net Loss per Common Share is computed by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding during each period. The Company has included the Pre-Funded Warrants issued in January 2024 and September 2024 (See Note 6) in its computation of basic and diluted net loss per share due to their nominal exercise prices. The cumulative dividends accrued on the Series A Preferred Stock during the period are reflected as an addition to net loss in determining basic and diluted net loss attributable to common stockholders.

As the Company has reported a net loss for all periods presented, the calculation of diluted net loss per common share is the same as basic net loss per common share for those periods.

As a result of the Reverse Stock Splits, which were effective as of August 12, 2024 at a ratio of 1:12, February 24, 2025 at a ratio of 1:5, and January 20, 2026 at a ratio of 1:4, all shares of outstanding common stock and net loss per common share calculations have been retroactively adjusted for all periods presented.

Related Parties

Parties are considered to be related to the Company if the parties, directly or indirectly, through one or more intermediaries, control, are controlled by, or are under common control with the Company. Related parties also include principal owners of the Company, its management, members of the immediate families of principal owners of the Company and its management and other parties with which the Company may deal with if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through March 30, 2026, which is the date the financial statements were issued. See Note 12.

Recently Adopted and Issued Accounting Pronouncements

From time to time, the FASB issues Accounting Standards Updates ("ASU") to amend the authoritative literature in the ASC. The Company regularly evaluates new ASUs to determine the impact that these pronouncements may have on the consolidated financial statements. Other than the pronouncements listed below, the Company believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, or (iii) are not applicable to the Company's consolidated financial statements or related disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07") which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses and segment profit or loss. ASU 2023-07 also requires entities with a single reportable segment to provide all segment disclosures under ASC 280, including the new required disclosures under the ASU. The Company adopted ASU 2023-07 on a retrospective basis for the 2024 annual period, and for interim periods beginning in 2025. The impact is limited to the Company's financial statement disclosures, which are presented in the Segment Information section above.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (ASC 740): Improvements to Income Tax Disclosures* ("ASU 2023-09") which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 was effective for the Company's annual period ending December 15, 2025. The impact of the adoption is limited to the Company's financial statement disclosures, which are presented on a prospective basis. See Note 9 – Income Taxes.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which applies to all public business entities that file financial statements with the SEC. The amendments in this ASU require public business entities to disclose on an annual and interim basis, disaggregated information about certain income statement expense line items. The new standard is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. The Company is currently evaluating the impact that ASU 2024-03 will have on its financial statement disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software* ("ASU 2025-06"), which amends certain aspects of the accounting for and disclosure of software costs under ASC 350-40. The amendments modernize the recognition and disclosure framework for internal-use software costs, removing the previous "development stage" model and introducing a more judgment-based approach. The ASU is effective for all entities for interim and annual periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact that ASU 2025-06 will have on its consolidated financial statements.

In September 2025, the FASB issued ASU 2025-07, *Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract* ("ASU 2025-07"). ASU 2025-07 adds a new scope exception from derivative accounting under ASC 815 for certain non-exchange-traded contracts with customers with an underlying that is based on operations or activities specific to one of the parties to the contract. Further, ASU 2025-07 clarifies that an entity should apply the guidance in ASC 606 to a contract with stock-based noncash consideration. The ASU is effective for annual periods beginning after December 15, 2026 and interim periods within those annual periods, with early adoption permitted. The Company is currently evaluating the impact that ASU 2025-06 will have on its consolidated financial statements.

3. INVENTORY

Inventory consists of the following major classes:

	December 31, 2025	December 31, 2024
Raw Material (API)	$ 75,662	$ -
Work in Process	446,957	284,883
Finished Goods	385,982	157,881
Inventory before Allowance	908,601	442,764
Reserve for Expiring Inventory	(251,677)	-
Inventory	**$ 656,924**	**$ 442,764**

4. PROPERTY AND EQUIPMENT

As of December 31, 2025 and 2024, Property and Equipment, net consists of:

	December 31, 2025	December 31, 2024

Lab Equipment	$ 366,791	$ 233,411
Machinery	55,800	55,800
Computer Equipment	11,598	7,000
Furniture	3,030	3,030
Property and Equipment, at cost	437,219	299,241
Accumulated Depreciation	(190,854)	(149,433)
Property and Equipment, Net	**$ 246,365**	**$ 149,808**

Depreciation expenses for the years ended December 31, 2025 and 2024 were in the amount of $43,324 and $11,726, respectively.

5. INTANGIBLE ASSETS

As of December 31, 2025 and 2024, Intangible Assets, net consist of:

	December 31, 2025	December 31, 2024
Patents	$ 207,428	$ 127,603
Website Development Costs	131,622	104,622
Intangible Assets, at cost	339,050	232,225
Accumulated Amortization	(114,689)	(75,141)
Intangible Assets, net	**$ 224,361**	**$ 157,084**

During the years ended December 31, 2025 and 2024, the Company capitalized website development-related costs of $27,000 and $25,374 respectively, in connection with the upgrade and enhancement of functionality of the corporate website at www.60degreespharma.com. Amortization expense for the years ended December 31, 2025, and 2024 was in the amount of $39,548 and $38,502, respectively. During the years ended December 31, 2025 and 2024, write-downs for expired or obsolete patents totaled $0 and $108,424, respectively.

The following table summarizes the estimated future amortization expense for our patents and website development costs as of December 31, 2025:

Period	Patents	Website Development Costs
2026	$ 7,337	$ 21,432
2027	7,337	12,094
2028	7,337	7,985
2029	7,337	-
2030	7,337	-
Thereafter	31,468	-
Total	**$ 68,153**	**$ 41,511**

The Company additionally has $114,697 in capitalized patent expenses that will become amortizable as the patents they are associated with are awarded.

6. STOCKHOLDERS' EQUITY

Pursuant to the Certificate of Incorporation of 60 Degrees Pharmaceuticals, Inc., the Company's authorized shares consist of (a) 150,000,000 shares of common stock, par value $0.0001 per share and (b) 1,000,000 shares of preferred stock, par value $0.0001 per share, of which 80,965 have been designated as Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"). As of December 31, 2025, 1,163,142 shares of Common Stock and 76,480 shares of Series A Preferred Stock are issued and outstanding.

Following stockholder approval in July 2024, on July 30, 2024, the Company filed an Amendment to the Certificate of Incorporation with the Secretary of State of Delaware to effect the 1:12 Reverse Stock Split of the issued and outstanding shares of the Company's common stock, which was effective as of August 12, 2024. As of the effective time of the 1:12 Reverse Stock Split, every twelve (12) issued and outstanding shares of the Company's common stock were automatically combined and converted into one (1) issued and outstanding share of the Company's common stock, reducing the number of shares of common stock outstanding from 21,219,937 shares to 1,768,337 shares (not including the effects of the 1:5 Reverse Stock Split or the 1:4 Reverse Stock Split discussed below). No fractional shares of common stock were issued in connection with the Reverse Stock Split and all fractional shares were rounded up to the nearest whole share with respect to outstanding shares of common stock. The Company issued an additional 4,675 shares of common stock on August 19, 2024 for rounding due to fractional shares (93,563 not including the effects of the 1:5 Reverse Stock Split or the 1:4 Reverse Stock Split discussed below).

Following stockholder approval in November 2024, on February 18, 2025, the Company filed an additional Amendment to the Certificate of Incorporation with the Secretary of State of Delaware to effect the 1:5 Reverse Stock Split of the issued and outstanding shares of the Company's common stock, which was effective as of February 24, 2025. As of the effective time of the 1:5 Reverse Stock Split, every five (5) issued and outstanding shares of the Company's common stock were automatically combined and converted into one (1) issued and outstanding share of the Company's common stock, reducing the number of shares of common stock outstanding from 7,364,554 shares to 1,472,891 shares (not including the effects of the 1:4 Reverse Stock Split discussed below). No fractional shares of common stock were issued in connection with the 1:5 Reverse Stock Split. All fractional shares were rounded up to the nearest whole share with respect to outstanding shares of common stock.

Following stockholder approval in October 2025, on January 14, 2026, the Company filed an additional Amendment to the Certificate of Incorporation with the Secretary of State of Delaware to effect the 1:4 Reverse Stock Split of the issued and outstanding shares of the Company's common stock, which was effective as of January 20, 2026. As of the effective time of the 1:4 Reverse Stock Split, every four (4) issued and outstanding shares of the Company's common stock were automatically combined and converted into one (1) issued and outstanding share of the Company's common stock, reducing the

number of shares of common stock outstanding from 5,436,441 shares to 1,359,091 shares. No fractional shares of common stock were issued in connection with the 1:4 Reverse Stock Split. All fractional shares were rounded up to the nearest whole share with respect to outstanding shares of common stock. See Note 12 – Subsequent Events.

The Reverse Stock Splits did not change the authorized number of shares of common stock or preferred stock, the par value of the common stock, or the number of issued and outstanding shares of Series A Preferred Stock. All references to numbers of shares of the Company's common stock and per share information in these consolidated financial statements have been retroactively adjusted, as appropriate, to reflect the Reverse Stock Splits, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

Common Stock

January 2024 Offering

On January 29, 2024, the Company, entered into an Underwriting Agreement with WallachBeth Capital LLC, relating to the Company's public offering (the "January 2024 Offering") of 21,921 units at an offering price of $92.40 per unit and 4,164 pre-funded units at an offering price of $90.00 per pre-funded unit. Each unit consisted of one share of common stock and one warrant exercisable for one share of common stock (the "January 2024 Warrants"). Each pre-funded unit consists of one pre-funded warrant exercisable for one share of common stock (the "January 2024 Pre-Funded Warrants") and one warrant identical to the January 2024 Warrants included in the units. The January 2024 Pre-Funded Warrants have an exercise price of $2.40 per share, were immediately exercisable beginning on January 31, 2024 until exercised in full. The January 2024 Warrants have an exercise price of $101.64 per share and are exercisable beginning on January 31, 2024 until January 31, 2029.

The Company granted WallachBeth Capital LLC a 45-day over-allotment option to purchase up to 3,289 shares of the Company's common stock at a price of $92.40 per share and/or 3,913 January 2024 Warrants at a price of $2.40 per warrant and/or 625 January 2024 Pre-Funded Warrants at a price of $90.00 per pre-funded warrant, or any combination thereof, in all cases less the underwriting discount. WallachBeth Capital LLC partially exercised its over-allotment option with respect to 3,410 January 2024 Warrants on January 31, 2024, and purchased an additional one share of common stock at a purchase price of $90.00 per share and one January 2024 Warrant at a purchase price of $2.40 per warrant on February 14, 2024.

The Company also issued to WallachBeth Capital LLC warrants (the "January 2024 Representative Warrants") to purchase 1,565 shares of the Company's common stock at an exercise price of $101.64 per share. The January 2024 Representative Warrants are exercisable beginning on January 31, 2024 until January 31, 2029.

The units and pre-funded units were offered and sold pursuant to the Company's Registration Statement on Form S-1 (File No. 333-276641), declared effective by the SEC on January 29, 2024. The closing of the January 2024 Offering occurred on January 31, 2024, generating net proceeds to the Company of approximately $1.9 million, after deducting underwriting discounts and commissions and the payment of other offering expenses payable by the Company of approximately $510,000.

2024 ATM Agreement

On July 12, 2024, the Company entered into an At-the-Market Issuance Sales Agreement (the "2024 ATM Agreement") with WallachBeth Capital LLC as sales agent, to sell shares of common stock having an aggregate offering price of up to $1,253,603 from time to time, through an "at the market offering" program (the "2024 ATM Offering"). The offer and sale of shares of common stock from the ATM Offering were made pursuant to the Company's shelf registration statement on Form S-3 and accompanying base prospectus (Registration Statement No. 333-280796) contained therein which became effective on July 18, 2024. The prospectus supplement was subsequently amended four times to increase the maximum aggregate offering price under the ATM Agreement. From July 19, 2024 to August 1, 2024, the Company sold a total of 33,897 shares in the ATM Offering for gross proceeds of $1,994,583. The Company and Wallachbeth Capital LLC entered into a Waiver and Termination Agreement, agreeing to terminate the 2024 ATM Agreement effective September 3, 2025.

January 2025 Offering

On January 28, 2025, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company sold, in a registered direct offering priced at-the-market under the rules of Nasdaq, an aggregate of 51,079 shares of common stock at a purchase price of $20.42 per share. The shares were offered pursuant to a "shelf" registration statement on Form S-3 (Registration No. 333-280796). In a concurrent private placement, the Company also issued to the investors unregistered warrants (the "January 2025 Warrants") to purchase up to an aggregate of 102,158 shares of common stock at an exercise price of $15.42 per share. The January 2025 Warrants are exercisable upon issuance, or January 30, 2025, and expire twenty-four months from the date of issuance, or January 30, 2027. The registered direct offering and concurrent private placement (together, the "January 2025 Offering") closed on January 30, 2025, resulting in net proceeds to the Company of approximately $804,346, after deducting the placement agent fees and other offering expenses paid by the Company.

As compensation for acting as the placement agent for the January 2025 Offering, in addition to certain cash fees, the Company issued H.C. Wainwright & Co., LLC (the "Placement Agent") warrants to purchase up to 3,833 shares of common stock at an exercise price of $25.53 (the "January 2025 Agent Warrants"). The January 2025 Agent Warrants were exercisable upon issuance and expire twenty-four months from the date of issuance.

February 2025 Offering

On February 5, 2025, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company sold, in a registered direct offering priced at-the-market under the rules of Nasdaq, an aggregate of 75,176 shares of the Company's common stock at a purchase price of $14.30 per share. In a concurrent private placement, the Company separately issued to the investors unregistered warrants to purchase up to an aggregate of 75,176 shares of common stock at an exercise price of $11.80 per share (the "February 2025 Warrants"). The February 2025 Warrants were immediately exercisable upon issuance and expire twenty-four months from the date of issuance. The registered direct offering and concurrent private placement (together, the "February 2025 Offering") closed on February 6, 2025, resulting in net proceeds to the Company of approximately $908,627, after deducting the placement agent fees and other offering expenses paid by the Company.

As compensation for acting as the placement agent for the February 2025 Offering, in addition to certain cash fees, the Company issued the Placement Agent warrants to purchase up to 5,640 shares of common stock at an exercise price of $17.88 (the "February 2025 Agent Warrants"). The February 2025 Agent Warrants were exercisable upon issuance and expire twenty-four months from the date of issuance.

July 2025 Offering

On July 15, 2025, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company sold, in a registered direct offering (the "July 2025 Offering"), 438,332 units at an offering price of $7.60 per unit and 219,569 pre-funded units at an offering price of $7.596 per pre-funded unit. Each unit consisted of (i) one share of common stock, (ii) one series A-1 warrant exercisable for one share of common stock (the "July 2025 A-1 Warrants"), and (iii) one series A-2 warrant exercisable for one share of common stock (the "July 2025 A-2 Warrants" and together with the July 2025 A-1 Warrants, the "July 2025 Warrants"). Each pre-funded unit consists of one pre-funded warrant exercisable for one share of common stock (the "July 2025 Pre-Funded Warrants") and warrants identical to the July 2025 Warrants included in the units. The July 2025 Pre-Funded Warrants have an exercise price of $0.004 per share, and were immediately exercisable beginning on July 16, 2025 until exercised in full. The July 2025 A-1 Warrants have an exercise price of $7.60 per share and are exercisable beginning on July 16, 2025 until July 15, 2030. The July 2025 A-2 Warrants have an exercise price of $7.60 per share and are exercisable beginning on July 16, 2025 until January 15, 2027.

As compensation for acting as the placement agent for the July 2025 Offering, the Company also issued to H.C. Wainwright & Co., LLC warrants (the "July 2025 Placement Agent Warrants") to purchase up to 49,342 shares of common stock. The July 2025 Placement Agent Warrants have an exercise price equal to $9.50 per share and are exercisable upon issuance, or July 16, 2025, and expire five years from the date of issuance, or July 15, 2030.

The July 2025 Offering was made pursuant to the Company's registration statement on Form S-1 (File No. 333-288550), which was declared effective by the Securities and Exchange Commission (the "SEC") on July 15, 2025, and the final prospectus, which was filed with the SEC on July 16, 2025. The Offering closed on July 16, 2025, resulting in net proceeds to the Company of approximately $4,281,300, after deducting placement agent fees and other offering expenses paid by the Company.

2025 ATM Agreement

On September 5, 2025, the Company entered into an At-The-Market Sales Agreement (the "2025 ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") pursuant to which the Company may, from time to time, offer and sell shares of its common stock, having aggregate gross sales proceeds of up to $1,397,532 (the "2025 ATM Offering"). As compensation for acting as the sales agent for the 2025 ATM Offering, Wainwright will be entitled to a commission of 3.0% of the gross proceeds from sales of shares in the 2025 ATM Offering.

The common stock under the 2025 ATM Agreement was issued and sold pursuant to the Company's shelf registration statement on Form S-3 and accompanying base prospectus (Registration Statement No. 333-280796), which was declared effective by the SEC on July 18, 2024, and a prospectus supplement dated September 5, 2025 relating to the offer and sale of the shares pursuant to the 2025 ATM Agreement. As of December 31, 2025, 136,991 shares were issued under the 2025 ATM Agreement, resulting in net proceeds of $405,114, after deducting the placement agent fees and other offering expenses paid by the Company. See Note 12 – Subsequent Events.

Preferred Stock Conversions

During the years ended December 31, 2025 and 2024, the Company converted an aggregate of 0 and 2,323 shares of Series A Preferred Stock, respectively, held by Knight Therapeutics Inc. into 0 and 3,667 shares of common stock, respectively.

Warrant Exercises

During the year ended December 31, 2025, the Company issued 315,869 shares of common stock upon the exercise of 315,869 pre-funded warrants, resulting in aggregate cash proceeds to the Company of $2,804. During the year ended December 31, 2024, the Company issued 52,792 shares of common stock upon the exercise of 52,792 pre-funded warrants, resulting in aggregate cash proceeds to the Company of $10,963.

Other Events

On April 1, 2024, the Company entered into an Amendment to the Debt Exchange Agreement with Trevally, LLC ("Trevally"), which amends the original agreement with Trevally (executed in January 2023). Pursuant to the Amendment, Trevally agreed to return 500 shares of the Company's common stock, initially issued to Trevally in January 2023 as advance consideration for agreeing to complete the synthesis of research materials for the Company. Trevally returned the previously issued shares for no consideration on April 3, 2024. Trevally delivered the completed research materials to the Company on July 1, 2024.

Common Stock Warrants

As of December 31, 2025 and 2024, the Company accounts for all issued and outstanding warrants to purchase common stock as equity-classified instruments based on the guidance in ASC 480 and ASC 815.

September 2024 Private Placement

On September 4, 2024, the Company entered into a Securities Purchase Agreement with an institutional investor, agreeing to issue and sell in a private placement offering (the "Private Placement") (i) pre-funded warrants to purchase 144,928 shares of common stock (the "September 2024 Pre-Funded Warrants"), (ii) series A warrants to purchase 144,928 shares of common stock (the "Series A Warrants"), and (iii) series B warrants to purchase 144,928 shares of common stock (the "Series B Warrants) at a price of $27.60 per Pre-Funded Warrant and accompanying Series A and Series B Warrants. The Private Placement closed on September 5, 2024, generating net proceeds to the Company of $3,414,502, after deducting placement agent fees and offering expenses.

The September 2024 Pre-Funded Warrants have an exercise price of $0.02 per share and were immediately exercisable on September 5, 2024 and may be exercised at any time until exercised in full. The Series A and Series B Warrants have an exercise price of $27.60 per share and were exercisable beginning on the effective date of stockholder approval to approve the issuance of the shares underlying the Series A and Series B Warrants and the September 2024 Agent Warrants, defined below, to comply with applicable listing rules and regulations of the Nasdaq Stock Market ("Stockholder Approval"), which was later received on November 6, 2024 (the "Stockholder Approval Date"). The Series A Warrants expire five years after the Stockholder Approval Date or November 6, 2029, and the Series B Warrants will expire 18 months after the Stockholder Approval Date, or May 6, 2026.

As compensation for acting as the placement agent for the Private Placement, the Company issued to H.C. Wainwright & Co., LLC warrants to purchase up to 10,870 shares of stock (the "September 2024 Agent Warrants"). The September 2024 Agent Warrants have substantially the same terms as the Series A Warrants, except that the September 2024 Agent Warrants have an exercise price equal to $34.50 per share.

The following table presents a summary of the activity for the Company's equity-classified warrants during the year ended December 31, 2024:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Total outstanding, December 31, 2023	13,190	$ 1,479.86	4.47
Granted[1]	480,879	24.01	3.47
Exercised	(52,792)	0.21	Indefinite
Forfeited	-	-	-
Expired	-	-	-
Total outstanding, December 31, 2024[1]	441,277	$ 70.37	3.26
Total exercisable, December 31, 2024[1]	441,277	$ 70.37	3.26

(1) Weighted average remaining contractual life calculations exclude (i) 4,164 Pre-Funded Warrants issued January 2024 that do not have a contractual expiration date, for which 0 remained outstanding at December 31, 2024 and (ii) 144,928 Pre-Funded Warrants issued September 2024 that do not have a contractual expiration date, for which 96,300 remained outstanding and were exercisable at December 31, 2024.

During the year ended December 31, 2024, the Company received aggregate cash proceeds of $10,963 upon the exercise of 4,164 January 2024 Pre-Funded Warrants and 48,628 September 2024 Pre-Funded Warrants.

The following table presents a summary of the activity for the Company's equity-classified warrants during the year ended December 31, 2025:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Total outstanding, December 31, 2024[1]	441,277	$ 70.37	3.26
Granted[2]	1,771,520	7.41	2.76
Exercised	(315,869)	0.009	Indefinite
Forfeited	-	-	-
Expired	-	-	-
Total outstanding, December 31, 2025	1,896,928	$ 23.29	2.57
Total exercisable, December 31, 2025	1,896,928	$ 23.29	2.57

(1) Weighted average remaining contractual life at December 31, 2024 excludes 96,300 Pre-Funded Warrants issued September 2024 that do not have a contractual expiration date, for which 0 warrants remain outstanding and exercisable at December 31, 2025.

(2) Weighted average remaining contractual life excludes 219,569 Pre-Funded Warrants issued July 2025 that do not have a contractual expiration date, for which 0 warrants remain outstanding and exercisable at December 31, 2025.

During the year ended December 31, 2025, the Company received aggregate cash proceeds of $2,804 upon the exercise of 96,300 September 2024 Pre-Funded Warrants and 219,569 July 2025 Pre-Funded Warrants.

The following table summarizes the significant assumptions used in determining the fair value of equity classified warrants on the respective grant or reclassification dates for the years ended December 31, 2025 and 2024:

	2025	2024
Stock price	$ 6.56 - 16.00	$ 28.80 - 67.20
Exercise price	$ 7.60 - 25.53	$ 27.60 - 101.64
Risk-free interest rate	3.98% - 4.21%	3.54% - 3.98%
Expected volatility	95.00%	95.00%
Expected term (years)	1.50 - 5.00	1.50 - 5.00
Expected dividend yield	0.00%	0.00%

Series A Preferred Stock

As described in Note 8, as a result of the completion of the IPO and as required under the terms of the Knight Debt Conversion Agreement, the Company converted the entirety of the accumulated interest on the Convertible Knight Loan as of March 31, 2022 into 80,965 shares of Series A Preferred Stock. During the years ended December 31, 2025 and 2024, the Company converted an aggregate of 0 and 2,323 shares of Series A Preferred Stock, respectively, into 0 and 3,667 shares of common stock, respectively, at the applicable conversion rate detailed below.

The holders of shares of Series A Preferred Stock have the rights, preferences, powers, restrictions and limitations as set forth below.

Voting Rights - The holders of shares of Series A Preferred Stock are not entitled to any voting rights.

Dividends - From and after the date of issuance of any share of Series A Preferred Stock, cumulative dividends shall accrue, whether or not declared by the Board and whether or not there are funds legally available for the payment of dividends, on a daily basis in arrears at the rate of 6.0% per annum on the sum of the Liquidation Value (as defined below). Accrued dividends shall be paid in cash only when, as and if declared by the Board out of funds legally available therefor or upon a liquidation or redemption of the Series A Preferred Stock. On March 31 of each calendar year, any accrued and unpaid dividends shall accumulate and compound on such date and are cumulative until paid or converted. Holders of shares of Series A Preferred Stock are entitled to receive accrued and accumulated dividends prior to and in preference to any dividend, distribution, or redemption on shares of Common Stock or any other class of securities that is designated as junior to the Series A Preferred Stock. During the year ended December 31, 2024, accrued dividends on outstanding shares of Series A Preferred Stock totaled $483,301. During the year ended December 31, 2025, dividends in the amount of $501,056 accrued on outstanding shares of Series A Preferred Stock. As of December 31, 2025, cumulative dividends on outstanding shares of Series A Preferred Stock amount to $1,205,071. To date, the Company has not declared or paid any dividends.

Liquidation Rights - In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series A Preferred Stock then outstanding will share ratably in any distribution of the remaining assets and funds of the Company with all other stockholders as if each share of Series A Preferred Stock had been converted by the Company to Common Stock as described below.

Conversion Rights - The Company has the right, in its sole discretion, to convert all or any portion of the outstanding shares of Series A Preferred Stock (including any fraction of a share), plus the aggregate accrued or accumulated and unpaid dividends thereon into a number of shares of Common Stock determined by (i) multiplying the number of shares to be converted by $100 per share, as adjusted for any stock splits, stock dividends, recapitalizations or similar transactions with respect to the Series A Preferred Stock (but unchanged as a result of the Reverse Stock Splits impacting the common stock on August 12, 2024, February 24, 2025, and January 20, 2026) (the "Liquidation Value"), (ii) plus all accrued and accumulated and unpaid dividends on such shares to be converted, and then (ii) dividing the result by the then-effective Conversion Price in effect, provided that such conversion would not result in the holders of shares of Series A Preferred Stock owning more than 19.9% of the outstanding shares of common stock on an as-converted basis. The "Conversion Price" is equal to the lesser of (a) the Liquidation Value, (b) the offering price per share of Common Stock in the Company's IPO, or $1,200 per share, as adjusted for the Reverse Stock Splits, or (c) the 10-day volume weighted average price per share of Common Stock, as reasonably determined by the Company.

7. DEBT

SBA COVID-19 EIDL

On May 14, 2020, the Company received COVID-19 EIDL lending from the Small Business Administration (SBA) in the amount of $150,000. The loan bears interest at an annual rate of 3.75% calculated on a monthly basis. Monthly payments of $731 were required beginning in November 2022, with a final balloon payment equal to the remaining principal due at the maturity date of October 12, 2050. The balance as of December 31, 2025 and 2024 is $152,775 and $155,891, respectively. The current maturity at December 31, 2025 is $8,772 and the long-term liability is $144,003 ($8,772 and $147,119 at December 31, 2024, respectively). The loan is collateralized by all tangible and intangible personal property of the Company. The Company is prohibited from accepting future advances under any superior liens on the collateral without the prior consent of SBA.

The current future payment obligations of the principal are as follows:

Period	Principal Payments
2026	$ 713
2027	3,229
2028	3,337
2029	3,480
2030	3,612
Thereafter	135,629
Total	**$ 150,000**

8. DERIVATIVE LIABILITIES

In accordance with the provisions of ASC 815, derivative liabilities are initially measured at fair value at the commitment date and subsequently remeasured at each reporting period, with any increase or decrease in the fair value recorded in the results of operations within other income (expense), net as the change in fair value of derivative liabilities.

As of December 31, 2025 and 2024, derivative liabilities consist of the contingent milestone payment due to Knight Therapeutics, Inc. ("Knight"), a former lender of the Company, as required by the Debt Conversion Agreement executed between the Company and Knight on January 9, 2023, as subsequently amended (the "Knight Debt Conversion Agreement"). Key points of this agreement were as follows:

The Parties agreed to fix Knight's cumulative debt to the value as it stood on March 31, 2022, which consisted of principal and accumulated interest. As a result of the completion of the IPO, the cumulative outstanding principal as of March 31, 2022 converted into 4,619 shares of common stock (representing 19.9% ownership of the Company's common stock after giving effect to the IPO), and the entirety of the accumulated interest as of March 31, 2022 converted into 80,965 shares of Series A Preferred Stock, in full satisfaction of the Company's obligations with respect to the outstanding principal and accumulated interest.

The Parties agreed that the Company will make a milestone payment of $10 million to Knight if, after the IPO, the Company sells Arakoda™ or if a Change of Control (as per the definition included in the original loan agreement dated on December 10, 2015) occurs, provided that the purchaser of Arakoda™ or individual or entity gaining control of the Borrower is not the Lender or an affiliate of the Lender.

For the period ending upon the earlier of (i) 10 years after the closing of the IPO, or (ii) the conversion or redemption in full of the Series A Preferred Stock, the Company will pay to Knight a royalty equal to 3.5% of the Company's net sales (the "Royalty") on a quarterly basis, where "Net Sales" has the same meaning as in the Company's license agreement with the U.S. Army for tafenoquine.

Upon consummation of the IPO, the Company concluded that the contingent milestone payment is a freestanding financial instrument that meets the definition of a derivative under ASC 815, and accordingly, the fair value of the derivative liability is marked to market each reporting period until settled. The Royalty due to Knight was determined to be an embedded component of the Series A Preferred Stock, however, is exempt from derivative accounting under the ASC 815 scope exception for specified volumes of sales or service revenues. Therefore, the Company accrues a royalty expense as sales are made.

The Company uses a probability-weighted expected return method to determine the fair value of the contingent milestone payment. The valuation model uses significant unobservable inputs (Level 3), incorporating management's assumptions regarding the timing and probability of discrete potential exit scenarios, forward interest rate curves, and a weighted average cost of capital based on implied and market yields to discount expected cash flows.

The valuation of the contingent milestone payment requires significant judgment and is sensitive to changes in assumptions related to the expected timing of payment, the likelihood of potential exit scenarios, and the selected discount rate. In developing these assumptions, management considers various qualitative and quantitative factors, including the anticipated progression toward clinical, commercial, and profitability milestones and the potential for a strategic transaction following achievement of each milestone. These factors are evaluated collectively to assess the probability-weighted timing of the contingent payment under each potential exit scenario reflected in the valuation. As of December 31, 2025 and 2024, the discount rates applied in the valuation were 12.49% and 11.65%, respectively.

Changes in any of the assumptions used in the valuation could result in a materially different fair value measurement and, as a result, could lead to materially different gains or losses recognized in the Consolidated Statements of Operations and Comprehensive Loss upon recurring remeasurement.

A reconciliation of the beginning and ending balances for the derivative liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows for the year ended December 31, 2025:

	Contingent Milestone Payment
Derivative liabilities - December 31, 2024	$ 640,830
Change in fair value	(266,089)
Derivative liabilities - December 31, 2025	$ 374,741

A reconciliation of the beginning and ending balances for the derivative liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows for the year ended December 31, 2024:

	Contingent Milestone Payment
Derivative liabilities - December 31, 2023	$ 2,306,796
Change in fair value	(1,665,966)
Derivative liabilities - December 31, 2024	$ 640,830

Changes in the fair value of derivative liabilities are included as a component of other income (expense), net in the accompanying consolidated statements of operations and comprehensive loss. During the years ended December 31, 2025 and 2024, the Company recorded a net gain on the change in the fair value of derivative liabilities of $266,089 and $1,665,966, respectively.

9. INCOME TAXES

Loss before provision (benefit) for income taxes for the years ended December 31, 2025 and 2024 consisted of the following:

	For the Year Ended December 31,	
	2025	2024
United States	$ (6,908,764)	$ (7,372,282)
Foreign	(459,561)	(583,381)
Total Loss before Income Taxes	**$ (7,368,325)**	**$ (7,955,663)**

The components of the provision (benefit) for income taxes consisted of the following:

	For the Year Ended December

	31,	
	2025	2024
Current:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total current provision (benefit)	-	-
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
Total deferred provision (benefit)	-	-
Total Benefit	**$ -**	**$ -**

The reconciliation between income taxes computed at the U.S. statutory income tax rate to the Company's provision (benefit) for income taxes for the year ended December 31, 2025, after the adoption of ASU 2023-09, is as follows:

	For the Year Ended December 31,	
	2025	
Benefit for income taxes at 21% rate	$ (1,547,348)	21.0%
State income taxes, net of federal benefit	-	0.0
Foreign tax effects		
Australia		
Change in valuation allowance	88,925	(1.2)
Other items	7,582	(0.1)
Non-taxable or non-deductible items	(63,020)	0.9
Stock-based compensation	45,544	(0.6)
Tax credits	(90,670)	1.2
Change in valuation allowance	1,558,987	(21.2)
Other items	-	-
Benefit for Income Taxes	**$ -**	**0.0%**

The reconciliation between income taxes computed at the U.S. statutory income tax rate to the Company's provision (benefit) for income taxes for the year ended December 31, 2024, before the adoption of ASU 2023-09, is as follows:

	For the Year Ended December 31,	
	2024	
Benefit for income taxes at 21% rate	$ (1,670,637)	21.0%
State income taxes, net of federal benefit	(588,221)	7.4
Tax credits	(437,296)	5.5
Impact of non-U.S. earnings	(22,103)	0.3
Permanent differences	(347,008)	4.4
Other reconciling items, net	30,411	(0.4)
Change in valuation allowance	3,034,854	(38.1)
Benefit for Income Taxes	**$ -**	**0.00%**

Significant components of the Company's deferred tax assets (liabilities) as of December 31, 2025 and 2024 are as follows:

	As of December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carry-forward	$ 6,557,593	$ 4,191,575
Tax credits	527,966	437,296
Non-deductible reserves	75,213	44,733
Capitalized R&D costs	975,924	1,268,685
Share-based compensation	58,890	41,830
Other temporary differences	1,374	-
Gross deferred tax assets	8,196,960	5,984,119
Less valuation allowance	(8,151,443)	(5,915,350)
Total deferred tax assets, net of valuation allowance	45,517	68,769
Deferred tax liabilities:		
Fixed asset depreciation	(10,865)	(2,783)
Prepaid expenses	(34,652)	(65,986)
Total deferred tax liabilities	(45,517)	(68,769)
Net deferred tax liabilities	**$ -**	**$ -**

The valuation allowance increased by $2,236,093 during 2025. In determining the need for a valuation allowance, the Company has given consideration to its worldwide cumulative loss position when assessing the weight of the sources of taxable income that can be used to support the realization of deferred tax assets. The Company has assessed, on a jurisdictional basis, the available means of recovering deferred tax assets, including the ability to carry-back net operating losses, the existence of reversing temporary differences, the availability of tax planning strategies and available sources of future taxable income. The Company has determined that it is more likely than not that the Company will not recognize the benefits of the U.S. Federal, state and net deferred tax assets, and, as a result, a full valuation allowance has been set against its net deferred tax assets as of December 31, 2025 and December 31, 2024.

At December 31, 2025, the Company had U.S. federal and state net operating loss carryforwards of approximately $17,028,834 and $17,026,834 respectively, and U.S. federal tax credits of $527,966. At December 31, 2024, the Company had U.S. federal and state net operating loss carryforwards of approximately $9,235,194 and $9,234,194 respectively, and U.S. federal tax credits of $437,296. The U.S. federal and state net operating losses carryforward indefinitely but may only be used to offset 80% of annual taxable income due to the Tax Cuts and Jobs Act. The U.S. federal tax credits begin to expire in 2042. The Company had $7,487,256 and $6,601,381 of foreign net operating loss carryforwards which carryforward indefinitely at December 31, 2025 and December 31, 2024, respectively.

Utilization of the NOL carryforwards may be subject to limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and interest limitation carryforwards that can be utilized annually to offset future taxable income and tax, respectively. There could be additional ownership changes in the future, which may result in additional limitations on the utilization of the NOL and tax credit carryforwards.

The Company conducts business globally and, as a result, it files income tax returns in U.S. federal and state jurisdictions and in Australia. In the normal course of business, the Company may be subject to examination by taxing authorities throughout the world. The tax years that remain subject to examination by major tax jurisdictions include the years ended December 31, 2022, 2023, 2024 and 2025. As of December 31, 2025, the Company is not under income tax examination in any jurisdiction.

During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. The Company establishes reserves for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These reserves are established when the Company believes that certain positions might be challenged despite its belief that its tax return positions are fully supportable. The Company adjusts these reserves in light of changing facts and circumstances, such as the outcome of tax examinations. As of December 31, 2025 and December 31, 2024, no reserves for uncertain tax positions have been established.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the years ended December 31, 2025 and December 31, 2024 the Company did not recognize interest and penalties related to unrecognized tax benefits.

---

10. SHARE-BASED COMPENSATION

The following is a summary of share-based compensation expenses reported in the Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2025 and 2024:

	For the Year Ended December 31,	
	2025	**2024**
Research and Development	$ -	$ 3,227,300
General and Administrative Expenses	456,344	381,348
Total Share-Based Compensation Expense Included in Operating Expenses	**$ 456,344**	**$ 3,608,648**

Share-Based Compensation under 2022 Equity Incentive Plan

On November 22, 2022, the Company adopted the 2022 Equity Incentive Plan (the "2022 Plan"), which provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units and performance awards to eligible employees, directors and consultants, to be granted from time to time by the Board of Directors of the Company. The 2022 Plan provides for an automatic increase in the number of shares available for issuance beginning on January 1, 2023 and each January 1 thereafter, by 4% of the number of outstanding shares of common stock on the immediately preceding December 31, or such number of shares as determined by the Board of Directors. Additionally, on July 16, 2024, November 6, 2024, and October 8, 2025 the Company's stockholders approved an increase to the number of shares available under the 2022 Plan by 20,834 shares, 25,000 shares, and 62,500 shares, respectively. As of December 31, 2025, the number of remaining shares available for issuance under the 2022 Plan is equal to 68,760.

Stock Options

The Company grants stock options to employees, non-employees, and Directors with exercise prices equal to the closing price of the underlying shares of the Company's common stock on the Nasdaq Capital Market on the date that the options are granted. Options granted generally have a term of five to ten years from the grant date and are subject to vesting as determined in the individual award agreement. The Company estimates the fair value of stock options on the grant date by applying the Black-Scholes option pricing valuation model.

The following table summarizes the significant assumptions used in determining the fair value of options granted during the years ended December 31, 2025 and 2024:

	2025	**2024**
Weighted-average grant date fair value	$ 15.24	$ 35.12
Risk-free interest rate	3.54%-4.36%	3.62%-4.17%
Expected volatility	90.00%-107.65%	86.00%-87.00%
Expected term (years)	3.50-4.50	6.41-10.00
Expected dividend yield	0.00%	0.00%

The following table summarizes the Company's stock option activities during the year ended December 31, 2025:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (Years)
Options outstanding, December 31, 2024	4,414	$ 257.15	$ -	9.38
Granted	38,000	21.91	-	7.00
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	-	-	-	-
Options outstanding, December 31, 2025	42,414	$ 46.39	$ -	6.41
Options vested and exercisable, December 31, 2025	21,940	$ 47.18	$ -	6.49

The following table summarizes the Company's stock option activities during the year ended December 31, 2024:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (Years)
Options outstanding, December 31, 2023	160	$ 1,272.00	$ -	4.53
Granted	4,254	218.98	-	10.00
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	-	-	-	-
Options outstanding, December 31, 2024	4,414	$ 257.15	$ -	9.38
Options vested and exercisable, December 31, 2024	1,114	$ 466.91	$ -	8.73

The aggregate intrinsic value in the tables above reflects the difference between the Company's closing stock price on the last trading day of the period and the exercise price of the options, multiplied by the number of in-the-money stock options. The intrinsic value of stock options changes based on the price of the Company's common stock.

On July 16, 2024, the effective date of shareholder approval to increase the number of shares available under the 2022 Plan, the Company determined that the grant date criteria (as defined in ASC 718) was met, and therefore granted 3,212 stock options to certain directors, executives, and non-employees, in accordance with the terms of the individuals' employment or directors' agreements, as applicable. On September 26, 2024, the Board of Directors approved the grant of an additional 1,042 stock options to an executive.

In December 2024, the Board approved the grant of a total of 30,000 stock options to two executives at a per share exercise price equal to the closing price of our common stock on January 2, 2025. On January 2, 2025, the Company determined that the grant date criteria (as defined in ASC 718) was met, and therefore granted of a total of 30,000 stock options to executives. On October 21, 2025, the Company's Board of Directors approved the grant of 8,000 non-qualified stock options to each of the four directors (2,000 options per director) at a per share exercise price of $5.84. These stock options were fully vested on the date of grant and have a term of seven years.

For the year ended December 31, 2025, the Company recognized $279,873 of compensation expense related to stock option awards ($32,767 for the year ended December 31, 2024). No stock options were exercised, forfeited, or expired during the period presented. As of December 31, 2025, the Company had $415,553 of unrecognized share-based compensation expense related to unvested options that is expected to be recognized over a weighted-average period of approximately 3.00 years.

Annual Performance Bonus

In December 2024, the Board approved the payment of 2024 performance bonuses to executives of the Company. Each executive was provided the option of receiving up to $20,000 in cash, with the remainder paid in shares of common stock determined based on the closing market price on January 2, 2025. All shares issued are eligible for net settlement up to the maximum allowable amount according to the IRS of 22%. As the number of shares is variable, the Company determined this represents a liability for the fixed monetary amount that will be settled in shares. On January 20, 2025, the Company issued a total of 3,953 shares of common stock to the executives in settlement of the share-based portion of the 2024 performance bonuses. Approximately 688 shares were withheld to cover payroll tax withholdings. As of December 31, 2024, the share-based liability amounted to $121,544, which was presented as a component of Accounts Payable and Accrued Expenses on the accompanying Consolidated Balance Sheet.

Share-Based Payments to Vendors for Services

In 2023, the Company issued shares of common stock as share-based payments to certain vendors in exchange for services to be rendered to the Company in the future. For fully vested, nonforfeitable equity instruments that are granted at the date the Company and a nonemployee enter into an agreement for goods or services, the Company recognizes the fair value of the equity instruments as a prepaid asset on the grant date, as defined in ASC 718. The corresponding cost is expensed over the service period depending on the specific facts and circumstances of the agreement with the nonemployee. As of December 31, 2025, the unamortized balance of prepaid assets related to these share-based payments for which the grant date criteria has been met is $195,887, which is presented as a component of Prepaid and Other Assets on the accompanying Consolidated Balance Sheet. Of this amount, $66,177 will

be recognized ratably over the remaining service period through May 15, 2026. The remaining $129,710 will be recognized as the related research and development services are provided, which the Company estimates will occur within one year.

The agreements with the nonemployees do not include any provisions to claw back the share-based payments in the event of nonperformance by the nonemployees. Subject to applicable federal and state securities laws, the nonemployees can sell the received equity instruments.

11. COMMITMENTS AND CONTINGENCIES

Operating Lease

The Company is a party to a single lease with CXI Corp for its office space located in Washington, DC, which was most recently renewed in December 2025 for an additional one-year term that expires on March 31, 2027. As the term of the office lease is 12 months, the lease is not recorded on the balance sheet. The Company recognizes lease expense on this lease as short-term lease costs. Operating lease costs, including short-term leases, were in the amount of $20,350 and $28,867 for the years ended December 31, 2025 and 2024, respectively.

Board of Directors

In November and December 2022, the Company signed agreements with four director nominees (Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey) which came into effect on July 11, 2023, the date the Company's Registration Statement was declared effective. Each director is entitled to receive cash compensation of $11,250 quarterly. In addition, the two non-audit committee chairs (Toovey, Field) will receive $1,250 per quarter and the audit committee chair (Allen) will receive an additional $2,000 per quarter. In addition, each director is entitled to receive annual equity-based compensation awards, with the amounts and terms to be determined by the Compensation Committee.

In November 2024, the Company paid each non-executive director an additional $20,000 of cash compensation in lieu of granting equity-based compensation awards for the year ended December 31, 2024.

In October 2025, the Company granted a total of 8,000 non-qualified stock options to each member of the Company's Board of Directors (2,000 options per director) at a per share exercise price of $5.84. These stock options were fully vested on the date of grant and have a term of seven years.

Contingencies

The Company's operations are subject to a variety of local and state regulations. Failure to comply with one or more of those regulations could result in fines, restrictions on its operations, or losses of permits that could result in the Company ceasing operations.

Contingent Compensation

Following the Company's IPO and the conversion of the outstanding debt pursuant to the Knight Debt Conversion Agreement, as discussed in Note 8, the Company is obligated to pay Knight a contingent milestone payment of $10 million if the Company sells Arakoda™ or if a Change of Control occurs. The Company accounts for the contingent milestone payment as a derivative liability (See Note 8).

On July 15, 2015, the Company 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 the Company 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. 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. The Company must make a minimum annual royalty payment of 3% of Net Sales (as defined in the U.S. Army Agreement) for Net Sales less than $35 million, and 5% of Net Sales greater than $35 million, with US government sales excluded from the definition of Net Sales. In addition, the Company must pay fees upon the achievement of certain milestones. The Company accrues the minimum annual royalty when the related sales occur. The achievement of the remaining milestones under the U.S. Army Agreement are not considered probable and thus no accruals for the related milestone payments have been made.

On December 20, 2024, the Company entered into a Patent License Agreement with Tufts Medical Center ("Tufts MC"), pursuant to which the Company obtained a license to research and commercialize certain patent applications covering jointly developed inventions related to the use of tafenoquine for treatment and/or prevention of babesiosis. (the "Tufts MC Agreement"). The term of the Tufts MC Agreement will continue until the expiration or final abandonment of the last patent application or issued patent for the use of tafenoquine for treatment and/or prevention of babesiosis, unless terminated earlier by the parties. On the earlier of (x) the date of patent issuance or (y) the date of regulatory approval for the use of tafenoquine product in treatment of babesiosis, the Company must make royalty payments equal to 4% of Net Sales (as defined in the Tufts MC Agreement) of tafenoquine products sold in a format labeled for use in the treatment of babesiosis or 2% of Net Sales of tafenoquine products sold in a format not labeled for use in the treatment of babesiosis. In addition, for all sublicense revenue received by 60P from sales of sublicensed products, the Company must make payments equal to 20% of the revenue received by the Company for sales of tafenoquine products sold in a format labeled for use in the treatment of babesiosis or 10% of the revenue received for sales of tafenoquine that are sold in a format not labeled for use in the treatment of babesiosis. As of December 31, 2025, the royalty period has not commenced, thus no accruals have been made.

(e) Litigation, Claims and Assessments

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of December 31, 2025, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the results of the Company's operations.

12. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through March 30, 2026, which is the date the consolidated financial statements were issued.

2025 ATM Agreement

Pursuant to the 2025 ATM Agreement described in Note 6, between January 1, 2026 and January 22, 2026, the Company sold an aggregate of 418,602 shares at a weighted average price per share of $2.07, generating net proceeds to the Company of $834,705, after deducting commissions and certain other offering expenses.

1:4 Reverse Stock Split

On January 14, 2026, the Company filed an amendment to its Certificate of Incorporation with the Secretary of State of Delaware to effect the 1:4 Reverse Stock Split. On January 20, 2026, the Company effected the 1:4 Reverse Stock Split of its common stock, and our common stock began trading on The Nasdaq Capital Market on a split adjusted basis. See Notes 2 and 6 for further details.

The Company's stockholders approved a reverse stock split at a ratio ranging from 1:3 to 1:10 at the 2025 Annual Stockholders Meeting on October 8, 2025, and subsequently on December 17, 2025, the Company's Board of Directors approved the implementation of the reverse stock split at a ratio of 1:4.

As of the effective time of the 1:4 Reverse Stock Split, every four (4) issued and outstanding shares of the Company's common stock were automatically combined and converted into one (1) issued and outstanding share of the Company's common stock, reducing the number of shares of common stock outstanding from 5,436,441 shares to 1,359,091 shares. The 1:4 Reverse Stock Split did not change the authorized number of shares of common stock or preferred stock. Proportional adjustments were made to the number of shares of common stock issuable upon exercise or conversion of the Company's equity awards, warrants, and other equity instruments convertible into common stock, as well as the respective exercise prices, if applicable in accordance with the terms of the instruments. No fractional shares of common stock were issued in connection with the 1:4 Reverse Stock Split. All fractional shares were rounded up to the nearest whole share with respect to outstanding shares of common stock.

Unless otherwise noted, all references to numbers of shares of the Company's common stock and per share information presented in these consolidated financial statements have been retroactively adjusted, as appropriate, to reflect the 1:4 Reverse Stock Split (as well as the 1:5 Reverse Stock Split in February 2025 and the 1:12 Reverse Stock Split in August 2024), including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

Nasdaq Delisting Notice

On January 20, 2026, the Company received a written notice from the Nasdaq Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") indicating that Nasdaq staff has determined to delist the Company's common stock and warrants from The Nasdaq Capital Market because the Company's common stock failed to maintain a minimum bid price of $1.00 per share for 30 consecutive business days, in violation of Nasdaq Listing Rule 5550(a)(2). The Company paid the $20,000 for the hearing fee and requested an appeal with Nasdaq, pursuant to the Notice, which stayed the suspension of trading and the filing of the Form 25-NSE pending the Panel's decision.

On February 11, 2026, the Company was notified by Nasdaq that the Company regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) and that the Company is therefore in compliance with the Nasdaq Capital Market's listing requirements. As a result, the hearing before the Nasdaq Hearings Panel that had been scheduled for February 19, 2026, has been cancelled, and this matter was closed. The Company's common stock will continue to be listed and traded on The Nasdaq Capital Market.

March 2026 ATM Agreement

On March 2, 2026, the Company filed a prospectus supplement pursuant to Rule 424(b)(5) (the "2026 ATM Prospectus Supplement") in connection with the Company's At-The-Market Offering Agreement, with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which the Company may, from time to time, offer and sell additional shares of its common stock having aggregate sales proceeds of up to $1,308,000 (the "2026 ATM Prospectus Supplement "). The 2026 ATM Prospectus Supplement was subsequently amended on March 11, 2026, to increase the maximum aggregate offering price under the 2026 ATM Offering by $981,000 (the "2026 ATM Prospectus Supplement Amendment," and together with the 2026 ATM Prospectus Supplement the "2026 ATM Offering").

As compensation for acting as the sales agent for the 2026 ATM Offering, Wainwright is entitled to a commission of 3.0% of the gross proceeds from the sales of shares in the 2026 ATM Offering.

The common stock that may be sold pursuant to the 2026 ATM Prospectus Supplement will be issued and sold pursuant to the Company's shelf registration statement on Form S-3 and accompanying base prospectus (Registration Statement No. 333-280796), which was declared effective by the SEC on July 18, 2024, and the 2026 ATM Prospectus Supplement relating to the offer and sale of the shares pursuant to the 2025 ATM Agreement.

Between March 2, 2026 and March 25, 2026, the Company sold an aggregate of 1,055,106 shares at a weighted average price per share of $2.49 generating net proceeds to the Company of $2,545,297, after deducting commissions and certain other offering expenses.

There have been no other events or transactions during this time which would have a material effect on these consolidated financial statements.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2025. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles (GAAP). As of December 31, 2025, our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework).

Based on this assessment, our management concluded that our internal control over financial reporting was not effective as of December 31, 2025, due to the existence of material weaknesses in our internal control over financial reporting. These material weaknesses are described below:

1. Inadequate Design of Policies and Procedures: We did not design policies and procedures at a sufficient level of precision to support the operating effectiveness of controls to prevent and detect potential errors.

2. Lack of Documentation: There was a failure to maintain adequate documentation to evidence the operating effectiveness of certain control activities and a lack of proper levels of supervision and review of complex accounting matters.

3. Access Control and Segregation of Duties: Inadequate controls in place related to maintaining appropriate access to certain systems and maintaining appropriate segregation of duties within those systems.

Management has undertaken a remediation plan to address these material weaknesses. During the year ended December 31, 2025, we continued to enhance our internal control over financial reporting through various initiatives, including investing in information technology systems, enhancing the organizational structure, providing guidance and training to employees and further developing detailed policies and procedures.

We expect to remediate these material weaknesses in the first half of 2026. However, there may be additional material weaknesses identified that could require additional time and resources to remediate. We remain committed to ensuring that our internal control over financial reporting is designed and operating effectively.

Although we did not include an attestation report of the independent registered public accounting firm in this Annual Report on Form 10-K, we acknowledge the deficiencies in our internal control over financial reporting and are actively working towards remediation and improvement. We will continue to monitor and evaluate the effectiveness of our internal control over financial reporting to ensure timely and accurate financial reporting.

Attestation Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to the deferral allowed under the Jumpstart Our Business Startups Act of 2012 for emerging growth companies.

Changes in Internal Control over Financial Reporting

Other than with respect to the remediation efforts discussed above, there was no change in our internal control over financial reporting that occurred during the year ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The following table sets forth the name, age and position of each of our executive officers, directors and director nominees as of March 30, 2026.

Name	Age	Position	Director Since
Geoffrey Dow	52	Chief Executive Officer, President and Director	June 1, 2022
Tyrone Miller	51	Chief Financial Officer	
Kristen Landon	59	Chief Commercial Officer	
Charles Allen	50	Director	July 11, 2023
Cheryl Xu	58	Director	July 11, 2023
Stephen Toovey	72	Director	July 11, 2023
Paul Field	63	Director	July 11, 2023

Executive Officers and Directors

Geoffrey Dow is our Chief Executive Officer, President, and is also one of our directors. Dr. Dow has over 20 years of product development experience in tropical diseases and has an extensive publication and patent history. His decades of hands-on experience include 13 years in key leadership and advisory roles in the antimalarial drug development program at the Walter Reed Army Institute of Research and at the U.S. Army Medical Materiel Development Activity. Dr. Dow co-founded 60P in 2010. Since then, he has been involved in various projects, including leading the project development team in securing FDA-regulatory approval for Tafenoquine (as Arakoda) for malaria prophylaxis, securing a supply chain and access relating to Arakoda, managing post-marketing regulatory commitments, ensuring the successful prosecution of supporting patents on which Dr. Dow was an inventor, and ensuring the company adheres to GMP, quality, and pharmacovigilance requirements. Dr. Dow has also published a number of important safety reviews, clinical trials, non-clinical studies, on which he was a thought leader or contributor, which dispelled many of the myths about 8-aminoquinolines. As a scientist, experienced industry project manager and inventor, Dr. Dow's ultimate goal is to develop and secure the regulatory approval and commercial success of products, old and new, for new indications in infectious disease. Dr. Dow received a B.Sc. (Hons) in Veterinary and Biomedical Science from Murdoch University, Perth, Western Australia ("Murdoch") in 1994, a Ph.D. in Veterinary and Biomedical Science from Murdoch in 2000 and an MBA from the University of Maryland at College Park in 2012. We believe that Mr. Dow is well qualified to serve as a Director given his product development experience in tropical diseases.

Tyrone Miller is our Chief Financial Officer. Mr. Miller joined us in 2014 and has held a number of roles since then, including Treasurer. He worked with the founder and Chief Executive Officer of 60P and raised over $6 million in external financing. Mr. Miller also established a multinational financial reporting system and worked with consultants in designing tax and credit strategies. He also provides key strategic advice in areas of financing and business planning to 60P. In addition, he is the founder and Principal of Tax & Accounting Practice at Miller Tax & Advisory since 2011. In that role, Mr. Miller advises owners of closely held businesses on accounting, financial and tax matters and has designed accounting systems for private sector businesses. From 2002 to 2011, he was a Senior Accountant at Sachs Figurelli, LLC, where he prepared and processed corporate and individual tax returns, consulted on reengineering accounting processes for construction, restaurant and professional services businesses and managed staff in preparation and processing of payroll and personal property returns. Mr. Miller is currently a Certified Public Accountant. He received a Bachelor's of Business Administration with a concentration in International Business from Emory University in 1996.

Kristen Landon is our Chief Commercial Officer. Ms. Landon joined us in 2024 and brings over 26 years' experience building and transforming pharmaceutical brands in both start-up and large multinational companies. Ms. Landon has launched and relaunched over a dozen brands, many with peak revenues in excess of $100 million across therapeutic categories including women's health, infectious disease, dermatology, nephrology, and hematology/oncology. Most recently, Ms. Landon served as Senior Vice President of Marketing and Communications at TherapeuticsMD with responsibility for the branded portfolio, marketing insights, and corporate communications. Prior commercial leadership roles include VP Marketing at Radius Health, VP Marketing at Sprout Pharmaceuticals (acquired by Valeant), Executive Director Women's Health at Actavis Plc, and positions of increasing responsibility in sales and marketing at Forest Labs, Abbott Labs, and Novartis. Ms. Landon holds an MBA from Silberman College of Business at Fairleigh Dickinson University, and a Bachelor's degree from Kean University.

Charles Allen is one of our directors since July 11, 2023 and since February 5, 2014 has served as the Chief Executive Officer of BTCS Inc. ("BTCS") and the Chairman of the Board of BTCS since September 11, 2014. Mr. Allen is responsible for BTCS' overall corporate strategy and direction. Since December 2, 2022, Mr. Allen has been a director of Innovation1 Biotech Inc. Since January 12, 2018, Mr. Allen has been the Chief Executive Officer of Global Bit Ventures Inc. ("GBV"). Since October 10, 2017, Mr. Allen has been a director of GBV. Mr. Allen has extensive experience in business strategy and structuring and executing a variety of investment banking and capital markets transactions, including financings, initial public offerings, and mergers and acquisitions. Prior to his work in the blockchain industry at BTCS, he worked domestically and internationally on projects in technology, media, natural resources, logistics, medical services, and financial services. He has served as a managing director at numerous boutique investment banks focused on advising and raising capital for small and mid-size companies. Mr. Allen received a Bachelor of Science in Mechanical Engineering from Lehigh University and a Master of Business Administration from the Mason School of Business at the College of William & Mary. The Board concluded that Mr. Allen's background and leadership experiences in the financial industry qualify him to be a member of the Board.

Cheryl Xu is one of our directors since July 11, 2023 and until recently served as Biogen's Vice President, Public Policy & Government Affairs since 2020. Ms. Xu was PhRMA's first Representative to China. Subsequently she started a consulting business in 2005, advising well-known multinational companies such as Pfizer, J&J and UnitedHealth Group on their market access and expansion strategies in China. Cheryl has provided consultations to both the U.S. and Chinese governments on pharmaceutical policies including strengthening of IP protection and monitoring system for China's API exports. Prior to that, she was the Director of International Finance at Pharmacia based in New Jersey from 1998 to 2003. Ms. Xu received her Bachelor of Science degree in Physics from Peking University, and Master of Business Administration in Finance from Washington University in St. Louis. The Board concluded that Ms. Xu's background and leadership experiences in the pharmaceutical industry qualify her to be a member of the Board.

Dr. Stephen Toovey is one of our directors since July 11, 2023 and is an infectious and tropical disease physician. Dr. Toovey has worked in the pharmaceutical industry and academia in both developed and developing countries, and currently specializes in the research of influenza and other respiratory viruses, malaria, rabies and the neurological aspects of infectious diseases. He is currently the Chief Executive Officer of Pegasus, a medical and scientific services company and has held that position since 2008. Dr. Toovey also advises a number of pharmaceutical companies and biotech organizations on infection and immunology related matters, from translation through Phase IV, and founded numerous pharmaceutical and pharma-related companies, with the most recent being the co-founding of Ark Biosciences in 2014. Dr. Toovey served as Chief Medical Officer of Ark Biosciences from 2014 until 2020. In addition, he held a teaching and clinical post at the Royal Free and University College Medical School in London, United Kingdom,

Academic Centre for Travel Medicine and Vaccines, World Health Organization Collaborating Center, appointed in 2008. He has been editor of the journal Travel Medicine and Infectious Disease since its foundation in 2003. Dr. Toovey has authored over 100 publications in peer reviewed medical journals, contributed to a number of textbooks and has presented at over 50 scientific meetings. Dr. Toovey received his PhD from the University of Ghent. The Board concluded that Dr. Toovey's background and leadership experiences in the pharmaceutical industry and academia qualify him to be a member of the Board.

Paul Field is one of our directors since July 11, 2023. Paul has over 30 years of business development experience across a range of disease areas, and a deep network in the global biopharmaceutical industry. He is currently a corporate advisor at Imunexus since 2020, Marinova since 2018, and GARDP (Switzerland) since 2018. He was until recently the Australian representative of FIND (Switzerland) from 2018 to 2021 and a business development advisor to the drug discovery company Biocurate from 2018 to 2020. Paul was previously the life sciences specialist at Austrade from 2014 to 2018, the Australian Government's investment promotion agency, where he facilitated foreign direct investment into Australian research in neglected tropical diseases, infectious diseases, autoimmune diseases, cancer and other therapeutic areas. Paul was the founder and Executive Chairman of Bio-Link from 2005 to 2014, a privately owned biotechnology business development company. His work at Bio-Link involved the commercialization of discovery, pre-clinical and early-stage clinical programs undertaken by Australian biotech companies and medical research institutions. Paul has served on a number of Boards of Directors, and he is a Fellow of the Australian Institute of Company Directors. The Board concluded that Mr. Field's background and leadership experiences in the biotechnology industry qualify him to be a member of the Board.

Significant Employees

We are a virtually managed pharmaceutical company for which the significant employees are its officers.

Code of Ethics

Our Board has adopted a written code of business conduct and ethics ("Code") that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. We intend to post on our website a current copy of the Code and all disclosures that are required by law in regard to any amendments to, or waivers from, any provision of the Code.

Board Leadership Structure and Risk Oversight

Our Board has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our Board to understand our risk identification, risk management, and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, cybersecurity, strategic, and reputational risk.

Board of Directors

Our Board consists of five members. Our business and affairs are managed under the direction of our Board.

Directors serve until the next annual meeting and until their successors are elected and qualified. Officers are appointed to serve until their successors have been elected and qualified.

Director Independence

Our Board is composed of a majority of "independent directors" as defined under the rules of Nasdaq. We use the definition of "*independence*" applied by Nasdaq to make this determination. Nasdaq Listing Rule 5605(a)(2) provides that an "*independent director*" is a person other than an officer or employee of the company or any other individual having a relationship which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Nasdaq listing rules provide that a director cannot be considered independent if:

the director is, or at any time during the past three (3) years was, an employee of the company;

the director or a family member of the director accepted any compensation from the company in excess of $120,000 during any period of twelve (12) consecutive months within the three (3) years preceding the independence determination (subject to certain exemptions, including, among other things, compensation for board or board committee service);

the director or a family member of the director is a partner in, controlling shareholder of, or an executive officer of an entity to which the company made, or from which the company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year or $200,000, whichever is greater (subject to certain exemptions);

the director or a family member of the director is employed as an executive officer of an entity where, at any time during the past three (3) years, any of the executive officers of the company served on the compensation committee of such other entity; or

the director or a family member of the director is a current partner of the company's outside auditor, or at any time during the past three (3) years was a partner or employee of the company's outside auditor, and who worked on the company's audit

Under such definitions, our Board has undertaken a review of the independence of each director and director nominee. Based on information provided by each director concerning his or her background, employment and affiliations, our Board has determined that Charles Allen, Stephen Toovey and Paul Field, are independent directors of the Company.

Committees of the Board of Directors

Our Board has three standing committees: (i) an audit committee (the "Audit Committee"); (ii) a compensation committee (the "Compensation Committee"); and (iii) a nominating and corporate governance committee (the "Nominating and Corporate Governance Committee"). Our Board has not yet adopted procedures by which stockholders may recommend nominees to the Board. The composition and responsibilities of each of the committees of our Board are described below. Members serve on these committees until their resignation or until as otherwise determined by our Board.

Audit Committee

We have established the Audit Committee consisting of Charles Allen, who is the Chairman of the Audit Committee, Stephen Toovey and Paul Field. Charles Allen qualifies as an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act. Our Board adopted an Audit Committee Charter on March 16, 2023, of which was deemed effective as of July 11, 2023. The Audit Committee's duties, which are specified in our Audit Committee Charter, include, but are not limited to:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in our annual disclosure report;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- reviewing and approving all related-party transactions;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies; and
- approving reimbursement of expenses incurred by our management team in identifying potential target businesses.

The Audit Committee is composed exclusively of "independent directors" who are "financially literate" as defined under the Nasdaq listing standards. The Nasdaq listing standards define "financially literate" as being able to read and understand fundamental financial statements, including a company's balance sheet, income statement and cash flow statement.

Compensation Committee

We have established the Compensation Committee, which is composed exclusively of independent directors consisting of Paul Field, who is the Chairman of the Compensation Committee, Charles Allen and Stephen Toovey. Each member of the Compensation Committee is a non-employee director, as defined under Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Code. Our Board adopted a Compensation Committee Charter on March 16, 2023, which was deemed effective as of July 11, 2023. The Compensation Committee's duties, which are specified in our Compensation Committee Charter, include, but are not limited to:

- reviews, approves and determines, or makes recommendations to our Board regarding the compensation of our executive officers;
- administers our equity compensation plans;
- reviews and approves, or makes recommendations to our Board, regarding incentive compensation and equity compensation plans; and
- establishes and reviews general policies relating to compensation and benefits of our employees.

Nominating and Corporate Governance Committee

We have established the Nominating and Corporate Governance Committee, which is composed exclusively of independent directors consisting of Stephen Toovey, who is the Chairman of the Nominating and Corporate Governance Committee, Charles Allen and Paul Field. Our Board adopted a Nominating and Corporate Governance Committee Charter on March 16, 2023, of which was deemed effective as of July 11, 2023. The Nominating and Corporate Governance Committee's duties, which are specified in our Nominating and Corporate Governance Audit Committee Charter, include, but are not limited to:

- identifying, reviewing and evaluating candidates to serve on our Board consistent with criteria approved by our Board;

evaluating director performance on our Board and applicable committees of our Board and determining whether continued service on our Board is appropriate; and

corporate governance matters.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Involvement in Certain Legal Proceedings

Except as disclosed below, to our knowledge, none of our current directors or executive officers has, during the past ten (10) years:

been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two (2) years prior to that time;

been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his or her involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;

been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Meetings of the Board of Directors

During our fiscal year ended December 31, 2025, the Board met from time to time informally and acted by written consent on numerous occasions.

Indemnification and Limitation on Liability of Directors

Our certificate of incorporation, as corrected, limits the liability of our directors to the fullest extent permitted by Delaware law. Nothing contained in the provisions will be construed to deprive any director of his or her right to all defenses ordinarily available to the director, nor will anything herein be construed to deprive any director of any right he or she may have for contribution from any other director or other person.

At present, there is no pending litigation or proceeding involving any of our directors, officers, employees or agents where indemnification will be required or permitted. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Board Diversity

We seek diversity in experience, viewpoint, education, skill and other individual qualities and attributes to be represented on our Board. We believe directors should have various qualifications, including individual character and integrity, business experience, leadership ability, strategic planning skills, ability and experience, requisite knowledge of our industry and finance, accounting and legal matters, communications and interpersonal skills and the ability and willingness to devote time to our Company. We also believe the skill sets, backgrounds and qualifications of our directors, taken as a whole, should provide a significant mix of diversity in personal and professional experience, background, viewpoints, perspectives, knowledge and abilities. Nominees are not to be discriminated against on the basis of race, religion, national origin, sex, sexual orientation, disability or any other basis proscribed by law. The assessment of prospective directors is made in the context of the perceived needs of our Board from time to time.

Our Board seeks members from diverse professional backgrounds who combine a solid professional reputation and knowledge of our business and industry with a reputation for integrity. Our Board does not have a formal policy concerning diversity and inclusion but is in the process of establishing a policy on diversity. Diversity of experience, expertise and viewpoints is one of many factors the Nominating and Corporate Governance Committee considers when recommending director nominees to our Board. Further, our Board is committed to actively seeking highly qualified women and individuals from minority groups and the LGBTQ+ community to include in the pool from which new candidates are selected. Our Board also seeks members that have experience in positions with a high degree of responsibility or are, or have been, leaders in the companies or institutions with which they are, or were, affiliated, but may seek other members with different backgrounds, based upon the contributions they can make to our Company.

BOARD DIVERSITY MATRIX

	As of December 31, 2025	As of December 31, 2024

Total Number of Directors:	5				5			
Part I: Gender Identity	**Female**	**Male**	**Non-Binary**	**Did Not Disclose Gender**	**Female**	**Male**	**Non-Binary**	**Did Not Disclose**
Directors	1	4	-	-	1	4	-	-
Part II: Demographic Background								
African American or Black	-	-	-	-	-	-	-	-
Alaskan Native or American Indian	-	-	-	-	-	-	-	-
Asian	1	-	-	-	1	-	-	-
Hispanic or Latino	-	-	-	-	-	-	-	-
Native Hawaiian or Pacific Islander	-	-	-	-	-	-	-	-
White	-	3	-	-	-	3	-	-
Two or More Races or Ethnicities	-	1	-	-	-	1	-	-
LGBTQ+	-	-	-	-	-	-	-	-
Did Not Disclose Demographic Background	-	-	-	-	-	-	-	-

Insider Trading Policy

We adopted an insider trading policy that governs the purchase, sale, and/or other transactions of our securities by our directors, officers, employees and other covered persons. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K for the fiscal year ended December 31, 2025. In addition, with regard to the Company's trading in its own securities, it is our policy to comply with applicable federal securities laws.

Item 11. Executive Compensation.

The following table summarizes compensation for the years ended December 31, 2025, 2024, and 2023 for all individuals serving as our principal executive officer or acting in a similar capacity during the last completed fiscal year ("PEO"), regardless of compensation level, two most highly compensated executive officers other than the PEO who were serving as executive officers at the end of the last completed fiscal year, and up to two additional individuals for whom disclosure would have been provided pursuant to paragraph (m)(2)(ii) of Item 402 of Regulation S-K but for the fact that the individual was not serving as an executive officer of the smaller reporting company at the end of the last completed fiscal year (each a "Named Executive Officer").

Summary Compensation Table

Name and Principal Position	Year	Base Salary ($)[1]	Cash Bonus ($)	Stock Bonus ($)	Option Award ($)[2]	Total
Geoffrey Dow	2025	$ 250,000	$	$ -	$ 477,750	$ 727,750
President and Chief Executive Officer	2024	228,000	20,000	24,175	51,250	323,425
(Principal Executive Officer)	2023	125,555	-	-	-	125,555
Tyrone Miller	2025	$ 215,000	$	$ -	$ 68,250	$ 283,250
Chief Financial Officer	2024	204,000	20,000	19,525	41,000	284,525
(Principal Financial and Accounting Officer)	2023	135,632	-	-	-	135,632
Kristen Landon	2025	$ 300,000	$ 11,791	$ -	$ -	$ 311,791
Chief Commercial Officer	2024	300,000	113,570	38,125	19,167	470,862
	2023	-	-	-	-	-

(1) We periodically review, and may increase, base salaries in accordance with our normal annual compensation review for each of our named executive officers.

(2) Represents the aggregate grant date fair value of options granted during the fiscal year, computed in accordance with FASB ASC Topic 718. Company to confirm salary and bonus amounts for 2025 in table below.

Equity Awards

On July 12, 2023, Dr. Dow was granted a five-year option to purchase a cumulative total of no more than 1,250 shares of our common stock over five years, vesting on the last day of each quarter in each calendar year for five years and (ii) Mr. Miller was granted a five-year option to purchase a cumulative total of no more than 1,000 shares of our common stock vesting on the last day of each quarter in each calendar year for five years. The per share exercise price of the options was initially equal to the per share closing price of our common stock on the date of grant and had a cashless exercise provision. In November 2023, the Board reset the exercise price of the options to be equal to $240.00 and modified the vesting provisions of the option to vest annually in equal tranches over five years, rather than quarterly, with the first vesting date being December 31, 2024. The initial grant and subsequent amendment of these options was contingent upon the stockholders of the Company approving the amendment to the exercise price of the options and approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan in order to comply with Listing Rule 5635(c) of The Nasdaq Stock Market LLC. On July 16, 2024, the Company's stockholders approved the proposal to increase the number of shares available under the 2022 Plan. As of that date, Dr. Dow and Mr. Miller's option grants, as subsequently amended, were considered effective.

In February 2024, subject to and contingent upon the stockholders of the Company approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan, we granted Ms. Landon a five-year option to purchase a total of 1,042 shares of our common stock with a per share exercise price to be determined by the Board on the date of grant. The options had a cashless exercise price and vest annually over five years, with the first vesting date being December 31, 3024. On September 26, 2024, the Board approved the grant of the options to Ms. Landon at a per share exercise price of $27.40.

In December 2024, the Board approved the grant of 26,250 options to Dr. Dow and 3,750 options to Mr. Miller as equity-based long-term incentive awards, which vest in five equal tranches on the last date of each fiscal year over five years, with the first vesting date being December 31, 2024. The options were

granted on January 2, 2025 with a per share exercise price of $26.20, the closing stock price on the grant date, and have a seven-year term.

Employment Agreements

Dow Employment Agreement. We entered into an Employment Agreement dated as of January 12, 2023, with Geoffrey Dow (the "Dow Employment Agreement"), our Chief Executive Officer and Chairman of our Board. The term of the Dow Employment Agreement began on January 12, 2023 for an initial period of two years, with subsequent automatic renewals unless either party thereto provides notice to terminate at least 90 days prior to the applicable renewal date. The Dow Employment Agreement initially provided Dr. Dow an annual base salary of $228,000 (increased to $250,000 for fiscal year 2025), bonuses to the extent certain events occur or if applicable performance goals are met and employee benefits that are generally given to our senior executives. Contingent on the receipt of shareholder approval to increase the number of shares available under the 2022 Plan, Dr. Dow was granted a five-year option to purchase a cumulative total of no more than 1,250 shares of our common stock, vesting on the last day of each quarter in each calendar year over five years. The per share exercise price of the option was initially equal to the per share closing price of our common stock on the date of the initial public offering and shall have a cashless exercise provision. In November 2023, the Board reset the exercise price of the option to be equal to $240.00 and modified the vesting provisions of the option to vest annually in equal tranches over five years, rather than quarterly, with the first vesting date being December 31, 2024. The initial grant and subsequent amendment of Dr. Dow's options was contingent upon the stockholders of the Company approving the amendment to the exercise price of the options and approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan in order to comply with Listing Rule 5635(c) of The Nasdaq Stock Market LLC. On July 16, 2024, the Company's stockholders approved the proposal to increase the number of shares available under the 2022 Plan. As of that date, Dr. Dow's option grant, as subsequently amended, was considered effective.

We may terminate Dr. Dow's employment for Cause, as defined in the Dow Employment Agreement, at any time upon notice to Dr. Dow setting forth in reasonable detail the nature of such Cause. We also may terminate Dr. Dow's employment other than for Cause at any time upon thirty (30) days' written notice to him. Dr. Dow may terminate his employment for Good Reason, as defined in the Dow Employment Agreement, at any time upon thirty (30) days' written notice to us. In the event that Dr. Dow's employment is terminated other than for Cause or for Good Reason, Dr. Dow will be entitled to, among other things, a continuation of his annual salary plus health insurance benefits for a period not exceeding 18 months. In addition, in the event of a Change in Control, as defined in the Dow Employment Agreement, on, or at any time during the 24 months following, the Change in Control, (i) we terminate Dr. Dow's employment for any reason other than Cause or Disability, as defined in the Dow Employment Agreement, or (ii) Dr. Dow terminates his employment for Good Reason, Dr. Dow will be entitled to Change in Control severance.

Dr. Dow is subject to non-competition and non-solicitation during the term of his employment and for a period of 24 months after termination of his employment.

Miller Employment Agreement. We entered into an Employment Agreement dated as of January 12, 2023 with Tyrone Miller (the "Miller Employment Agreement"), our Chief Financial Officer. The term of the Miller Employment Agreement began on January 12, 2023 and will continue for a period of two years, with subsequent automatic renewals unless either party thereto provides notice to terminate at least 90 days prior to the applicable renewal date. The Miller Employment Agreement initially provided Mr. Miller an annual base salary of $204,000 (increased to $215,000 for fiscal year 2025), bonuses to the extent certain events occur or if applicable performance goals are met and employee benefits that are generally given to our senior executives. Contingent on the receipt of shareholder approval to increase the number of shares available under the 2022 Plan, Mr. Miller was granted a five-year option to purchase a cumulative total of no more than 1,000 shares of our common stock, vesting on the last day of each quarter in each calendar year over five years. The per share exercise price of the option was initially equal to the per share closing price of our common stock on the date of the initial public offering and shall have a cashless exercise provision. In November 2023, the Board reset the exercise price of the option to be equal to $240.00 and modified the vesting provisions of the option to vest annually in equal tranches over five years, rather than quarterly, with the first vesting date being December 31, 2024. The initial grant and subsequent amendment of Mr. Miller's options was contingent upon the stockholders of the Company approving the amendment to the exercise price of the options and approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan in order to comply with Listing Rule 5635(c) of The Nasdaq Stock Market LLC. On July 16, 2024, the Company's stockholders approved the proposal to increase the number of shares available under the 2022 Plan. As of that date, Mr. Miller's option grant, as subsequently amended, was considered effective.

We may terminate Mr. Miller's employment hereunder for Cause, as defined in the Miller Employment Agreement, at any time upon notice to Mr. Miller setting forth in reasonable detail the nature of such Cause. We also may terminate Mr. Miller's employment other than for Cause at any time upon thirty (30) days' written notice to him. Mr. Miller may terminate his employment for Good Reason, as defined in the Miller Employment Agreement, at any time upon thirty (30) days' written notice to us. In the event that Mr. Miller's employment is terminated other than for Cause or for Good Reason, Mr. Miller will be entitled to, among other things, a continuation of his annual salary plus health insurance benefits for a period not exceeding 18 months. In addition, in the event of a Change in Control, as defined in the Miller Employment Agreement, on, or at any time during the 24 months following, the Change in Control, (i) we terminate Mr. Miller's employment for any reason other than Cause or Disability, as defined in the Miller Employment Agreement, or (ii) Mr. Miller terminates his employment for Good Reason, Mr. Miller will be entitled to Change in Control severance.

Mr. Miller is subject to non-competition and non-solicitation during the term of his employment and for a period of 24 months after termination of his employment.

Landon Employment Agreement. We entered into an Employment Agreement dated as of February 7, 2024 with Kristen Landon (the "Landon Employment Agreement"), our Chief Commercial Officer. The term of the Landon Employment Agreement began on February 12, 2024 and will continue at will, meaning that Ms. Landon or the Company may terminate the employment relationship at any time, with or without cause, and with or without notice and for any reason or no particular reason. The Landon Employment Agreement provides Ms. Landon an annual base salary of $300,000, sales bonuses and bonuses to the extent certain events occur or if applicable performance goals are met and employee benefits that are generally given to our senior executives. Contingent on the receipt of shareholder approval to increase the number of shares available under the 2022 Plan, Ms. Landon was granted a five-year option to purchase a total of 1,042 shares of our common stock with a per share exercise price to be determined by the Board on the date of grant. The options had a cashless exercise price and vest annually over five years, with the first vesting date being December 31, 3024. On September 26, 2024, after the receipt of stockholder approval to increase the number of shares available under the 2022 Plan, the Board approved the grant of the options to Ms. Landon at a per share exercise price of $27.40.

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2025

	Option Awards					Stock Awards	
Name	Number of securities underlying unexercised options, exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
Geoffrey Dow, President and Chief Executive Officer (Principal Executive Officer)[1]	500	-	750	$ 240.00	July 16, 2034	-	$ -
	10,500	-	15,750	$ 26.20	January 2, 2032	-	$ -
Tyrone Miller, Chief Financial Officer (Principal Financial and Accounting Officer)[2]	400	-	600	$ 240.00	July 16, 2034	-	$ -
	1,500	-	2,250	$ 26.20	January 2, 2032	-	$ -
Kristen Landon, Chief Commercial Officer[3]	418	-	624	$ 27.40	September 26, 2034	-	$ -

(1) Dr. Dow's option grant to purchase a total of 1,250 shares of our common stock vests annually on the last date of each fiscal year in five equal tranches, with the first vesting date being December 31, 2024, and Dr. Dow's option grant to purchase a total of 26,250 shares of our common stock vests annually on the last date of each fiscal year in five equal tranches, with the first vesting date being December 31, 2024.

(2) Mr. Miller's option grant to purchase a total of 1,000 shares of our common stock vests annually on the last date of each fiscal year in five equal tranches, with the first vesting date being December 31, 2024, and Mr. Miller's option grant to purchase a total of 3,750 shares of our common stock vests annually on the last date of each fiscal year in five equal tranches, with the first vesting date being December 31, 2024.

(3) Ms. Landon's option grant to purchase a total of 1,042 shares of our common stock vests annually on the last date of each fiscal year in five equal tranches, with the first vesting date being December 31, 2024.

2022 Equity Incentive Plan

Overview

On November 22, 2022, our Board and our stockholders approved the 60 Degrees Pharmaceuticals, Inc. 2022 Equity Incentive Plan. The 2022 Plan governs equity awards to our employees, directors, officers, consultants and other eligible participants. Initially, the maximum number of shares of our common stock that may be subject to awards under the 2022 Plan was equal to 995. The 2022 Plan provides for an automatic increase in the number of shares available for issuance beginning on January 1, 2023 and each January 1 thereafter, by 4% of the number of outstanding shares of common stock on the immediately preceding December 31, or such number of shares as determined by the Board of Directors. As of March 30, 2026, the Board has reserved 162,889 shares of common stock issuable upon the grant of awards under the Plan, of which 115,284 shares remain available for issuance.

The purpose of the 2022 Plan is to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to employees, directors and consultants, and to promote the success of our business. The administrator of the 2022 Plan may, in its sole discretion, amend, alter, suspend or terminate the 2022 Plan, or any part thereof, at any time and for any reason. We will obtain stockholder approval of any 2022 Plan amendment to the extent necessary and desirable to comply with legal and regulatory requirements relating to the administration of equity-based awards. Unless earlier terminated by the administrator, the 2022 Plan will terminate ten years from the date it is adopted by our Board.

Plan Administration

One or more committees appointed by our Board will administer the 2022 Plan. Initially, the Compensation Committee shall administer the 2022 Plan. In addition, if we determine it is desirable to qualify transactions under the 2022 Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured with the intent that they satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of the 2022 Plan, the administrator has the power to administer the 2022 Plan and make all determinations deemed necessary or advisable for administering the 2022 Plan, including the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2022 Plan, determine the terms and conditions of awards (including the exercise price, the time or times at which the awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of the 2022 Plan and awards granted under it, prescribe, amend and rescind rules relating to the 2022 Plan, rules and regulations relating to sub-plans established for the purpose of facilitating compliance with applicable non-U.S. laws, easing the administration of the 2022 Plan and/or for qualifying for favorable tax treatment under applicable non-U.S. laws, in each case as the administrator may deem necessary or advisable and modify or amend each award (subject to the provisions of the 2022 Plan), including the discretionary authority to extend the post-termination exercisability period of awards and to extend the maximum term of an option or stock appreciation right (subject to the provisions of the 2022 Plan), to allow Participants to satisfy withholding tax obligations in a manner permissible under the 2022 Plan, to authorize any person to execute on behalf of us any instrument required to effect the grant of an award previously granted by the administrator and to allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type which may have a higher or lower exercise price or different terms, awards of a different type or cash, or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants.

Eligibility

Awards under the 2022 Plan, other than incentive stock options, may be granted to our employees (including our officers and directors) or a parent or subsidiary, members of our Board, or consultants engaged to render bona fide services to us or a parent or subsidiary. Incentive stock options may be granted only to our employees or a subsidiary, provided the services (i) are not in connection with the offer or sale of securities in a capital-raising transaction, and (ii) do not directly promote or maintain a market for our securities, in each case, within the meaning of Form S-8 promulgated under the Securities Act, and provided further, that a consultant will include only those persons to whom the issuance of shares may be registered under Form S-8 promulgated under the Securities Act.

Stock Options

Stock options may be granted under the 2022 Plan. The exercise price of options granted under the 2022 Plan generally must at least be equal to the fair market value of our common stock on the date of grant. The term of each option will be as stated in the applicable award agreement; provided, however, that the term may be no more than 10 years from the date of grant. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, they may exercise their option for the period of time stated in their option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the termination of service. An option may not be exercised later than the expiration of its term. Subject to the provisions of the 2022 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights

Stock appreciation rights may be granted under the 2022 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, they may exercise their stock appreciation right for the period of time stated in their stock appreciation right agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of the 2022 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock

Restricted stock may be granted under the 2022 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of the 2022 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever conditions to vesting it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units

RSUs may be granted under the 2022 Plan. RSUs are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of the 2022 Plan, the administrator determines the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of Company-wide, divisional, business unit or individual goals (including continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned RSUs in the form of cash, in shares of our common stock or in some combination thereof. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any vesting requirements will be deemed satisfied.

Performance Awards

Performance awards may be granted under the 2022 Plan. Performance awards are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will set objectives or vesting provisions, that, depending on the extent to which they are met, will determine the value of the payout for the performance awards. The administrator may set vesting criteria based on the achievement of Company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), or any other basis determined by the administrator in its discretion. Each performance award's threshold, target, and maximum payout values are established by the administrator on or before the grant date. After the grant of a performance award, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance award. The administrator, in its sole discretion, may pay earned performance awards in the form of cash, in shares, or in some combination thereof.

Non-transferability of Awards

Unless the administrator provides otherwise, the 2022 Plan generally does not allow for the transfer of awards other than by will or by the laws of descent and distribution and only the recipient of an award may exercise an award during their lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments

In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2022 Plan, the administrator will adjust the number and class of shares that may be delivered under the 2022 Plan or the number, and price of shares covered by each outstanding award and the numerical share limits set forth in the 2022 Plan.

Dissolution or Liquidation

In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control

The 2022 Plan provides that in the event of our merger with or into another corporation or entity or a "change in control" (as defined in the 2022 Plan), each outstanding award will be treated as the administrator determines, including, without limitation, that (i) awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and kind of shares and prices; (ii) upon written notice to a participant, that the participant's awards will terminate upon or immediately prior to the consummation of such merger or change in control; (iii) outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon consummation of such merger or change in control and, to the extent the administrator determines, terminate upon or immediately prior to the effectiveness of such merger or change in control; (iv) (A) the termination of an award in exchange for an amount of cash or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated by us without payment) or (B) the replacement of such award with other rights or property selected by the administrator in its sole discretion; or (v) any combination of the foregoing. The administrator will not be obligated to treat all awards, all awards a participant holds, or all awards of the same type, similarly. In the event that awards (or portion thereof) are not assumed or substituted for in the event of a merger or change in control, the participant will fully vest in and have the right to exercise all of their outstanding options and stock appreciation rights, including shares as to which such awards would not otherwise be vested or exercisable, all restrictions on restricted stock and RSUs or performance awards will lapse and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met, in all cases, unless specifically provided otherwise under the applicable award agreement or other written agreement between the participant and us or any of our subsidiaries or parents, as applicable. If an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that the option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the vested option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, the outside director will fully vest in and have the right to exercise options and/or stock appreciation rights as to all of the shares underlying such award, including those shares which would not be vested or exercisable, all restrictions on restricted stock and RSUs will lapse, and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met, unless specifically provided otherwise under the applicable award agreement or other written agreement between the participant and us or any of our subsidiaries or parents, as applicable.

Clawback

Awards will be subject to any clawback policy that we are required to adopt pursuant to the listing standards of any national securities exchange or association on which our securities are listed or as is otherwise required by the Dodd-Frank Act or other applicable laws. The administrator also may specify in an award agreement that the participant's rights, payments or benefits with respect to an award will be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain specified events. The administrator may require a participant to forfeit, return or reimburse us all or a portion of the award or shares issued under the award, any amounts paid under the award and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment and Termination

The administrator has the authority to amend, suspend or terminate the 2022 Plan provided such action does not impair the existing rights of any participant. The 2022 Plan automatically will terminate on November 22, 2032, unless it is terminated sooner.

Non-Employee Director Remuneration Policy

Our Board has not adopted a non-employee director remuneration policy.

Clawback Policy

On November 23, 2023, our Board adopted an executive compensation recoupment policy consistent with the requirements of the Exchange Act Rule 10D-1 and the Nasdaq listing standards thereunder, to help ensure that incentive compensation is paid based on accurate financial and operating data, and the correct calculation of performance against incentive targets. Our policy addresses recoupment of amounts from performance-based awards paid to all corporate officers, including awards under our equity incentive plans, in the event of a financial restatement to the extent that the payout for such awards would have been less, or in the event of fraud, or intentional, willful or gross misconduct that contributed to the need for a financial restatement.

Board Compensation

In November and December 2022, we signed agreements with four directors (Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey). Each director receives cash compensation of $11,250 per quarter. In addition, the two non-audit committee chairs (Mr. Toovey and Mr. Field) receive $1,250 per quarter

and the audit committee chair (Mr. Allen) receives an additional $2,000 per quarter. On July 11, 2023, each director received (i) a one-off issuance of 42 shares of common stock, (ii) a fully vested, non-qualified option to purchase 40 shares of common stock at a per share exercise price of $1,272.00, and (iii) 17 restricted stock units vesting in two even quarterly tranches on September 30, 2023 and December 31, 2023. Contingent on the receipt of shareholder approval to increase the number of shares authorized under the 2022 Plan, each director was entitled to receive 32 additional non-qualified options at a per share exercise price of $1,272.00, vesting 100% on the first anniversary of our IPO. On July 16, 2024, our stockholders approved the proposal to increase the number of shares available under the 2022 Plan and on such date, the directors' additional option grants were considered effective and were fully vested on the date of grant. In November 2024, the Board approved a cash payment of $20,000 to each non-executive director in lieu of equity-based fees for 2024 services. On October 21, 2025, the Board approved the grant of 8,000 stock options to each of the four directors (2,000 per director) at a per share exercise price of $5.84. These stock options were fully vested on the date of grant and have a term of seven years.

Compensation Committee Review

The Compensation Committee shall, if it deems necessary or prudent in its discretion, reevaluate and approve in January of each such year (or in any event prior to the first Board meeting of such fiscal year) the cash and equity awards (amount and manner or method of payment) to be made to non-employee directors for such fiscal year. In making this determination, the Compensation Committee shall utilize such market standard metrics as it deems appropriate, including, without limitation, an analysis of cash compensation paid to independent directors of our peer group.

The Compensation Committee shall also have the power and discretion to determine in the future whether non-employee directors should receive annual or other grants of options to purchase shares of common stock or other equity incentive awards in such amounts and pursuant to such policies as the Compensation Committee may determine utilizing such market standard metrics as it deems appropriate, including, without limitation, an analysis of equity awards granted to independent directors of our peer group.

Policies and Practices for Granting Certain Equity Awards

Our policies and practices regarding the granting of equity awards are carefully designed to ensure compliance with applicable securities laws and to maintain the integrity of our executive compensation program. The Compensation Committee is responsible for the timing and terms of equity awards to executives and other eligible employees.

The timing of equity award grants is determined with consideration to a variety of factors, including but not limited to, the achievement of pre-established performance targets, market conditions and internal milestones. The Company does not follow a predetermined schedule for the granting of equity awards; instead, each grant is considered on a case-by-case basis to align with the Company's strategic objectives and to ensure the competitiveness of our compensation packages.

In determining the timing and terms of an equity award, the Board or the Compensation Committee may consider material nonpublic information to ensure that such grants are made in compliance with applicable laws and regulations. The Board's or the Compensation Committee's procedures to prevent the improper use of material nonpublic information in connection with the granting of equity awards include oversight by legal counsel and, where appropriate, delaying the grant of equity awards until the public disclosure of such material nonpublic information.

The Company is committed to maintaining transparency in its executive compensation practices and to making equity awards in a manner that is not influenced by the timing of the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation. The Company regularly reviews its policies and practices related to equity awards to ensure they meet the evolving standards of corporate governance and continue to serve the best interests of the Company and its shareholders.

Participation of Employee Directors; New Directors

Unless separately and specifically approved by the Compensation Committee in its discretion, none of our employee directors shall be entitled to receive any remuneration for service as a director (other than expense reimbursement as per prevailing policy).

Director Compensation
As of December 31, 2025

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Charles Allen	53,000	-	8,240	-	-	61,240
Cheryl Xu	45,000	-	8,240	-	-	53,240
Stephen Toovey	50,000	-	8,240	-	-	58,240
Paul Field	50,000	-	8,240	-	-	58,240

(1) Represents the aggregate grant date fair value of options granted during the fiscal year, computed in accordance with FASB ASC Topic 718.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table presents information regarding beneficial ownership of our equity interests as of March 27, 2026 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of any class of our voting securities;
- our Named Executive Officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and, thus, represents voting or investment power with respect to our securities as of March 30, 2026. In computing the number and percentage of shares beneficially owned by a person, shares that may be acquired by such person within 60 days of March 30, 2026 are counted as outstanding, while these shares are not counted as outstanding for computing the percentage ownership of any other person. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all equity interests beneficially owned, subject to community property laws where applicable.

Name of Beneficial Owner[1]	Title	Number of Shares Beneficially Owned	Percent of Class
Officers and Directors			
Geoffrey Dow	President, Chief Executive Officer and Director	27,825(2)	1.05%
Tyrone Miller	Chief Financial Officer	3,219(3)	*
Kristen Landon	Chief Commercial Officer	1,553(4)	*
Charles Allen	Director	2,131(5)	*
Cheryl Xu	Director	6,026(6)	*
Stephen Toovey	Director	2,131(7)	*
Paul Field	Director	2,131(8)	*
Officers and Directors as a Group (total of 7 persons)		**45,016**	**1.69%**

* Less than 1%

(1) Percentages based on 2,636,788 shares of common stock issued and outstanding as of March 30, 2026 plus shares of common stock the person has the right to acquire within 60 days thereafter. Unless otherwise indicated, the principal address of the named executives and directors is c/o 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036. On January 20, 2026, the Company effectuated a 1-for-4 Reverse Stock Split of its outstanding common stock. Accordingly, all share numbers presented in this table have been adjusted to reflect the Reverse Stock Split.

(2) Includes (i) 14,001 shares of our common stock held in the name of Geoffrey Dow, (ii) 2,780 shares of common stock held by the Geoffrey S. Dow Revocable Trust (the "Dow Trust"), of which Geoffrey Dow is the trustee and has control over the voting and disposition of the shares of common stock held by the Dow Trust, (iii) 44 shares of common stock issuable upon exercise of warrants issued to the Geoffrey S. Dow Revocable Trust, (iv) 500 shares underlying fully vested options exercisable into common stock at a per share exercise price of $240.00, and (v) 10,500 shares underlying fully vested options exercisable into common stock at a per share exercise price of $26.20.

(3) Includes (i) 1,319 shares of our common stock held in the name of Tyrone Miller, (ii) 400 shares underlying fully vested options exercisable into common stock at a per share exercise price of $240.00 and (iii) 1,500 shares underlying fully vested options exercisable into common stock at a per share exercise price of $26.20.

(4) Ms. Landon beneficially owns a total of 1,553 shares of common stock, of which includes (i) 1,135 shares of common stock held in the name of Ms. Landon, and (ii) 418 shares underlying fully vested options exercisable into common stock at a per share exercise price of $27.40.

(5) Mr. Allen beneficially owns a total of 2,131 shares of common stock, of which includes (i) 59 shares of common stock held in the name of Mr. Allen, (ii) 72 shares underlying fully vested options exercisable into common stock at a per share exercise price of $1,272.00, and (iii) 2,000 shares underlying fully vested options exercisable into common stock at a per share exercise price of $5.84.

(6) Ms. Xu beneficially owns a total of 6,026 shares of common stock, of which includes (i) 3,954 shares of common stock held in the name of Ms. Xu, (ii) 72 shares underlying fully vested options exercisable into common stock at a per share exercise price of $1,272.00, and (iii) 2,000 shares underlying fully vested options exercisable into common stock at a per share exercise price of $5.84.

(7) Mr. Toovey beneficially owns a total of 2,131 shares of common stock, of which includes (i) 59 shares of common stock held in the name of Mr. Toovey, (ii) 72 shares underlying fully vested options exercisable into common stock at a per share exercise price of $1,272.00, and (iii) 2,000 shares underlying fully vested options exercisable into common stock at a per share exercise price of $5.84.

(8) Mr. Field beneficially owns a total of 2,131 shares of common stock, of which includes (i) 42 shares of common stock held by the Field Family Trust, of which Mr. Field is a trustee and has control over the voting and disposition of the shares of common stock held by the Field Family Trust, (ii) 17 shares of common stock held in the name of Mr. Field, (iii) 72 shares underlying fully vested options exercisable into common stock at a per share exercise price of $1,272.00, and (iv) 2,000 shares underlying fully vested options exercisable into common stock at a per share exercise price of $5.84.

Equity Plan Information

See Part II, Item 5 "*Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*" of this Annual Report on Form 10-K.

Changes in Control

There are no arrangements, to our knowledge, including any pledge by any person of securities of the Company, the operation of which may at a subsequent date result in a change in control of the Company.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Not applicable.

Item 14. Principal Accountant Fees and Services.

During the years ended December 31, 2025 and 2024, we engaged RBSM LLP as our independent registered public accounting firm. For the years ended December 31, 2025 and 2024, we incurred fees, as discussed below:

	Fiscal Year Ended December 31,	
	2025	2024
Audit Fees[1]	$ 163,000	$ 163,069
Audit-Related Fees[2]	116,576	60,000
Tax Fees	-	-
All Other Fees	-	-
Total	$ 279,576	$ 223,069

(1) Audit fees consist of fees relating to the audit of the Company's annual consolidated financial statements and reviews of interim condensed consolidated financial statements.

(2) Audit-related fees consisted of reviews of the Company's registration statements, consents, and the completion of comfort letter procedures associated with the Company's securities offerings.

Our policy is to pre-approve all audit and permissible non-audit services performed by the independent accountants. These services may include audit services, audit-related services, tax services and other services. Under our Audit Committee's policy, pre-approval is generally provided for particular services or categories of services, including planned services, project-based services and routine consultations. In addition, the Audit Committee may also pre-approve particular services on a case-by-case basis. Our Audit Committee approved all services that our independent public accountants provided to us in the past two fiscal years.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. ***Financial Statements***: The following Financial Statements and Supplementary Data of 60 Degrees Pharmaceuticals, Inc. and the Report of Independent Registered Public Accounting Firm included in Part II, Item 8:

   Audited Consolidated Balance Sheets at December 31, 2025 and 2024;

   Audited Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2025 and 2024;

   Audited Consolidated Statements of Shareholders' Equity for the years ended December 31, 2025 and 2024;

   Audited Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024; and

   Notes to Audited Consolidated Financial Statements.

2. ***Exhibits***:

Exhibit No:	Description of Exhibit:	Previously Filed and Incorporated by Reference herein:	Date Filed:
3.1	Certificate of Incorporation of the Registrant	Exhibit 3.1 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
3.2	Certificate of Designation of Series A Preferred Stock	Exhibit 3.2 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
3.3	Certificate of Correction to Certificate of Incorporation of the Registrant	Exhibit 3.3 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
3.4	Amended and Restated Bylaws of the Registrant	Exhibit 3.4 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
4.1	Description of the Registrants' Securities	Exhibit 4.1 to Annual Report on Form 10-K (File No: 001-41719)	April 1, 2024
4.2	Form of Pre-Funded Warrant in January 2024 public offering	Exhibit 4.2 to Registration Statement on Form S-1 (File No: 333-276641)	January 22, 2024
4.3	Form of Representative Warrant in January 2024 public offering	Exhibit 4.3 to Registration Statement on Form S-1 (File No: 333-276641)	January 22, 2024
4.4	Form of Warrant Agent Agreement in January 2024 public offering	Exhibit 4.4 to Registration Statement on Form S-1 (File No: 333-276641)	January 22, 2024

10.1	Securities Purchase Agreement dated as of May 19, 2022, by and between the Registrant and Geoffrey Dow	Exhibit 10.1 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.2	Common Stock Purchase Warrant dated as of May 19, 2022, issued by the Registrant to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018	Exhibit 10.2 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.3	Securities Purchase Agreement dated as of May 19, 2022, by and between Registrant and Mountjoy Trust	Exhibit 10.4 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.4	Common Stock Purchase Warrant dated as of May 19, 2022, issued by the Registrant to Mountjoy Trust	Exhibit 10.5 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023

10.5	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Bigger Capital Fund, LP	Exhibit 10.7 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.6	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Bigger Capital Fund, LP	Exhibit 10.8 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.7	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Cavalry Investment Fund, LP	Exhibit 10.10 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.8	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Cavalry Investment Fund, LP	Exhibit 10.11 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.9	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Walleye Opportunities Master Fund Ltd	Exhibit 10.13 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.10	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Walleye Opportunities Master Fund Ltd	Exhibit 10.14 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.11	Inter-Institutional Agreement dated as of February 15, 2021, by the Registrant and Florida State University Research Foundation	Exhibit 10.19 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.12	Exclusive License Agreement dated as of September 15, 2016, between National University of Singapore, Singapore Health Services Pte Ltd, the Registrant and 60P Australia Pty Ltd	Exhibit 10.20 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.13	Master Consultancy Agreement dated as of May 29, 2013, by and between the Registrant and BioIntelect Pty Ltd	Exhibit 10.21 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.14#	Employment Agreement dated as of January 12, 2023, between the Registrant and Geoffrey Dow	Exhibit 10.22 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.15#	Employment Agreement dated as of January 12, 2023, between the Registrant and Tyrone Miller	Exhibit 10.23 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.16	Agreement and Plan of Merger dated as of June 1, 2022, by and between the Registrant and 60 Degrees Pharmaceuticals, LLC	Exhibit 10.33 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.17	Exclusive License Agreement dated as of May 30, 2014, between National University of Singapore, Singapore Health Services Pte Ltd, the Registrant and 60P Australia Pty Ltd	Exhibit 10.34 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.18#	2022 Equity Incentive Plan	Exhibit 10.35 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.19	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Cyberbahn Federal Solutions, LLC	Exhibit 10.36 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.20	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Cyberbahn Federal Solutions, LLC	Exhibit 10.37 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.21	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Ariana Bakery Inc	Exhibit 10.39 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.22	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Ariana Bakery Inc	Exhibit 10.40 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023

10.23	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Sabby Volatility Warrant Master Fund, Ltd.	Exhibit 10.42 to Registration Statement on Form S-1 (File No:	January 31, 2023

		333-269483)	
10.24	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Sabby Volatility Warrant Master Fund, Ltd.	Exhibit 10.43 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.25	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Steel Anderson	Exhibit 10.45 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.26	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Steel Anderson	Exhibit 10.46 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.27	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Bixi Gao & Ling Ling Wang	Exhibit 10.48 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.28	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Bixi Gao & Ling Ling Wang	Exhibit 10.49 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.29#	Board of Directors Agreement dated as of November 28, 2022, as amended, by and between the Registrant and Charles Allen	Exhibit 10.56 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.30#	Board of Directors Agreement dated as of November 28, 2022, as amended, by and between the Registrant and Stephen Toovey	Exhibit 10.57 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.31#	Board of Directors Agreement dated as of December 9, 2022, as amended, by and between the Registrant and Cheryl Xu	Exhibit 10.58 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.32#	Board of Directors Agreement dated as of December 15, 2022, as amended, by and between the Registrant and Paul Field	Exhibit 10.59 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.33	Securities Purchase Agreement dated as of January 28, 2025, by and between the Registrant and certain investors	Exhibit 10.1 of the Current Report on Form 8-K	January 30, 2025
10.34	Form of Warrant	Exhibit 4.1 of the Current Report on Form 8-K	January 30, 2025
10.35	Placement Agent Warrant dated as of January 28, 2025, issued by the Registrant to the placement agent	Exhibit 4.2 of the Company's Report of Foreign Private Issuer on Form 8-K	January 30, 2025
10.36	Securities Purchase Agreement dated as of February 5, 2025, by and between the Registrant and the investors	Exhibit 10.1 of the Current Report on Form 8-K	February 6, 2025
10.37	Form of Warrant	Exhibit 4.1 of the Current Report on Form 8-K	February 6, 2025
10.38	Placement Agent Warrant dated as of January 28, 2025, issued by the Registrant to the placement agent	Exhibit 4.2 of the Current Report on Form 8-K	February 6, 2025
10.39	Form of Securities Purchase Agreement	Exhibit 10.1 of the Current Report on Form 8-K	September 6, 2024
10.40	Form of Registration Rights Agreement	Exhibit 10.2 of the Current Report on Form 8-K	September 6, 2024
10.41	Form of Pre-Funded Warrant	Exhibit 10.3 of the Current Report on Form 8-K	September 6, 2024
10.42	Form of Series A Warrants	Exhibit 10.4 of the Current Report on Form 8-K	September 6, 2024
10.43	Form of Series B Warrants	Exhibit 10.5 of the Current Report on Form 8-K	September 6, 2024
10.44	Form of Placement Agent Warrant	Exhibit 10.6 of the Current Report on Form 8-K	September 6, 2024
10.45	Form of Pre-Funded Warrant in January 2024 public offering	Exhibit 4.2 to Registration Statement on Form S-1 (File No: 333-276641)	January 22, 2024
10.46	Form of Representative Warrant in January 2024 public offering	Exhibit 4.3 to Registration Statement on Form S-1 (File No: 333-276641	January 22, 2024
10.47	Form of Warrant Agent Agreement in January 2024 public offering	Exhibit 4.4 to Registration Statement on Form S-1 (File No: 333-276641)	January 22, 2024

14.1	Code of Conduct	Exhibit 99.4 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
19.1	Insider Trading Policy	*	
21.1	List of Subsidiaries	Exhibit 21.1 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
23.1	Consent of RBSM LLP dated as of March 27, 2025	*	
31.1	Certification of Principal Executive Officer filed pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-	*	

	Oxley Act of 2002		
31.2	Certification of Principal Financial Officer filed pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*	
32.1	Certification of Chief Executive Officer furnished pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**	
32.2	Certification of Chief Financial Officer furnished pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**	
97.1	Clawback Policy	Exhibit 97.1 to Annual Report on Form 10-K (File No: 001-41719	April 1, 2024
99.1	Audit Committee Charter	Exhibit 99.5 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
99.2	Compensation Committee Charter	Exhibit 99.6 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
99.3	Nominating and Corporate Governance Committee Charter	Exhibit 99.7 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
101	Interactive Data Files	*	
101.INS	Inline XBRL Instance Document	*	
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*	
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*	
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*	

Management contract or compensatory plan.

* Filed herewith.

** Furnished herewith and not to be incorporated by reference into any filing of 60 Degrees Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

60 DEGREES PHARMACEUTICALS, INC.

Dated: March 30, 2026

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

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Position	Date
/s/ Geoffrey Dow Geoffrey Dow	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2026
/s/ Tyrone Miller Tyrone Miller	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2026
/s/ Charles Allen Charles Allen	Director	March 30, 2026
/s/ Cheryl Xu Cheryl Xu	Director	March 30, 2026
/s/ Stephen Toovey Stephen Toovey	Director	March 30, 2026
/s/ Paul Field	Director	March 30, 2026

60 DEGREES PHARMACEUTICALS, INC.

INSIDER TRADING POLICY

Purpose

This Insider Trading Policy (this "Policy") provides guidelines with respect to transactions in the securities of 60 Degrees Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and the handling of confidential information about the Company and the companies with which the Company does business.

The Company's Board of Directors ("Board") has adopted this Policy to promote compliance with federal, state, and foreign securities laws that prohibit certain persons who are aware of material nonpublic information about a company from: (i) trading in securities of that company (e.g., purchasing and selling of securities, including purchases and sales of options and warrants on securities, as well as short sales); or (ii) providing material nonpublic information to other persons who may trade on the basis of that information.

Persons Subject to the Policy

This Policy applies to all officers of the Company and its subsidiaries, all members of the Board and all employees of the Company and its subsidiaries. The Company may also determine that other persons should be subject to this Policy, such as contractors or consultants who have access to material nonpublic information. This Policy also applies to family members, other members of a person's household and entities controlled by a person covered by this Policy, as described below.

Transactions Subject to the Policy

This Policy applies to transactions in the Company's securities (collectively referred to in this Policy as "Company Securities"), including the Company's common stock, options to purchase common stock, or any other type of securities that the Company may issue, including, but not limited to, preferred stock, convertible debentures and warrants, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's Securities. There are certain exceptions that are discussed in this Policy under "Transactions Under Company Plans," "Transactions Not Involving a Purchase or Sale," and "Rule 10b5-1 Plans."

Individual Responsibility

Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in Company Securities while in possession of material nonpublic information.

Persons subject to this Policy must not engage in illegal trading and must avoid the appearance of improper trading. Each individual is responsible for making sure that he or she complies with this Policy, and that any family member, household member, or entity whose transactions are subject to this Policy, as discussed below, also comply with this Policy.

In all cases, the responsibility for determining whether an individual is in possession of material nonpublic information rests with that individual, and any action on the part of the Company, the Compliance Officer, or any other employee or director pursuant to this Policy or otherwise does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws.

You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this Policy or applicable securities laws, as described below in more detail under the heading "Consequences of Violations."

Administration of the Policy

[_____] shall serve as the Compliance Officer for the purposes of this Policy. The Compliance Officer is authorized to consult with the Company's securities counsel without notice and at such times as he may deem necessary or appropriate at the expense of the Company. All determinations and interpretations by the Compliance Officer shall be final and not subject to further review. The duties of the Compliance Officer include, but are not limited to, the following:

assisting with implementation and enforcement of this Policy;

circulating this Policy to all employees and ensuring that this Policy is amended as necessary to remain up-to-date with insider trading laws;

ensuring that the Company obtain and maintain written acknowledgments from employees that they have read the policy;

overseeing the responses to questions from individual employees;

providing for employee training sessions;

ensuring that relevant files on policy compliance and implementation are maintained;

pre-clearing all trading in securities of the Company in accordance with the procedures as discussed in this Policy under "Pre-Clearance Procedures";

providing approval of any Rule 10b5-1 plans as discussed in this Policy under "Rule 10b5-1 Plans" and any prohibited transactions as discussed in this Policy; and

providing a reporting system with an effective whistleblower protection mechanism.

Statement of Policy

It is the policy of the Company that no director, officer, or other employee of the Company (or any other person designated by this Policy or by the Compliance Officer as subject to this Policy) who is aware of material nonpublic information relating to the Company may, directly, or indirectly through family members or other persons or entities:

1. Engage in transactions in Company Securities, except as otherwise specified in this Policy under the headings "Transactions Under Company Plans," "Transactions Not Involving a Purchase or Sale," and "Rule 10b5-1 Plans";

2. Recommend the purchase or sale of any Company Securities;

3. Disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons, including, but not limited to, family, friends, business associates, investors, and expert consulting firms, unless any such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or

4. Assist anyone engaged in the above activities.

In addition, it is the policy of the Company that no director, officer, or other employee of the Company or any other person designated as subject to this Policy who, in the course of working for the Company, learns of material nonpublic information about a company with which the Company does business, including a customer or supplier of the Company, may trade in that company's securities until the information becomes public or is no longer material.

There are no exceptions to this Policy, except as specifically noted herein. Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure), or small transactions, are not excepted from this Policy. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

Definition of Material Nonpublic Information

Information is considered "material" if a reasonable investor would consider that information important in making a decision to buy, hold, or sell securities. Any information that could be expected to affect a company's stock price, whether it is positive or negative, should be considered material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances and is often evaluated by enforcement authorities with the benefit of hindsight. While it is not possible to define all categories of material information, some examples of information that ordinarily would be regarded as material are:

Projections of future earnings or losses, or other earnings guidance;

Changes to previously announced earnings guidance, or decisions to suspend earnings guidance;

A pending or proposed merger, acquisition, or tender offer;

A pending or proposed acquisition or disposition of a significant asset;

A pending or proposed joint venture;

A Company restructuring;

Significant related party transactions;

A change in dividend policy, the declaration of a stock split, or an offering of additional securities;

Bank borrowings or other financing transactions out of the ordinary course of business;

The establishment of a repurchase program for Company Securities;

A change in the Company's pricing or cost structure;

Major marketing changes;

A change in management;

A change in auditors or notification that the auditor's report may no longer be relied upon;

Development of a significant new product, process, or service;

Pending or threatened significant litigation, or the resolution of such litigation;

Impending bankruptcy or the existence of severe liquidity problems;

The gain or loss of a significant customer or supplier;

The results of clinical trials or testing of the Company's products or services;

A significant cybersecurity incident, such as a data breach, or any other significant disruption in the Company's operations or loss, potential loss, breach, or unauthorized access of its property or assets, whether at its facilities or through its information technology infrastructure; or

The imposition of an event-specific restriction on trading in the Company's Securities or the securities of another company or the extension or termination of such restriction.

Information that has not been disclosed to the public is generally considered to be nonpublic information. In order to establish that the information has been disclosed to the public, it may be necessary to demonstrate that the information has been widely disseminated. Information generally would be considered widely disseminated if it has been disclosed through the Dow Jones "broad tape," newswire services, a broadcast on widely-available radio or television programs, publication in a widely-available newspaper, magazine or news website, or public disclosure documents filed with the Securities and Exchange Commission ("SEC") that are available on the SEC's website, or subject to the Compliance Officer's determination, disclosure on the Company's website, or through social media.

By contrast, information would likely not be considered widely disseminated if it is available only to the Company's employees. Nonpublic information may also include: (i) information available to a select group of analysts or brokers or institutional investors; (ii) undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and (iii) information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally two (2) trading days).

Once information is widely disseminated, it is still necessary to provide the investing public with sufficient time to absorb the information. As a general rule, information should not be considered fully absorbed by the marketplace until after the second (2nd) business day after the day on which the information is released. If, for example, the Company were to make an announcement on a Monday, you should not trade in Company Securities until Thursday. Depending on the particular circumstances, the Company may determine that a longer or shorter period should apply to the release of specific material nonpublic information. For purposes of this Policy, a "business day" is any day that The Nasdaq Stock Market LLC is open for trading.

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Compliance Officer or assume that the information is nonpublic and treat it as confidential.

Transactions by Family Members and Others

This Policy applies to your family members who reside with you (including a spouse, a child, a child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings, and in-laws), anyone else who lives in your household, and any family members who do not live in your household but whose transactions in Company Securities are directed by you or are subject to your influence or control, such as parents or children who consult with you before they trade in Company Securities (collectively referred to as "Family Members").

You are responsible for the transactions of these other persons and therefore should make them aware of the need to confer with you before they trade in Company Securities, and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account.

This Policy does not, however, apply to personal securities transactions of Family Members where the purchase or sale decision is made by a third party not controlled by, influenced by or related to you or your Family Members.

Transactions by Entities that You Influence or Control

This Policy applies to any entities that you influence or control, including any corporations, partnerships, or trusts (collectively referred to as "Controlled Entities"), and transactions by these Controlled Entities should be treated for the purposes of this Policy and applicable securities laws as if they were for your own account.

Transactions Under Company Plans

This Policy does not apply in the case of the following transactions, if currently applicable, except as specifically noted:

Stock Option Exercises

This Policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's plans, or to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Restricted Stock Awards

This Policy does not apply to the vesting of restricted stock, or the exercise of a tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock. The Policy does apply, however, to any market sale of restricted stock.

401(k) Plan

This Policy does not apply to purchases of Company Securities in the Company's 401(k) plan resulting from your periodic contribution of money to the plan pursuant to your payroll deduction election.

This Policy does apply, however, to certain elections you may make under the 401(k) plan, including: (i) an election to increase or decrease the percentage of your periodic contributions that will be allocated to the Company stock fund; (ii) an election to make an intra-plan transfer of an existing account balance into or out of the Company stock fund; (iii) an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of your Company stock fund balance; and (iv) an election to pre-pay a plan loan if the pre-payment will result in allocation of loan proceeds to the Company stock fund. It should be noted that sales of Company Securities from a 401(k) account are also subject to Rule 144, and therefore affiliates should ensure that a Form 144 is filed when required.

Employee Stock Purchase Plan

This Policy does not apply to purchases of Company Securities in the employee stock purchase plan resulting from your periodic contribution of money to the plan pursuant to the election you made at the time of your enrollment in the plan. This Policy also does not apply to purchases of Company Securities resulting from lump sum contributions to the plan, provided that you elected to participate by lump sum payment at the beginning of the applicable enrollment period.

This Policy does apply, however, to your election to participate in the plan for any enrollment period, and to your sales of Company Securities purchased pursuant to the plan.

Dividend Reinvestment Plan

This Policy does not apply to purchases of Company Securities under the Company's dividend reinvestment plan resulting from your reinvestment of dividends paid on Company Securities.

This Policy does apply, however, to voluntary purchases of Company Securities resulting from additional contributions you choose to make to the dividend reinvestment plan, and to your election to participate in the plan or increase your level of participation in the plan. This Policy also applies to your sale of any Company Securities purchased pursuant to the plan.

Other Similar Transactions

Any other purchase of Company Securities from the Company or sales of Company Securities to the Company are not subject to this Policy.

Transactions Not Involving a Purchase or Sale

Bona fide gifts are not transactions subject to this Policy, unless the person making the gift has reason to believe that the recipient intends to sell the Company Securities while the officer, employee, or director is aware of material nonpublic information, or the person making the gift is subject to the trading restrictions specified below under the heading "Additional Procedures" and the sales by the recipient of the Company Securities occur during a blackout period.

Further, transactions in mutual funds that are invested in Company Securities are not transactions subject to this Policy.

Special and Prohibited Transactions

Certain transactions are of concern not only because of insider trading considerations, but also because of the appearance created by the transaction and the potential repercussions that the transaction may have with investors, regulators, and others.

Accordingly, the Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this Policy engage in certain types of transactions. It therefore is the Company's policy that any persons covered by this Policy may not engage in any of the following transactions, or should otherwise consider the Company's preferences as described below.

Short-Term Trading

Short-term trading of Company Securities may be distracting to the person and may unduly focus the person on the Company's short-term stock market performance instead of the Company's long-term business objectives. For these reasons, any director, officer, or other employee of the Company who purchases Company Securities in the open market may not sell any Company Securities of the same class during the six (6) months following the purchase or vice versa. Directors and officers should note the short-term trading restrictions of Section 16(b) of the Securities Exchange Act of 1934, as amended ("Exchange Act").

Short Sales

Short sales of Company Securities (i.e., the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. For these reasons, short sales of Company Securities are prohibited. In addition, Section 16(c) of the Exchange Act prohibits officers and directors from engaging in short sales. (Short sales arising from certain types of hedging transactions are governed by the paragraph below captioned "Hedging Transactions.")

Publicly-Traded Options

Given the relatively short term of publicly-traded options, transactions in options may create the appearance that a director, officer, or employee is trading based on material nonpublic information and focus a director's, officer's, or other employee's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in put options, call options, or other derivative securities, on an exchange or in any other organized market, are prohibited by this Policy. (Option positions arising from certain types of hedging transactions are governed by the next paragraph below.)

Hedging Transactions

Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars, and exchange funds. Such transactions may permit a director, officer, or employee to continue to own Company Securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the director, officer, or employee may no longer have the same objectives as the Company's other shareholders. Therefore, directors, officers, and employees are prohibited from engaging in any such transactions.

Margin Accounts and Pledged Securities

Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged or hypothecated as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Company Securities, directors, officers, and other employees are prohibited from holding Company Securities in a margin account and are strongly discouraged from pledging Company Securities as collateral for a loan. Any person wishing to enter into a legitimate loan pledge arrangement must first submit the proposed transaction in writing for approval by the Compliance Officer at least two (2) weeks prior to the proposed execution of documents evidencing the proposed transaction and must set forth a justification for the proposed transaction and clearly demonstrate the financial capacity to repay the loan without resorting to the pledged securities. The person making the request shall have no other contact with the Compliance Officer on that matter and the Compliance Officer's decision shall be final and binding. (Pledges of Company Securities arising from certain types of hedging transactions are governed by the paragraph above captioned "Hedging Transactions.")

Standing and Limit Orders

Standing and limit orders, except standing and limit orders under approved Rule 10b5-1 Plans, as described below, create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a director, officer, or other employee is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on Company Securities. If a person subject to this Policy determines that they must use a standing order or limit order, the order should be limited to short duration and should otherwise comply with the restrictions and procedures outlined below under the heading "Additional Procedures."

Additional Procedures

The Company has established additional procedures in order to assist the Company in the administration
of this Policy, to facilitate compliance with laws prohibiting insider trading while in possession of material nonpublic information, and to avoid the appearance of any impropriety. These additional procedures are applicable only to those individuals described below.

Pre-Clearance Procedures

The persons designated by the Compliance Officer as being subject to these procedures, as well as the Family Members and Controlled Entities of such persons, may not engage in any transaction in Company Securities without first obtaining pre-clearance of the transaction from the Compliance Officer.

A written request for pre-clearance should be submitted to the Compliance Officer at least two (2) business days in advance of the proposed transaction. The Compliance Officer is under no obligation to approve a transaction submitted for pre-clearance, and may determine not to permit the transaction. If a person seeks preclearance and permission to engage in the transaction is denied, then he or she should refrain from initiating any transaction in Company Securities, and should not inform any other person of the restriction.

When a request for pre-clearance is made, the requestor should carefully consider whether he or she may be aware of any material nonpublic information about the Company, and should describe fully those circumstances to the Compliance Officer. The requestor should also indicate whether he or she has effected any non-exempt "opposite-way" transactions within the past six months, and should be prepared to report the proposed transaction on an appropriate Form 4 or Form 5. The requestor should also be prepared to comply with SEC Rule 144 and file Form 144, if necessary, at the time of any sale.

All pre-cleared trades must be effected within five (5) business days of receipt of pre-clearance unless an exception is granted. Transactions not effected within the time limit are subject to pre-clearance again. Within three (3) business days after the execution of the transaction, the requestor shall notify the Compliance Officer of the date and size of the transaction.

The Compliance Officer shall document and maintain records relating to the pre-clearing request, the date of grant or denial, and other pertinent information.

Blackout Periods

The persons designated by the Compliance Officer as subject to this restriction, as well as their Family Members or Controlled Entities, may not conduct any transactions involving the Company's Securities (other than as specified by this Policy), during a "Blackout Period" beginning two weeks prior to the end of each fiscal quarter and ending on the second (2nd) business day following the date of the public release of the Company's earnings results for that quarter. In other words, these persons may only conduct transactions in Company Securities during the "Window Period" beginning on the third (3rd) business day following the public release of the Company's quarterly earnings and ending fifteen (15) days prior to the close of the next fiscal quarter.

Under certain very limited circumstances, a person subject to this restriction may be permitted to trade during a Blackout Period, but only if the Compliance Officer, with the advice of securities counsel if requested by the Compliance Officer, concludes that the person does not in fact possess material nonpublic information and may otherwise trade.

Persons wishing to trade during a Blackout Period must make such request in writing to the Compliance Officer for approval at least three (3) business days in advance of any proposed transaction involving Company Securities. All such trades are subject to the pre-clearance procedures set forth above under "Pre-Clearance Procedures."

Event-Specific Trading Restriction Periods

From time to time, an event may occur that is material to the Company and is known by only a few executives or directors (e.g., negotiation of mergers, acquisitions or dispositions, investigation and assessment of cybersecurity incidents, or new product developments). The involved directors or officers shall promptly notify the Compliance Officer of such event. While such event remains material and nonpublic, the Company may impose special blackout periods ("Special Blackout Period") during which executive officers, directors, and such other persons designated by the Compliance Officer, together with their family members, are prohibited from trading in the Company's securities. If the Company imposes a Special Blackout Period, it will notify those affected and will not announce its existence other than to those who are aware of the event giving rise to the Special Blackout Period. If you know of the event, then even if the Compliance Officer has not designated you as a person who should not trade due to an event-specific restriction, you should not trade while you are aware of material nonpublic information. Exceptions will not be granted during an event-specific trading restriction period. Any person made aware of the existence of a Special Blackout Period should not disclose its existence to any other person.

In addition, the Company's financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the Compliance Officer, designated persons should refrain from trading in Company Securities even later than the typical Blackout Period described above.

Exceptions

The quarterly trading restrictions and event-specific trading restrictions do not apply to those transactions to which this Policy does not apply, as described above under the headings "Transactions Under Company Plans" and "Transactions Not Involving a Purchase or Sale." Further, the requirement for pre-clearance, the quarterly trading restrictions, and event-specific trading restrictions do not apply to transactions conducted pursuant to approved Rule 10b5-1 plans, described under the heading "Rule 10b5-1 Plans."

Rule 10b5-1 Plans

Rule 10b5-1 under the Exchange Act provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a Rule 10b5-1 plan for transactions in Company Securities that meets certain conditions specified in Rule 10b-5-1 (a "Rule 10b5-1 Plan"). If the plan meets the requirements of Rule 10b5-1, Company Securities may be purchased or sold without regard to certain insider trading restrictions.

To comply with the Policy, a Rule 10b5-1 Plan must be approved by the Compliance Officer and meet the requirements of Rule 10b5-1 and the Company's "Guidelines for Rule 10b5-1 Plans," which may be obtained from the Compliance Officer. In general, a Rule 10b5-1 Plan must be entered into at a time when the person entering into the plan is not aware of material nonpublic information. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded, or the date of the trade. The plan must either specify the amount, pricing, and timing of transactions in advance or provide a third party irrevocable authority to effect such transactions at its own discretion, so long as the third party does not possess material inside information about the Company at the time of the transaction.

Any Rule 10b5-1 Plan must be submitted in writing for approval by the Compliance Officer no less than five (5) business days prior to the entry into the Rule 10b5-1 Plan. No further pre-approval of transactions conducted pursuant to the Rule 10b5-1 Plan will be required.

The Company may, on a case-by-case basis, announce publicly (whether by press release, on the Company website, or otherwise) that a key insider has established a pre-arranged plan at the time the plan is entered into, in order to mitigate potentially adverse publicity if a programmed trade on behalf of that insider occurs on some later date when the insider is in possession of material nonpublic information about the Company.

Post-Termination Transactions

This Policy continues to apply to transactions in Company Securities even after termination of service to the Company. If an individual is in possession of material nonpublic information when his or her service terminates, that individual may not trade in Company Securities until that information has become public or is no longer material.

Consequences of Violations

The purchase or sale of securities while aware of material nonpublic information, or the disclosure of material nonpublic information to others who then trade in the Company's Securities, is prohibited by the federal and state laws. Insider trading violations are pursued vigorously by the SEC, U.S. attorneys, and state enforcement authorities as well as the laws of foreign jurisdictions.

In addition, a person who "tips" others may also be liable for transactions by the tippees to whom he or she has disclosed material nonpublic information. Tippers can be subject to the same penalties and sanctions as the tippees, and the SEC has imposed large penalties even when the tipper did not profit from the transaction.

Punishment for insider trading violations is severe, and could include significant fines and imprisonment. While the regulatory authorities concentrate their efforts on the individuals who trade, or who "tip" inside information to others who trade, the federal securities laws also impose potential liability on companies and other "controlling persons" if they fail to take reasonable steps to prevent insider trading by company personnel.

The SEC can seek substantial civil penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation," which would apply to the Company and/or management and supervisory personnel. These controlling persons may be held liable for up to the greater of $2.3 million or three times the amount of the profits gained or losses avoided. Even for violations that result in a small or no profit, the SEC can seek penalties from a company and/or its management and supervisory personnel as controlling persons.

In addition, an individual's failure to comply with this Policy may subject the individual to Company-imposed sanctions, including dismissal for cause, whether or not the employee's failure to comply results in a violation of law. Needless to say, a violation of law, or even an SEC investigation that does not result in prosecution, can tarnish a person's reputation and irreparably damage a career. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory.

Company Assistance

Any person who has a question about this Policy or its application to any proposed transaction may obtain additional guidance from the Compliance Officer, who can be reached by telephone at [_____] or via e-mail at [_____].

Certification

All persons subject to this Policy must certify their understanding of, and intent to comply with, this Policy. Please complete and sign the accompanying Certification page and return to [_____] at: [_____].

CERTIFICATION

I hereby acknowledge receipt of 60 Degrees Pharmaceuticals, Inc.'s Insider Trading Policy, and certify that I have read, understand, and will comply with this policy. I further acknowledge that I have been designated an "Insider" for purposes of the Insider Trading Policy and will comply with the provisions applicable to such persons. I understand that my failure to comply in all respects with the Insider Trading Policy is a basis for termination for cause of my employment or other service relationship with 60 Degrees Pharmaceuticals, Inc.

Date: _____ Signature: _____

Print Name: _____

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-3 (No. 333-282221) of our report dated March 30, 2026, relating to the consolidated financial statements of 60 Degrees Pharmaceuticals, Inc. as of and for the two years ended December 31, 2025 included in this Annual Report on Form 10-K for 60 Degrees Pharmaceuticals, Inc. (which report includes an explanatory paragraph regarding the Company's ability to continue as a going concern).

We also consent to the reference to our firm under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ RBSM LLP

Las Vegas, Nevada
March 30, 2026

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Geoffrey Dow, President and Chief Executive Officer of 60 Degrees Pharmaceuticals, Inc. (the "Company"), certify that:

(1) I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods represented in this report;

(4) The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

(5) The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and to the Audit Committee of the Board of Directors (or persons fulfilling the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

March 30, 2026

/s/ Geoffrey Dow
Geoffrey Dow
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Tyrone Miller, Chief Financial Officer of 60 Degrees Pharmaceuticals, Inc. (the "Company"), certify that:

(1) I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods represented in this report;

(4) The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

(5) The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and to the Audit Committee of the Board of Directors (or persons fulfilling the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

March 30, 2026

/s/ Tyrone Miller
Tyrone Miller
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of 60 Degrees Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Geoffrey Dow, President and Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 30, 2026

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of 60 Degrees Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Tyrone Miller, Chief Financial Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 30, 2026

/s/ Tyrone Miller
Tyrone Miller
Chief Financial Officer
(Principal Financial Officer)