As filed with the Securities and Exchange Commission on August 14, 2026

Registration No. 333-_____

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

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

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

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

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

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

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

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

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

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

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

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Subject To Completion, Dated August 14, 2026

PROSPECTUS

Up to 1,769,593 Shares of Common Stock, Common Stock underlying certain Pre-Funded Warrants, Common Warrants and Placement Agent Warrants

This prospectus relates to the offer and sale from time to time, on a resale basis, by the selling stockholders identified herein and any of their respective transferees, pledgees, assignees, donees, distributees, or other successors-in-interest, of up to an aggregate of 1,769,593 shares of our common stock, par value $0.0001 per share ("Common Stock"), consisting of: (i) 191,571 shares of common stock, (ii) 383,142 shares of Common Stock issuable upon exercise of pre-funded warrants held by certain selling stockholders (the "Pre-Funded Warrants"), (iii) 574,713 shares of Common Stock issuable upon exercise of Series A warrants (the "Series A Warrants"), (iv) 574,713 shares of Common Stock issuable upon exercise of Series B warrants (the "Series B Warrants," together with Series A Warrants, the "Common Warrants") (and collectively with the Pre-Funded Warrants and Common Warrants, the "Purchase Warrants"), and (v) 45,454 shares of Common Stock issuable upon the exercise of placement agent warrants (the "Placement Agent Warrants" and together with the Purchase Warrants, the "Warrants") that were issued to H.C. Wainwright & Co., LLC ("Wainwright" or the "Placement Agent") as partial compensation for Wainwright acting as placement agent in connection with the Private Placement (as defined below) and are held by certain designees (and certain of their assignees) of Wainwright. The Warrants were issued to the selling stockholders in connection with a private placement we completed on July 30, 2026 (the "Private Placement"). We refer to the 1,769,593 shares of Common Stock and the Common Stock underlying the Warrants being registered herein as the "Registered Securities."

We are not offering any shares of our Common Stock for sale by us under this prospectus. We are registering the shares of Common Stock covered by this prospectus to be sold by the selling stockholders under the terms of a registration rights agreement dated July 30, 2026, entered into with the selling stockholders in connection with the Private Placement. We will not receive any of the proceeds from the sale by the selling stockholders of the Common Stock. Upon any exercise of the Warrants for cash, however, we will receive the exercise price of the respective Warrants.

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

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

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

Our Common Stock is listed for trading on the Nasdaq Capital Market under the symbol "SXTP." On August 13, 2026, the last reported sale price of our Common Stock on the Nasdaq Capital Market was $1.18 per share.

Investing in our securities involves a high degree of risk. See the information contained under "Risk Factors" on page 39 of this prospectus and in the documents incorporated herein by reference. You should read this entire prospectus carefully before you make your investment decision.

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

The date of this prospectus is August 14, 2026.

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IMPORTANT INFORMATION ABOUT THIS PROSPECTUS

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

We have not authorized anyone to give any information or to make any representation to you other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any of our shares of Common Stock other than the shares of our Common Stock covered hereby, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy any securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about, and to observe, any restrictions as to the offering and the distribution of this prospectus applicable to those jurisdictions.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- Our ability to effectively operate our business segments;
- Our ability to manage our research, development, expansion, growth and operating expenses;
- Our ability to evaluate and measure our business, prospects and performance metrics;
- Our ability to compete, directly and indirectly, and succeed in a highly competitive and evolving industry;
- Our ability to respond and adapt to changes in technology and customer behavior;
- Our ability to protect our intellectual property and to develop, maintain and enhance a strong brand; and
- other factors (including the risks contained in the section of this prospectus entitled "*Risk Factors*") relating to our industry, our operations and results of operations.

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

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

PROSPECTUS SUMMARY

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

2026 Annual Meeting of Stockholders

On August 5, 2026, we conducted our virtual 2026 Annual Meeting of Stockholders (the "2026 Annual Meeting"). Our stockholders of record at the close of business on July 2, 2026, the record date for the determination of stockholders entitled to vote at the 2026 Annual Meeting, approved the proposals to (1) elect five directors to serve until the 2027 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 800,000 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 1:5 to 1:10 inclusive, as may be determined at the appropriate time by the Board of Directors, in its sole discretion; (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, 2026 and (5) to approve a payment to management of a success fee five percent (5%) of deal proceeds between a deal value of $40 million and $100 million, and six percent (6%) of deal proceeds for a deal value in excess of $100 million, in the event of a change of control, strategic transaction or sale of Arakoda, to be awarded as cash or equity to members of the management team, as determined by the Board of Directors in its sole discretion.

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 is 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 Prospectus Supplement

On March 2, 2026, we filed a prospectus supplement pursuant to Rule 424(b)(5), updating the amount we were permitted to offer and sell under the 2025 ATM Agreement to allow for additional gross sales proceeds of $1,308,000 (the "2026 ATM Prospectus Supplement"). The 2026 ATM Prospectus Supplement was subsequently amended on March 11, 2026, and March 13, 2026, to increase the maximum aggregate offering price by $981,000 and $565,000, respectively (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 sold pursuant to the 2026 ATM Prospectus Supplement 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, the prospectus supplement dated September 5, 2025, 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 $2,535,047, after deducting commissions and certain other offering expenses. We currently expect to use the net proceeds from the 2026 ATM Offering for similar general corporate purposes, including supporting our sales and marketing initiatives and ongoing clinical and preclinical research.

Due to the decline in our stock price, as of June 30, 2026, we did not have available capacity to sell additional shares under the 2025 ATM Agreement and related prospectus supplements based on the limitations of General Instruction I.B.6 of Form S-3, which restricts the aggregate market value of securities we may sell during any 12-month period to one-third of our public float. Our ability to resume sales under the 2025 ATM Agreement and related prospectus supplements will depend on future increases in our stock price or the passage of time such that prior sales are no longer counted within the trailing 12-month measurement period.

Reverse Stock Split and Nasdaq Delisting Notice

On January 20, 2026, we received a notice from the Listing Qualifications Department of the Nasdaq Stock Market LLC ("Nasdaq") indicating that Nasdaq staff had determined to delist our common stock and warrants from The Nasdaq Capital Market because our 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). Upon receipt of the notice, we paid $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.

At the 2025 Annual Stockholders Meeting in October 2025, our stockholders approved an amendment to our Certificate of Incorporation to effect a reverse stock split of our common stock at a range of ratios between 1:3 to 1:10, and on December 17, 2025, our Board of Directors approved the implementation of the reverse stock split at a ratio of 1:4 (the "1:4 Reverse Stock Split"). Beginning January 20, 2026, our common stock traded on The Nasdaq Capital Market on a split adjusted basis.

Following the implementation of the 1:4 Reverse Stock Split, on February 11, 2026, we were notified by Nasdaq that we regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) and were therefore in compliance with the Nasdaq Capital Market's listing requirements. As a result, the hearing before the Nasdaq Hearings Panel scheduled for February 19, 2026 was cancelled and the matter was closed. Our common stock and warrants will continue to be listed and traded on The Nasdaq Capital Market.

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 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 1:4 Reverse Stock Split 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 Quarterly Report on Form 10-Q have been retroactively restated, as appropriate, to reflect the effects of the 1:4 Reverse Stock Split.

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 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 100,000 prescriptions). Barriers to entry include low brand awareness in the prescriber community, the low cost of some of the generic alternatives and the requirement for a blood test to assess G6PD status prior to travel. 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]

1 See https://www.cdc.gov/lyme/signs-symptoms/chronic-symptoms-and-lyme-disease.html.
2 Conclusions from Company-commissioned market research.

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 60,000 individuals, representing approximately $30 million in sales (based on the Arakoda wholesale acquisition cost).[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]

- 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 weekly Tafenoquine for at least six weeks in combination with standard of care cured 100% 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]

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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 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, and factoring in diagnostic screening data from our chronic babesiosis trial.

7 Same as Note 6, but inclusive of the effect of sensitive molecular tests like Igenx and Galaxy molecular screens becoming widely 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.

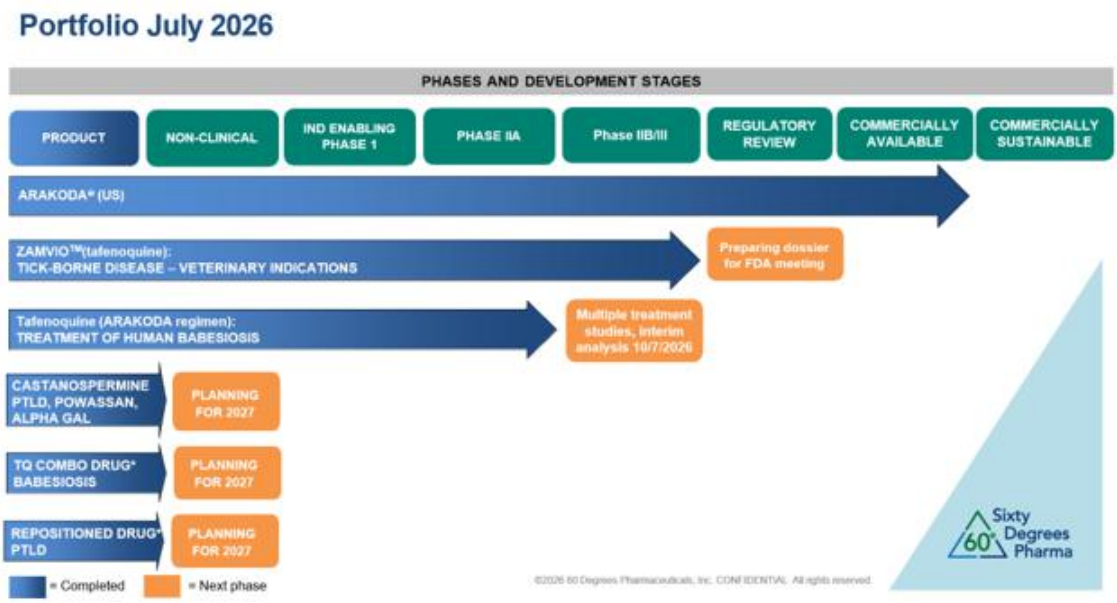
Viral Diseases

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.

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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/Castanospermine

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 but FDA objected. We now intended to conduct preclinical studies to evaluate the potential efficacy of this molecule for prescription indications related to tick-borne diseases such as alpha-gal syndrome and post-treatment Lyme disease

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.

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 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 sales staff and available at medical congresses and will also reside on ARAKODA.com.

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, Westchester Medical Center and Brigham & Women's Hospital. The first patient was randomized on June 25, 2024, 19 patients have completed the study and 28 have been randomized. An interim analysis is planned and will occur before October 6, 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. Two more were enrolled in June 2026. 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, nine 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.

31 See entry for NCT06478641 on the clinicaltrials.gov website
32 See entry for NCT06656351 on the clinicaltrials.gov websitev
33 Breitschwerdt et al. Pathogens 2025 Dec 19;15(1):2. doi: 10.3390/pathogens15010002.

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 castanospermine for tick-borne disease has been assessed.

Australian Chestnut Extract/Castanospermine

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 intends to evaluate the utility of castanospermine for tick-borne diseases in animal models.

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.

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 By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	Pending	Hong Kong	Pending		62023078645.6	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	11,633,391	US		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 Prevention of Non-Viral Tick-Borne Diseases And Symptoms Thereof	Pending	Japan	Pending		2025-561995	19-Apr-2044*
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.

40 21 U.S.C. § 360n(a)(1).

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.

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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.

THE OFFERING

Common Stock Offered by the Selling Stockholders[(1)]:	We are registering the resale by the selling stockholders named in this prospectus, or their permitted transferees, up to an aggregate of shares of our Common Stock, par value $0.0001, consisting of: ● 191,571 shares of common stock, par value $0.0001 per share; ● 383,142 shares of Common Stock issuable upon exercise of Pre-Funded warrants at an exercise price of $0.0001 per share; ● 574,713 shares of Common Stock issuable upon exercise of Series A Warrants at an exercise price of $1.74 per share; ● 574,713 shares of Common Stock issuable upon exercise of Series B Warrants at an exercise price of $1.74 per share; and ● 43,103 shares of Common Stock issuable upon the excise of the Placement Agent Warrants at an exercise price of $2.175 per share. ● 2,351 shares of Common Stock issuable upon exercise of previously issued Placement Agent Warrants at various dates with a weighted average exercise price of $14.96 per share.
Plan of Distribution:	The selling stockholders will determine when and how it will sell the Common Stock offered in this prospectus, as described in "Plan of Distribution" on page 43 of this prospectus.
Use of Proceeds:	We will not receive any proceeds from the sale of shares of our Common Stock by the selling stockholders.
Risk Factors:	Investing in our Common Stock involves significant risks. See "Risk Factors" on page 39 of this prospectus and under similar headings in the documents incorporated by reference into this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our Common Stock.
Nasdaq symbol:	"SXTP" and "SXTPW."

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

RISK FACTORS

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

USE OF PROCEEDS

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

SELLING STOCKHOLDERS

This prospectus relates to the offer and sale from time to time, on a resale basis, by the selling stockholders identified herein or their permitted transferees, of up to an aggregate of 1,769,593 shares of our common stock, par value $0.0001 per share ("Common Stock"), consisting of: (i) 191,571 shares of common stock, (ii) 383,142 shares of Common Stock issuable upon exercise of pre-funded warrants held by certain selling stockholders (the "Pre-Funded Warrants"), (iii) 574,713 shares of Common Stock issuable upon exercise of Series A warrants (the "Series A Warrants"), (iv) 574,713 shares of Common Stock issuable upon exercise of Series B warrants (the "Series B Warrants," together with Series A Warrants, the "Common Warrants") (and collectively with the Pre-Funded Warrants and Common Warrants, the "Purchase Warrants"), and (v) 45,454 shares of Common Stock issuable upon the exercise of placement agent warrants (the "Placement Agent Warrants" and together with the Purchase Warrants, the "Warrants") that were issued to H.C. Wainwright & Co., LLC ("Wainwright" or the "Placement Agent") as partial compensation for Wainwright acting as placement agent in connection with the Private Placement (as defined below) and are held by certain designees (and certain of their assignees) of Wainwright, inclusive of 2,351 warrants issued to the Placement Agent as compensation in previous financing transactions. The Warrants were issued to the selling stockholders in connection with a private placement we completed on July 30, 2026.

The shares of Common Stock being registered for resale hereby consist of the shares that have been issued or are issuable upon exercise of outstanding Warrants that were issued in connection with the Private Placement.

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

All information with respect to share ownership has been furnished by the selling stockholders. The Common Stock being offered is being registered to permit secondary trading of the shares and the selling stockholders may offer all or part of the Common Stock owned for resale from time to time. Except as set forth in this prospectus with respect to Wainwright, which acted as the placement agent in connection with the private placement and other offerings we consummated, and except for certain ownership of our securities, the selling stockholders have not had any material relationship with us within the past three years.

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

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

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the selling stockholders. The second column lists the number of shares of Common Stock beneficially owned by each selling stockholder, based on its ownership of the shares of Private Placement Common Stock and Warrants, as of August 13, 2026, assuming exercise of the Warrants held by the selling stockholders on that date, without regard to any limitations on exercises.

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

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

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

The following table sets forth certain information concerning the selling stockholders and the shares of Common Stock beneficially owned by them and offered by them in this prospectus. The percentage of ownership of the selling stockholders in the following table is based upon 3,516,988 shares of Common Stock outstanding as of August 13, 2026.

Name of Selling Stockholder	Number of Shares Owned Prior to Offering[1]	Maximum Number of Shares to be Sold Pursuant to this Prospectus[1]	Number of Shares Owned After Offering[2]	Percentage of Shares Owned After Offering[2]
Armistice Capital Master Fund Ltd[3]	222,285	574,713	222,285	4.9%
Intracoastal Capital LLC[4]	882,256	574,713	307,543	6.8%
Lind Global Fund III LP[5]	191,571	574,713	0	0.0%
Augustus Trading LLC[6]	27,640	27,640	0	0.0%
Wilson Drive Holdings LLC[7]	3,806	3,806	0	0.0%
Charles Worthman[9]	1,129	431	698	0.0%
Noam Rubinstein[9]	35,577	13,577	22,000	0.0%

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

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

(3) The securities to be sold pursuant to this prospectus consist of up to 574,713 (subject to adjustments) shares of Common Stock, consisting of 191,571 shares of Common Stock issued or issuable upon exercise of Pre-Funded Warrants, 191,571 shares of Common Stock issuable upon exercise of Series A Warrants and 191,571 shares of Common Stock issuable upon exercise of Series B Warrants, all of which are directly held by Armistice Capital Master Fund Ltd. (the "Master Fund"), a Cayman Islands exempted company, and may be deemed to be indirectly beneficially owned by Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the managing member of Armistice Capital. Armistice Capital Master Fund Ltd also owns 144,928 Series A Warrants, with an adjusted strike price of $27.60. The Pre-Funded Warrants are subject to a 9.99% beneficial ownership limitation and the Common Warrants are subject to a 4.99% beneficial ownership limitations, which limitations prohibit the Selling Stockholder and its affiliates owning, after exercise, a number of shares of Common Stock in excess of the beneficial ownership limitation. The address of the Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(4) The securities to be sold pursuant to this prospectus consist of up to 574,713 (subject to adjustments) shares of Common Stock, consisting of 191,571 shares of Common Stock issued or issuable upon exercise of Pre-Funded Warrants, 191,571 shares of Common Stock issuable upon exercise of Series A Warrants and 191,571 shares of Common Stock issuable upon exercise of Series B Warrants. Mitchell P. Kopin ("Mr. Kopin") and Daniel B. Asher ("Mr. Asher"), each of whom are managers of Intracoastal Capital LLC ("Intracoastal"), have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of the securities reported herein that are held by Intracoastal. The address of the Intracoastal is c/o Intracoastal Capital LLC, 245 Palm Trail, Delray Beach FL 33483.

(5) The securities to be sold pursuant to this prospectus consist of up to 574,713 (subject to adjustments) shares of Common Stock, consisting of 191,571 shares of Common Stock, 191,571 shares of Common Stock issuable upon exercise of Series A Warrants and 191,571 shares of Common Stock issuable upon exercise of Series B Warrants, all of which are directly held by Lind Global Fund III LP (the "Lind"), and may be deemed to be indirectly beneficially owned by Jeff Easton. Lind Global Partners III LLC, the general partner of Lind Global Fund III LP, may be deemed to have sole voting and dispositive power with respect to the shares held by Lind Global Fund III LP. The address of Lind is c/o 444 Madison Ave, Floor 41, New York, NY 10022.

(6) The number of shares beneficially owned prior to this offering consist of shares of common stock issuable upon exercise of placement agent warrants which have been issued as compensation. Orsium Capital LLC, the authorized agent to Augustus Trading LLC, has discretionary authority to vote and dispose of the securities held by Augustus Trading LLC and may be deemed to be the beneficial owner (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of these securities. Olivier Morali, in his capacity as managing member of Orsium Capital LLC, may also be deemed to have investment discretion and voting power over the shares held by Augustus Trading LLC. Orsium Capital LLC and Mr. Morali each disclaims any beneficial ownership of these securities. The business address of Augustus Trading LLC is 600 Lexington Avenue, 32nd Floor, New York, NY 10022.

(7) The number of shares beneficially owned prior to this offering consist of shares of common stock issuable upon exercise of placement agent warrants which have been issued as compensation. 1,455 of the securities held prior to the offering are held by Wilson Drive Holdings LLC and 2,351 of the securities are held by Craig Schwabe Craig Schwabe is the managing member of Wilson Drive Holdings LLC and has the power to vote and dispose the securities held. Neither Wilson Drive Holdings LLC nor Mr. Schwabe is a broker-dealer. Mr. Schwabe is affiliated with the following registered broker-dealers: H.C. Wainwright & Co., LLC, Rodman & Renshaw LLC and Stockblock Securities LLC. The securities were acquired in the ordinary course of business and, at the time the securities were acquired, the selling stockholder had no agreement or understanding, directly or indirectly, with any person to distribute such securities. Mr. Schwabe has not held any position or office or has had any other material relationship with the Company (or its predecessors or affiliates) during the past three years. The business address of Wilson Drive Holdings LLC is 600 Lexington Avenue, 32nd Floor, New York, NY 10022.

(8) Each of the selling stockholders is affiliated with H.C. Wainwright & Co., LLC, a registered broker-dealer with a business address of c/o H.C. Wainwright & Co., 430 Park Ave, 3rd Floor, New York, NY 10022. The number of shares beneficially owned prior to this offering consist of shares of common stock issuable upon exercise of placement agent warrants which have been issued as compensation. Each of the selling stockholder has the voting and dispositive power over the securities held, acquired the placement agent warrants in the ordinary course of business and, at the time the placement agent warrants were acquired, the selling stockholder had no agreement or understanding, directly or indirectly, with any person to distribute such securities.

PLAN OF DISTRIBUTION

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

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

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the Registered Securities owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Registered Securities, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the Registered Securities in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

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

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

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

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

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

In order to comply with the securities laws of some states, if applicable, the Registered Securities may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the Registered Securities may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

DESCRIPTION OF SECURITIES

Description of Capital Stock

General

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

As of August 13, 2026, our authorized capital stock presently consists of 150,000,000 shares of Common Stock, par value $0.00001 per share, and 1,000,000 shares of "blank check" preferred stock, par value $0.00001 per share, of which 68,080 shares of preferred stock have been designated as "Series A Non-Voting Convertible Preferred Stock" ("Series A Preferred Stock").

Common Stock

The holders of our Common Stock are entitled to the following rights:

Voting Rights. Each share of our Common Stock entitles its holder to one vote per share on all matters to be voted or consented upon by the stockholders.

Dividend Rights. Subject to limitations under Delaware law, holders of our Common Stock are entitled to receive ratably such dividends or other distributions, if any, as may be declared by our Board out of funds legally available therefor.

Liquidation Rights. In the event of liquidation, dissolution or winding up of our business, the holders of our Common Stock are entitled to share ratably in the assets available for distribution after the payment of all of our debts and other liabilities.

Other Matters. The holders of our Common Stock have no subscription, redemption or conversion privileges; in addition, such Common Stock does not entitle its holders to pre-emptive rights. All of the outstanding shares of our Common Stock are fully paid and non-assessable.

Preferred Stock

Our Certificate of Incorporation authorizes 1,000,000 shares of "blank check" preferred stock, par value $0.0001 per share. We have currently authorized 80,965 shares of Series A Preferred Stock with the following terms and rights: (i) 6% dividend, (ii) non-voting; (iii) not redeemable; and (iv) convertible into shares of Common Stock, solely at the Company's discretion, determined by (A) multiplying the number of shares of Series A Preferred Stock to be converted by $100, (B) adding to the result all accrued and accumulated and unpaid dividends on such shares to be converted, if any, and then (C) dividing the result by a price equal to the lower of (1) $100, (2) the price paid for the shares of Common Stock in the IPO and (3) the 10-day volume weighted average share price immediately preceding our election to convert the shares of Series A Preferred Stock; provided that the conversion of the shares of Series A Preferred Stock does not result in the holder's ownership of Common Stock exceeding 19.9%. As of August 13, 2026, there are 68,080 shares of Series A Preferred Stock issued and outstanding.

The Board may provide for the issue of any or all of the unissued and undesignated shares of the preferred stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board providing for the issuance of such shares and as may be permitted by law, without stockholder approval. Our Board is able to determine, with respect to any series of preferred stock, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate, if any, of the series;
- the dates at which dividends, if any, will be payable;
- the redemption rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;

- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of the affairs of our Company;

- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of our Company or any other entity, and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates and provisions for any adjustments to such prices or rates, the date or dates as of which the shares will be convertible, and all other terms and conditions upon which the conversion may be made;

- the ranking of such series with respect to dividends and amounts payable on our liquidation, dissolution or winding-up, which may include provisions that such series will rank senior to our Common Stock with respect to dividends and those distributions;

- restrictions on the issuance of shares of the same series or any other class or series; or

- voting rights, if any, of the holders of the series.

The issuance of preferred stock could adversely affect, among other things, the voting power of holders of Common Stock and the likelihood that stockholders will receive dividend payments and payments upon our liquidation, dissolution or winding up. The issuance of preferred stock could also have the effect of delaying, deferring or preventing a change in control of us.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");

- an affiliate of an interested stockholder; or

- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

- our Board approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction; or

- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of Common Stock.

Potential Effects of Authorized but Unissued Stock

Our shares of common and preferred stock are available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions, payment as a dividend on the capital stock or as equity compensation to our service providers under our equity compensation plans.

The existence of unissued and unreserved Common Stock and preferred stock may enable our Board to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, our Board has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our Certificate of Incorporation. The purpose of authorizing the Board to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Also, if we issue additional shares of our authorized, but unissued, Common Stock, these issuances will dilute the voting power and distribution rights of our existing Common Stockholders.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock will be Equity Stock Transfer, LLC ("Equity Stock Transfer"), located at 237 West 37th Street, Suite 602, New York, NY 10018. The phone number and facsimile number for Equity Stock Transfer are (212) 575-5757 and (347) 584-3644, respectively. Additional information about Equity Stock Transfer can be found on its website at *www.equitystock.com*.

Listing

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

Description of Warrants

July 2026 Warrants

On July 30, 2026, in connection with the Private Placement, we issued (i) Pre-Funded Warrants to purchase up to an aggregate of 383,142 shares at an exercise price of $0.001 per share; (ii) Series A Common Stock Warrants to purchase up to an aggregate of 574,713 shares of Common Stock at an exercise price of $1.74 per share; and (iii) Series B Common Stock Warrants to purchase up to an aggregate of 574,713 shares of Common Stock at an exercise price of $1.74 per share.

The Pre-Funded Warrants are exercisable immediately upon issuance and expire when exercised in full at an exercise price of $0.001 per share. The Series A Warrants will expire five (5) years from the effective date of the registration statement covering the resale of the shares issuable upon exercise of thereof (the "Effective Date") and the Series B Warrants will expire twenty-four (24) months from the Effective Date.

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

The Company also issued to H.C. Wainwright or its designees warrants the Placement Agent Warrants to purchase up to an aggregate of 43,103 shares of Common Stock at an exercise price equal to $2.175 per share. The Placement Agent Warrants are exercisable beginning on the date of issuance for a period of five (5) years.

DIVIDEND POLICY

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

LEGAL MATTERS

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

EXPERTS

The financial statements of 60 Degrees Pharmaceuticals, Inc. as of December 31, 2025 and 2024 and for the years then ended incorporated in this registration statement and prospectus by reference to our Annual Report on Form 10-K, for the year ended December 31, 2025, have been audited by RBSM LLP, an independent registered public accounting firm, as stated in their report thereon, incorporated herein by reference, and have been incorporated in this registration statement and prospectus in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

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

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

- The Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, filed with the SEC on March 30, 2026;
- The Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2026, filed with the SEC on August 14, 2026;
- The Registrant's Preliminary Schedule 14A, filed with the SEC on June 8, 2026, and the Registrant's Definitive Schedule 14A, filed with the SEC on July 2, 2026;
- The Registrant's Current Reports on Form 8-K filed with the SEC on January 8, 2026, January 21, 2026, January 23, 2026, February 12, 2026, March 12, 2026, March 13, 2026, March 20, 2026, May 18 2026, June 3, 2026, July 9, 2026, July 20, 2026, August 4, 2026 and August 6, 2026 ; and
- The description of the Registrant's Common Stock, which is contained in a registration statement on Form 8-A12B filed with the SEC on June 27, 2023, under the Exchange Act, including any amendment or report filed for the purpose of updating such description.

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

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

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

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

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

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

60 Degrees Pharmaceuticals, Inc.
Up to 1,769,593 Shares of Common Stock, Common Stock underlying certain Pre-Funded Warrants, Common Warrants and Placement Agent Warrants

PROSPECTUS

August 14, 2026

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

	Amount to Be Paid
U.S. Securities and Exchange Commission registration fee	$ 284
Legal fees and expenses	125,000*
Accounting fees and expenses	5,000*
Miscellaneous	5,000*
Total	$ 135,284*

* These fee and expense amounts are estimated.

Item 15. Indemnification of Directors and Officers

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

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

Item 16. Exhibits and Financial Statement Schedules

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

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4. That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

5. That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefits plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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

(d) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Washington, District of Columbia, on August 14, 2026.

60 DEGREES PHARMACEUTICALS, INC.

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

POWER OF ATTORNEY

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

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

Name	Position	Date
/s/ Geoffrey Dow Geoffrey Dow	President, Chief Executive Officer and Director (Principal Executive Officer)	August 14, 2026
/s/ Tyrone Miller Tyrone Miller	Chief Financial Officer (Principal Financial and Accounting Officer)	August 14, 2026
/s/ Cheryl Xu Cheryl Xu	Director	August 14, 2026
/s/ Stephen Toovey Stephen Toovey	Director	August 14, 2026
/s/ Eric Francois Eric Francois	Director	August 14, 2026
**/s/ Paul Field* Paul Field	Director	August 14, 2026

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

EXHIBIT INDEX

Exhibit No.	Description
4.1	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed with the SEC on August 4, 2026).
4.2	Form of Series A Warrant (incorporated herein by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed with the SEC on August 4, 2026).
4.3	Form of Series B Warrant (incorporated herein by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed with the SEC on August 4, 2026).
4.4	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 10.5 to the registrant's Current Report on Form 8-K filed with the SEC on August 4, 2026).
5.1*	Opinion of Sichenzia Ross Ference Carmel LLP
10.1	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the SEC on August 4, 2026).
10.2	Form of Registration Rights Agreement (incorporated herein by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the SEC on August 4, 2026).
23.1*	Consent of RBSM LLP dated as of August 14, 2026.
23.3*	Consent of Sichenzia Ross Ference Carmel LLP (to be included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).
107*	Filing Fee Table

* Filed herewith

Exhibit 5.1

August 14, 2026
60 Degrees Pharmaceuticals, Inc.
1025 Connecticut Avenue NW Suite 1000
Washington, D.C.

Re: Registration Statement on Form S-3

To Whom It May Concern,

We are counsel to 60 Degrees Pharmaceuticals, Inc., a Delaware corporation (the "Company"), in connection with the filing and preparing of a registration statement on Form S-3, and as may be further amended or supplemented (the "Registration Statement"), to be filed with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Act"), relating to the registration of up to an aggregate of 1,769,593 shares (the "Resale Shares") of common stock, par value $0.0001 per share (the "Common Stock"), consisting of: (i) 191,571 shares of Common Stock, (ii) 383,142 shares of Common Stock issuable upon exercise of pre-funded warrants held by certain selling stockholders (the "Pre-Funded Warrants"), (iii) 574,713 shares of Common Stock issuable upon exercise of Series A warrants (the "Series A Warrants"), and (iv) 574,713 shares of Common Stock issuable upon exercise of Series B warrants (the "Series B Warrants") and (v) 45,454 share of Common Stock issuable upon the exercise of placement agent warrants (the "Placement Agent Warrants", and together with the Pre-Funded Warrants, Series A Warrants and Series B Warrants, the "Warrants"). The Warrants were issued to the selling stockholders in connection with a private placement the Company completed on July 30, 2026.

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

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

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

1. The 191,571 shares of Common Stock referenced in clause (i) above have been validly issued, are fully paid and nonassessable.

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

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

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

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

Very truly yours,

/s/ Sichenzia Ross Ference Carmel LLP

Sichenzia Ross Ference Carmel LLP

1185 AVENUE OF THE AMERICAS | 31ST FLOOR | NEW YORK, NY | 10036
T (212) 930-9700 | F (212) 930-9725 | WWW.SRFC.LAW

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement of 60 Degrees Pharmaceuticals, Inc. on Form S-3 of our report dated March 30, 2026 relating to the financial statements of 60 Degrees Pharmaceuticals, Inc., as of December 31, 2025 and 2024 and for each of the years in the two-year period ended December 31, 2025 (which report includes an explanatory paragraph regarding the Company's ability to continue as a going concern).

We also consent to the reference to us under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ RBSM LLP

Houston, TX
August 14, 2026

CALCULATION OF FILING FEE TABLES

S-3

60 Degrees Pharmaceuticals, Inc.

Table 1: Newly Registered and Carry Forward Securities

Line Item Type	Security Type	Security Class Title	Notes	Fee Calculation Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
				Newly Registered Securities					
Fees to be Paid	Equity	Common Stock, par value $0.0001 per share	(1)	Other	1,769,593	$ 1.16	$ 2,052,727.88	0.0001381	$ 283.48
						Total Offering Amounts:	$ 2,052,727.88		283.48
						Total Fees Previously Paid:			0.00
						Total Fee Offsets:			0.00
						Net Fee Due:			$ 283.48

Offering Note(s)

(1) Consists of an aggregate of 1,769,593 shares of Common Stock registered for sale by certain of the selling stockholders named in this registration statement including (i) 191,571 shares of common stock, (ii) 383,142 shares of Common Stock issuable upon exercise of pre-funded warrants held by certain selling stockholders, (iii) 574,713 shares of Common Stock issuable upon exercise of Series A warrants, (iv) 574,713 shares of Common Stock issuable upon exercise of Series B warrants and (v) 45,454 share of Common Stock issuable upon the exercise of placement agent warrants that were issued to designees of H.C. Wainwright & Co., LLC.

Determined pursuant to Rule 457(c) under the Securities Act of 1933, as amended, solely for the purpose of calculating the registration fee. The price shown is the average of the high and low selling price of the Common Stock on August 12, 2026, which is a date within 5 business days prior to the date of filing of this Registration Statement, as reported on the Nasdaq Capital Market.