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

FORM 10-K

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

For the Fiscal Year Ended December 31 , 2023

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

For the transition period from _____ until _____

Commission File Number: 001-41719

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

Delaware	**45-2406880**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1025 Connecticut Avenue NW Suite 1000 Washington , D.C .	**20036**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

Yes ☒ No ☐

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

Yes ☒ No ☐

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

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

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

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

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

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

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

Yes ☐ No ☒

The aggregate market value of the Registrant's common stock, held by non-affiliates of the Registrant was approximately $ 11,551,806 as of July 14, 2023. Note that July 14, 2023, the closing date of the Registrant's initial public offering, is used to calculate the aggregate market value held by non-

affiliates since the Registrant was not publicly traded on June 30, 2023.

As of April 1, 2024, the Registrant had 11,570,578 shares of common stock, par value $0.0001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None .

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

Cautionary Note Regarding Forward-Looking Statements and Industry Data

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

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

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

PART I

Item 1. Description of Business.

Overview

We are a specialty pharmaceutical company with a goal of using cutting-edge biological science and applied research to further develop and commercialize new therapies for the prevention and treatment of infectious diseases. We have successfully achieved regulatory approval of Arakoda, a malaria preventative treatment that has been on the market since late 2019. Currently, 60P's pipeline under development covers development programs for vector-borne, fungal, and viral diseases utilizing three of the Company's future products: (i) new products that contain the Arakoda regimen of Tafenoquine; (ii) new products that contain Tafenoquine; and (iii) Celgosivir. Additionally, we are conducting due diligence activities in relation to potential in-licensing of a product relevant to Lyme disease and an antimalarial combination partner for Tafenoquine for *P. vivax* malaria.

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 member's membership interest in 60P LLC was correspondingly converted into common stock of 60 Degrees Pharmaceuticals, Inc., par value $0.0001 per share, with a cost-basis equal to $5.00 per share.

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

We own 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.

Business Developments

The following highlights recent material developments in our business:

- On January 22, 2024, we announced that we are planning a pivotal babesiosis study with tafenoquine following our January 17, 2024 FDA Meeting; and
- On December 26, 2023, we announced IRB approval of a Phase IIA study to evaluate tafenoquine for babesiosis, an emerging tick-borne disease.

Recent Developments

Monash University Agreement

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

January 2024 Public Offering

On January 29, 2024, we entered into an Underwriting Agreement with WallachBeth Capital LLC, as representative of the underwriters listed on Schedule I thereto (the "Underwriting Agreement"), relating to our public offering (the "2024 Offering") of 5,260,901 units (the "Units") at an offering price of $0.385 per Unit and 999,076 pre-funded units (the "Pre-Funded Units") at an offering price of $0.375 per Pre-Funded Unit. Each Unit consists of one share of common stock and one warrant exercisable for one share of common stock (the "Warrant"). Each Warrant has an exercise price of $0.4235 per share (110% of the offering price per Unit), is exercisable immediately upon issuance and expires five years from the date of issuance. Each Pre-Funded Unit consists of one pre-funded warrant exercisable for one share of common stock (the "Pre-Funded Warrant") and one warrant identical to the Warrants included in the Units. The purchase price of each Pre-Funded Unit is equal to the price per Unit sold to the public in the offering, minus $0.01, and the exercise price of each Pre-Funded Warrant is $0.01 per share. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full.

The underwriters were granted an option, exercisable within 45 days after the closing of the offering, to purchase up to 789,136 shares of our common stock at a price of $0.375 per share and/or 938,997 Warrants at a price of $0.01 per Warrant and/or 149,862 Pre-Funded Warrants at a price of $0.375 per Pre-Funded Warrant, or any combination of additional shares of common stock, Warrants and/or Pre-Funded Warrants, representing, in the aggregate, up to 15% of the number of Units sold in the offering, 15% of the Warrants underlying the Units and Pre-Funded Units sold in the offering and 15% of the Pre-Funded Warrants underlying the Pre-Funded Units sold in the offering, in all cases less the underwriting discount to cover over-

allotments, if any. On January 31, 2024, WallachBeth Capital LLC partially exercised its over-allotment option with respect to 818,177 Warrants. On February 14, 2024, WallachBeth Capital LLC partially exercised its over-allotment option with respect to 50 shares of common stock and 50 Warrants.

The net proceeds to us from the 2024 Offering were approximately $1.9 million, after deducting underwriting discounts and commissions and the payment of other offering expenses associated with the 2024 Offering that were payable by us. We paid the Underwriter an underwriting discount equal to 8.0% of the gross proceeds of the 2024 Offering and a non-accountable expense fee equal to 1.5% of the gross proceeds of the 2024 Offering.

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

We intend to use the net proceeds from the 2024 Offering for increasing capitalization and financial flexibility, and relaunching our malaria prevention project in the U.S. later in 2024.

Our officers and directors have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of common stock or other securities convertible into or exercisable or exchangeable for shares of common stock until July 29, 2024 without the prior written consent of WallachBeth Capital LLC.

Mission

Our mission is to address the unmet medical need associated with infectious diseases through the development and commercialization of new small molecule therapeutics, focusing on synthetic drugs (made by chemists in labs, excluding biologics) with good safety profiles based on prior clinical studies, in order to reduce cost, risk, and capitalize on existing research. Our present focus is the expansion of Arakoda sales for malaria prevention and to demonstrate clinical benefit for other disease indications.

Market Opportunity

In 2018, the FDA approved Arakoda for malaria prevention in individuals 18 years and older, an indication for which there has historically been approximately 550,000 prescriptions combined (one prescription per three weeks of travel) in the United States each year for the current market-leading product (atovaquone-proguanil) and one of the legacy weekly administered antimalarials, mefloquine. 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. For the calendar year 2023, our U.S. sales of Arakoda (not excluding returns) to pharmacies and other outlets was 1,632 boxes (a gross value of $383,520 at a WAC price of $235 per box), a substantial increase from the 570 boxes of Arakoda sold in 2022. We are currently assessing a targeted marketing strategy that will extract value from the current malaria prophylaxis indication and will continue our efforts to develop Arakoda for other applications.

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

- Treatment of Tick-Borne Diseases. There are at least 38,000 cases of potentially treatable acute symptomatic babesiosis (red blood cell infections caused by deer tick bites) in the United States each year.[1] Approximately 650 of these cases are hospitalizations. [2] 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.[3] This is much longer than equivalent serious parasitic diseases such as malaria where the goal is a three-day regimen. Separately, *Babesia* parasites are a common co-infection of patients experiencing chronic symptoms post-treatment Lyme disease syndrome (PTLDS). The size of this patient population is unclear, but it might be as high as 9,500 new cases and 190,000 cases cumulatively in the United States – this is based on the observation that *Babesia* parasites are a co-infection in Lyme patients about 10% of the time, and there may be up to 95,200 new cases of PTLDS each year, and a cumulative incidence in the U.S. of about 1,900,000.[4] Arakoda has the potential to be added to the existing standard of care for treatment of acute babesiosis, making it more convenient and effective, and is already being used off-label to treat chronic babesiosis.

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

- 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 but this calculation represents only about 12% of actual treated tick bites based on observations from comparable ex-U.S health systems.[5] 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.

  Babesiosis is a serious parasitic disease analogous to malaria and there are no vaccines relevant for the U.S. population for either. Although the risk of contracting malaria while exposed is low, the Centers for Diseases Control (CDC), nevertheless recommends, and the FDA approves drugs for, prevention of malaria. Every year, seasonally in the U.S. there is a population of individuals engaged in outdoor activities in the Northeast and Midwest who are at much greater risk of contracting babesiosis through a tick bite. While the number of prescriptions that might protect this population is not known, and requires refinement, it may be as high as 1.16 million per year, assuming that the number of potentially seasonally at-risk individuals (about 17.5 million U.S. individuals) who might consider taking chemoprophylaxis for babesiosis is similar to the proportion of at-risk U.S. travellers (about 8.2 million) to malaria-endemic countries who take malaria prophylaxis (about 6.7%).[6] Arakoda has the potential to be added to the existing standard of care for treatment of babesiosis, and to be a market leading product for pre- and post-exposure prophylaxis of babesiosis.

1 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 the fact that according to Krause et al (AJTMH 2003;6:431-436) about 80% of cases are symptomatic (thus 476,000*10%*80% = 38,000 cases of babesiosis per year).

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

3 According to IDSA guidelines.

4 The new case estimate for PTLDS is based on the observations of Krugeler (*Emerg Infect Dis* 2021;27:616-61) who reported that there are 476,000 cases of Lyme disease each year, multiplied by up to as 20% failure rate of primary antibiotic treatment regimens used as a modeling assumption by DeLong et al (*BMC Public Health* 2019;19(1):352). The cumulative prevalence data is from modeling work showing a cumulative prevalence of 1,900,000 PTLDS cases in 2020 (Delong et al. *BMC Public Health* 2019;19(1):352). The adjustments for babesiosis are based on the Krause et al. (JAMA 1996;275:1657-16602) who reported babesiosis as a coinfection in about 10% of Lyme patients.

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

6 According to the National Travel and Tourism Office, in 2015 there were approximately 8.2 million travelers, inclusively, to Africa, Latin America and countries in Asia (India, Philippines, other) with endemic malaria from the United States each year. According to Company estimates malaria prescriptions historically were 550,000 annually making the proportion of potentially at-risk travelers approximately 6.7% (550,000/8,200,000). According to CDC (see https:/www.cdc.gov/parasites/babesiosis/data-statistics/index.html), the following states have an annual incidence of babesiosis of at last 0.4 reported cases per 100,000 residents: ME, NH, VN, WI, MN, NY, PA, NJ, RI, CT, DE, MA, and 80+% of cases occur in June, July and August. The total population of these states is approximately 69 million, making the totally seasonally at-risk population about 17.3 million (69.3 million*0.25). Therefore, the potential number of prescriptions babesiosis prophylaxis each year might be 1.16 million (6.7%*17.34 million).

- Treatment of *Candida* infections. According to the CDC, there are 50,000 cases of candidiasis (a type of fungal infection) each year in the United States and up to 1,900 clinical cases of *C. auris*, for which there are few available treatments, have been reported to date. [7] Arakoda has the potential to be a market leading therapy for treatment/prevention of *C. auris*, and to be added to the standard of care regimens for other *Candida* infections.

- Prevention of fungal pneumonias. There are up to ~ 91-92,000 new medical conditions each year in the United States including acute lymphoblastic leukemia (up to 6.540 cases) and large B-cell lymphoma (up to 18,000 cases) patients receiving CAR-T therapy, solid organ transplant patients (up to 42,887 cases), allogeneic (~ 9,000 cases) and autologous (~ 15,000 cases) hematopoietic stem cell transplant patients for whom the use of antifungal prophylaxis is recommended.[8] Despite the availability and use of antifungal prophylaxis, the risk of some patient groups contracting fungal pneumonia exceeds the risk of contracting malaria during travel to West Africa.[9] Arakoda has the potential to be added to existing standard of care regimens for the prevention of fungal pneumonias.

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, both of which are associated with at least 4.1 million cases globally according to the European CDC (Dengue)[10] and up to 240,000 hospitalizations (RSV) in children less than five years of age and adults greater than 65 years of age in the United States each year according to the CDC.[11] As outlined in the "*Strategy*" section below, we expect to evaluate Celgosivir in additional non-clinical disease models before making a decision regarding clinical development.

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

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

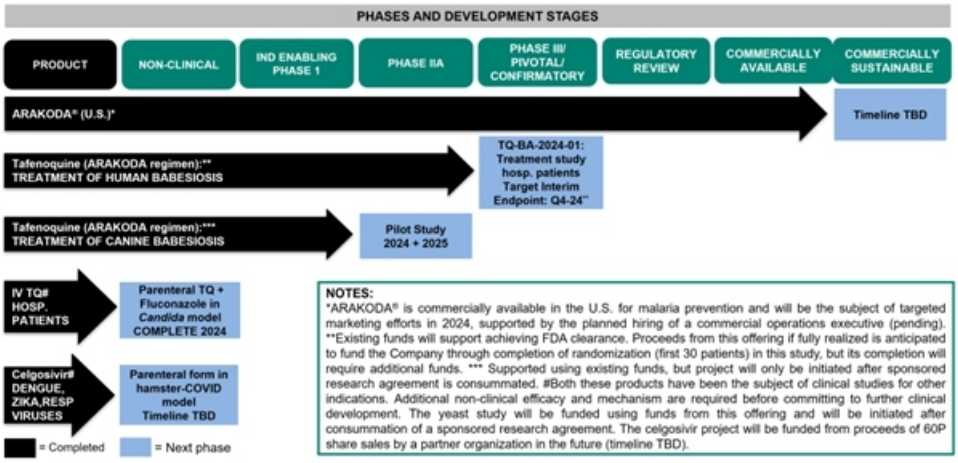
9 Aguilar-Guisado et al Clin Transplant 2011;25:E629–38; Mace et al MMWR 202;70:1–35

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

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

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

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

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

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

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

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

Tafenoquine 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.[17] Our work followed Legacy Studies that show Tafenoquine is effective for treatment and prevention of *Pneumocystis* pneumonia in animal models.[18] We believe that if added to the standard of care for anti-fungal and yeast infection treatments for general use, Tafenoquine has the potential to improve patient outcomes in terms of recovery from yeast infections, and prevention of fungal pneumonias in immunosuppressed patients. There are limited treatment options available for these indications, and Tafenoquine's novel mechanism of action might also mitigate problems of resistance. Clinical trial(s) to prove safety and efficacy, and approval by the FDA and other regulators, would be required before Tafenoquine could be marketed for these indications.

Tafenoquine is effective in animal models of babesiosis (tick borne red blood cell infections). In two of three recent clinical case studies, Tafenoquine administered after failure of conventional antibiotics in immunosuppressed babesiosis patients resulted in cures.[19] Consequently, we believe that (i) if combined with standard of care products, Tafenoquine has the potential to reduce the duration of treatment with antibiotic therapy in immunosuppressed patients and the time to parasite clearance in non-immunosuppressed patients and (ii) that once appropriate clinical studies have been conducted, it is likely that Tafenoquine would be quickly embraced for post-exposure prophylaxis of babesiosis in patients with tick bites and suspected of being co-infected with Lyme disease. Clinical trial(s) to prove safety and efficacy, and approval by FDA and other regulators, would be required before Tafenoquine could be marketed for these indications.

Celgosivir

Celgosivir is a host targeted glucosidase inhibitor that was developed separately by other sponsors for HIV then for hepatitis C. [20] 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.[21] Celgosivir (as with other Dengue antivirals) exhibits greater capacity to cure Dengue infections in animal models when administered prior to symptom onset compared to post-symptom onset. In animal models, this problem can be addressed for Celgosivir, by administering the same dose of drug split into four doses per day rather than two doses per day (as was the case in the Singaporean clinical trial).[22] This observation led to the filing and approval of a patent related to Dengue, which we licensed from the National University of Singapore.

15 See prescribing information at www.arakoda.com.

16 See prescribing information at www.arakoda.com.

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

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

19 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.

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

21 Low et. al., Lancet ID 2014; 14:706-715.

22 Watanabe et al, Antiviral Research 2016; 10:e19.

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

Competitive Strengths

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

Strategy

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

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

Expansion of U.S. Arakoda Sales

Hiring of Chief Commercial Officer. In February 2024, the Company hired a Chief Commercial Officer, Kristen Landon, to lead its activities relating to commercialization of Arakoda for malaria prevention. The Company's planned activities for the first two quarters of 2024 are summarized below.

Acceptability and Demand of the Arakoda Product Profile . Market research will be conducted to understand current brand awareness and usage among prescribers and product acceptability among consumers, determine barriers to use, acceptability of differential price points, and demand of Arakoda relative to its main competitors. Generic atovaquone-proguanil 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 quantified and communicated with stakeholders.

Market Segment Definition and Targeting . We plan to purchase additional sales data in order to define the list of top prescribers of atovaquone-proguanil, the main generic competitor to Arakoda for malaria prophylaxis Beginning in the third quarter of 2024, we plan to reach out to prescribers covering the top 80% of atovaquone-proguanil prescribers in order to educate them about the value proposition of Arakoda. We will also compile a list of the top institutions/organization that have ex-U.S. deployed workforces and internal occupational health and safety programs, and target these organizations with

messaging regarding the convenience and global effectiveness of Arakoda. We do not initially plan to target U.S. government agencies as these organizations, such as the Department of Defense, are expected to be extremely price sensitive until operational considerations justify the use of superior products (the DOD used inexpensive doxycycline for malaria prevention in the low malaria risk setting of Afghanistan, but chose superior weekly mefloquine, despite safety concerns, for the Ebola mission to west Africa in 2014, where malaria rates were extremely high).

Digital Revamp and Collateral. We will work with an Agency of Record to test brand positioning and key marketing messages that we believe best highlight the features and benefits of Arakoda, namely the convenience of the travel and post-travel regimen and global effectiveness. Once these activities are completed, we will develop a marketing campaign that clearly articulates the brand's value proposition including, key marketing messages and the development of promotional materials. The Arakoda website will be updated to reflect the aforementioned marketing messaging to support the relaunch of the product.

Revised Forecast. Once the above activities are completed (which we expect to be by the end of the second quarter of 2024), we will develop an internal three-year forecast for the malaria indication.

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 combination of Tafenoquine with atovaquone leads to complete radical cure and to the conference of sterile immunity.[23] In three case studies in individuals with immunosuppression and/or refractory parasites, Tafenoquine alone or combination with various standard of care antimalarials and antibiotics successfully cleared parasites leading to three consecutive negative PCR tests, and prevention of further relapses in two of three individuals.[24] Collectively these data suggest Tafenoquine might have utility as monotherapy in patients with uncomplicated babesiosis and improve clinical outcomes in hospitalized/immunosuppressed patients already administered standard of care antibiotic regimens.

23 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

24 Marcos et al. IDCases 2022;27:e01460; Rogers et al. Clin Infect Dis. 2022 Jun 10:ciac473, Prasad and Wormsner. Pathogens 2022;11:1015.

In November 2023, we submitted a request for an advice (Type C) meeting to FDA to discuss our Tafenoquine babesiosis program. In that correspondence we proposed to the FDA that for a supplementary indication for Tafenoquine for babesiosis, it would be appropriate to conduct a single randomized placebo-controlled study in low-risk patients and a case series in high-risk patients. On January 17, 2024, during the requested regulatory advice meeting, the FDA stated that in principle, a single pivotal study could support a supplementary New Drug Application, provided that it included high-risk patients and incorporated a clinical endpoint as the primary endpoint. The clinical trial design that we discussed with FDA would have randomized symptomatic hospitalized patients diagnosed with babesiosis and at low risk of relapse who are taking azithromycin/atovaquone to receive four daily doses of Tafenoquine or placebo. This initial protocol had previously been approved by an ethics committee, and submitted to clinicaltrials.gov for public disclosure. We are now redrafting this protocol, per the FDA's advice, as a pivotal study which will also include high risk patients, and be powered off a clinical endpoint. We remain on track to recruit patients in three hospitals in the North-Eastern United States, beginning in the summer of 2024, with a goal of reaching an interim analysis point by the end of 2024. If we do not achieve statistical significance, a sample re-estimation will be conducted, and additional subjects will be recruited during the 2025 tick season.

We will also be submitting a compassionate use IND to FDA so we can provide commercial Arakoda for use in immunosuppressed patients with babesiosis – the data collected under that future protocol will support data generated from the randomized study. We may, if resources permit, submit a similar compassionate use protocol to the FDA for the use of Tafenoquine for treatment of chronic babesiosis.

We have signed an agreement with North Carolina State University to support a pilot study of Tafenoquine for treatment of canine babesiosis in the United States under a sponsored research program. Should this collaboration be successful, we believe that the data from that study may provide supportive data for the clinical babesiosis development program, and could provide proof of concept for an expanded study to prove utility for veterinary indications.

From a commercial standpoint we are conducting market research and engaging with Key Opinion Leaders (KOLs) to further understand the commercial demand in acute and chronic babesiosis, including an assessment of the pre and post exposure prophylaxis opportunity. We will review current treatment regimens including diagnosis criteria and management of disease, understand the patient burden, and assess the competitive landscape.

Parenteral Tafenoquine for Fungal Infections

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

Combination Partner for Tafenoquine for Malaria

Most new antimalarial treatment products are developed as drug combinations to proactively combat drug resistance. We believe that Tafenoquine, due to its long half-life and activity against all parasite species and strains, would be an ideal partner in a drug combination. Recently, Kentucky Technology Inc. ("KTI"), completed Phase IIA studies in *P. vivax* malaria, in which they evaluated the safety and efficacy of SJ733, their ATP4 inhibitor in combination with Tafenoquine as the combination partner drug. Recently it was announced 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 expects to receive a detailed feasibility assessment and business plan for the project in Q1 2024, including an assessment of potential PRV eligibility. The Company will utilize this information to make a business decision about whether it wishes to license commercial rights to SJ733.

Celgosivir for Antiviral Diseases

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

Post-Marketing Requirements

We have an FDA post-marketing requirement to conduct a malaria prophylaxis study of Arakoda in pediatric and adolescent subjects. We proposed to the FDA, in late 2021, that this might not be safe to execute given that malaria prevention is administered to asymptomatic individuals and that methemoglobinemia (damage to the hemoglobin in blood that carries oxygen) occurred in 5% of patients, and exceeded a level of 10% in 3% of individuals in a study conducted by another sponsor in pediatric subjects with symptomatic vivax malaria.[25] 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 early 2024. We estimate the cost of conducting the study proposed by the FDA, if conducted in the manner suggested by the FDA, would be $2 million, and, due to the time periods required to secure protocol approvals from the FDA and Ethics Committees, could not be initiated any earlier than the third quarter of 2025. The funds from our January 2024 public offering to be expended on such a pediatric study will be limited to the minimum required to support protocol preparation and regulatory interactions with the FDA.

Potential In Licensing Activities

We may in the future engage a business development consultant to assist us with in-licensing additional late-stage development or early commercial stage infectious disease assets that complement our existing product portfolio and business plan. We are particularly interested in securing the rights to new products targeted at tick-borne diseases.

Capitalization and Future Financing

As outlined in "Liquidity and Capital Resources", following the recent public offering in which we netted approximately $1.9 million, our runway is through approximately October 31, 2024. To simplify the financing effort in August 2024, we expect that we will become shelf eligible and if we seek additional funding at that time, we will seek to file a shelf registration statement on Form S-3 to register our securities for sale to the public. Additionally, if we are able to develop a more robust forecast for Arakoda for the malaria indication, we may seek non-dilutive royalty-based funding or an equity line of credit to support further commercialization of Arakoda. There is no assurance that funds will be available on acceptable terms.

Competitors and Competitive Advantage

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

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

We are targeting additional indications for the Arakoda regimen of Tafenoquine, of which the priority is treatment of Babesiosis. In hospitalized patients, the Arakoda regimen will be partnered with the existing standard of care. For follow-on prevention indications for babesiosis there are no competing products.

25 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-April-2033*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	2014228035	Australia			2014228035	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	MY-170991-A	Malaysia			PI2015002372	14-Mar-2034*

Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	378015	Mexico			MX/a/2015/013115	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11201507254V	Singapore			11201507254V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	Pending	Singapore	Pending		10201908089V	14-Mar-2034*
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	9763921	US		9/19/2017	14/772,873	14-Mar-2034^
Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue	10517854	US		12/31/2019	15/706,845	14-Mar-2034^
Dosing Regimens Of Celgosivir For The Treatment Of Dengue	11219616	US		1/11/2022	16/725,387	14-Mar-2034^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	2015358566	Australia			2015358566	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	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	Pending	Singapore	Pending		10201904908Q	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	EP	Pending		15865264.4	02-Dec-2035*
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	Hong Kong	Pending		18103081.4	02-Dec-2035*
Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects	11,744,828	US		9/5/2023	17/145,530	02-Dec-2035^
Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naïve Subjects	Pending	New Zealand	Pending		731813	02-Dec-2035*
Regimens of Tafenoquine for Prevention of Malaria in Malaria-Naive Subjects	Pending	US	Pending		18/240,049	02-Dec-2035^
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	2016368580	Australia			2016368580	09-Dec-2036*
Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue	Pending	Singapore	Pending		10201912141Y	09-Dec-2036*
Dosing Regimens Of Celgosivir For The Prevention Of Dengue	11000516	US		5/11/2011	16/060,945	09-Dec-2036^
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	EP	Pending		21764438.4	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	China	Pending		202180029643.7	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	Australia	Pending		2021231743	02-Mar-2041*

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
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	05-May-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	Pending	US	Pending		18/300,805	02-Mar-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Fungus By Administration Of Tafenoquine	Pending	US	Pending		17/683,679	02-Mar-2041^
Methods For The Treatment And Prevention Of Lung Infections Caused By Sars-Cov-2 Virus By Administration Of Tafenoquine	Pending	US	Pending		17/683,718	02-Mar-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	11369592	US		6/28/2022	17/180,140#	19-Feb-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	US	Pending		17/664,693#	19-Feb-2041^
Treatment Of Human Coronavirus Infections Using Alpha-Glucosidase Glycoprotein Processing Inhibitors	Pending	EP	Pending		2021757552#	19-Feb-2041*
Methods For The Treatment And Prevention Of Non-Viral Tick-Borne Diseases And Symptoms Thereof	*Provisional*	US	*Provisional*		63/461,060	~21-Apr-2044&
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	Pending	US	Pending		18/218,202	05-Jul-2043^
Methods To Treat Respiratory Infection Utilizing Castanospermine Analogs	Pending	*PCT*	Pending		PCT/US23/26884	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 Diseases Or Infections With MCP-1 Involvement By Administration Of Tafenoquine	Pending	*PCT*	Pending		PCT/US23/34169	30-Sep-2043

Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,328,061+	US	6-25-2019	15/584,952+	2-May-37
Treatment Of Zika Virus Infections Using Alpha Glucosidase Inhibitors	10,561,642+	US	2-18-2020	15/856,377+	2-May-37

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

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

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

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

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

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

All patents not designated with a “+” or a “#” list 60 Degrees Pharmaceuticals, Inc. as an applicant.

All estimated patent expiration dates and anticipated patent expiration assume payment of any maintenance/annuity fees during the patent term.

Trademarks

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

Key Relationships & Licenses

On May 30, 2014, we entered into the Exclusive License Agreement (the “2014 NUS-SHS Agreement”) with National University of Singapore (“NUS”)

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

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

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

On December 4, 2020, we entered into the Other Transaction Authority for Prototype Agreement ("OTAP Agreement") with the Natick Contracting Division of the U.S. government in which we will, among other things, conduct activities for a Phase II clinical trial to assess the safety and efficacy of Tafenoquine for the treatment of mild to moderate COVID-19 disease, with the goal of delivering Tafenoquine with an FDA Emergency Use Authorization ("EUA") approved as a countermeasure against COVID-19. The total amount of the OTAP Agreement is $4,999,814. The term of the OTAP Agreement 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 FUSRF granted us the right to manage the licensing of intellectual property created at FSURF. The term of the FSURF Agreement expires five years from February 15, 2021. After deduction of a 5% administrative fee by FSURF, capped at $15,000 annually, and reimbursement of patent prosecution expenses, we will receive 20% of license income and FSURF will receive 80% of license income. Payments of license income shall be paid in U.S. dollars quarterly each year. On February 19, 2021, we entered into an agreement with FSURF, subsequently amended on February 15, 2023, that collectively granted an option, effective through August 19, 2023, to us to license methods for purifying castanospermine and its use for the treatment of COVID-19. On August 19, 2021, we entered into an agreement with FSURF, subsequently amended on February 15, 2023, that collectively granted an option, effective through August 19, 2023, to us to license a patent relating to the use of alpha glucosidase inhibitors (including Castanospermine and Celgosivir) for treatment of Zika infections.

Ending upon July 12, 2033 or the conversion or redemption in full of all of the shares of Series A Preferred Stock owned by Knight, we will pay Knight a royalty equal to 3.5% of our net sales, where "net sales" has the same meaning as in our license agreement with the U.S. Army for Tafenoquine. Due to the success of the qualified IPO, at the end of the quarter and each quarter thereafter the royalty will be calculated, and payment will be made within fifteen days.

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

Either 60P Australia Pty Ltd or Monash University may terminate the Agreement immediately by notice to the other if (i) the defaulting party is in breach of the Agreement and the defaulting party fails to remedy the breach within 20 business days of receiving written notice of the breach from the terminating party; (ii) an insolvency event occurs in relation to the defaulting party; or (iii) the parties agree that a Milestone will not be met by its anticipated completion date. Monash University may unilaterally terminate the Agreement if any of the Services contravene Australian Sanctions Law.

Sales and Marketing

Following our recent hire of a new Chief Commercial Officer, in 2024, we plan to evaluate our "relaunch" strategy for Arakoda for malaria prevention in the United States. As described in the "Strategy" section this will consist of i) conducting market research to understand HCP and consumer demand which will inform our sales forecast. A targeted marketing strategy will be developed and implemented in the second half of 2024 and we will evaluate the need to hire a small account team and /or Medical Science Liaisons (MSL) If so, we may utilize a contract services organization to ensure greater flexibility and limit overhead. We may also choose to develop an omnichannel approach utilizing digital, non-personal promotion and possibly a tele sales model if an in-person field force does not support a positive return on investment.

In 2023, we began to see named-patient sales in Europe, without any adjustments to pricing, triggering the purchase of another partial lot of Arakoda by our European distributor. Sales volume has increased in Australia in response to repricing of Kodatef by our local distributor to be more competitive with

atovaquone-proguanil.

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 [26], 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 [27], 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.

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.

26 See Industry Research and Development Act 1986 (legislation.gov.au).

27 See Australian Government R&D Tax Incentive – Overseas R&D: Information Sheet.

Review and Approval of Drugs in the United States

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

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

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

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to

establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

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

The IND and IRB Processes

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

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

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

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

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

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

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

Human Clinical Studies in Support of an NDA

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

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

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

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

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

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

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

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

Submission of an NDA to the FDA

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

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

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

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

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

Fast-Track, Breakthrough Therapy and Priority Review Designations

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

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

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

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

Tropical Disease PRVs

The Tropical Disease Priority Review Voucher ("PRV") program was created by Congress under the Food and Drug Administration Amendments Act of 2007 ("FDAAA") in order to encourage innovation and public access to new medicines. Pursuant to Section 1102 of FDAAA, which amended section 524 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), along with later amendments, the FDA must award a PRV to certain applicants that obtain an approved NDA to treat certain tropical diseases. Congress later expanded the scope of diseases that were eligible for a PRV (e.g., a PRV for obtaining approval for a drug to treat rare pediatric diseases). A PRV entitles the holder of the voucher to designate a different drug application as qualifying for priority review from FDA. When a drug application is designated for priority review through use of a priority review voucher, that application must be reviewed by FDA no later than 6 months after receipt.[28] This guarantees a much more rapid review by FDA compared to the standard review time.

Tropical disease PRVs were created under the FDAAA to encourage pharmaceutical companies to develop treatments for specific neglected tropical diseases. As defined by the statute, tropical diseases refer to certain "infectious disease[s] for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations."[29] 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.[30]

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.

28 21 U.S.C. § 360n(a)(1).

29 21 U.S.C. § 360n(a)(3).

30 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.

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.

The FDA's Decision on an NDA

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

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

Post-Approval Requirements

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

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

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

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

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, the FDA's regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

Abbreviated New Drug Applications for Generic Drugs

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

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

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic

equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

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

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

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

Hatch-Waxman Patent Certification and the 30-Month Stay

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

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

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

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

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

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Safety and Innovation Act ("FDASIA"), in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. For drugs intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments.

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

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

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

Orphan Drug Designation and Exclusivity

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

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

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

Patent Term Restoration and Extension

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

Review and Approval of Medical Devices in the United States

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

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

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

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

require payment of significant user fees, unless an exemption is available.

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

Review and Approval of Drug Products in the European Union

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

Procedures Governing Approval of Drug Products in the European Union

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

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

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

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

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

Clinical Trial Approval

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

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

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the E.U. portal; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states; a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts—Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned; strictly defined deadlines for the assessment of clinical trial applications; and the involvement of the Ethics Committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Clinical Trials Regulation.

Data and Market Exclusivity in the European Union

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

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

Periods of Authorization and Renewals

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

Orphan Drug Designation and Exclusivity

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

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

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom (U.K.) voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the U.K. from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the U.K. provides a notice of withdrawal pursuant to the E.U. Treaty. Since the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K.

Regulatory Framework in Australia

The Therapeutic Goods Administration, through the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations is responsible for the efficacy, quality, safety and timely availability of drugs and medical devices in Australia. The mission statement of the TGA is "To ensure the safety, quality and

efficacy of therapeutic goods available in Australia at a standard equal to that of comparable countries, and that premarket assessment of therapeutic goods is conducted within a reasonable time."

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

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

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

Application

- Check to see data complies with Australian guidelines.
- Invoice sponsor for 75% of evaluation fee.

Evaluation

- Evaluate pharmaceutical and chemical data.
- Evaluate animal pharmacology and toxicology data.
- Evaluate clinical data.
- Evaluation Unit reviews reports (coordinates external evaluations if used), prepares a summary and makes an initial recommendation.
- Pre ADEC consultation with sponsor.
- Prepare approved product information and consider consumer product information.
- Submit final package of summaries and recommendations to the ADEC (six meetings per year).

Approval

- ADEC review and advice to the TGA.
- Final decision by the TGA.
- Finalize conditions of registration.
- Advice to sponsor, invoice final 25% of evaluation fee.
- For new chemical entity, advise drug information centers, forensic laboratories, etc.

Registration

- Sponsor applies to register the product on the Australian Register of Therapeutic Goods.
- Supply is permitted once the applicable number is allocated.

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

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

Other activities under the control of the TGA include:

- maintenance of the Australian Register of Therapeutic Goods for the registration and listing of products;
- control of drug and device exports from Australia;
- inspection and licensing of manufacturing premises;
- post marketing surveillance;
- adverse drug reaction monitoring;
- reports were received by the Adverse Drug Reactions Advisory Committee;
- medical device complaint reporting;
- drug and device recalls;
- laboratory testing, sample testing;
- complaint reporting and follow up; and

- drug and device advertising controls

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

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

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

Healthcare Law and Regulation

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

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

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

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

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

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

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

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

Healthcare Reform

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

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

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

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

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

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

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

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

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

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures were passed by the U.S. Senate.

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

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

replacement could have on our business.

In August 2022, the Inflation Reduction Act of 2022 was signed into law and requires the federal government to negotiate prices for some high-cost drugs covered under Medicare, requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries, and caps Medicare beneficiaries' out-of-pocket spending under the Medicare Part D benefit. We will monitor this issue to determine the effects of this legislation on our business.

Human Capital Resources

As of April 1, 2024, we had a total of three employees, all of whom are full-time. We also utilize the services of two part-time contractors.

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

Available Information

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

Item 1A. Risk Factors.

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

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

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

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

Given our current stage of cybersecurity development, we have not experienced any significant cybersecurity incidents to date. However, we recognize that the absence of a formalized cybersecurity framework may leave us vulnerable to cyberattacks, data breaches and other cybersecurity incidents. Such events could potentially lead to unauthorized access to, or disclosure of, sensitive information, disrupt our business operations, result in regulatory fines or litigation costs and negatively impact our reputation among customers and partners.

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

In addition, the Board will oversee any cybersecurity risk management framework and a dedicated committee of the Board or an officer appointed by the Board will review and approve any cybersecurity policies, strategies and risk management practices.

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

For a discussion of potential cybersecurity risks affecting us, please refer to the "Risk Factors" section of our Registration Statement on Form S-1 filed with the Securities and Exchange Commission on January 22, 2024 titled "*Cybersecurity risks could adversely affect our business and disrupt our operations*."

Item 2. Properties.

Our corporate headquarters are located at 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036. We do not own any physical property, plant or labs. We currently lease two offices at the above address and, as a result of the renewal of our lease for an additional one-year in January 2023, recognized a gross Right of Use Asset of $63,570 as of December 31, 2023 with offsetting accumulated depreciation of $50,053 ($99,615 as of December 31, 2022 with offsetting accumulated depreciation of $86,967). In December 2023, we executed a new lease amendment to relocate to a new office in the same building beginning April 1, 2024, and expiring on March 31, 2025.

Item 3. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings. We are not currently a party to any legal proceedings that, in the

opinion of our management, are likely to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

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

On March 28, 2024, the closing price for our common stock and warrants as reported on The Nasdaq Capital Market was $0.2610 per share and $0.0760, respectively.

Holders of Common Stock

On April 1, 2024, there were 14 holders of record of our common stock.

Transfer Agent

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

Dividend Policy

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

Unregistered Sales of Equity Securities

Common Stock

- On January 2, 2023, we issued a total of 100,000 shares of our common stock to our legal counsel for payment of certain legal fees.
- On January 26, 2023, we issued 405,000 shares of our common stock to Florida State University Research Foundation Inc. in exchange for its research and development services.
- On January 26, 2023, we issued 65,000 shares of our common stock to Latham BioPharm Group, LLC in exchange for its research and development services.
- On January 26, 2023, we issued 120,000 shares of our common stock to Trevally, LLC in exchange for provision of research chemicals.
- On January 26, 2023, we issued 8,500 shares of our common stock to ENA Healthcare Communications, LLC in exchange for marketing services.
- On January 26, 2023, we issued 54,000 shares of our common stock to 4C Pharma Solutions, LLC in exchange for the cancellation of debt and credit for pharmacovigilance services to be provided.
- On January 26, 2023, we issued 65,000 shares of our common stock to Hybrid Financial in exchange for its investor relations services.
- On January 26, 2023, we issued 20,000 shares of our common stock to Sheila Burke in exchange for public relations services provided by Method Health Communications LLC.
- On January 26, 2023, we issued 525,000 shares of our common stock to University of Kentucky School of Pharmacy in exchange for its research and development services.

- On January 26, 2023, we issued 37,500 shares of our common stock to Ludlow Business Services, Inc. in exchange for its investor relations services.
- On January 26, 2023, we issued 30,000 shares of our common stock to Elliot Berman in exchange for accounting services provided by Berman Accounting & Advisory P.A.
- On March 19, 2023, we issued 13,000 shares of our common stock to Delve Innovation Pty Ltd in exchange for its research and development services.

- On July 11, 2023, we issued 10,482 of our common stock to Geoffrey S. Dow Revocable Trust as a result of the conversion of the Convertible Promissory Note we issued to the Geoffrey S. Dow Revocable Trust on May 19, 2022.

- On July 11, 2023, we issued 52,411 shares of our common stock to Walleye Opportunities Master Fund Ltd. as a result of the conversion of the Convertible Promissory Note we issued to Walleye Opportunities Master Fund Ltd. on May 24, 2022.

- On July 11, 2023, we issued 62,893 shares of our common stock to Bigger Capital Fund, LP as a result of the conversion of the Convertible Promissory Note we issued to Bigger Capital Fund, LP on May 24, 2022.

- On July 11, 2023, we issued 52,411 shares of our common stock to Cavalry Investment Fund, LP. as a result of the conversion of the Convertible Promissory Note we issued to Cavalry Investment Fund, LP. on May 24, 2022.

- On July 11, 2023, we issued 20,964 shares of our common stock to Cyberbahn Federal Solutions, LLC. as a result of the conversion of the Convertible Promissory Note we issued to Cyberbahn Federal Solutions, LLC on May 8, 2023.

- On July 11, 2023, we issued 20,964 shares of our common stock to Ariana Bakery Inc as a result of the conversion of the Convertible Promissory Note we issued to Ariana Bakery Inc on May 8, 2023.

- On July 11, 2023, we issued 62,893 shares of our common stock to Sabby Volatility Warrant Master Fund, Ltd. as a result of the conversion of the Convertible Promissory Note we issued to Sabby Volatility Warrant Master Fund, Ltd. on May 8, 2023.

- On July 11, 2023, we issued 10,482 shares of our common stock to Steel Anderson as a result of the conversion of the Convertible Promissory Note we issued to Steel Anderson on May 8, 2023.

- On July 11, 2023, we issued 20,964 shares of our common stock to Bixi Gao & Ling Ling Wang as a result of the conversion of the Convertible Promissory Note we issued to Bixi Gao & Ling Ling Wang on May 8, 2023.

- On July 11, 2023, we issued a total of 40,000 restricted shares of common stock to the following directors and in the amounts listed: (i) Stephen Toovey (10,000 restricted shares of common stock), (ii) Charles Allen (10,000 restricted shares of common stock), (iii) Paul Field (10,000 restricted shares of common stock) and (iv) Cheryl Xu (10,000 restricted shares of common stock).

- On July 14, 2023, we issued a total of 29,245 restricted shares of our common stock to BioIntelect Pty Ltd as deferred equity compensation valued in the amount of $155,000.

- On July 14, 2023, we converted the entirety of debt owed to a noteholder to 214,934 shares of our common stock at the conversion price equal to the initial public offering price, of which were issued to Xu Yu.

- On July 14, 2023, we issued 1,108,337 restricted shares of common stock to Knight Therapeutics (Barbados) Inc.) (“Knight”) upon conversion of debt owed to Knight.

- On July 28, 2023, we issued 45,560 restricted shares of our common stock to Knight upon conversion of 2,162 shares of Series A Preferred Stock, at the conversion rate price detailed in Note 6 to the accompanying consolidated condensed financial statements.

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

Preferred Stock

- On July 14, 2023, we converted the accumulated interest from the debt owed to Knight into 80,965 shares of our Series A Preferred Stock, of which were issued to Knight.

The issuance of shares of Series A Preferred Stock listed above was deemed exempt from registration under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder in that the issuance of securities did not involve a public offering.

2022 Equity Incentive Plan

On November 22, 2022, the Board and majority stockholder adopted the 60 Degrees Pharmaceuticals, Inc. 2022 Equity Incentive Plan (the “2022 Plan”). The 2022 Plan provides for the grant of the following types of stock awards: (i) incentive stock options, (ii) nonstatutory stock options, (iii) stock appreciation rights, (iv) restricted stock awards, (v) restricted stock unit awards and (vi) other stock awards. The 2022 Plan is intended to help us secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for our success and any of our affiliates and provide a means by which the eligible recipients may benefit from increases in value of the common stock. Initially, the Board reserved 238,601 shares of common stock issuable upon the grant of awards under the 2022 Plan. The 2022 Plan provides for an automatic increase in the number of shares available for issuance beginning on January 1, 2023 and each January 1 thereafter, by 4% of the number of outstanding shares of common stock on the immediately preceding December 31, or such number of shares as determined by the Board of Directors.

EQUITY PLAN INFORMATION

Plan Category:	**Number of securities to be issued upon exercise or issuance of outstanding options, units, warrants and rights:**	**Weighted average exercise price of outstanding options, warrants and rights[(1)]:**	**Number of securities remaining available for future issuance:**
2022 Equity Incentive Plan:			
Equity compensation plans approved by security holders	293,736	$ 5.30	305

Equity compensation plans not approved by security holders	770,188	1.17	-
Total	**1,063,924**	**$ 1.36**	**305**

(1) The calculation for the weighted average exercise price of outstanding options, warrants and rights excludes 256,000 restricted stock units approved by security holders under the 2022 Plan as the awards do not have an exercise price.

Use of Proceeds from our Initial Public Offering

The registration statement for our initial public offering was declared effective by the SEC on July 11, 2023. The initial public offering consisted of 1,415,095 units, with each unit consisting of (i) one share of our common stock, (ii) one tradeable warrant having the right to purchase one share of our common stock at an exercise price of $6.095 per share and (iii) one non-tradeable warrant having the right to purchase one share of our common stock at an exercise price of $6.36 per share, at a public offering price of $5.30 per unit. On July 14, 2023, the initial public offering closed, and we received $6,454,325 in net proceeds from the initial public offering after deducting the underwriting discount and commission and other estimated initial public offering expenses payable by us.

There has been no material change in the planned use of proceeds from such use as described in our initial public offering registration statement.

As of December 31, 2023, we have utilized approximately $4,000,000 of the net proceeds as follows:

- $1,729,000 for working capital and general corporate purposes;
- $1,783,000 for debt repayment; and
- $488,000 research and development (clinical trials and related activities).

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Not applicable.

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

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

Components of Results of Operations

Product Revenues – net of Discounts and Rebates

To date, we have received the majority of our product revenues from sales of our Arakoda™ product to the US Department of Defense (the "DoD") and resellers in the U.S. and abroad. Foreign sales to both Australia and Europe are further subject to profit sharing agreements for boxes sold to customers. Currently, the procurement contract with the DoD has expired and DoD sales last happened in 2021. Sales to resellers in the US are subject to considerable discounts and rebates for services provided by our third-party logistics ("3PL") partner and wholesalers and pharmacy benefit managers ("PBMs").

Cost of Revenues, Gross Loss, and Gross Margin

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

Other Operating Revenues

Our research revenues have historically been derived mostly from a single, awarded research grant in the amount of $4,999,814 at the beginning of December 2020 (with an additional $720,000 awarded February 26, 2021) from the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (which may be referred to as "JPEO") to study Arakoda in mild-to-moderate COVID-19 patients. A majority of the study was completed in 2021 with the planned lab data analysis and the submission of the final study report completed during the first nine months of 2022. Research revenue was recognized when research expenses against the JPEO grant were recognized at the end of each month. Research revenues do not exceed directly related research expenses for a given period as the grant did not cover additional research beyond the scope of COVID-19.

We also earn research revenues from the Australian Tax Authority for qualified research activities conducted in Australia.

Operating Expenses

Research and Development

Research and development costs for the periods presented primarily consist of contracted R&D services and costs associated with preparation for our now halted COVID-19 clinical trial. We expense all research and development costs in the period in which they are incurred. Payments made prior to the receipt of goods or services to be used in research and development are recognized as prepaid assets and expensed over the service period as the services are provided. We have also issued shares of our common stock in exchange for research and development services.

General and Administrative Expenses

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

Interest and Other Income (Expense), Net

Interest expense consists of interest accrued on our outstanding debt obligations and related amortization of debt discounts and deferred issuance costs. Other components of other income (expense) include changes in the fair value of financial instruments, gains and losses on extinguishments of debt, and other miscellaneous income (expense). We now have interest income as a result of the IPO as certain cash proceeds are invested in Federal Deposit Insurance Corporation backed interest bearing accounts.

Results of Operations

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

	For the Year Ended December 31,	
Consolidated Statements of Operations Data:	**2023**	**2022**
Product Revenues – net of Discounts and Rebates	$ 253,573	$ 192,913
Service Revenues	-	30,295
Product and Service Revenues, net	253,573	223,208
Cost of Revenues	474,550	432,370
Gross Loss	(220,977)	(209,162)
Research Revenues	-	288,002
Net (Loss) Revenue	(220,977)	78,840
Operating Expenses:		
Research and Development	691,770	525,563
General and Administrative Expenses	4,241,836	1,303,722
Total Operating Expenses	4,933,606	1,829,285
Loss from Operations	(5,154,583)	(1,750,445)
Interest Expense	(2,286,637)	(3,989,359)
Derivative Expense	(399,725)	(504,613)
Change in Fair Value of Derivative Liabilities	(37,278)	(10,312)
(Loss) Gain on Debt Extinguishment	(1,231,480)	120,683
Change in Fair Value of Promissory Note	5,379,269	-
Other Expenses, net	(83,116)	(43,238)
Total Interest and Other Income (Expense), net	1,341,033	(4,426,839)
Loss from Operations before Provision for Income Taxes	(3,813,550)	(6,177,284)
Provision for Income Taxes	250	500
Net Loss including Noncontrolling Interest	(3,813,800)	(6,177,784)
Net (Loss) Income – Noncontrolling Interest	(48,098)	3,936
Net Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	$ (3,765,702)	$ (6,181,720)

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

	For the Year Ended December 31,	
Consolidated Statements of Operations Data:	**2023**	**2022**
Product Revenues – net of Discounts and Rebates	100.00%	86.43%
Service Revenues	-	13.57
Product and Service Revenues, net	100.00	100.00
Cost of Revenues	187.15	193.71
Gross Loss	(87.15)	(93.71)
Research Revenues	-	129.03
Net (Loss) Revenue	(87.15)	35.32
Operating Expenses:		
Research and Development	272.81	235.46
General and Administrative Expenses	1,672.83	584.08
Total Operating Expenses	1,945.64	819.54
Loss from Operations	(2,032.78)	(784.22)
Interest Expense	(901.77)	(1,787.28)
Derivative Expense	(157.64)	(226.07)
Change in Fair Value of Derivative Liabilities	(14.70)	(4.62)
(Loss) Gain on Debt Extinguishment	(485.65)	54.07

Change in Fair Value of Promissory Note	2,121.39	-
Other Expenses, net	(32.78)	(19.37)
Total Interest and Other Income (Expense), net	528.85	(1,983.28)
Loss from Operations before Provision for Income Taxes	(1,503.93)	(2,767.50)
Provision for Income Taxes	0.10	0.22
Net Loss including Noncontrolling Interest	(1,504.02)	(2,767.73)
Net (Loss) Income – Noncontrolling Interest	(18.97)	1.76
Net Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	(1,485.06)%	(2,769.49)%

Comparison of the Years Ended December 31, 2023, and 2022

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

	For the Year Ended December 31,			
Consolidated Statements of Operations Data:	**2023**	**2022**	**$ Change**	**% Change**
Product Revenues – net of Discounts and Rebates	$ 253,573	$ 192,913	$ 60,660	31.44%
Service Revenues	-	30,295	(30,295)	(100.00)
Product and Service Revenues, net	253,573	223,208	30,365	13.60
Cost of Revenues	474,550	432,370	42,180	9.76
Gross Loss	$ (220,977)	$ (209,162)	$ (11,815)	5.65%
Gross Margin %	(87.15)%	(93.71)%		

Product Revenues - net of Discounts and Rebates

Our product revenues – net of discounts and rebates were $253,573 for the year ended December 31, 2023, as compared to $192,913 for the year ended December 31, 2022. For the year ended December 31, 2023, our U.S. pharmaceutical distributor accounted for 72% of our total net product sales and Kodatef sales to our Australian distributor accounted for 21% of total net product sales (46% and 39% for the year ended December 31, 2022, respectively). The increase in product sales is primarily due to increased sales volume during the period and was partially offset by the reduction of our wholesale acquisition cost (sales price) of Arakoda™ (16 x 100 mg tablets) from $285 to $235 per box in January 2023.

We offer discounts and rebates to the civilian U.S. supply chain distribution channel. We record sales when our 3PL partner transfers boxes into their title model. Discounts and rebates are offered to our 3PL partner amounting to 12% along with a fixed monthly fee that started in 2023 (2% and no fixed fee in 2022). The product is then transferred usually to one of the three large U.S. pharmaceutical distributors where rebates are 10%. Lastly, we have relationships with several large pharmacy benefit managers (“PBMs”) that allow patients to purchase Arakoda at a discount. The rebate associated with PBMs ranges from 30 to 41.25% (15 to 39.75% in 2022) depending on the amount of coverage provided. For the year ended December 31, 2023, discounts and rebates were $216,031 compared to $59,552 for the year ended December 31, 2022.

Arakoda entered the U.S. civilian supply chain in the third quarter of 2019. For the year ended December 31, 2022, 570 boxes were sold to pharmacies and dispensaries. Sales volume increased by 186% to 1,632 boxes sold to pharmacies and dispensaries for the year ended December 31, 2023. This growth in sales volumes is a combination of natural organic growth, the reduction in the wholesale acquisition cost of $285 per box to $235 per box effective January 2023, and increased prescribing by doctors of Arakoda off-label for usage treatment of babesiosis. The sales volume growth to pharmacies and dispensaries ties more closely to the growth in discounts and rebates previously discussed than our reported sales to our 3PL.

Kodatef sales to our distributor Biocelect in Australia for the year ended December 31, 2023 were $53,718 ($86,763 for the year ended December 31, 2022). Sales to Biocelect are currently subject to a profit share distribution once the original transfer price has been recouped. As of December 31, 2023, no profit share has been due to us ($0 as of December 31, 2022), though we did settle the historical profit share through September 30, 2022 for $24,486 (AUD$35,000) on January 16, 2023.

Arakoda sales to our distributor Scandinavian Biopharma in Europe for the year ended December 31, 2023 were $18,000 ($18,000 for the year ended December 31, 2022). The distributor has also reported increased interest from consumers in Europe seeking treatment for Babesiosis.

Service Revenues

During the year ended December 31, 2022, we earned $30,295 from storing Arakoda purchased by the United States Army Medical and Materiel Development Activity (USAMMDA), compared to $0 earned during the year ended December 31, 2023. The service revenue contract from USAMMDA ended on August 31, 2022, though an insignificant amount was earned on the contract in the beginning of 2024 in association with final payment of the storage revenue receivable from 2022.

Cost of Revenues, Gross Loss, and Gross Margin

Cost of revenues was $474,550 for the year ended December 31, 2023, as compared to $432,370 for the year ended December 31, 2022. The increase in cost of goods sold is in part, due to the 31.44% increase in product sales over the same periods, as well as higher write-offs for expired inventory, which increased to $191,111 for the year ended December 31, 2023 (up from $162,222 for the year ended December 31, 2022). Despite higher write-offs, the Gross Margin % increased to (87.15)% for the year ended December 31, 2023 from (93.71)% for the year ended December 31, 2022.

Other Operating Revenues

	For the Year Ended December 31,			
Consolidated Statements of Operations Data:	**2023**	**2022**	**$ Change**	**% Change**
Research Revenues	$ -	$ 288,002	$ (288,002)	(100.00)%

The research revenues earned by us were $0 for the year ended December 31, 2023, as compared to $288,002 for the year ended December 31, 2022. Our research revenues for the year ended December 31, 2022 were primarily derived from remnants of a research grant received in 2021 to study Arakoda in mild-to-moderate COVID-19 patients. The study was completed in 2022, therefore we recognized $0 in research revenues from the COVID-19 grant during the year ended December 31, 2023. We also earn research revenues from the Australian Tax Authority for research expenses conducted in Australia. The revenue was $42,250 for the year ended December 31, 2022 compared to $0 for the year ended December 31, 2023. We had been accruing anticipated research rebates quarterly but after the COVID-19 research cancellation, in the fourth quarter of 2023, we made the decision not to file for the research rebate and reversed the previously accrued revenues and charged them to research and development.

Operating Expenses

	For the Year Ended December 31,			
Consolidated Statements of Operations Data:	**2023**	**2022**	**$ Change**	**% Change**
Research and Development	$ 691,770	$ 525,563	$ 166,207	31.62%
General and Administrative Expenses	4,241,836	1,303,722	2,938,114	225.36
Total Operating Expenses	$ 4,933,606	$ 1,829,285	$ 3,104,321	169.70%

Research and Development

Research and development costs increased during the year ended December 31, 2023 when compared to the year ended December 31, 2022. Research and development costs incurred during the year ended December 31, 2022 related to our Phase II clinical trial to assess the safety and efficacy of tafenoquine for the treatment of mild to moderate COVID-19 disease, which was completed in the third quarter of 2022. During the year ended December 31, 2023, we incurred initial costs related to our Phase II B clinical trial, which was then suspended in the fourth quarter of 2023. Direct COVID-19-related trial costs are 83% of the costs for the year ended December 31, 2023 at $574,609 and 49% of the costs at $256,581 for the year ended December 31, 2022.

General and Administrative Expenses

For the year ended December 31, 2023, our general and administrative expenses increased by 225.36% or $2,938,114 from the year ended December 31, 2022. During the year ended December 31, 2023, we incurred significantly higher compensation expenses as a result of compensation arrangements with our directors, which came into effect on the date of our IPO, and year-end bonuses of restricted stock units to our executives. Pursuant to these arrangements, we recognized $528,926 in stock-based compensation expense and $99,000 in cash compensation to our directors during the year ended December 31, 2023 ($0 and $0 for the year ended December 31, 2022, respectively). Additionally, during the year ended December 31, 2023, we incurred $969,581 in accounting, audit, legal and professional fees, $304,581 of insurance expenses, and $668,639 of investor-related outreach expenses (up from $656,089, $84,879, and $142 for the year ended December 31, 2022, respectively).

Interest and Other Income (Expense), Net

	For the Year Ended December 31,			
Consolidated Statements of Operations Data:	**2023**	**2022**	**$ Change**	**% Change**
Interest Expense	$ (2,286,637)	$ (3,989,359)	$ 1,702,722	(42.68)%
Derivative Expense	(399,725)	(504,613)	104,888	(20.79)
Change in Fair Value of Derivative Liabilities	(37,278)	(10,312)	(26,966)	261.50
(Loss) Gain on Debt Extinguishment	(1,231,480)	120,683	(1,352,163)	(1,120.43)
Change in Fair Value of Promissory Note	5,379,269	-	5,379,269	N/A
Other Expenses, net	(83,116)	(43,238)	(39,878)	92.23
Total Interest and Other Income (Expense), net	$ 1,341,033	$ (4,426,839)	$ 5,767,872	(130.29)%

Interest Expense

For the year ended December 31, 2023, we recognized $2,286,637 of interest expense ($3,989,359 for the year ended December 31, 2022). The decrease in interest expense is the result of the settlement or conversion of a majority of our outstanding debt obligations upon the closing of our IPO on July 14, 2023. Cash paid for interest was $179,117 and $2,193 for the years ended December 31, 2023 and December 31, 2022, respectively.

Derivative Expense

For the year ended December 31, 2023, we recognized $399,725 of derivative expense in connection with the raising of $555,000 in net proceeds from our bridge funding in May 2023. We recognized $504,613 of derivative expense during the year ended December 31, 2022 from the bridge funding raise in May 2022, generating $979,275 in net proceeds. The decrease in derivative expense is related to the initial fair value of the related derivative liabilities in excess of the proceeds received.

Change in Fair Value of Derivative Liabilities

For the year ended December 31, 2023, we recognized a loss due to the change in fair value of derivative liabilities of $37,278 compared to $10,312 for the year ended December 31, 2022.

(Loss) Gain on Debt Extinguishment

For the year ended December 31, 2023, we recognized a $1,231,480 net loss on debt extinguishment, compared to a $120,683 net gain on debt extinguishment for the year ended December 31, 2022. The gain recognized for the year ended December 31, 2022 was due to our renegotiation of the Xu Yu promissory note in December 2022 to add an equity conversion feature, which was accounted for under the debt extinguishment model. The loss for the year ended December 31, 2023 is related, in part to the exchange of the cumulative outstanding debt pursuant to the Knight Debt Conversion Agreement in January 2023, as well as losses recognized upon extinguishment of our interim bridge financing notes, all of which were settled or converted upon our IPO in July 2023. The net amount for the year ended December 31, 2023 was partially offset by a debt extinguishment gain of $223,077 recognized on conversion of the Xu Yu promissory note on the date of our IPO.

Change in Fair Value of Promissory Note

For the year ended December 31, 2023, we recognized a net gain of $5,379,269 related to the change in the fair value of the promissory note with Knight, which was carried at fair value. The gain relates to the mark to market adjustment recognized immediately prior to the automatic conversion of the outstanding debt obligation into our equity shares upon the closing of our IPO. Our cumulative debt outstanding with Knight was not measured at fair value on a recurring basis prior to the Knight Debt Conversion Agreement executed in January 2023, hence we recorded a $0 change in fair value for the year ended December 31, 2022.

Other Expenses, net

For the year ended December 31, 2023, we recognized $83,116 in other expenses compared to $43,238 for the year ended December 31, 2022. During the year ended December 31, 2023, $48,236 was recognized in other expense due to a one-time write off of an uncollectible receivable from our 3PL for an uninvoiced return.

Liquidity and Capital Resources

For the year ended December 31, 2023 and 2022, our net cash used in operating activities was $4,542,910 and $1,009,980, respectively and the cash balance was $2,142,485 as of December 31, 2023 ($264,865 as of December 31, 2022). To date, we have funded our operations through debt and equity financings. Based on current internal projections, taking into consideration the net proceeds of approximately $1.9 million received in connection with the offering completed in January 2024, recent growth in Arakoda sales, and preparatory clinical trial activities, we estimate that we will have sufficient funds to remain viable through October 31, 2024. We cannot give assurance that we can increase our cash balances or limit our cash consumption and thus maintain sufficient cash balances for our planned operations or future acquisitions. Future business demands may lead to cash utilization at levels greater than recently experienced. We may need to raise additional capital in the future. However, we cannot assure you that we will be able to raise additional capital on acceptable terms, or at all.

Going Concern

As of December 31, 2023, we had an accumulated deficit of $32,580,850. In their audit report for the fiscal year ended December 31, 2023, our auditors have expressed their concern as to our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate cash flows from operations and obtain financing.

The consolidated financial statements for the years ended December 31, 2023, and December 31, 2022, respectively, included an explanatory note referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. The accompanying financial statements are prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of obligations in the normal course of business. However, we have not demonstrated the ability to generate enough revenues to date to cover operating expenses and have accumulated losses to date. This condition, among others, raises substantial doubt about our ability to continue as a going concern for one year from the date these financial statements are issued.

In view of these matters, continuation as a going concern is dependent upon our ability to meet financial requirements, raise additional capital, and achieve gross profitability from our single marketed product. We plan to fund our operations through third party and related party debt/advances, private placement of restricted securities and the issuance of stock in a subsequent offering until such a time as we are able to generate profitable operations or a business combination may be achieved.

Our consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2023:

		Payments Due By Period			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 Years
Principal obligations on the debt arrangements	$ 150,000	$ -	$ 683	$ 6,570	$ 142,747
Interest obligations on the debt arrangements	112,892	8,772	16,861	10,974	76,285
Operating leases	13,650	13,650	-	-	-
Accounts payable and accrued expenses	506,206	506,206	-	-	-
Total	$ 782,748	$ 528,628	$ 17,544	$ 17,544	$ 219,032

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

Cash Flows

	Year Ended December 31,			
	2023	2022	$ Change	% Change
Net Cash Provided By (Used In):				
Operating Activities	$ (4,542,910)	$ (1,009,980)	$ (3,532,930)	349.80%
Investing Activities	(115,888)	(60,133)	(55,755)	92.72
Financing Activities	6,474,565	1,221,706	5,252,859	429.96
Effect of Foreign Currency Translation on Cash Flow	61,853	(2,127)	63,980	(3,007.99)
Net Increase in Cash	$ 1,877,620	$ 149,466	$ 1,728,154	1,156.22%

Cash Used in Operating Activities

Net cash used in operating activities was $4,542,910 for the year ended December 31, 2023, as compared to $1,009,980 for the year ended December 31, 2022. Our net cash used in operating activities increased as a result of higher general and administrative expenses of $4,241,836 for the year ended December 31, 2023 ($1,303,722 for the year ended December 31, 2022), primarily related to higher legal, accounting, and professional fees, and investor-related outreach expenses preceding our IPO in July 2023. In addition, we paid more cash to settle our accounts payable and other accrued liabilities during the year ended December 31, 2023 when compared to the year ended December 31, 2022.

Cash Used in Investing Activities

Net cash used in investing activities was $115,888 for the year ended December 31, 2023, as compared to $60,133 for the year ended December 31, 2022. The increase in cash used in investing activities is primarily attributable to higher purchases of property and equipment of $57,623 for the year ended December 31, 2023, as compared to $0 for the year ended December 31, 2022.

Cash Provided by Financing Activities

Net cash provided by financing activities was $6,474,565 for the year ended December 31, 2023, as compared to $1,221,706 for the year ended December 31, 2022. The increase in net cash provided by financing activities is attributable to net proceeds of $6,454,325 generated from our IPO, which closed on July 14, 2023, as well as $1,131,771 received from the exercise of warrants, partially offset by repayments of certain of our outstanding debt obligations in July 2023. Cash provided by financing activities for the year ended December 31, 2022 was primarily due to our interim bridge debt financing raise in May 2022 and advances from related parties.

Effect of Foreign Currency Translation on Cash Flow

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

Critical Accounting Policies, Significant Judgments, and Use of Estimates

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

Revenue Recognition

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

Inventory

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

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

Share-Based Payments

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

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

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

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

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

Derivative Liabilities

We assess the classification of our derivative financial instruments each reporting period, which formerly consisted of bridge shares, convertible notes payable, and certain warrants, and determined that such instruments qualified for treatment as derivative liabilities as they met the criteria for liability classification under ASC 815 (excluding certain warrants issued in connection with the IPO). As of December 31, 2023, our derivative financial instruments consist of contingent payment arrangements.

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

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

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

Income Taxes

From January 1, 2022 to May 31, 2022, 60 Degrees Pharmaceuticals, LLC was a C-corporation for income tax purposes before the incorporation/merger into 60 Degrees Pharmaceuticals, Inc. on June 1, 2022. The District of Columbia ("DC") taxes corporations on form D-20 (DC Corporation Franchise Tax Return) and returns have a minimum tax due of $250 if gross receipts are at $1 million or less and $1,000 if above. The tax years that remain subject to examination by major tax jurisdictions include the years ended December 31, 2020, 2021, 2022 and 2023.

60P Australia Pty Ltd. is subject to the taxes of the Australian Taxation Office and 60P Singapore Pte Ltd. was subject to the taxes of the Inland Revenue Authority of Singapore prior to its dissolution as of March 31, 2022.

We account for income taxes under the liability method, and deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying values of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided on deferred tax assets if it is determined that it is more likely than not that the deferred tax asset will not be realized in the following five years. In determining the need for a valuation allowance, we have given consideration to our worldwide cumulative loss position when assessing the weight of the sources of taxable income that can be used to support the realization of deferred tax assets.

We have assessed, on a jurisdictional basis, the available means of recovering deferred tax assets, including the ability to carry-back net operating losses, the existence of reversing temporary differences, the availability of tax planning strategies and available sources of future taxable income. On the basis of this evaluation, we have determined that it is more likely than not that we will not recognize the benefits of the U.S. Federal, state and net deferred tax assets, and, as a result, a full valuation allowance has been set against our net deferred tax assets as of December 31, 2023 and December 31, 2022.

During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. We establish reserves for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These reserves are established when we believe that certain positions might be challenged despite our belief that our tax return positions are fully supportable. We adjust these reserves in light of changing facts and circumstances, such as the outcome of tax examinations. As of December 31, 2023 and December 31, 2022, we have not established any reserves for uncertain tax positions.

We recognize interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the years ended December 31, 2023 and 2022, we did not recognize interest and penalties related to unrecognized tax benefits.

Off-Balance Sheet Arrangements

During 2023 and 2022, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

JOBS Act Accounting Election

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

Recent Accounting Pronouncements

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

financial statements.

In August 2020, FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Among other changes, the new guidance removes from GAAP separation models for convertible debt that require the convertible debt to be separated into a debt and equity component, unless the conversion feature is required to be bifurcated and accounted for as a derivative or the debt is issued at a substantial premium. As a result, after adopting the guidance, entities will no longer separately present such embedded conversion features in equity and will instead account for the convertible debt wholly as debt. The new guidance also requires use of the "if-converted" method when calculating the dilutive impact of convertible debt on earnings per share, which is consistent with our current accounting treatment under the current guidance. The guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, but only at the beginning of the fiscal year. We adopted this pronouncement on January 1, 2022; however, the adoption of this standard did not have a material effect on our consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. This new standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. Early adoption is permitted, including adoption in an interim period. If an issuer elects to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The adoption of this standard in 2022 did not have a material effect on our financial statements.

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers, which requires an acquirer in a business combination to recognize and measure contract assets and contract liabilities in accordance with Accounting Standards Codification Topic 606. ASU 2021-08 is effective for fiscal years beginning after December 15, 2022, and early adoption is permitted. The adoption of ASU 2021-08 did not have an effect on our financial statements.

In November 2023, the FASB issued 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses and segment profit or loss. The ASU also requires entities with a single reportable segment to provide all segment disclosures under ASC 280, including the new required disclosures under the ASU. The ASU is effective for all public entities with fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The ASU must be applied retrospectively. We are currently evaluating the impact that ASU 2023-07 will have on our financial statement disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (ASC 740): Improvements to Income Tax Disclosures, which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. We are currently evaluating the impact that ASU 2023-09 will have on our financial statement disclosures.

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

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

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 60 Degrees Pharmaceuticals, Inc. (formerly known as 60 Degrees Pharmaceuticals, LLC) and subsidiary ("the Company") as of December 31, 2023 and 2022, and the related statements of operations and comprehensive loss, shareholders' and members' deficit, and cash flows for each of the years in the two-year period ended December 31, 2023, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

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

the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ RBSM LLP

PCAOB ID Number 587

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

Las Vegas, Nevada

April 1, 2024

60 DEGREES PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash	$ 2,142,485	$ 264,865
Accounts Receivable	231,332	45,965
Prepaid and Other Assets	4,402,602	200,967
Deferred Offering Costs	-	68,629
Inventory, net (Note 3)	466,169	518,578
Total Current Assets	**7,242,588**	**1,099,004**
Property and Equipment, net (Note 4)	57,761	21,300
Other Assets:		
Right of Use Asset (Note 12)	13,517	12,647
Long-Term Prepaid Expense	242,647	-
Intangible Assets, net (Note 5)	227,258	164,255
Total Other Assets	**483,422**	**176,902**
Total Assets	**$ 7,783,771**	**$ 1,297,206**
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts Payable and Accrued Expenses	$ 506,206	$ 758,668
Lease Liability (Note 12)	13,650	13,000
Deferred Compensation (Note 7)	-	325,000
Related Party Notes, net *(including accrued interest)* (Note 8)	-	195,097
Debenture (Note 8)	-	4,276,609
SBA EIDL (including accrued interest) (Note 8)	8,772	2,750
Promissory Notes *(including accrued interest)* (Note 8)	-	16,855,887
Derivative Liabilities (Note 9)	2,306,796	1,129,840
Derivative Liabilities - Related Parties (Note 9)	-	364,360
Total Current Liabilities	**2,835,424**	**23,921,211**
Long-Term Liabilities:		
Deferred Compensation (Note 7)	-	255,000
SBA EIDL *(including accrued interest)* (Note 8)	150,251	160,272
Promissory Notes *(including accrued interest)* (Note 8)	-	1,109,783
Total Long-Term Liabilities	**150,251**	**1,525,055**
Total Liabilities	**2,985,675**	**25,446,266**
Commitments and Contingencies (Note 12)		
SHAREHOLDERS' EQUITY (DEFICIT)		
Series A Preferred Stock, $ 0.0001 par value, 1,000,000 shares authorized; 78,803 and 0 issued and outstanding as of December 31, 2023 and December 31, 2022, respectively (Note 6)	9,858,040	-
Common Stock, $ 0.0001 par value, 150,000,000 shares authorized; 5,810,089 and 2,386,009 issued and outstanding as of December 31, 2023 and December 31, 2022, respectively (Note 6)	581	239
Additional Paid-in Capital	27,456,802	5,164,461
Accumulated Other Comprehensive Income	135,561	73,708
Accumulated Deficit	(32,580,850)	(28,815,148)
60P Shareholders' Equity (Deficit):	4,870,134	(23,576,740)

Noncontrolling Interest	(72,038)	(572,320)
Total Shareholders' Equity (Deficit)	**4,798,096**	**(24,149,060)**
Total Liabilities and Shareholders' Equity (Deficit)	**$ 7,783,771**	**$ 1,297,206**

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

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

	For the Years Ended December 31,	
	2023	**2022**
Product Revenues – net of Discounts and Rebates	$ 253,573	$ 192,913
Service Revenues	-	30,295
Product and Service Revenues, net	253,573	223,208
Cost of Revenues	474,550	432,370
Gross Loss	(220,977)	(209,162)
Research Revenues	-	288,002
Net (Loss) Revenue	(220,977)	78,840
Operating Expenses:		
Research and Development	691,770	525,563
General and Administrative Expenses	4,241,836	1,303,722
Total Operating Expenses	4,933,606	1,829,285
Loss from Operations	(5,154,583)	(1,750,445)
Interest Expense	(2,286,637)	(3,989,359)
Derivative Expense	(399,725)	(504,613)
Change in Fair Value of Derivative Liabilities	(37,278)	(10,312)
(Loss) Gain on Debt Extinguishment	(1,231,480)	120,683
Change in Fair Value of Promissory Note	5,379,269	-
Other Expenses, net	(83,116)	(43,238)
Total Interest and Other Income (Expense), net	1,341,033	(4,426,839)
Loss from Operations before Provision for Income Taxes	(3,813,550)	(6,177,284)
Provision for Income Taxes (Note 10)	250	500
Net Loss including Noncontrolling Interest	(3,813,800)	(6,177,784)
Net (Loss) Income – Noncontrolling Interest	(48,098)	3,936
Net Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	(3,765,702)	(6,181,720)
Comprehensive Loss:		
Net Loss	(3,813,800)	(6,177,784)
Unrealized Foreign Currency Translation Gain (Loss)	61,853	(2,127)
Total Comprehensive Loss	(3,751,947)	(6,179,911)
Net (Loss) Income – Noncontrolling Interest	(48,098)	3,936
Comprehensive Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	(3,703,849)	(6,183,847)
Cumulative Dividends on Series A Preferred Stock	(220,714)	-
Net Loss - attributed to common stockholders	**$ (3,924,563)**	**$ (6,183,847)**
Net Loss per Common Share:		
Basic and Diluted	$ (0.99)	$ (2.61)
Weighted Average Number of Common Shares Outstanding		
Basic and Diluted	3,960,280	2,367,729

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

60 DEGREES PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' AND MEMBERS' EQUITY (DEFICIT)

	For the Year Ended December 31, 2022									
	Members' Equity		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit) Attributable to 60P	Noncontrolling Interest on Shareholders	Total Shareholders' Deficit
	Units	Amount	Shares	Amount						

Balance—December 31, 2021	**18,855,165**	**$4,979,365**	**-**	**$ -**	**$ -**	**$(22,633,428)**	**$ 75,835**	**$ (17,578,228)**	**$ (576,256)**	**$ (18,154,484)**
Net foreign translation loss through May 31, 2022	-	-	-	-	-	-	(28,654)	(28,654)	(611)	(29,265)
Net (loss) income through May 31, 2022	-	-	-	-	-	(1,949,246)	-	(1,949,246)	1,370	(1,947,876)
Business combination June 1, 2022: 60P LLC into 60P, Inc. (Note 6)	(18,855,165)	(4,979,365)	2,348,942	235	4,979,130	-	-	-	-	-
Issuance of common stock	-	-	37,067	4	185,331	-	-	185,335	-	185,335
Net foreign translation gain after June 1, 2022	-	-	-	-	-	-	26,527	26,527	611	27,138
Net (loss) income after June 1, 2022	-	-	-	-	-	(4,232,474)	-	(4,232,474)	2,566	(4,229,908)
Balance—December 31, 2022	**-**	**$ -**	**2,386,009**	**$ 239**	**$5,164,461**	**$(28,815,148)**	**$ 73,708**	**$ (23,576,740)**	**$ (572,320)**	**$ (24,149,060)**

	For the Year Ended December 31, 2023									
	Series A Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Shareholders' Equity (Deficit) Attributable	Noncontrolling Interest on	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	to 60P	Shareholders	(Deficit)
Balance—December 31, 2022	**-**	**$ -**	**2,386,009**	**$ 239**	**$ 5,164,461**	**$(28,815,148)**	**$ 73,708**	**$ (23,576,740)**	**$ (572,320)**	**$ (24,149,060)**
Cancellation of common stock	-	-	(1,451,000)	(145)	145	-	-	-	-	-
Share-based compensation to vendors for services	-	-	1,482,799	148	5,682,908	-	-	5,683,056	-	5,683,056
Conversion of debt into common stock upon initial public offering	-	-	1,707,179	171	7,989,427	-	-	7,989,598	-	7,989,598
Conversion of debt into Series A Preferred Stock upon initial public offering	80,965	10,128,500	-	-	-	-	-	10,128,500	-	10,128,500
Warrants reclassed from derivative liabilities to equity	-	-	-	-	838,748	-	-	838,748	-	838,748
Issuance of common stock pursuant to IPO, net of underwriting discounts, commissions, and deferred offering costs of $ 1,266,740	-	-	1,415,095	141	6,235,135	-	-	6,235,276	-	6,235,276
Issuance of common stock upon exercise of warrants	-	-	184,447	18	1,131,753	-	-	1,131,771	-	1,131,771
Voluntary conversion of Series A Preferred Stock into common stock	(2,162)	(270,460)	45,560	5	270,455	-	-	-	-	-
Share-based compensation under 2022 Equity Incentive Plan	-	-	40,000	4	528,922	-	-	528,926	-	528,926

Contribution from noncontrolling interest	-	-	-	-	(548,380)	-	-	(548,380)	548,380	-
Deemed capital contribution for related party compensation expense (Note 11)	-	-	-	-	163,228	-	-	163,228	-	163,228
Net foreign translation gain	-	-	-	-	-	-	61,853	61,853	-	61,853
Net loss	-	-	-	-	-	(3,765,702)	-	(3,765,702)	(48,098)	(3,813,800)
Balance—December 31, 2023	**78,803**	**$ 9,858,040**	**5,810,089**	**$ 581**	**$27,456,802**	**$(32,580,850)**	**$ 135,561**	**$ 4,870,134**	**$ (72,038)**	**$ 4,798,096**

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

60 DEGREES PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Years Ended December 31,	**2023**	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	($ 3,813,800)	($6,177,784)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation	21,162	27,648
Amortization	29,157	5,118
Amortization of Debt Discount	669,148	1,090,387
Amortization of ROU Asset	50,053	46,020
Amortization of Note Issuance Costs	67,728	74,496
Amortization of Capitalized Share-Based Payments	994,643	-
Share-Based Compensation to Vendors for Services	212,605	-
Share-Based Compensation under 2022 Equity Incentive Plan	528,926	-
Deemed Capital Contribution for Related Party Compensation Expense (Note 11)	163,228	-
Gain (Loss) on Debt Extinguishment	1,231,480	(120,683)
Change in Fair Value of Derivative Liabilities	37,278	10,312
Derivative Expense	399,725	504,613
Change in Fair Value of Promissory Note	(5,379,269)	-
Inventory Reserve	(160,338)	160,338
Changes in Operating Assets and Liabilities:		
Accounts Receivable	(185,367)	100,397
Prepaid and Other Assets	(522,370)	24,902
Inventory	212,747	10,126
Accounts Payable and Accrued Liabilities	(214,734)	169,990
Accrued Interest	1,265,361	2,685,678
Reduction of Lease Liability	(50,273)	(46,795)
Deferred Compensation	(100,000)	425,257
Net Cash Used in Operating Activities	**(4,542,910)**	**(1,009,980)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Capitalization of Patents	(39,982)	(33,063)
Purchases of Property and Equipment	(57,623)	-
Acquisition of Intangibles	(18,283)	(27,070)
Net Cash Used in Investing Activities	**(115,888)**	**(60,133)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of Deferred Offering Costs	(150,420)	(68,629)
Proceeds from IPO and Over-Allotment, net of underwriting discounts and commissions paid at closing of $ 1,047,692	6,454,325	-
Proceeds from the Exercise of Warrants	1,131,771	-
Proceeds from Notes Payable	650,000	800,000
Proceeds from Notes Payable - Related Parties	-	305,000
Repayment of Notes Payable	(1,611,111)	-
Proceeds from Advances - Related Party	250,000	185,335
Repayment of Related Party Advances	(250,000)	-
Net Cash Provided by Financing Activities	**6,474,565**	**1,221,706**
Foreign Currency Translation Gain (Loss)	61,853	(2,127)
Change in Cash	1,877,620	149,466
Cash—Beginning of Period	264,865	115,399
Cash—End of Period	**$ 2,142,485**	**$ 264,865**
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid During the Year for Interest	$ 179,117	$ 2,193
Cash paid During the Year for Income Taxes	$ 1,000	$ 1,000

NONCASH INVESTING/FINANCING ACTIVITIES		
Conversion of Debt into Common Stock	$ 7,989,598	$ -
Conversion of Related Party Advance into Common Stock	$ -	$ 185,335
Conversion of Debt into Series A Preferred Stock	$10,128,500	$ -
Conversion of Series A Preferred Stock into Common Stock	$ 270,460	$ -
Capitalized Share-Based Payments to Vendors	$ 4,916,555	$ -
Additions to ROU Assets for Lease Renewal	$ 50,922	$ -
Additions to Lease Liabilities for Lease Renewal	$ 50,570	$ -
Conversion of 60P LLC Member Units to Common Stock	$ -	$4,979,365
Debt Discount Recorded in Connection with Derivative Liabilities	$ 650,000	$1,105,000
Stock Issued for Payment of Deferred Compensation	$ 520,000	$ -
Stock Issued for Acquisition of Intangibles	$ 33,895	$ -
Fair Value of Warrants Issued to Underwriters	$ 301,416	$ -
Reclassification of Liability-classified Warrants to Equity-classified	$ 838,748	$ -

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

60 DEGREES PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS

60 Degrees Pharmaceuticals, Inc. was incorporated in Delaware on June 1, 2022 and merged on the same day with 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company organized on September 9, 2010 ("60P LLC"). 60 Degrees Pharmaceuticals, Inc. and its subsidiary (referred to collectively as the "Company", "60P", or "60 Degrees Pharmaceuticals") is a specialty pharmaceutical company that specializes in the development and marketing of new medicines for the treatment and prevention of infectious diseases. 60P achieved FDA approval of its lead product, ARAKODA® (tafenoquine), for malaria prevention, in 2018. Currently, 60P's pipeline under development covers development programs for tick-borne fungal and other viral diseases utilizing three of the Company's future products: (i) new products that contain the Arakoda regimen of tafenoquine; (ii) new products that contain tafenoquine; and (iii) celgosivir. The Company's headquarters are located in Washington, D.C., with a majority-owned subsidiary in Australia.

Initial Public Offering

On July 14, 2023, the Company closed its initial public offering consisting of 1,415,095 units at a price of $ 5.30 per unit for $ 6,454,325 in net proceeds, after deducting the underwriting discount and commission and other estimated offering expenses paid by the Company at closing (the "IPO"). Each unit consisted of one share of common stock of the Company, par value $ 0.0001 per share, one tradeable warrant to purchase one share of common stock at an exercise price of $ 6.095 per share (a "Tradeable Warrant"), and one non-tradeable warrant to purchase one share of the Company's common stock at an exercise price of $ 6.36 per share (a "Non-tradeable Warrant"). The Tradeable Warrants and Non-Tradeable Warrants are immediately exercisable on the date of issuance and will expire five years from the date of issuance (July 12, 2023 to July 12, 2028).

The Company granted the underwriters a 45-day over-allotment option to purchase up to 212,265 shares of the Company's common stock at a price of $ 5.28 per share and/or 212,265 Tradeable Warrants at a price of $ 0.01 per Tradeable Warrant and/or 212,265 Non-tradeable Warrants at $ 0.01 per Non-tradeable Warrant, or any combination thereof (the "Over-Allotment"). On July 13, 2023, the underwriters partially exercised the Over-Allotment and purchased an additional 100,644 Tradeable Warrants and 100,644 Non-tradeable Warrants. The Company also issued to the underwriters warrants to purchase 84,906 shares of the Company's common stock, at an exercise price of $ 5.83 per share, equal to 110 % of the offering price per unit (the "Representative Warrants"). The Representative Warrants are exercisable for a period of five years from the date of issuance (July 14, 2023 to July 14, 2028).

The units were offered and sold pursuant to the Company's Registration Statement on Form S-1, as amended (File No. 333-269483), originally filed with the Securities and Exchange Commission (the "SEC") on January 31, 2023 (the "Registration Statement") and the final prospectus filed with the SEC pursuant to Rule 424(b)(4) of the Securities Act of 1933, as amended. The Registration Statement was declared effective by the SEC on July 11, 2023. The common stock and tradeable warrants began trading on The Nasdaq Capital Market on July 12, 2023 under the symbols "SXTP" and "SXTPW," respectively. The closing of the IPO occurred on July 14, 2023. See Note 6 for further details.

Risks and Uncertainties

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

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

Going Concern

The Company's financial statements are prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of obligations in the normal course of business. However, the Company has not demonstrated the ability to generate enough revenues to date to cover operating expenses and has accumulated losses to date. This condition, among others, raises substantial doubt about the ability of the Company to continue as a going concern for one year from the date these financial statements are issued.

In view of these matters, continuation as a going concern is dependent upon the Company's ability to meet its financial requirements, raise additional capital, and achieve gross profitability from their single marketed product. The financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company not continue as a going concern.

Management plans to fund operations of the Company through third party and related party debt/advances, private placement of restricted securities and the issuance of stock in a subsequent offering until such a time as the business achieves profitability or a business combination may be achieved.

On December 31, 2023, the Company had cash and cash equivalents totaling $ 2,142,485 , as compared to cash and cash equivalents totaling $ 264,865 at December 31, 2022. During the twelve months ended December 31, 2023, the Company used cash of $ 4,542,910 in its operating activities.

The Company's future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance that it will ever achieve or maintain profitability. The Company has historically funded its operations primarily with proceeds from sales of common stock and warrants for the purchase of common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements.

The Company expects to need to raise additional capital under structures available to the Company, including debt and/or equity offerings, which may not be on favorable terms. The Company would not have sufficient funds to meet its obligations within twelve months from the issuance date of these consolidated financial statements. As such, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt about the Company's ability to continue as a going concern. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises funds through collaborations, or other similar arrangements with third parties, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company and/or may reduce the value of its common stock. If the Company is unable to raise additional funds through equity or debt financings when needed, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market its product candidates even if the Company would otherwise prefer to develop and market such product candidates itself.

The Company also expects to use cash and cash equivalents to fund activities relating to commercial support for its existing product and any future clinical research trials and operating activities. The Company's future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining regulatory approvals and complying with applicable laws and regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

The Company's capital commitments over the next twelve months include interest obligations on the Company's debt arrangements of $ 8,772 , $ 13,650 for payments due under operating lease liabilities, and $ 506,206 to satisfy accounts payable and accrued expenses.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The financial statements of 60P and its subsidiaries are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The Company has prepared the accompanying consolidated financial statements pursuant to the instructions to Form 10-K and Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC"). In the opinion of management, all adjustments considered necessary for a fair presentation of the Company's financial position, results of operations and cash flows have been included and are of a normal and recurring nature.

Principles of Consolidation and Noncontrolling Interest

The Company's consolidated financial statements include the financial statements of its majority owned subsidiary 60P Australia Pty Ltd, as well as the financial statements of 60P Singapore Pty Lte, a wholly owned subsidiary of 60P Australia Pty Ltd. All significant intercompany accounts and transactions have been eliminated in consolidation. 60P Singapore Pty Lte was closed via dissolution as of March 31, 2022. 60P Singapore Pty Lte was originally set up to conduct research in Singapore. The entity had no assets and its liabilities were to both 60P Australia Pty Ltd, its direct owner, and 60P. Through consolidation accounting the closure of the business unit resulted in a currency exchange gain.

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

On August 2, 2023, Geoffrey Dow assigned his interest in 60P Australia Pty Ltd, of 904,436 common shares to the Company for no consideration, thereby increasing the proportional ownership of 60P, Inc. in 60P Australia Pty Ltd from 87.53 % to 96.61 %. The purpose of this assignment was to eliminate the related party conflict associated with Geoffrey Dow's ultimate beneficial ownership in 60P Australia Pty Ltd being greater than that of other 60P, Inc. shareholders. The increase in the Company's proportional interest is reflected as a Contribution from Noncontrolling Interest in the accompanying Consolidated Statements of Shareholders' and Members' Equity (Deficit).

Use of Estimates

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

Cash and Cash Equivalents

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

Accounts Receivable and Allowance for Doubtful Accounts

The Company records accounts receivable at net realizable value. This value includes an appropriate allowance for estimated uncollectible accounts to reflect any loss anticipated on the trade accounts receivable balances and charged to the provision for doubtful accounts. Based on the Company's history there has been no need to make a recording to Allowance for Doubtful Accounts. Most of the Company's revenue has been earned via government contracts, an Australian pharmaceutical distributor and a large American pharmaceutical distributor. There was no allowance as of December 31, 2023 and December 31, 2022. As the Company continues to engage with smaller distributors, we will continue to analyze whether an allowance should be established. At December 31, 2023, the US government accounted for 13 % of the outstanding accounts receivable balance (66 % at December 31, 2022) and the American pharmaceutical distributor accounted for 79 % of the outstanding accounts receivable balance (30 % for the year ended December 31, 2022).

Inventory

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

The Company regularly monitors its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value, and records write-downs for inventory that has expired, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected sales requirements. Any write-downs of inventories are charged to Cost of Revenues in the Consolidated Statements of Operations and Comprehensive Loss. During the year ended December 31, 2023, write-downs for expired inventory totaled $ 191,111 ($ 162,222 for the year ended December 31, 2022).

Property and Equipment

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

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

Impairment of Long-lived Assets

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

Intangible Assets

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

Website Development Costs

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

Gain/Loss on Debt Extinguishment

Gain or loss on debt extinguishment is generally recorded upon an extinguishment of a debt instrument or the conversion of certain of the Company's convertible debt determined to have variable share settlement features. Gain or loss on extinguishment of debt is calculated as the difference between the reacquisition price and net carrying amount of the debt, which includes unamortized debt issuance costs and the fair value of any related derivative instruments. In the case of debt instruments for which the fair value option has been elected, the net carrying value is equal to its fair value on the date of extinguishment and no gain or loss is recognized.

Derivative Liabilities

The Company assesses the classification of its derivative financial instruments each reporting period, which formerly consisted of bridge shares, convertible notes payable, and certain warrants, and determined that such instruments qualified for treatment as derivative liabilities as they met the criteria for liability classification under ASC 815. As of December 31, 2023, the Company's derivative financial instruments consist of contingent payment arrangements.

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

derivative liabilities. The Company uses a Monte Carlo Simulation Model to determine the fair value of these instruments.

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

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

Equity-Classified Warrants

The Company accounts for the Tradeable Warrants, the Non-tradeable Warrants, the Representative Warrants, and the Bridge Warrants (following the IPO, see Note 6) as equity-classified instruments based on an assessment of the warrants' specific terms and applicable authoritative guidance in ASC 480 and ASC 815. This assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the respective issuance dates and as of each subsequent reporting period while the warrants are outstanding.

IPO and Over-Allotment

The Over-Allotment option granted to the underwriters was evaluated in accordance with the guidance in ASC 480 and ASC 815 and was determined to meet all of the criteria for equity classification. The Company allocated the proceeds from the sale of the IPO units (net of offering costs paid at closing and deferred offering costs incurred prior to the IPO) between the common stock, the Tradeable Warrants, the Non-tradeable Warrants, and the Over-Allotment, using the relative fair value method.

Original Issue Discount ("OID")

For certain notes issued, the Company may provide the debt holder with an original issue discount. The original issue discount is recorded as a debt discount and is amortized to interest expense using the effective interest method over the life of the debt in the Consolidated Statements of Operations and Comprehensive Loss.

Debt Issuance Costs

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

Income Taxes

60 Degrees Pharmaceuticals, Inc. is a corporation and has accepted the default taxation status of C corporation. The Merger in 2022 (See Note 6) did not materially impact tax matters as 60P LLC had elected to be taxed as a C corporation for income tax purposes at the beginning of 2022. The District of Columbia ("DC") taxes corporations on form D-20 (DC Corporation Franchise Tax Return) and returns have a minimum tax due of $ 250 if gross receipts are at $ 1 million or less and $ 1,000 if above. The tax years that remain subject to examination by major tax jurisdictions include the years ended December 31, 2020, 2021, 2022 and 2023.

60P Australia Pty Ltd. is subject to the taxes of the Australian Taxation Office and 60P Singapore Pte Ltd. was subject to the taxes of the Inland Revenue Authority of Singapore prior to its dissolution as of March 31, 2022.

Management assesses, on a jurisdictional basis, the available means of recovering deferred tax assets, including the ability to carry-back net operating losses, the existence of reversing temporary differences, the availability of tax planning strategies and available sources of future taxable income. On the basis of this evaluation, the Company has determined that it is more likely than not that the Company will not recognize the benefits of the U.S. Federal, state and net deferred tax assets, and, as a result, a full valuation allowance has been set against its net deferred tax assets as of December 31, 2023 and December 31, 2022.

During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. The Company establishes reserves for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These reserves are established when the Company believes that certain positions might be challenged despite its belief that its tax return positions are fully supportable. The Company adjusts these reserves in light of changing facts and circumstances, such as the outcome of tax examinations. As of December 31, 2023 and December 31, 2022, no reserves for uncertain tax positions have been established.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the years ended December 31, 2023 and 2022 the Company did not recognize interest and penalties related to unrecognized tax benefits.

Concentrations

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

Significant customers represent any customer whose business makes up 10 % of receivables or revenues. At December 31, 2023, significant customers represented 92 % of receivables (consisting of three customers and two significant customers at 79 % and 13 %, respectively) and 93 % of total net revenues (consisting of two significant customers at 72 % and 21 %, respectively). At December 31, 2022, 96 % of the Company's receivables (consisting of three customers and two significant customers at 66 % and 30 %), and 100 % of total net revenues (consisting of four customers and three significant at 40 %, 39 % and 14 %, respectively).

Currently, the Company has exclusive relationships with distributors in Australia and Europe. A failure to perform by any of our current distributors would create disruption for patients in those markets. The US government has historically been the Company's largest customer through a purchase support contract and a clinical study. Both of those activities ended in 2022 and near-term receivables and revenues from the government are not currently anticipated to be significant.

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

As of December 31, 2023, 0 % (85 % at December 31, 2022) of the Company's non-related party debt is held by Knight Therapeutics, previously the senior secured lender and also a publicly traded Canadian company.

Business Segments

The Company uses the "management approach" to identify its reportable segments. The management approach requires companies to report segment financial information consistent with information used by management for making operating decisions and assessing performance as the basis for identifying the Company's reportable segments. To date, the Company has managed its business in one identifiable segment.

Revenue Recognition

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

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

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

Research and Development Costs

The Company accounts for research and development costs in accordance with FASB ASC Subtopic No. 730-10, Research and Development ("ASC 730-10"). Under ASC 730-10, research and development costs are expensed as incurred. Accordingly, internal research and development costs are expensed as incurred. Prepaid research and development costs are deferred and amortized over the service period as the services are provided.

The Company recorded $ 691,770 in research and development costs during the year ended December 31, 2023 ($ 525,563 for the year ended December 31, 2022). During the year ended December 31, 2023, the Company has also issued shares of common stock to nonemployees in exchange for research and development services. The Company recognizes prepaid research and development costs on the grant date, as defined in FASB ASC Subtopic No. 718, Compensation–Stock Compensation. See Note 11 for further details.

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

The carrying value of the Company's financial instruments included in current assets and current liabilities (such as cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses) approximate their fair value due to the short-term nature of such instruments.

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

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

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

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

The Company may choose to elect the FVO for certain eligible financial instruments, such as certain Promissory Notes, in order to simplify the accounting treatment. Items for which the FVO has been elected are presented at fair value in the Consolidated Balance Sheets and any change in fair value unrelated to credit risk is recorded in Other Expense, net in the Consolidated Statements of Operations and Comprehensive Loss. Changes in fair value related to credit risk are recognized in Other Comprehensive Loss. As a result of the completion of the IPO, all financial instruments for which the FVO was elected were extinguished. See Note 8 for more information on the extinguishment of the Promissory Notes.

The Company's financial instruments recorded at fair value on a recurring basis at December 31, 2023, and December 31, 2022 include Derivative Liabilities, which are carried at fair value based on Level 3 inputs. See Note 9 for more information on Derivative Liabilities.

Liabilities measured at fair value at December 31, 2023 and 2022 are as follows:

	December 31, 2023

	Level 1	Level 2	Level 3	Total
Liabilities:				
Derivative Liabilities	$ -	$ -	$ 2,306,796	$ 2,306,796
Total	$ -	$ -	$ 2,306,796	$ 2,306,796

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Derivative Liabilities	$ -	$ -	$ 1,494,200	$ 1,494,200
Total	$ -	$ -	$ 1,494,200	$ 1,494,200

There were no transfers of financial instruments between Level 1, Level 2, and Level 3 during the periods presented. However, certain liabilities measured at fair value and using Level 3 inputs were extinguished during the year. A rollforward of level 3 liabilities measured at fair value for the years ended December 31, 2023 and 2022 are presented in Notes 8 and 9 for Promissory Notes and Derivative Liabilities, respectively.

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

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

As of December 31, 2023 and 2022, the fair value of Cash and Cash Equivalents, Accounts Receivable, Prepaid Expenses and Other Current Assets, and Accounts Payable and Accrued Expenses approximated their carrying values due to the short-term nature of these assets and liabilities.

Foreign Currency Transactions and Translation

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

For the purpose of presenting consolidated financial statements, the assets and liabilities of the group's foreign operations are mostly translated at exchange rates prevailing on the reporting date. Income and expense items are translated at the average exchange rates for the period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the dates of the transactions are used. Exchange differences arising, if any, are recognized as a component of other comprehensive income (loss) as Unrealized Foreign Currency Translation Gain (Loss).

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

	Average Exchange Rate			
	Year Ended December 31,		As of	
Currency	2023	2022	December 31, 2023	December 31, 2022
1 AUD =	0.66 USD	0.69 USD	0.68 USD	0.68 USD
1 SGD =	NA	1.02 AUD*	NA	1.02 AUD*

* Through 4/30/2022 (account closure date)

Reclassifications

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

Share-Based Payments

On November 22, 2022, the Company adopted the 2022 Equity Incentive Plan also referred to as ("2022 Plan"). The 2022 Plan and related share-based awards are discussed more fully in Note 11.

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

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

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

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

For fully vested, nonforfeitable equity instruments that are granted at the date the Company and a nonemployee enter into an agreement for goods or services, the Company recognizes the fair value of the equity instruments on the grant date. The corresponding cost is recognized as an immediate expense or a prepaid asset and expensed over the service period depending on the specific facts and circumstances of the agreement with the nonemployee. See Note 11 for further details.

Leases

The Company applies ASC Topic 842, *Leases* (“ASC 842”) to its operating leases, which are reflected on the consolidated balance sheets within Right of Use (ROU) Asset and the related current and non-current operating Lease Liability. ROU assets represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments arising from lease agreements. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectation regarding the terms. Variable lease costs such as common area maintenance, property taxes and insurance are expensed as incurred.

The Company determines if an arrangement is a lease at contract inception. The Company’s contracts are determined to contain a lease when all of the following criteria, based on the specific circumstances of the arrangement, are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

At the commencement date, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The Company’s lease agreement does not provide an implicit rate. As a result, the Company utilizes an estimated incremental borrowing rate (“IBR”), to discount lease payments, which represents the rate of interest the Company would pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment.

Net Loss per Common Share

Net Loss per Common Share is computed by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding during each period. For the purposes of calculating the weighted average number of common shares outstanding for periods prior to the Merger (See Note 6), each of 60P LLC’s outstanding membership units as of June 1, 2022 have been retrospectively adjusted for the equivalent number of common shares issued pursuant to the Merger. The cumulative dividends accrued on the Series A Preferred Stock during the period are reflected as an addition to net loss in determining basic and diluted net loss attributable to common stockholders.

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

Related Parties

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

Segment Information

A single management team that reports to the Chief Executive Officer comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through April 1, 2024, which is the date the financial statements were issued. See Note 13.

Recently Adopted and Issued Accounting Pronouncements

From time to time, the FASB issues Accounting Standards Updates (“ASU”) to amend the authoritative literature in the ASC. Management believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, (iii) are not applicable to the Company or (iv) are not expected to have a significant impact on these consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity (“ASU 2020-06”), as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Among other changes, the new guidance removes from U.S. GAAP separation models for convertible debt that require the convertible debt to be separated into a debt and equity component, unless the conversion feature is required to be bifurcated and accounted for as a derivative or the debt is issued at a substantial premium. As a result, after adopting the guidance, entities will no longer separately present such embedded conversion features in equity and will instead account for the convertible debt wholly as debt. The new guidance also requires use of the “if-converted” method when calculating the dilutive impact of convertible debt on earnings per share, which is consistent with the Company’s current accounting treatment under the current guidance. The guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, but only at the beginning of the fiscal year. The Company adopted this pronouncement on January 1, 2022; however, the adoption of this standard did not have a material effect on the Company’s

consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options.

This latter standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard.

Early adoption is permitted, including adoption in an interim period. If an issuer elects to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company's adoption of this standard in 2022 did not have a material effect on the Company's consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers, which requires an acquirer in a business combination to recognize and measure contract assets and contract liabilities in accordance with Accounting Standards Codification Topic 606. ASU 2021-08 is effective for fiscal years beginning after December 15, 2022 and early adoption is permitted. The Company's adoption of ASU 2021-08 did not have an effect on its consolidated financial statements.

In November 2023, the FASB issued 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses and segment profit or loss. The ASU also requires entities with a single reportable segment to provide all segment disclosures under ASC 280, including the new required disclosures under the ASU. The ASU is effective for all public entities with fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The ASU must be applied retrospectively. The Company is currently evaluating the impact that ASU 2023-07 will have on its financial statement disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (ASC 740): Improvements to Income Tax Disclosures, which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that ASU 2023-09 will have on its financial statement disclosures.

3. INVENTORY

Inventory consists of the following major classes:

	December 31, 2023	December 31, 2022
Raw Material (API)	$ -	$ 397,487
Work in Process	278,987	97,486
Finished Goods	187,182	183,943
Total Inventory	**466,169**	678,916
Reserve for Expiring Inventory	-	(160,338)
Inventory, net	**$ 466,169**	**$ 518,578**

4. PROPERTY AND EQUIPMENT

As of December 31, 2023 and 2022, Property and Equipment, net consists of:

	December 31, 2023	December 31, 2022
Lab Equipment	$ 132,911	$ 132,911
Machinery	55,800	-
Computer Equipment	14,084	12,261
Furniture	3,030	3,030
Property and Equipment, at cost	205,825	148,202
Accumulated Depreciation	(148,064)	(126,902)
Property and Equipment, Net	**$ 57,761**	**$ 21,300**

Depreciation expenses for the years ended December 31, 2023 and 2022 were in the amount of $ 21,162 and $ 27,648 , respectively.

5. INTANGIBLE ASSETS

As of December 31, 2023 and 2022, Intangible Assets, net consist of:

	December 31, 2023	December 31, 2022
Patents	$ 185,595	$ 145,613
Website Development Costs	79,248	27,070
Intangible Assets, at cost	264,843	172,683
Accumulated Amortization	(37,585)	(8,428)
Intangible Assets, net	**$ 227,258**	**$ 164,255**

During the years ended December 31, 2023 and 2022, the Company capitalized website development or related costs of $ 52,178 and $ 27,070 , respectively, in connection with the upgrade and enhancement of functionality of the corporate website at www. 60degreespharma.com. Amortization expense for the years ended December 31, 2023, and 2022 was in the amount of $ 29,157 and $ 5,118 , respectively.

The following table summarizes the estimated future amortization expense for our patents and website development costs as of December 31, 2023:

Period	Patents	Website Development Costs
2024	$ 6,612	$ 26,416
2025	6,612	23,303
2026	6,612	3,974
2027	6,612	-
2028	6,612	-
Thereafter	41,817	-
Total	**$ 74,877**	**$ 53,693**

The Company additionally has $ 93,545 in capitalized patent expenses that will become amortizable as the patents they are associated with are awarded.

6. STOCKHOLDERS' EQUITY

On June 1, 2022, 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 "Merger"). The value of each outstanding member's membership interest in 60P LLC was correspondingly converted into common stock of 60 Degrees Pharmaceuticals, Inc., par value $ 0.0001 per share, with a cost basis equal to $ 5 per share.

Pursuant to the Certificate of Incorporation of 60 Degrees Pharmaceuticals, Inc., the Company's authorized shares consist of (a) 150,000,000 shares of common stock, par value $ 0.0001 per share and (b) 1,000,000 shares of preferred stock, par value $ 0.0001 per share, of which 80,965 have been designated as Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"). As of December 31, 2023, 5,810,089 shares of Common Stock and 78,803 shares of Series A Preferred Stock are issued and outstanding.

Common Stock

On June 30, 2022 the Company issued 37,067 shares of common stock to its Chief Executive Officer for $ 185,335 at a purchase price of $ 5 per share.

In January and March 2023, the Board of Directors, with the consent of Tyrone Miller and Geoffrey S. Dow, respectively, approved resolutions to cancel an aggregate of 192,101 shares of common stock issued to Tyrone Miller and 1,258,899 shares of common stock issued to the Geoffrey S. Dow Revocable Trust to allow the Company to issue new shares to vendors in exchange for valuable services to be provided for use in the Company's operations. The cancelled shares represented approximately 61 % of the issued and outstanding shares as of December 31, 2022.

In January and March 2023, the Company issued a total of 1,443,000 shares of common stock to certain vendors as payment for services rendered or to be provided to the Company.

In connection with the closing of the Company's IPO as discussed in Note 1, the Company issued common stock as follows:

- As a result of the effectiveness of the Registration Statement on July 11, 2023, the Company issued a total of 40,000 restricted shares of common stock to the following directors and in the amounts listed: (i) Stephen Toovey (10,000 restricted shares of common stock), (ii) Charles Allen (10,000 restricted shares of common stock), (iii) Paul Field (10,000 restricted shares of common stock) and (iv) Cheryl Xu (10,000 restricted shares of common stock), by virtue of the terms of the agreements discussed in Note 12.
- On July 13, 2023, the Company issued 31,447 shares of common stock upon the exercise of 31,447 Bridge Warrants (as defined below).
- On July 14, 2023, the IPO closed, and the Company issued 1,415,095 shares of common stock from the sale of units at a price of $ 5.30 per unit, generating $ 6,454,325 in net proceeds, after deducting the underwriting discount and commission and other estimated IPO expenses paid at closing. As a result of the completion of the IPO and as required under the terms of the respective agreements, on July 14, 2023:
    - The Company issued an aggregate of 383,908 shares of common stock upon conversion of the 2022 and 2023 Bridge Notes and the Related Party Notes described in Note 8.
    - The Company issued 29,245 shares of common stock to BioIntelect as deferred equity compensation valued in the amount of $ 155,000 .
    - The Company issued 214,934 shares of common stock upon conversion of the Xu Yu Note, including the Amendment described in Note 8.
    - The Company issued 1,108,337 shares of common stock to Knight upon conversion of the cumulative outstanding principal as of March 31, 2022 at the conversion price detailed in Note 8 (representing 19.9 % of our outstanding common stock after giving effect to the IPO).
- On July 17, 2023 the Company issued 60,000 shares of common stock upon the exercise of 60,000 Non-tradeable Warrants.
- On July 17, 2023, the Company issued 93,000 shares of common stock upon the exercise of 93,000 Tradeable Warrants.
- On July 28, 2023, the Company issued 45,560 shares of common stock to Knight upon conversion of 2,162 shares of Series A Preferred Stock.

On December 28, 2023, the Company issued 10,554 shares of common stock to Red Chip as deferred equity compensation valued in the amount of $ 40,000 , as required by the terms of the investment relations consulting agreement described in Note 7.

Common Stock Warrants

In May 2022 and May 2023, in connection with the issuance of the Related Party Notes and the 2022 and 2023 Bridge Notes as described in Note 8, the

Company issued five-year warrants to each of the noteholders with an exercise price dependent on the IPO price (collectively, the “Bridge Warrants”). The number of shares issuable upon exercise of the warrants was contingent on the number of shares issued upon conversion of the notes following the Company’s IPO. As of the closing of the Company’s IPO, the Bridge Warrants became exercisable into an aggregate of 231,917 shares of the Company’s common stock, 79,926 of which are held by related parties and have an exercise price of $ 4.77 (90 % of the IPO price), and 151,991 with an exercise price of $ 5.83 (110 % of the IPO Price). Prior to the IPO, the Bridge Warrants were classified as derivative liabilities in accordance with the provisions of ASC 815 and were carried at their respective fair values. (See Note 9). In connection with the IPO, the terms of the Bridge Warrants became fixed. The Company determined the event resulted in equity classification for the Bridge Warrants and, accordingly, the Company remeasured the warrant liabilities to fair value, and reclassified the warrants to Additional Paid-in Capital.

On July 12, 2023, the Company executed a Warrant Agent Agreement with Equity Stock Transfer, LLC, acting as warrant agent for the IPO, which sets forth the procedures for registering, transferring and exercising the Tradeable Warrants and Non-tradeable Warrants issued in connection with the IPO. The Company accounts for the Tradeable Warrants, the Non-tradeable Warrants, and the Representative Warrants (defined in Note 1) as equity-classified financial instruments.

There were no equity-classified warrants issued or outstanding prior to the Company’s IPO. The following table presents information related to stock warrants at December 31, 2023:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Total outstanding, December 31, 2022	-	$ -	-
Reclassified from Derivative Liabilities	231,917	5.46	4.15
Granted	3,116,384	6.22	5.00
Exercised	(184,447)	6.14	5.00
Forfeited	-	-	-
Expired	-	-	-
Total outstanding, December 31, 2023	3,163,854	$ 6.17	4.47
Total exercisable, December 31, 2023	3,163,854	$ 6.17	4.47

There were no warrant exercises, forfeitures, or expirations prior to the IPO. During the year ended December 31, 2023, the Company received aggregate cash proceeds of $ 1,131,771 upon the exercise of 31,447 Bridge Warrants, 60,000 Non-tradeable Warrants, and 93,000 Tradeable Warrants.

The following table summarizes the significant assumptions used in determining the fair value of equity classified warrants on the respective grant or reclassification dates for the year ended December 31, 2023:

	2023
Stock price	$ 4.68 – 5.30
Exercise price	$ 4.77 – 6.36
Risk-free interest rate	4.07 - 4.40%
Expected volatility	90 – 105%
Expected term (years)	3.86 – 5.00
Expected dividend yield	0.00%

Series A Preferred Stock

As described in Note 8, as a result of the completion of the IPO and as required under the terms of the Knight Debt Conversion Agreement, the Company converted the entirety of the accumulated interest on the Convertible Knight Loan as of March 31, 2022 into 80,965 shares of Series A Preferred Stock at the Conversion Price detailed below. On July 25, 2023, the Company converted 2,162 shares of Series A Preferred Stock into 45,560 shares of Common Stock at the conversion rate detailed below. No shares of Series A Preferred Stock were issued or outstanding as of December, 31, 2022.

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

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

Dividends – From and after the date of issuance of any share of Seies A Preferred Stock, cumulative dividends shall accrue, whether or not declared by the Board and whether or not there are funds legally available for the payment of dividends, on a daily basis in arrears at the rate of 6.0 % per annum on the sum of the Liquidation Value (as defined below). Accrued dividends shall be paid in cash only when, as and if declared by the Board out of funds legally available therefor or upon a liquidation or redemption of the Series A Preferred Stock. On March 31 of each calendar year, any accrued and unpaid dividends shall accumulate and compound on such date, and are cumulative until paid or converted. Holders of shares of Series A Preferred Stock are entitled to receive accrued and accumulated dividends prior to and in preference to any dividend, distribution, or redemption on shares of Common Stock or any other class of securities that is designated as junior to the Series A Preferred Stock. From the issuance date of the Series A Preferred Stock, or July 14, 2023, to December 31, 2023, accrued dividends on outstanding shares of Series A Preferred Stock totaled $ 220,714 . As of December 31, 2023, the Company has not declared or paid any dividends.

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

Conversion Rights – The Company has the right, in its sole discretion, to convert all or any portion of the outstanding shares of Series A Preferred Stock (including any fraction of a share), plus the aggregate accrued or accumulated and unpaid dividends thereon into a number of shares of Common Stock determined by (i) multiplying the number of shares to be converted by $ 100 per share, as adjusted for any stock splits, stock dividends, recapitalizations

or similar transactions (the “Liquidation Value”), (ii) plus all accrued and accumulated and unpaid dividends on such shares to be converted, and then (ii) dividing the result by the then-effective Conversion Price in effect, provided that such conversion would not result in the holders of shares of Series A Preferred Stock owning more than 19.9 % of the outstanding shares of common stock on an as-converted basis. The “Conversion Price” is equal to the lesser of (a) the Liquidation Value, (b) the offering price per share of Common Stock in the Company’s IPO, or (c) the 10-day volume weighted average price per share of Common Stock, as reasonably determined by the Company.

7. DEFERRED COMPENSATION

In 2020, the Company received consulting services from Biointelect Pty Ltd. of Australia (“Biointelect”) with a value of $ 100,000 , which was payable contingent upon a future capital raise and was non-interest bearing. On May 5, 2022, the Company agreed to modify their contract with Biointelect. Previously, Biointelect potentially could earn $ 60,000 in deferred cash compensation and $ 400,000 in warrants in connection with a fundraise and other services provided. As the Company considered this compensation unlikely, it agreed to restructure by increasing the cash component to $ 100,000 , tying $ 155,000 in equity compensation to an IPO or future qualifying transaction while leaving $ 245,000 in equity compensation with the original triggering events. As a result of the completion of the IPO and as required under the terms of the agreement with BioIntelect, the Company issued 29,245 shares of common stock to BioIntelect as deferred equity compensation and remitted payment in cash of $ 100,000 in full satisfaction of its obligations with respect to the services provided.

Also in 2020, the Company entered into an agreement with Latham Biopharma for contingent compensation. On June 17, 2022 the Company and Latham Biopharma agreed to convert the $ 57,198 of deferred compensation that was earned and due and $ 12,500 of accrued expenses into a 100 % contingent deferred compensation amount of $ 38,900 in cash and $ 60,000 in common shares of the Company if, within five years after 2022 the Company nets at least $ 10,000,000 in an IPO or any private financing that secures the retirement and/or conversion to equity of all secured debt excluding the loans advanced by the Small Business Administration. Then before the year ended December 31, 2022, the Company and Latham Biopharma initiated an agreement that converted the entire deferred compensation into 65,000 shares valued at $ 5 per share. As of December 31, 2022, the Company recognized a contingent liability related to the subsequent agreement of $ 325,000 . On January 26, 2023, the Company issued 65,000 shares to Latham Biopharma in full satisfaction of its obligations with respect to the services provided.

In March 2023, the Company signed an investment relations consulting agreement with Red Chip. This agreement obligated the Company to issue Red Chip $ 40,000 of Rule 144 stock, based on the 30-day average of the publicly traded common shares after the IPO. All shares were deemed earned immediately upon signing, acceptance, and execution of the agreement. On December 28, 2023, the Company issued 10,554 shares to Red Chip in full satisfaction of its obligations with respect to the services provided.

8. DEBT

Knight Therapeutics, Inc.

On December 27, 2019 the Company restructured its cumulative borrowing with its senior secured lender, Knight Therapeutics, Inc. (‘Knight’), into a note for the principal amount of $ 6,309,823 and accrued interest of $ 4,160,918 and a debenture of $ 3,483,851 (collectively, the ‘Knight Loan’). The Knight Loan had a maturity date of December 31, 2023. The principal and accrued interest portion of the Knight Loan bore an annual interest rate of 15 %, compounded quarterly, whereas the debenture had a 9 % interest rate until April 23, 2023 at which point interest ceased accruing. As of December 31, 2022, the aggregate outstanding balance of the Knight Loan was $ 20,596,595 . In January 2023, the Company and Knight executed the Knight Debt Conversion Agreement, pursuant to which the parties agreed to add a conversion feature to the cumulative outstanding Knight Loans, which was accounted for as a debt extinguishment, described further below.

Note, including Amendment

On October 11, 2017 the Company issued a promissory note (“Note”) with an individual investor in the amount of $ 750,000 . The Note was set to mature 60 days after the Knight Loans were repaid. The Note originally bore an interest rate of 5 % from inception for the first six months and 10 % per annum thereafter both compounded quarterly. On December 11, 2022, the Company and the individual investor amended the Note (“the Amendment”). The Amendment added a provision to automatically convert the outstanding principal and accumulated interest through March 31, 2022 into common shares in the event the Company consummated an IPO. The Amendment also provided the lender the option to convert the outstanding principal and accumulated interest through March 31, 2022 into equity shares of the Company at the maturity date, which option would expire 30 days after maturity. Cumulative interest after March 31, 2022 was to be forfeited should the lender elect to convert the Note into equity.

At the Amendment date, the Company recorded a discount of $ 120,683 related to the excess fair value of the Note and incurred costs with third parties directly related to the Amendment of $ 1,767 , which were amortized over the remaining life of the debt using the effective interest method. Amortization of the discount on the Note for the years ended December 31, 2023 and 2022 was $ 52,628 and $ 4,955 , respectively. Interest expense related to the Note, for the years ended December 31, 2023 and 2022 was $ 66,558 and $ 115,546 , respectively.

As a result of the completion of the IPO and as required under the terms of the Note, including the Amendment, the outstanding principal and accrued interest through March 31, 2022 converted to 214,934 shares of our common stock at a conversion rate equal to the IPO price, in full satisfaction of the outstanding debt obligation. The Company recognized a debt extinguishment gain of $ 223,077 upon conversion, representing the difference (i) the reacquisition price, consisting of the fair value of the common shares issued, and (ii) the net carrying value of the debt, inclusive of unamortized discounts and issuance costs, on the date of conversion.

Promissory notes are summarized as follows at December 31, 2023:

	Knight Therapeutics	Note, including amendment	Bridge Notes	Total
Promissory Notes *(including accrued interest)*, at fair value	$ -	$ -	$ -	$ -
Promissory Notes *(including accrued interest)*	-	-	-	-
Less Current Maturities	-	-	-	-
Long Term Promissory Notes	$ -	$ -	$ -	$ -

Promissory notes are summarized as follows at December 31, 2022:

	Knight Therapeutics	Note, including amendment	Bridge Notes	Total
Promissory Notes *(including accrued interest)*	$ 16,319,986	$ 1,109,783	$ 535,901	$ 17,965,670

Less Current Maturities	16,319,986	-	535,901	16,855,887
Long Term Promissory Notes	$ -	$ 1,109,783	$ -	$ 1,109,783

Convertible Promissory Notes and Warrants

During May 2022, the Company executed promissory notes having a face amount of $ 888,889 . The notes contained an original issue discount of 10 % ($ 88,889) and debt issuance costs of $ 91,436 , resulting in net proceeds of $ 708,564 . These notes bore interest at 10 % with a default interest rate of 15 % and were unsecured. The notes were due at the earlier of one year from the issuance date or the closing of an IPO (the “2022 Bridge Notes”). In connection with the issuance of the 2022 Bridge Notes, the Company agreed to issue common stock to each noteholder equivalent to 100 % of the face amount of the note divided by the IPO price per share. Additionally, each of these note holders were entitled to receive five-year (5) fully vested warrants upon the closing of the IPO, with an exercise price of 110 % of the IPO price (See Note 6). In May 2023, the maturity date for the 2022 Bridge Notes was extended for an additional two months. In exchange for extension of the maturity date, the Company agreed to additional cash payments totaling $ 22,222 due to the holders of the 2022 Bridge Notes at maturity (the “Extension Payments”).

During May 2023, the Company executed promissory notes having an aggregate face amount of $ 722,222 . The notes contained an original issue discount of 10 % ($ 72,222) and the Company incurred debt issuance costs of $ 95,000 , resulting in net proceeds to the Company of $ 555,000 . These notes bore interest at 10 % with a default interest rate of 15 % and were unsecured. The notes were due at the earlier of one-year from the issuance date or the closing of an IPO (the “2023 Bridge Notes”). In connection with the issuance of the 2023 Bridge Notes, the Company also agreed to issue common stock to each note holder equivalent to 100 % of the face amount of the note divided by the IPO price per share. Additionally, each of these noteholders were entitled to receive five-year (5) fully vested warrants upon the closing of the IPO, with an exercise price of 110 % of the IPO price.

The Company performed an evaluation of the conversion features embedded in the Bridge Notes and the warrants and concluded that such instruments qualify for treatment as derivative liabilities under ASC 815 and require bifurcation from the host contract. Derivative liabilities are carried at fair value at each balance sheet date, and any changes in fair value are recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss. See Note 9 for further details.

As a result of the completion of the IPO and as required under the terms of the 2022 and 2023 Bridge Notes, the Company issued the holders 303,982 shares of common stock, determined by the outstanding principal balance of each note divided by the IPO price. In addition, the Company made cash payments to the holders of the 2022 and 2023 Bridge Notes totaling $ 1,749,488 for the outstanding principal, accrued interest and Extension Payments (2022 Bridge Notes only), in full settlement of the outstanding debt obligations. The embedded derivative liability (conversion feature) was marked to market on the settlement date, and the Company recognized a debt extinguishment loss of $ 614,670 upon settlement, representing the difference between (i) the reacquisition price, consisting of cash and shares, and (ii) the net carrying value of the debt including associated derivative liabilities on the date of conversion.

Related Party Notes

During May 2022, the Company executed convertible promissory notes with the Company’s Chief Executive Officer and a family member related to the Chief Executive Officer, having an aggregate face amount of $ 338,889 . The notes contained an original issue discount of 10 % ($ 33,888) and debt issuance costs of $ 34,289 , resulting in net proceeds of $ 270,711 . These notes bore interest at 6 % with a default interest rate of 15 % and were unsecured. The notes were due at the earlier of one-year (1) from the issuance date or the closing of an IPO (the “Related Party Notes”). In May 2023, the maturity date for the Related Party Notes was extended for an additional two months. In exchange for extension of the maturity date, the Company agreed to additional cash payments totaling $ 8,472 due to the holders of the Related Party Notes at maturity (the “Extension Payments”). Upon the closing of the IPO, these notes were mandatorily convertible at a conversion rate determined at a 20 % discount to the IPO price, discussed further below. Additionally, each of these note holders received five-year (5) fully vested warrants upon the closing of the IPO, with an exercise price of 90 % of the IPO price.

The Company performed an evaluation of the conversion features embedded in the Related Party Notes and the warrants and concluded that such instruments qualified for treatment as derivative liabilities under ASC 815 and required bifurcation from the host contract. See Note 9 for further details.

Bridge Notes and Related Party Notes are summarized as follows at December 31, 2023 and 2022:

	2022 Bridge Notes	Related Party Notes	2023 Bridge Notes
Issuance date of promissory notes	May 2022	May 2022	May 2023
Maturity date of promissory notes	**1**	**1**	**2**
Interest rate	10%	6%	10%
Default interest rate	15%	15%	15%
Collateral	Unsecured	Unsecured	Unsecured
Conversion rate	**3**	**3**	**3**
Face amount of notes	$ 888,889	$ 338,889	$ -
Less: unamortized debt discount	(407,555)	(155,443)	-
Add: accrued interest on promissory notes	54,567	11,651	-
Balance - December 31, 2022	$ 535,901	$ 195,097	$ -
Face amount of notes	-	-	-
Less: unamortized debt discount	-	-	-
Add: accrued interest on promissory notes	-	-	-
Balance – December 31, 2023	$ -	$ -	$ -

1 - earlier of 1 year from date of issuance or closing of IPO, later extended to July 2023
2 - earlier of 1 year from date of issuance or closing of IPO
3 - see discussion above for (a) and (b)

For the years ended December 31, 2023 and 2022, the Company recorded amortization of debt discounts, including issuance costs, of $ 670,550 and $

664,780 , respectively.

As a result of the completion of the IPO and as required under the terms of the Related Party Notes, the entirety of the outstanding principal balance converted to 79,926 shares of common stock at a conversion rate equal to 80 % of the IPO price, fully satisfying the Company's obligations with respect to the principal amount. In addition, the Company made cash payments to the related party holders totaling $ 31,968 in full settlement of the outstanding accrued interest and Extension Payments. The Company recognized a final mark to market adjustment of the embedded derivative liability (conversion feature), and as a result, no gain or loss was recognized on the debt extinguishment.

Knight Debt Conversion

On January 9, 2023, and in two subsequent amendments, the Company and Knight Therapeutics agreed to extinguish Knight's debt in the event of an IPO. Key points of this agreement are as follows:

- The Parties agreed to fix Knight's cumulative debt to the value as it stood on March 31, 2022, which consisted of $ 10,770,037 in principal and $ 8,096,486 in accumulated interest should the Company execute an IPO that results in gross proceeds of at least $ 7,000,000 prior to December 31, 2023. Should an IPO not occur by January 1, 2024 then all terms of the original debt would resume including any interest earned after March 31, 2022.

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

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

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

The Company evaluated the January 9, 2023 exchange agreement in accordance with ASC 470-50 and concluded that the debt qualified for debt extinguishment because a substantial conversion feature was added to the debt terms. Upon extinguishment, the Company recorded a loss upon extinguishment in the amount of $ 839,887 and elected to recognize the new debt under the ASC 825 fair value option until it is settled.

A reconciliation of the beginning and ending balances for the Convertible Knight Note, which is measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows for the year ended December 31, 2023:

	Convertible Knight Note, at fair value
Promissory Notes, at fair value at December 31, 2022	$ -
Fair value at modification date - January 9, 2023	21,520,650
Fair value - mark to market adjustment	(5,379,269)
Accrued interest recognized	1,293,549
Extinguishment of Promissory Notes	(17,434,930)
Promissory Notes, at fair value at December 31, 2023	$ -

As a result of the completion of the IPO and as required under the terms of the Knight Debt Conversion Agreement, the cumulative outstanding principal as of March 31, 2022 converted to 1,108,337 shares of common stock (representing 19.9% ownership of the Company's common stock after giving effect to the IPO). In addition, the entirety of the accumulated interest as of March 31, 2022 converted into 80,965 shares of Series A Preferred Stock at the conversion rate detailed above, in full satisfaction of the Company's obligations with respect to the accumulated interest. Upon consummation of the IPO and under the terms of the Knight Debt Conversion Agreement, the Company became obligated to the contingent milestone payments and the accumulated Royalty discussed above, which value was included in the reacquisition price of the debt upon extinguishment. The Company recognized a final mark-to-market adjustment of $6,105,066 to adjust the Convertible Knight Loan to its fair value on the date of settlement, and as a result, no gain or loss was recognized on the debt extinguishment.

The Company performed an evaluation of the contingent payment features and concluded that the contingent milestone payment is a freestanding

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

Debenture

On April 24, 2019, 60P entered into the Knight debenture of $ 3,000,000 with an original issue discount of $ 2,100,000 , which was being amortized using the effective interest method. The Company subsequently restructured the Knight Loans, including the debenture, pursuant to the Knight Debt Conversion Agreement (see above). $ 13,696 of the original issue discount was amortized to interest expense in 2023 prior to the amendment ($ 500,103 during the year ended December 31, 2022) and the unamortized original issue discount at December 31, 2023 was $ 0 ($ 279,061 at December 31, 2022) as a result of the debt conversion (discussed above), which was accounted for as a debt extinguishment.

The Knight debenture as of December 31, 2023 and 2022 consisted of the following:

	December 31, 2023	December 31, 2022
Original Debenture	$ -	$ 3,000,000
Unamortized Debt Discount	-	(279,061)
Debenture Prior to Accumulated Interest	-	2,720,939
Accumulated Interest	-	1,555,670
Debenture	**$ -**	**$ 4,276,609**

SBA COVID-19 EIDL

On May 14, 2020, the Company received COVID-19 EIDL lending from the Small Business Administration (SBA) in the amount of $ 150,000 . The loan bears interest at an annual rate of 3.75 % calculated on a monthly basis. The Company was committed to make $ 731 monthly payments first due June 4, 2021. On March 31, 2021, the SBA announced the deferment period was extended an additional eighteen months. Thus, the Company was first obligated to start making interest payments of $ 731 on November 4, 2022. The balance as of December 31, 2023 and 2022 is $ 159,023 and $ 163,022 , respectively. The current maturity at December 31, 2023 is $ 8,772 and the long-term liability is $ 150,251 ($ 2,750 and $ 160,272 at December 31, 2022, respectively). The loan is collateralized by all tangible and intangible personal property of the Company. The Company is prohibited from accepting future advances under any superior liens on the collateral without the prior consent of SBA.

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

Period	Principal Payments
2024	$ -
2025	-
2026	683
2027	3,228
2028	3,342
Thereafter	142,747
Total	**$ 150,000**

Due to the deferral, the Company is expected to make a balloon payment of approximately $ 28,154 to be due on 10/12/2050.

Related Party Advances

In March 2023, the Company received a $ 200,000 short term advance from the Geoffrey S. Dow Revocable Trust. In April 2023, the Company received $ 50,000 as a short-term advance from management. The Geoffrey S. Dow Revocable Trust contributed $ 23,000 and Tyrone Miller contributed $ 27,000 . On May 11, 2023, these short term advances were refunded in full for an aggregate amount of $ 250,000 .

9. DERIVATIVE LIABILITIES

In accordance with the provisions of ASC 815, derivative liabilities are initially measured at fair value at the commitment date and subsequently remeasured at each reporting period, with any increase or decrease in the fair value recorded in the results of operations within other income/expense as the change in fair value of derivative liabilities. As discussed in Note 8 above, certain of the Company's bridge shares, warrants and convertible notes (containing an embedded conversion feature) were previously accounted for as derivative liabilities. The bridge shares and related conversion features were derecognized upon conversion on the date of the IPO. The Bridge Warrants (defined in Note 6) were previously accounted for as derivative liabilities as there was an unknown exercise price and number of shares associated with each instrument. In connection with the IPO, the terms of the Bridge Warrants became fixed. The Company determined the event resulted in equity classification for the Bridge Warrants. Accordingly, the Company remeasured the warrant liabilities to fair value, and reclassified the warrants to additional paid-in capital on the IPO date. As of December 31, 2023, derivative liabilities consist of the contingent milestone payment due to Knight upon a future sale of Arakoda™ or a Change of Control (See Note 8). The valuation of the contingent milestone payment includes significant inputs such as the timing and probability of discrete potential exit scenarios, forward interest rate curves, and discount rates based on implied and market yields.

In connection with the valuation of the Company's derivative liabilities related to the 2022 Bridge Notes and warrants, the Company determined a fair value on the commitment date (May 24, 2022) of $ 1,483,888 . As the fair value of the derivative liabilities exceeded the net proceeds received of $ 979,275 , the Company recorded a debt discount at the maximum amount allowed (the face amount of the debt less the OID and debt issuance costs, as detailed in Note 8), which required the excess to be recorded as a derivative expense.

Derivative expense recorded during the year ended December 31, 2022 is summarized as follows:

Commitment Date	May 24, 2022
Fair value of derivative liabilities	$ 1,483,888
Less: face amount of debt	(979,275)
Derivative expense	$ 504,613

In connection with the valuation of the Company's derivative liabilities related to the 2023 Bridge Notes and warrants, the Company determined a fair value on the commitment date (May 8, 2023) of $ 954,725 . As the fair value of the derivative liabilities exceeded the net proceeds received of $ 555,000 , the Company recorded a debt discount at the maximum amount allowed (the face amount of the debt less the OID and debt issuance costs detailed in Note 8) and recorded the excess as derivative expense.

Derivative expense recorded during the year ended December 31, 2023 is summarized as follows:

Commitment Date	May 8, 2023
Fair value of derivative liabilities	$ 954,725
Less: face amount of debt	(555,000)
Derivative expense	$ 399,725

A reconciliation of the beginning and ending balances for the derivative liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows at December 31, 2023 and 2022:

	Bridge Shares	Warrants	Convertible Notes Payable	Contingent Milestone Payment	Total
Derivative liabilities - December 31, 2022	$ 834,352	$ 578,164	$ 81,684	$ -	$ 1,494,200
Fair value - mark to market adjustment	13,798	(15,320)	(1,312)	-	(2,834)
Fair value - commitment date	680,276	274,449	-	-	954,725
Fair value - mark to market adjustment prior to conversion or reclassification	(105,790)	1,455	(45,207)	-	(149,542)
Conversion of convertible promissory notes	(1,422,636)	-	(35,165)	-	(1,457,801)
Reclassification of warrants to equity	-	(838,748)	-	-	(838,748)
Recognition of contingent milestone liability	-	-	-	2,117,142	2,117,142
Fair value - mark to market adjustment	-	-	-	189,654	189,654
Derivative liabilities - December 31, 2023	$ -	$ -	$ -	$ 2,306,796	$ 2,306,796

A reconciliation of the beginning and ending balances for the derivative liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows at December 31, 2022 and 2021:

	Bridge Shares	Warrants	Convertible Notes Payable	Total
Derivative liabilities - December 31, 2021	$ -	$ -	$ -	$ -
Fair value - commitment date	823,687	565,007	95,194	1,483,888
Fair value - mark to market adjustment	10,665	13,157	(13,510)	10,312
Derivative liabilities – December 31, 2022	$ 834,352	$ 578,164	$ 81,684	$ 1,494,200

Changes in fair value of derivative liabilities (mark to market adjustment) are included in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss. During the year ended December 31, 2023, the Company recorded a net change in the fair of derivative liabilities of ($ 37,278). During the year ended December 31, 2022, the Company recorded a net change in the fair value of derivative liabilities of ($ 10,312).

On the respective commitment dates (Day 1 valuation), the fair value of the Company's potential future issuances of common stock related to common stock issued with promissory notes, warrants and embedded conversion features in convertible promissory notes was established with an estimate using the Monte Carlo Simulation Model to compute fair value. The Monte Carlo simulation requires the input of assumptions, including our stock price, the volatility of our stock price, remaining term in years, expected dividend yield, and risk-free rate. In addition, the valuation model considered the probability of the occurrence or nonoccurrence of an IPO within the terms of liability-classified financial instruments, as an IPO could potentially impact the settlement.

At each subsequent reporting period, the Company remeasures the fair value of liability-classified bridge shares, warrants and embedded conversion features in convertible promissory notes using the Monte Carlo simulation. The assumptions used to perform the Monte-Carlo Simulation as of the respective commitment dates, as well as December 31, 2022 were as follows:

Commitment Dates	May 2023	May 2022
Stock price	$ 5.30	$ 5.00
Volatility	115.1%	99.7%
Expected term (in years) - Notes	0.99	1.00 - 1.03
Expected term (in years) - Warrants	4.99	5.00
Risk-free interest rate	4.80%	2.76 % - 2.84%
Dividend yield	0%	0%
IPO probability (prior to note maturity date)	95%	95%

Mark to Market	December 31, 2022
Stock price	$ 5.00
Volatility	101.9%
Expected term (in years) - Notes	0.39 - 0.41
Expected term (in years) - Warrants	4.39

Risk-free interest rate	4.06%
Dividend yield	0%
IPO probability (prior to note maturity date)	95%

10. INCOME TAXES

Loss before provision (benefit) for income taxes for the years ended December 31, 2023 and 2022 consisted of the following:

	For the Year Ended December 31,	
	2023	**2022**
United States	$ (3,006,861)	$ (5,807,367)
Foreign	(806,689)	(369,917)
Total Loss before Income Taxes	**$ (3,813,550)**	**$ (6,177,284)**

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

	For the Year Ended December 31,	
	2023	**2022**
Current:		
Federal	$ -	$ -
State	250	500
Foreign	-	-
Total current provision (benefit)	250	500
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
Total deferred provision (benefit)	-	-
Total Benefit	**$ 250**	**$ 500**

The reconciliation between income taxes computed at the U.S. statutory income tax rate to the Company's provision (benefit) for income taxes for the years ended December 31, 2023 and 2022 are as follows:

	For the Year Ended December 31,			
	2023		**2022**	
Benefit for income taxes at 21% rate	$ (800,846)	21.0%	$ (1,297,230)	21.0%
State income taxes, net of federal benefit	(364,618)	9.6	(478,515)	7.7
Impact of non-U.S. earnings	(33,994)	0.9	(33,897)	0.5
Permanent differences	280,654	(7.4)	-	0.0
Change in fair value of promissory note	(1,129,646)	29.6	-	0.0
Non-deductible interest expense	304,962	- 8.0	-	0.0
Other reconciling items, net	2,042,657	(53.6)	683,359	(11.1)
Change in valuation allowance	(298,919)	7.8	1,126,783	(18.2)
Benefit for Income Taxes	**$ 250**	**(0.1)%**	**$ 500**	**(0.1)%**

Significant components of the Company's deferred tax assets (liabilities) as of December 31, 2023 and 2022 are as follows:

	As of December 31,	
	2023	**2022**
Deferred tax assets:		
Net operating loss carry-forward	$ 3,453,126	$ 3,338,726
Non-deductible reserves	1,058	-
Capitalized R&D costs	189,893	-
Lease liability	3,756	-
Share-based compensation	94,034	-
Gross deferred tax assets	3,741,867	3,338,726
Less valuation allowance	(3,043,135)	(3,338,726)
Total deferred tax assets, net of valuation allowance	698,732	-
Deferred tax liabilities:		
Right of use asset	(3,719)	-
Prepaid expenses	(695,013)	-
Total deferred tax liabilities	(698,732)	-
Net deferred tax liabilities	**$ -**	**$ -**

The valuation allowance increased by $ 295,591 during 2023. In determining the need for a valuation allowance, the Company has given consideration to its worldwide cumulative loss position when assessing the weight of the sources of taxable income that can be used to support the realization of deferred tax assets. The Company has assessed, on a jurisdictional basis, the available means of recovering deferred tax assets, including the ability to carry-back net operating losses, the existence of reversing temporary differences, the availability of tax planning strategies and available sources of future taxable income. The Company has determined that it is more likely than not that the Company will not recognize the benefits of the U.S. Federal, state and net deferred tax assets, and, as a result, a full valuation allowance has been set against its net deferred tax assets as of December 31, 2023 and December 31, 2022.

At December 31, 2023, the Company had U.S. federal and state net operating loss carryforwards of approximately $ 6,339,101 and $ 6,338,851

respectively. At December 31, 2022, the Company had U.S. federal and state net operating loss carryforwards of approximately $ 5,807,867 and $ 5,807,367 , respectively. The U.S. federal and state net operating losses carryforward indefinitely but may only be used to offset 80 % of annual taxable income due to the Tax Cuts and Jobs Act. The Company had $ 6,835,123 and $ 6,560,235 of foreign net operating loss carryforwards which carryforward indefinitely at December 31, 2023 and December 31, 2022, respectively.

The Company complies with the provisions of ASC 740-10 in accounting for its uncertain tax positions. ASC 740-10 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has determined that the Company has no significant uncertain tax positions requiring recognition under ASC 740-10 and therefore has not included a tabular roll forward of unrecognized tax benefits. As there are no uncertain tax positions recognized, interest and penalties have not been accrued. The Company is subject to income tax in the United States, as well as various state and international jurisdictions. The Company has not been audited by any state tax authorities in connection with income taxes. The Company has not been audited by international tax authorities or any states in connection with income taxes.

The Company's tax years December 31, 2020 through December 31, 2023 generally remain open to adjustment for all federal, state and foreign tax matters until its net operating loss and tax credit carryforwards are utilized or expire prior to utilization, and the applicable statutes of limitation have expired in the utilization year. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

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

The Company conducts business globally and, as a result, it files income tax returns in U.S. federal and state jurisdictions and in Australia. In the normal course of business, the Company may be subject to examination by taxing authorities throughout the world. The tax years that remain subject to examination by major tax jurisdictions include the years ended December 31, 2020, 2021, 2022 and 2023. As of December 31, 2023, the Company is not under income tax examination in any jurisdiction.

During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. The Company establishes reserves for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These reserves are established when the Company believes that certain positions might be challenged despite its belief that its tax return positions are fully supportable. The Company adjusts these reserves in light of changing facts and circumstances, such as the outcome of tax examinations. As of December 31, 2023 and December 31, 2022, no reserves for uncertain tax positions have been established.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the years ended December 31, 2023 and 2022 the Company did not recognize interest and penalties related to unrecognized tax benefits.

11. SHARE-BASED COMPENSATION

The following is a summary of share-based compensation expenses reported in the Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022:

	For the Year Ended December 31,	
	2023	**2022**
Research and Development	$ 192,371	$ -
General and Administrative Expenses	1,543,803	-
Total Share-Based Compensation Expense Included in Operating Expenses	**$ 1,736,174**	**$ -**

On November 22, 2022, the Company adopted the 2022 Equity Incentive Plan (the "2022 Plan"), which provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units and performance awards to eligible employees, directors and consultants, to be granted from time to time by the Board of Directors of the Company. The 2022 Plan provides for an automatic increase in the number of shares available for issuance beginning on January 1, 2023 and each January 1 thereafter, by 4% of the number of outstanding shares of common stock on the immediately preceding December 31, or such number of shares as determined by the Board of Directors. As of December 31, 2023, the number of remaining shares available for issuance under the 2022 Plan is equal to 305.

Stock Grants

On July 11, 2023, the Company recognized $ 187,200 of share-based compensation expense upon the issuance of 40,000 shares of common stock to the Company's Board of Directors, by virtue of the terms of the agreements described in Note 12, which is reflected in general and administrative expenses in the consolidated statement of operations.

Stock Options

The Company grants stock options to employees, non-employees, and Directors with exercise prices equal to the closing price of the underlying shares of the Company's common stock on the Nasdaq Capital Market on the date that the options are granted. Options granted generally have a term of five years from the grant date and are subject to vesting as determined in the individual award agreement. As of December 31, 2023, stock options granted under the 2022 Plan consist of options granted to directors of the Company on the IPO date, which were fully vested on the date of grant. The Company estimates the fair value of stock options on the grant date by applying the Black-Scholes option pricing valuation model.

The following table summarizes the significant assumptions used in determining the fair value of options on the respective grant dates or modification dates for the year ended December 31, 2023:

	2023
Weighted-average grant date fair value	$ 3.16
Risk-free interest rate	4.33%
Expected volatility	110.0%

Expected term (years)	3.18
Expected dividend yield	0.00%

The following table summarizes the Company's stock option activities:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (Years)
Options outstanding, December 31, 2022	-	$ -	$ -	-
Granted	37,736	5.30	-	5.00
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	-	-	-	-
Options outstanding, December 31, 2023	37,736	$ 5.30	$ -	4.53
Options vested and exercisable, December 31, 2023	37,736	$ 5.30	$ -	4.53

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

For the year ended December 31, 2023, the Company recognized $ 119,246 of compensation expense related to stock option awards ($0 for the year ended December 31, 2022). No stock options were exercised, forfeited, or expired during the period presented. At December 31, 2023, the Company had no unrecognized share-based compensation expense related to unvested options.

The Company also has compensation agreements with two executives and a consultant, which provide the individuals the right to an aggregate of 740,000 stock options that are subject to shareholder approval to increase the number of shares available under the 2022 Plan. These options are subject to vesting annually over five years with the first vesting date being December 31, 2024, and have an exercise price that was initially equal to the closing share price on the date of the IPO and later amended to $ 1.00 per share. Pursuant to the directors' agreements described in Note 12, the agreements provide for the issuance of an aggregate of 30,188 stock options to our directors with an exercise price of $ 5.30 per share, vesting 100 % on July 11, 2024, also contingent on the receipt of shareholder approval. For accounting and disclosure purposes, no fair value has been ascribed to these stock option awards as no grant date (as defined in ASC 718) has been established.

Restricted Stock Units

The following table summarizes the Company's RSU activity for the year ended December 31, 2023:

	Number of Units	Weighted Average Grant Date Fair Value
Unvested balance, December 31, 2022	-	$ -
Granted	256,000	0.87
Vested	(256,000)	0.87
Forfeited	-	-
Unvested balance, December 31, 2023	-	$ -

During the year ended December 31, 2023, the Company granted 256,000 RSUs to employees, non-employees, and Directors. The Company recognized $ 222,480 of compensation expense related to vested RSUs for the year ended December 31, 2023 ($0 for the year ended December 31, 2022). During the year ended December 31, 2023, 256,000 shares of common stock underlying RSUs vested. These shares are excluded from the number of shares outstanding at December 31, 2023, as the shares have not yet been issued to the respective employees, non-employees and Directors. At December 31, 2023, the Company had no unrecognized compensation cost related to unvested RSUs.

Share-Based Payments to Vendors for Services

During the year ended December 31, 2023, the Company issued 525,000 common stock shares and 405,000 common stock shares as share-based payments to two nonemployees, Kentucky Technology Inc. and Florida State University Research Fund, Inc., respectively, in exchange for research and development services to be rendered to the Company in the future. Kentucky Technology Inc. is expected to render research and development services to identify a combination drug partner for tafenoquine over a period of fifteen months. Florida State University Research Fund, Inc. is expected to render research and development services related to development of celgosivir over a period of up to five years. The Company recognizes prepaid research and development costs on the grant date, as defined in FASB ASC Subtopic No. 718, Compensation–Stock Compensation. As of December 31, 2023, the unamortized balance of prepaid assets related to these share-based payments for research and development costs for which the grant date criteria has been met and the services are expected to be rendered within one year is $ 2,730,685 ($ 0 at December 31, 2022), which is presented as a component of Prepaid and Other Assets on the accompanying Consolidated Balance Sheets.

In addition to share-based payments for research and development services, during the years ended December 31, 2023 and 2022, 552,799 and 0 common stock shares, respectively, were issued as fully vested, nonforfeitable equity instruments to nonemployees. 120,000 and 100,000 of the common stock shares issued during the year ended December 31, 2023, were issued to Trevally, LLC and Carmel, Milazzo & Feil LLP, respectively. Before June 30, 2024, Trevally, LLC is expected to provide castanopsermine, a stable starting material to support the manufacture of good manufacturing grade (GMP)-grade celgosivir for clinical studies. Sichenzia Ross Ference Carmel (formerly known as Carmel, Milazzo & Feil LLP) is expected to provide

legal services before April 30, 2026. As of December 31, 2023, the unamortized balance of current prepaid assets related to these share-based payments for which the services are expected to be rendered within one year is $ 776,471 ($ 0 at December 31, 2022), which is reported in Prepaid and Other Assets on the Consolidated Balance Sheets. The unamortized balance of noncurrent prepaid assets related to these share-based payments for which the services are expected to be rendered beyond one year is $ 242,647 ($0 at December 31, 2022), reported in Long-Term Prepaid Expense on the Consolidated Balance Sheets.

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

Deemed Capital Contribution for Related Party Compensation Expense

During the year ended December 31, 2023, the Company's Chief Executive Officer, Geoff Dow, and Chief Financial Officer, Tyrone Miller, agreed to forego payment of cash compensation for certain periods they were active employees of the Company. In accordance with SEC Staff Accounting Bulletin ("SAB") 5T, *Accounting for Expenses or Liabilities Paid by Principal Stockholder(s)* , the Company recorded $ 163,228 as general and administrative expense as a deemed capital contribution, which was reflected as an increase in Additional Paid-in Capital in the consolidated financial statements. The deemed capital contribution represents the compensation costs that would have been paid by the Company during the year ended December 31, 2023 had the officers not agreed to non-payment.

12. COMMITMENTS AND CONTINGENCIES

Operating Lease

On February 3, 2016, and subsequently amended, the Company entered into the lease agreement with CXI Corp to rent business premises. In January 2023, the lease was extended for an additional twelve-month term expiring on March 31, 2024. In December 2023, the Company executed an additional amendment with CXI Corp, pursuant to which the Company agreed to relocate to a new office space which is estimated to be available for use by the Company on or around April 1, 2024. The term covered by the new amendment expires on March 31, 2025.

Future minimum lease payments on a discounted and undiscounted basis under the Company's operating lease are as follows:

	Undiscounted Cash Flows
Discount rate	15.00%
2024	$ 13,992
Thereafter	-
Total undiscounted minimum future payments	13,992
Imputed interest	(342)
Total operating lease payments	13,650
Current lease liabilities	13,650
Non-current lease liabilities	$ -

Other information related to our operating lease is as follows:

	December 31, 2023
Weighted average remaining lease term (in years)	0.25
Weighted average discount rate	15.00%

Operating lease costs were in the amount of $ 55,084 and $ 51,894 for the year ended December 31, 2023, and 2022, respectively.

Board of Directors

In November and December 2022, the Company signed agreements with four director nominees (Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey) which come into effect on the date the Company's Registration Statement is declared effective. As described in Note 1, the Company's Registration Statement was declared effective on July 11, 2023. Each director is entitled to receive cash compensation of $ 11,250 quarterly. In addition, the two non-audit committee chairs (Toovey, Field) will receive $ 1,250 per quarter and the audit committee chair (Allen) will receive an additional $ 2,000 per quarter. On July 11, 2023, each director received (i) a one-off issuance of 10,000 shares of common stock, and (ii) a fully vested, non-qualified option to purchase 9,434 shares of common stock at an exercise price of $ 5.30 per share. In addition, each director is entitled to receive annual equity compensation after July 11, 2023, and annually thereafter unless determined otherwise by the Board, in the form of restricted stock units valued at $ 40,000 (vesting quarterly over twelve months, with a cost basis of $ 5.00 per share) and a non-qualified option to purchase $ 40,000 of common stock (twelve month vesting with an exercise price equal to $ 5.30), in each case equity compensation is contingent on the receipt of shareholder approval to increase the number of shares authorized under the 2022 Plan.

Contingencies

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

Contingent Compensation

Following the Company's IPO and the conversion of the outstanding debt pursuant to the Knight Debt Conversion Agreement as discussed in Note 8, the Company is obligated to pay Knight a contingent milestone payment of $ 10 million if the Company sells Arakoda™ or if a Change of Control occurs. The Company accounts for the contingent milestone payment as a derivative liability (See Note 9).

On July 15, 2015, the Company entered into the Exclusive License Agreement with the U.S. Army Medical Materiel Development Activity (the "U.S. Army"), which was subsequently amended (the "U.S. Army Agreement"), in which the Company obtained a license to develop and commercialize the licensed technology with respect to all therapeutic applications and uses excluding radical cure of symptomatic vivax malaria. The term of the U.S. Army Agreement will continue until the expiration of the last to expire of the patent application or valid claim of the licensed technology, or 20 years from the start date of the U.S. Army Agreement, unless terminated earlier by the parties. The Company must make a minimum annual royalty payment of 3 % of Net Sales (as defined in the U.S. Army Agreement) for Net Sales less than $ 35 million, and 5 % of Net Sales greater than $ 35 million, with US

government sales excluded from the definition of Net Sales. In addition, the Company must pay fees upon the achievement of certain milestones, including a sales-based milestone fee of $ 75,000 once cumulative Net Sales from all sources exceeds $ 6 million. The Company accrues the minimum annual royalty when the related sales occur. During the year ended December 31, 2023, the sales-based milestone target was achieved and therefore the Company has accrued a liability of $ 75,000 for the related payment, which is reflected in Accounts Payable and Accrued Expenses at December 31, 2023. The achievement of other milestones under the U.S. Army Agreement are not considered probable and thus no accruals for the related milestone payments have been made.

Litigation, Claims and Assessments

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of December 31, 2023, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the results of the Company's operations.

13. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through April 1, 2024, which is the date the financial statements were issued.

On January 10, 2024, the Company received a letter from the Listing Qualifications Staff of Nasdaq informing the Company that for the 10 consecutive business day period between December 26, 2023 through January 9, 2024, the closing bid price of the Company's common stock has been at $ 1.00 per share or greater. Accordingly, the Company regained compliance with Listing Rule 5550(a)(2) and the common stock and warrants of the Company were no longer subject to delisting.

On January 22, 2024, the Company announced that following a Type C meeting with the U.S. Food and Drug Administration on January 17, 2024, the Company is planning to conduct a pivotal clinical study in support of a future indication for tafenoquine for treatment of hospitalized babesiosis patients, the patient enrollment of which is scheduled to begin in the summer of 2024.

On January 29, 2024, the Company, entered into an Underwriting Agreement with WallachBeth Capital LLC (the "Underwriting Agreement"), relating to the Company's public offering (the "January 2024 Offering") of 5,260,901 units (the "Units") at an offering price of $ 0.385 per Unit and 999,076 pre-funded units (the "Pre-Funded Units") at an offering price of $ 0.375 per Pre-Funded Unit. Each Unit consisted of one share of common stock and one warrant exercisable for one share of common stock (the "Warrant"). Each Warrant has an exercise price of $ 0.4235 per share (110 % of the offering price per Unit), is exercisable immediately upon issuance and expires five years from the date of issuance. Each Pre-Funded Unit consists of one pre-funded warrant exercisable for one share of common stock (the "Pre-Funded Warrant") and one warrant identical to the Warrants included in the Units. The purchase price of each Pre-Funded Unit was equal to the price per Unit sold to the public in the offering, minus $ 0.01 , and the exercise price of each Pre-Funded Warrant is $ 0.01 per share. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full.

The Company granted WallachBeth Capital LLC an option, exercisable within 45 days after the closing of the offering, to purchase up to 789,136 shares of the Company's common stock at a price of $ 0.385 per share and/or 938,997 Warrants at a price of $ 0.01 per Warrant and/or 149,862 Pre-Funded Warrants at a price of $ 0.375 per Pre-Funded Warrant, or any combination of additional shares of common stock, Warrants and/or Pre-Funded Warrants, representing, in the aggregate, up to 15 % of the number of Units sold in the offering, 15 % of the Warrants underlying the Units and Pre-Funded Units sold in the offering and 15 % of the Pre-Funded Warrants underlying the Pre-Funded Units sold in the offering, in all cases less the underwriting discount to cover over-allotments, if any. On January 31, 2024, WallachBeth Capital LLC partially exercised its over-allotment option with respect to 818,177 Warrants.

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

The Units and Pre-Funded Units were offered and sold pursuant to the Company's Registration Statement on Form S-1 (File No. 333-276641), originally filed with the SEC on January 22, 2024 (the "January 2024 Registration Statement") and the final prospectus filed with the SEC pursuant to Rule 424(b)(4) of the Securities Act of 1933, as amended. The January 2024 Registration Statement was declared effective by the SEC on January 29, 2024. The closing of the January 2024 Offering occurred on January 31, 2024. The net proceeds to the Company from the Offering were approximately $ 1.9 million, after deducting underwriting discounts and commissions and the payment of other offering expenses payable by the Company. The Company intends to use the net proceeds from the January 2024 Offering for increasing capitalization and financial flexibility and relaunching its malaria prevention project in the U.S. later in 2024.

On February 1, 2024, the Company received proceeds of $ 4,995 upon the exercise of 499,538 Pre-Funded Warrants and issued 499,538 shares of common stock to the investors.

On February 13, 2024, the Company, through its majority-owned subsidiary, 60P Australia Pty Ltd, signed a research and development agreement with Monash University to evaluate the efficacy of parenteral tafenoquine on *Candida* spp, including *Candida auris* in an animal model. The Company advanced Monash approximately $ 65,173 in March 2024 and will pay approximately $ 65,000 upon completion, which is expected to be by Q4 2024.

On February 14, 2024, WallachBeth Capital LLC partially exercised its over-allotment option described above with respect to 50 shares of common stock at a purchase price of $ 0.3750 and 50 Warrants at a purchase price of $ 0.01 .

On February 27, 2024, the Company received a letter from The Nasdaq Capital Market stating that for the 31 consecutive business days ending on February 27, 2024, the Company's common stock had not maintained the minimum closing bid price of $ 1.00 per share required for continued listing on The Nasdaq Capital Market. The Company was provided an initial period of 180 calendar days, or until August 26, 2024, to regain compliance. If the Company cannot regain compliance during the compliance period or any subsequently granted compliance period, the common stock and warrants of the Company may be subject to delisting.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles (GAAP). As of December 31, 2023, our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework).

Based on this assessment, our management concluded that our internal control over financial reporting was not effective as of December 31, 2023, due to the existence of material weaknesses in our internal control over financial reporting. These material weaknesses are described below:

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

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

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

Management has undertaken a remediation plan to address these material weaknesses. During the year ended December 31, 2023, we continued to enhance our internal control over financial reporting through various initiatives, including investing in information technology systems, enhancing the organizational structure, providing guidance and training to employees and further developing detailed policies and procedures.

We expect to remediate these material weaknesses in the first half of 2024. However, there may be additional material weaknesses identified that could require additional time and resources to remediate. We remain committed to ensuring that our internal control over financial reporting is designed and operating effectively.

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

Attestation Report on Internal Control over Financial Reporting

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

Changes in Internal Control over Financial Reporting

Other than with respect to the remediation efforts discussed above, there was no change in our internal control over financial reporting that occurred during 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None .

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

Not applicable.

PART III

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

The following table sets forth the name, age and position of each of our executive officers, directors and director nominees as of April 1, 2024.

Name	Age	Position	Director Since
Geoffrey Dow	50	Chief Executive Officer, President and Director	June 1, 2022
Tyrone Miller	49	Chief Financial Officer	—
Kristen Landon	57	Chief Commercial Officer	—
Charles Allen	48	Director	July 12, 2023
Cheryl Xu	56	Director	July 12, 2023
Stephen Toovey	70	Director	July 12, 2023
Paul Field	61	Director	July 12, 2023

Executive Officers and Directors

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

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

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

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

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

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

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

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

Significant Employees

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

Code of Ethics

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

Board Leadership Structure and Risk Oversight

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

Board of Directors

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

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

Director Independence

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

- the director is, or at any time during the past three (3) years was, an employee of the company;
- the director or a family member of the director accepted any compensation from the company in excess of $120,000 during any period of twelve (12) consecutive months within the three (3) years preceding the independence determination (subject to certain exemptions, including, among other things, compensation for board or board committee service);
- the director or a family member of the director is a partner in, controlling shareholder of, or an executive officer of an entity to which the company made, or from which the company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year or $200,000, whichever is greater (subject to certain exemptions);

- the director or a family member of the director is employed as an executive officer of an entity where, at any time during the past three (3) years, any of the executive officers of the company served on the compensation committee of such other entity; or
- the director or a family member of the director is a current partner of the company's outside auditor, or at any time during the past three (3) years was a partner or employee of the company's outside auditor, and who worked on the company's audit.

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

Committees of the Board of Directors

Our Board has three standing committees: (i) an audit committee (the "Audit Committee"); (ii) a compensation committee (the "Compensation Committee"); and (iii) a nominating and corporate governance committee (the "Nominating and Corporate Governance Committee"). Our Board has not yet adopted procedures by which stockholders may recommend nominees to the Board. The composition and responsibilities of each of the committees

of our Board are described below. Members serve on these committees until their resignation or until as otherwise determined by our Board.

Audit Committee

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

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in our annual disclosure report;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- reviewing and approving all related-party transactions;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work;

- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies; and
- approving reimbursement of expenses incurred by our management team in identifying potential target businesses.

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

Compensation Committee

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

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

Nominating and Corporate Governance Committee

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

- identifying, reviewing and evaluating candidates to serve on our Board consistent with criteria approved by our Board;
- evaluating director performance on our Board and applicable committees of our Board and determining whether continued service on our Board is appropriate;
- evaluating nominations by stockholders of candidates for election to our Board; and
- corporate governance matters.

Family Relationships

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

Involvement in Certain Legal Proceedings

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

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two (2) years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his or her involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Meetings of the Board of Directors

During our fiscal year ended December 31, 2023, the Board met from time to time informally and acted by written consent on numerous occasions.

Indemnification and Limitation on Liability of Directors

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

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

Board Diversity

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

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

BOARD DIVERSITY MATRIX

	As of December 31, 2023				As of December 31, 2022			
Total Number of Directors:	**5**				**1**			
Part I: Gender Identity	**Female**	**Male**	**Non-Binary**	**Did Not Disclose Gender**	**Female**	**Male**	**Non-Binary**	**Did Not Disclose**
Directors	1	4	—	—	—	1	—	—
Part II: Demographic Background								
African American or Black	—	—	—	—	—	—	—	—
Alaskan Native or American Indian	—	—	—	—	—	—	—	—

Asian	1	—	—	—	—	—	—	—
Hispanic or Latino	—	—	—	—	—	—	—	—
Native Hawaiian or Pacific Islander	—	—	—	—	—	—	—	—
White	—	3	—	—	—	1	—	—
Two or More Races or Ethnicities	—	1	—	—	—	—	—	—
LGBTQ+	—	—	—	—	—	—	—	—
Did Not Disclose Demographic Background	—	—	—	—	—	—	—	—

Item 11. Executive Compensation.

The following table summarizes compensation for the years ended December 31, 2023 and 2022 for all individuals serving as our principal executive officer or acting in a similar capacity during the last completed fiscal year ("PEO"), regardless of compensation level, two most highly compensated executive officers other than the PEO who were serving as executive officers at the end of the last completed fiscal year, and up to two additional individuals for whom disclosure would have been provided pursuant to paragraph (m)(2)(ii) of Item 402 of Regulation S-K but for the fact that the individual was not serving as an executive officer of the smaller reporting company at the end of the last completed fiscal year (each a "Named Executive Officer").

Summary Compensation Table

Name and Principal Position	Year	Base Salary($)[1]	Guaranteed Payments($)[1]	Stock Award($)	Total($)
Geoffrey Dow	2023	$ 125,555	$ -	$ -	$ 125,555
President and Chief Executive Officer	2022	54,510	$ -	$ -	$ 54,510
(Principal Executive Officer)					
Tyrone Miller	2023	$ 135,632	$ -	$ -	$ 135,632
Chief Financial Officer	2022	148,672	$ -	$ -	$ 148,672
(Principal Financial and Accounting Officer)					

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

Equity Awards

On July 12, 2023, Dr. Dow was granted a five-year option to purchase a total of 15,000 shares of our common stock on the last day of each quarter in each calendar year (for a cumulative total or no more than 300,000 shares over five years) and (ii) Mr. Miller was granted a five-year option to purchase a total of 12,000 shares of our common stock on the last day of each quarter in each calendar year (for a cumulative total or no more than 240,000 shares over five years). The per share exercise price of the options were initially equal to the per share closing price of our common stock on the date of grant and shall have a cashless exercise provision. In November 2023, the Board reset the exercise price of the options to be equal to $1 and modified the vesting provisions of the option to vest annually over five years, rather than quarterly, with the first vesting date being December 31, 2024. The amendment of these options shall take effect upon the stockholders of the Company approving the amendment to the exercise price of the options and approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan in order to comply with Listing Rule 5635(c) of The Nasdaq Stock Market LLC.

Employment Agreements

Dow Employment Agreement. We entered into an Employment Agreement dated as of January 12, 2023, with Geoffrey Dow (the "Dow Employment Agreement"), our Chief Executive Officer and Chairman of our Board. The term of the Dow Employment Agreement began on January 12, 2023, and will continue for a period of two years, with subsequent automatic renewals unless either party thereto provides notice to terminate at least 90 days prior to the applicable renewal date. The Dow Employment Agreement provides Dr. Dow an annual base salary of $228,000, bonuses to the extent certain events occur or if applicable performance goals are met and employee benefits that are generally given to our senior executives. Contingent on the receipt of shareholder approval to increase the number of shares available under the 2022 Plan, Dr. Dow was granted a five-year option to purchase a total of 15,000 shares of our common stock that vest on the last day of each quarter in each calendar year (for a cumulative total or no more than 300,000 shares over five years). The per share exercise price of the option was initially equal to the per share closing price of our common stock on the date of the initial public offering and shall have a cashless exercise provision. In November, the Board reset the exercise price of the option to be equal to $1 and modified the vesting provisions of the option to vest annually over five years, rather than quarterly, with the first vesting date being December 31, 2024. The amendment of the options shall take effect upon the stockholders of the Company approving the amendment to the exercise price of the options and approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan in order to comply with Listing Rule 5635(c) of The Nasdaq Stock Market LLC.

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

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

Miller Employment Agreement. We entered into an Employment Agreement dated as of January 12, 2023 with Tyrone Miller (the "Miller Employment Agreement"), our Chief Financial Officer. The term of the Miller Employment Agreement began on January 12, 2023 and will continue for a period of two years, with subsequent automatic renewals unless either party thereto provides notice to terminate at least 90 days prior to the applicable renewal date. The Miller Employment Agreement provides Mr. Miller an annual base salary of $204,000, bonuses to the extent certain events occur or if applicable

performance goals are met and employee benefits that are generally given to our senior executives. Contingent on the receipt of shareholder approval to increase the number of shares available under the 2022 Plan, Mr. Miller was granted a five-year option to purchase a total of 12,000 shares of our common stock that vest on the last day of each quarter in each calendar year (for a cumulative total or no more than 240,000 shares over five years). The per share exercise price of the option was initially equal to the per share closing price of our common stock on the date of the initial public offering and shall have a cashless exercise provision. In November, the Board reset the exercise price of the option to be equal to $1 and modified the vesting provisions of the option to vest annually over five years, rather than quarterly, with the first vesting date being December 31, 2024. The amendment of the options shall take effect upon the stockholders of the Company approving the amendment to the exercise price of the options and approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan in order to comply with Listing Rule 5635(c) of The Nasdaq Stock Market LLC.

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

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

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2023

	Option Awards					Stock Awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
Geoffrey Dow, President and Chief Executive Officer (Principal Executive Officer)	—	300,000	—	1.00	December 31, 2029	—	—
Tyrone Miller, Chief Financial Officer (Principal Financial and Accounting Officer)	—	240,000	—	1.00	December 31, 2029	—	—

(1) Dr. Dow was granted a five-year option to purchase a total of 15,000 shares of our common stock that vest on the last day of each quarter in each calendar year (for a cumulative total or no more than 300,000 shares over five years). The per share exercise price of the option was initially equal to the per share closing price of our common stock on the date of the initial public offering and shall have a cashless exercise provision. In November 2023, the Board reset the exercise price of the option to be equal to $1 and modified the vesting provisions of the option to vest annually over five years, rather than quarterly, with the first vesting date being December 31, 2024. The amendment of the options shall take effect upon the stockholders of the Company approving the amendment to the exercise price of the options and approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan in order to comply with Listing Rule 5635(c) of The Nasdaq Stock Market LLC.

(2) Mr. Miller was granted a five-year option to purchase a total of 12,000 shares of our common stock that vest on the last day of each quarter in each calendar year (for a cumulative total or no more than 240,000 shares over five years). The per share exercise price of the option was initially equal to the per share closing price of our common stock on the date of the initial public offering and shall have a cashless exercise provision. In November 2023, the Board reset the exercise price of the option to be equal to $1 and modified the vesting provisions of the option to vest annually over five years, rather than quarterly, with the first vesting date being December 31, 2024. The amendment of the options shall take effect upon the stockholders of the Company approving the amendment to the exercise price of the options and approving the amendment to the 2022 Plan to increase the number of shares available under the 2022 Plan in order to comply with Listing Rule 5635(c) of The Nasdaq Stock Market LLC.

2022 Equity Incentive Plan

Overview

On November 22, 2022, our Board and our stockholders approved the 60 Degrees Pharmaceuticals, Inc. 2022 Equity Incentive Plan. The 2022 Plan governs equity awards to our employees, directors, officers, consultants and other eligible participants. Initially, the maximum number of shares of our common stock that may be subject to awards under the 2022 Plan was equal to 238,601.

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

Authorized Shares

Initially, the maximum number of shares of our common stock that may be subject to awards under the 2022 Plan was equal to 238,601. The 2022 Plan provides for an automatic increase in the number of shares available for issuance beginning on January 1, 2023 and each January 1 thereafter, by 4% of the number of outstanding shares of common stock on the immediately preceding December 31, or such number of shares as determined by the Board

of Directors. As of December 31, 2023, the number of remaining shares available for issuance under the 2022 Plan is equal to 305.

Plan Administration

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

Eligibility

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

Stock Options

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

Stock Appreciation Rights

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

Restricted Stock

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

Restricted Stock Units

RSUs may be granted under the 2022 Plan. RSUs are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of the 2022 Plan, the administrator determines the terms and conditions of RSUs, including the vesting criteria

and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of Company-wide, divisional, business unit or individual goals (including continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned RSUs in the form of cash, in shares of our common stock or in some combination thereof. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any vesting requirements will be deemed satisfied.

Performance Awards

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

Non-transferability of Awards

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

Certain Adjustments

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

Dissolution or Liquidation

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

Merger or Change in Control

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

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

Clawback

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

Amendment and Termination

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

Non-Employee Director Remuneration Policy

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

Clawback Policy

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

Board Compensation

In November and December 2022, we signed agreements with four directors (Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey). Each director receives cash compensation of $11,250 per quarter. In addition, the two non-audit committee chairs (Mr. Toovey and Mr. Field) receive $1,250 per quarter and the audit committee chair (Mr. Allen) receives an additional $2,000 per quarter. Each director received a one-off issuance of common stock of value $50,000 (cost basis of $5 per share) and a non-qualified option to purchase an additional $50,000 of common stock (exercise price is $5.30). Each director is also entitled to receive annual equity compensation after July 11, 2023, and renewing annually thereafter unless determined otherwise by the Board, in the form of restricted stock units valued at $40,000 (vesting quarterly over twelve months, with a cost basis of $5 per share) and a non-qualified option to purchase $40,000 of common stock (twelve month vesting with an exercise price equal to $5.30), in each case contingent on the receipt of shareholder approval to increase the number of shares authorized under the 2022 Plan. See Note 11 for further details.

Compensation Committee Review

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

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

Policies and Practices for Granting Certain Equity Awards

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

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

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

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

Participation of Employee Directors; New Directors

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

Director Compensation
As of December 31, 2023

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Charles Allen	26,500	65,520	29,811	-	-	121,831
Cheryl Xu	22,500	65,520	29,811	-	-	117,831
Stephen Toovey	25,000	65,520	29,811	-	-	120,331
Paul Field	25,000	65,520	29,811	-	-	120,331

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

The following table presents information regarding beneficial ownership of our equity interests as of April 1, 2024, by:

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

Beneficial ownership is determined in accordance with the rules of the SEC and, thus, represents voting or investment power with respect to our securities as of April 1, 2024. In computing the number and percentage of shares beneficially owned by a person, shares that may be acquired by such person within 60 days of April 1, 2024 are counted as outstanding, while these shares are not counted as outstanding for computing the percentage ownership of any other person. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all equity interests beneficially owned, subject to community property laws where applicable.

Name and Address of Beneficial Owner[1]	Title	Number of Shares Beneficially Owned	Percent of Class
Officers and Directors			
Geoffrey Dow	President, Chief Executive Officer and Director	773,107[2]	6.63%
Tyrone Miller	Chief Financial Officer	176,928[3]	1.52%
Kristen Landon	Chief Commercial Officer	—	—
Charles Allen	Director	23,434[4]	*
Cheryl Xu	Director	238,368[5]	2.06%
Stephen Toovey	Director	23,434[6]	*
Paul Field	Director	23,434[7]	*
Officers and Directors as a Group (total of 7 persons)		1,258,705	10.67%
5%+ Stockholders			
Knight Therapeutics International S.A.[8]		1,153,897	9.97%

* Less than 1%.

(1) Percentages based on 11,570,578 shares of common stock issued and outstanding as of April 1, 2024 plus shares of common stock the person has the right to acquire within 60 days thereafter. Unless otherwise indicated, the principal address of the named directors and 5% stockholders of the Company is c/o 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036.
(2) Includes (i) 10,482 shares of our common stock held in the name of Geoffrey Dow, (ii) 667,143 shares of common stock held by the Geoffrey S. Dow Revocable Trust (the "Dow Trust"), of which Geoffrey Dow is the trustee and has control over the voting and disposition of the shares of common stock held by the Dow Trust, (iii) 10,482 shares of common stock issuable upon exercise of warrants issued to the Geoffrey S. Dow Revocable Trust and (iv) 85,000 shares of common stock issuable pursuant to fully vested restricted stock units to Geoffrey Dow, which are approved but have not been issued as of the date of this prospectus.
(3) Includes (i) 101,928 shares of our common stock held in the name of Tyrone Miller, and (ii) 75,000 shares of common stock issuable pursuant to fully vested restricted stock units to Tyrone Miller, which are approved but have not been issued as of the date of this prospectus.
(4) Mr. Allen beneficially owns a total of 23,434 shares of common stock, of which includes (i) 10,000 shares of common stock held in the name of Mr. Allen, (ii) 9,434 shares of common stock issuable upon the exercise of vested options and (iii) 4,000 shares of fully vested restricted stock units which are approved but have not been issued as of the date of this prospectus.
(5) Ms. Xu beneficially owns a total of 238,368 shares of common stock, of which includes (i) 224,934 shares of common stock held in the name of Ms. Xu, (ii) 9,434 shares of common stock issuable upon the exercise of vested options and (iii) 4,000 shares of fully vested restricted stock units which are approved but have not been issued as of the date of this prospectus.
(6) Mr. Toovey beneficially owns a total of 23,434 shares of common stock, of which includes (i) 10,000 shares of common stock held in the name of Mr. Toovey, (ii) 9,434 shares of common stock issuable upon the exercise of vested options and (iii) 4,000 shares of fully vested restricted stock units which are approved but have not been issued as of the date of this prospectus.
(7) Mr. Field beneficially owns a total of 23,434 shares of common stock, of which includes (i) 10,000 shares of common stock held by the Field Family Trust, of which Mr. Field is a trustee and has control over the voting and disposition of the shares of common stock held by the Field Family Trust, (ii) 9,434 shares of common stock issuable to Mr. Field upon the exercise of vested options and (iii) 4,000 shares of fully vested restricted stock units which are approved but have not been issued as of the date of this prospectus.
(8) Knight Therapeutics Inc. wholly owns Knight Therapeutics International S.A. Arvind Utchanah has voting and dispositive control over the shares held by Knight Therapeutics International S.A. The principal address of Knight is 3400 de Maisonneuve W. Suite 1055, Montreal, QC Canada H3Z 3B8.

Equity Plan Information

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

Changes in Control

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

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

On May 19, 2022, we issued the Convertible Promissory Note to Mountjoy Trust in the amount of $294,444.42 and a per annum interest rate of 6%. As of

September 30, 2023, the outstanding balance of this note was repaid in full. Immediately prior to the closing of our initial public offering, the balance of such note converted at a price equal to 80% of $5.30. We also issued to Mountjoy Trust a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 100% of the common stock issued to Mountjoy Trust as a result of the conversion of the note on the pricing date of our initial public offering at the exercise price equal to 90% of $5.30. John Dow, a relative of Geoffrey Dow, our President, Chief Executive Officer and Director, is the trustee of the Mountjoy Trust.

On December 31, 2021, the majority member, Geoffrey Dow, converted cumulative borrowings and interest into 3,942,919 member units with a par value of $1.00 and thus all debt owed to the majority member was extinguished. We issued 37,067 shares to Geoffrey Dow (at $5.00 per share) on August 28, 2022, in recognition of capital contributions of $185,335 made between January 1, 2022 and April 1, 2022. There are no other outstanding related party debt or obligations.

On January 2, 2023, we issued a total of 100,000 shares of our common stock to our legal counsel for payment of legal fees.

In March 2023, we received a $200,000 short term advance from the Geoffrey S. Dow Revocable Trust. In April and May 2023, we received a $23,000 short term advance from the Geoffrey S. Dow Revocable Trust and $27,000 from Tyrone Miller. These were reimbursed on May 11, 2023.

In August 2023, Geoffrey S. Dow transferred 904,436 of his shares in 60P Australia Pty Ltd to the Company for no consideration.

Item 14. Principal Accountant Fees and Services.

During the year ended December 31, 2023 and 2022, we engaged RBSM LLP as our independent registered public accounting firm. For the years ended December 31, 2023 and 2022, we incurred fees, as discussed below:

	Fiscal Year Ended December 31,	
	2023	2022
Audit Fees[(1)]	$ 184,000	$ 120,000
Audit-Related Fees[(2)]	$ 75,000	$ 10,000
Tax Fees	$ -	$ -
All Other Fees	$ -	$ -
Total	$ 259,000	$ 130,000

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

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

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

1. ***Financial Statements***: The following Financial Statements and Supplementary Data of 60 Degrees Pharmaceuticals, Inc. and the Report of Independent Registered Public Accounting Firm included in Part II, Item 8:
   - Consolidated Balance Sheets at December 31, 2023 and 2022;
   - Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022;
   - Consolidated Statements of Shareholders' and Members' Equity (Deficit) for the years ended December 31, 2023 and 2022;
   - Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022; and
   - Notes to Consolidated Financial Statements.
2. ***Exhibits***:

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

4.4	Form of Warrant Agent Agreement in January 2024 public offering	Exhibit 4.4 to Registration Statement on Form S-1 (File No: 333-276641)	January 22, 2024
10.1	Securities Purchase Agreement dated as of May 19, 2022, by and between the Registrant and Geoffrey Dow	Exhibit 10.1 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.2	Common Stock Purchase Warrant dated as of May 19, 2022, issued by the Registrant to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018	Exhibit 10.2 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.3	Securities Purchase Agreement dated as of May 19, 2022, by and between Registrant and Mountjoy Trust	Exhibit 10.4 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.4	Common Stock Purchase Warrant dated as of May 19, 2022, issued by the Registrant to Mountjoy Trust	Exhibit 10.5 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.5	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Bigger Capital Fund, LP	Exhibit 10.7 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.6	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Bigger Capital Fund, LP	Exhibit 10.8 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.7	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Cavalry Investment Fund, LP	Exhibit 10.10 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.8	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Cavalry Investment Fund, LP	Exhibit 10.11 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.9	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Walleye Opportunities Master Fund Ltd	Exhibit 10.13 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.10	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Walleye Opportunities Master Fund Ltd	Exhibit 10.14 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023

10.11	Inter-Institutional Agreement dated as of February 15, 2021, by the Registrant and Florida State University Research Foundation	Exhibit 10.19 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.12	Exclusive License Agreement dated as of September 15, 2016, between National University of Singapore, Singapore Health Services Pte Ltd, the Registrant and 60P Australia Pty Ltd	Exhibit 10.20 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.13	Master Consultancy Agreement dated as of May 29, 2013, by and between the Registrant and BioIntelect Pty Ltd	Exhibit 10.21 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.14#	Employment Agreement dated as of January 12, 2023, between the Registrant and Geoffrey Dow	Exhibit 10.22 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.15#	Employment Agreement dated as of January 12, 2023, between the Registrant and Tyrone Miller	Exhibit 10.23 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.16	Agreement and Plan of Merger dated as of June 1, 2022, by and between the Registrant and 60 Degrees Pharmaceuticals, LLC	Exhibit 10.33 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.17	Exclusive License Agreement dated as of May 30, 2014, between National University of Singapore, Singapore Health Services Pte Ltd, the Registrant and 60P Australia Pty Ltd	Exhibit 10.34 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.18#	2022 Equity Incentive Plan	Exhibit 10.35 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.19	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Cyberbahn Federal Solutions, LLC	Exhibit 10.36 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.20	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Cyberbahn Federal Solutions, LLC	Exhibit 10.37 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.21	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Ariana Bakery Inc	Exhibit 10.39 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.22	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Ariana Bakery Inc	Exhibit 10.40 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.23	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Sabby Volatility Warrant Master Fund, Ltd.	Exhibit 10.42 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.24	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Sabby Volatility Warrant Master Fund, Ltd.	Exhibit 10.43 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.25	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Steel Anderson	Exhibit 10.45 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.26	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Steel Anderson	Exhibit 10.46 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.27	Securities Purchase Agreement dated as of May 8, 2023, by and between Registrant and Bixi Gao & Ling Ling Wang	Exhibit 10.48 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.28	Common Stock Purchase Warrant dated as of May 8, 2023, issued by the Registrant to Bixi Gao & Ling Ling Wang	Exhibit 10.49 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.29#	Board of Directors Agreement dated as of November 28, 2022, as amended, by and between the Registrant and Charles Allen	Exhibit 10.56 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.30#	Board of Directors Agreement dated as of November 28, 2022, as amended, by and between the Registrant and Stephen Toovey	Exhibit 10.57 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
10.31#	Board of Directors Agreement dated as of December 9, 2022, as amended, by and between the Registrant and Cheryl Xu	Exhibit 10.58 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023

10.32#	Board of Directors Agreement dated as of December 15, 2022, as amended, by and between the Registrant and Paul Field	Exhibit 10.59 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
14.1	Code of Conduct	Exhibit 99.4 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023
21.1	List of Subsidiaries	Exhibit 21.1 to Registration Statement on Form S-1 (File No: 333-269483)	January 31, 2023

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

Management contract or compensatory plan.

* Filed herewith.

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

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

60 DEGREES PHARMACEUTICALS, INC.

Dated: April 1, 2024

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

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

Name	Position	Date
/s/ Geoffrey Dow Geoffrey Dow	President, Chief Executive Officer and Director (Principal Executive Officer)	April 1, 2024
/s/ Tyrone Miller Tyrone Miller	Chief Financial Officer (Principal Financial and Accounting Officer)	April 1, 2024
/s/ Charles Allen Charles Allen	Director	April 1, 2024
/s/ Cheryl Xu Cheryl Xu	Director	April 1, 2024
/s/ Stephen Toovey Stephen Toovey	Director	April 1, 2024
/s/ Paul Field Paul Field	Director	April 1, 2024

Exhibit 4.1

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

The following description sets forth certain material terms and provisions of the common stock and warrants of 60 Degrees Pharmaceuticals, Inc., a Delaware corporation which are registered under Section 12(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This description also summarizes relevant provisions of the Delaware General Corporation Law ("DGCL"). The following description is a summary and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, the relevant provisions of the DGCL, and to our Certificate of Incorporation, as corrected (collectively, the "Certificate of Incorporation"), and our Amended and Restated Bylaws (the "Bylaws"), which are filed as exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, of which this Exhibit is a part, and are incorporated by reference herein. We encourage you to read the Certificate of Incorporation and the Bylaws, and the relevant provisions of the DGCL for additional information. Unless the context requires otherwise, all references to "we," "us," "our" and the "Company" in this Exhibit 4.1 refer solely to 60 Degrees Pharmaceuticals, Inc.

Authorized and Outstanding Capital Stock

Our authorized capital stock presently consists of 151,000,000 shares of common stock, par value $0.0001 per share, and 1,000,000 shares of "blank check" preferred stock, par value $0.0001 per share, of 80,965 have been designated as Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"). As of April 1, 2024, we had 11,070,990 shares of common stock outstanding and 78,803 shares of our Series A Preferred Stock issued and outstanding.

Common Stock

Voting

Holders of shares of the common stock are entitled to one vote for each share held of record on matters properly submitted to a vote of our stockholders. Stockholders are not entitled to vote cumulatively for the election of directors.

Dividends

Subject to the dividend rights of the holders of any outstanding series of preferred stock, holders of shares of common stock will be entitled to receive ratably such dividends, if any, when, as, and if declared by our Board of Directors ("Board") out of the Company's assets or funds legally available for such dividends or distributions.

Liquidation and Distribution

In the event of any liquidation, dissolution, or winding up of the Company's affairs, holders of the common stock would be entitled to share ratably in the Company's assets that are legally available for distribution to its stockholders. If the Company has any preferred stock outstanding at such time, holders of the preferred stock may be entitled to distribution preferences, liquidation preferences, or both. In such case, the Company must pay the applicable distributions to the holders of its preferred stock before it may pay distributions to the holders of common stock.

Conversion, Redemption, and Preemptive Rights

Holders of the common stock have no preemptive, subscription, redemption or conversion rights.

Sinking Fund Provisions

There are no sinking fund provisions applicable to the common stock.

Warrants

In our July 2023 initial public offering, we issued 1,415,095 tradeable warrants.

Exercisability

The warrants are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the Warrant Agent, by utilizing the exercise form on the reverse side of the warrant certificate completing and executing as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. Under the terms of the Warrant Agent Agreement, we must use our best efforts to maintain the effectiveness of the registration statement and current prospectus relating to common stock issuable upon exercise of the warrants until the expiration of the warrants. If we fail to maintain the effectiveness of the registration statement and current prospectus relating to the common stock issuable upon exercise of the warrants, the holders of the warrants shall have the right to exercise the warrants solely via a cashless exercise feature provided for in the warrants, until such time as there is an effective registration statement and current prospectus relating to common stock issuable upon exercise of the warrants.

Exercise Limitation

A holder may not exercise any portion of a warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of the outstanding common stock after exercise, as such percentage ownership is determined in accordance with the terms of the warrant, except that upon prior notice from the holder to us, the holder may waive such limitation up to a percentage not in excess of 9.99%.

Exercise Price

The exercise price per whole share of common stock purchasable upon exercise of the Tradeable Warrants is $6.095 per share (based on a public offering price of $5.30 per Unit) or 115% of the public offering price of the common stock. The exercise price per whole share of common stock purchasable upon exercise of the Non-tradeable Warrants is $6.36 per share (based on a public offering price of $5.30 per Unit) or 120% of the public offering price of the common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock

splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability

Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Rights as a Stockholder

The warrant holders do not have the rights or privileges of holders of common stock or any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

Governing Law

The warrants and the warrant agency agreement are governed by New York law.

STOCK EXCHANGE LISTING

Our common stock and warrants are listed on The Nasdaq Capital Market under the symbol “SXTP” and “SXTPW,” respectively.

TRANSFER AGENT AND REGISTRAR

Our transfer agent and registrar for all securities registered under Section 12 of the Exchange Act is Equity Stock Transfer, LLC, located at 237 W 37th St Suite 602, New York, NY 10018. Their telephone number is (212) 575-5757.

ANNUAL STOCKHOLDER MEETINGS

The Bylaws provide that annual stockholder meetings will be held wholly or partially by means of remote communication or at such place, within or without the State of Delaware, on such date and at such time as may be determined by the Board, the Chief Executive Officer of the Company or the Chairman of the Board (the “Chairman”) and as will be designated in the notice of the annual meeting.

ANTI-TAKEOVER EFFECTS OF THE CERTIFICATE OF INCORPORATION AND BYLAWS AND CERTAIN PROVISIONS OF THE DGCL

The Certificate of Incorporation and Bylaws contain and the DGCL contains provisions, which are summarized in the following paragraphs, that are intended to enhance the likelihood of continuity and stability in the composition of the Board. These provisions are intended to avoid costly takeover battles, reduce the Company’s vulnerability to a hostile change of control and enhance the ability of the Board to maximize stockholder value in connection with any unsolicited offer to acquire the Company. However, these provisions may have an anti-takeover effect and may delay, deter or prevent a merger or acquisition of the Company by means of a tender offer, a proxy contest or other takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the prevailing market price for the shares of common stock of the Company held by stockholders.

Authorized but Unissued Capital Stock

The DGCL does not require stockholder approval for any issuance of authorized shares. However, the listing requirements of The Nasdaq Stock Market LLC (“Nasdaq”) which would apply if and so long as the common stock of the Company remains listed on Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. Additional shares that may be used in the future may be issued for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions.

The Board may generally issue preferred shares on terms calculated to discourage, delay or prevent a change of control of the Company or the removal of the Company’s management. Moreover, the Company’s authorized but unissued shares of preferred stock will be available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, to facilitate acquisitions and employee benefit plans.

One of the effects of the existence of unissued and unreserved common stock or preferred stock may be to enable the Board to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of the Company’s management and possibly deprive the Company’s stockholders of opportunities to sell their shares of the common stock of the Company at prices higher than prevailing market prices.

Removal of Directors; Vacancies

Subject to the rights, if any, of the holders of any series of preferred stock to elect additional directors under circumstances specified in a preferred stock designation, any director may be removed from office by the stockholders at any time, with or without cause and, in each case, only by the affirmative vote of the holders of a majority of the voting power of the outstanding voting stock, voting together as a single class, at any annual meeting or special meeting of the stockholders where the notice of which states that the removal of a director or directors is among the purposes of the meeting and identifies the director or directors proposed to be removed.

Subject to the rights, if any, of the holders of any future series of preferred stock to elect additional directors under circumstances specified in a preferred stock designation, newly created directorships resulting from any increase in the number of directors and any vacancies on the Board resulting from death, disability, resignation, disqualification, removal or other cause will be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board, or by a sole remaining director. Any director elected in accordance with the preceding sentence will hold office until the next annual meeting of stockholders and until such director's successor is duly elected and qualified or until his or her earlier death, disability, resignation, disqualification or removal.

Special Stockholder Meetings

Subject to the rights of the holders of any future series of preferred stock, special meetings of stockholders may be called only (i) by the Chairman, (ii) by the Chief Executive Officer of the Company or (iii) by the Secretary of the Company acting at the request of the Chairman, the Chief Executive Officer of the Company or a majority of the total number of directors that the Company would have if there were no vacancies on its Board. At any annual meeting or special meeting of stockholders, only such business will be conducted or considered as has been brought before such meeting in the manner provided in the Bylaws.

Requirements for Advance Notification of Director Nominations and Stockholder Proposals

The Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the Board or a committee of the Board. In order for any matter to be properly brought before a meeting, a stockholder will have to comply with advance notice requirements and provide the Company with certain information. Generally, to be timely, a stockholder's notice relating to any nomination or other business to be brought before an annual meeting must be delivered to the Secretary of the Company at the Company's principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the immediately preceding annual meeting of stockholders. Notwithstanding the foregoing, in the event that the number of directors to be elected to the Board at the annual meeting is increased effective after the time period for which nominations would otherwise be due and there is no public announcement by the Company naming the nominees for the additional directorships at least 100 days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice will also be considered timely, but only with respect to nominees for the additional directorships, if it will be delivered to the Secretary of the Company at the principal executive offices of the Company not later than the close of business on the 10th day following the day on which such public announcement is first made by the Company.

To be timely, a stockholder's notice relating to the nomination of a director to the Board to be brought before a special meeting, if permitted, will be delivered to the Secretary of the Company at the principal executive offices of the Company not earlier than the close of business on the 120th day prior to such special meeting and not later than the close of business on the later of the 90th day prior to such special meeting or the 10th day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting.

These notice provisions may defer, delay or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to influence or obtain control of the Company.

Consent of Stockholders in Lieu of Meeting

Subject to the rights of the holders of any series of preferred stock, any action required or permitted to be taken by the stockholders may be taken only at a duly called annual or special meeting of stockholders and may not be taken without a meeting by means of any consent in writing of such stockholder.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, the Company's stockholders will have appraisal rights in connection with a merger or consolidation of the Company. Pursuant to the DGCL, stockholders who properly request and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Stockholders' Derivative Actions

Under the DGCL, any of the Company's stockholders may bring an action in the Company's name to procure a judgment in the Company's favor, also known as a derivative action, provided that the stockholder bringing the action is a holder of the Company's shares at the time of the transaction to which the action relates or such stockholder's stock thereafter devolved by operation of law.

Amendment of the Certificate of Incorporation

The Certificate of Incorporation provides that the Company reserves the right at any time from time to time to amend, alter, change or repeal any provision contained in the Certificate of Incorporation.

Amendment of the Bylaws

The Bylaws may be amended in any respect or repealed at any time, either (a) at any meeting of stockholders, provided that any amendment or supplement proposed to be acted upon at any such meeting has been properly described or referred to in the notice of such meeting, or (b) by the Board, provided that no amendment adopted by the Board may vary or conflict with any amendment adopted by the stockholders in accordance with the Certificate of Incorporation and the Bylaws.

Exclusive Forum Selection

The Certificate of Incorporation provides that, unless the Company consents in writing to the selection of an alternative forum, (a) the Court of Chancery (the "Chancery Court") of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware) will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action, suit or proceeding brought on behalf of the Company, (ii) any action, suit or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or stockholder of the Company to the Company or to the Company's stockholders, (iii) any action, suit or proceeding arising pursuant to any provision of the DGCL or the Bylaws or the Certificate of Incorporation (as either may be amended and/or restated from time to time) or as to which the DGCL confers jurisdiction on the Chancery Court or (iv) any action, suit or proceeding asserting a claim against the Company governed by the internal affairs doctrine. Notwithstanding the foregoing, the exclusive forum provision will not apply to any claim for which the federal courts of the United States have exclusive jurisdiction.

Limitations on Liability and Indemnification of Officers and Directors

The DGCL authorizes corporations to limit or eliminate the personal liability of directors and certain officers to corporations and their stockholders for monetary damages for breaches of directors' fiduciary duties, subject to certain exceptions. The Certificate of Incorporation includes a provision that eliminates the personal liability of directors for monetary damages for any breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL. The effect of these provisions is to eliminate the rights of the Company and its stockholders, through stockholders' derivative suits on the Company's behalf, to recover monetary damages from a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior. However, exculpation does not apply to any director for any breach of the director's duty of loyalty to the Company or its stockholders, or if the director has acted in bad faith, knowingly or intentionally violated the law, authorized illegal dividends or redemptions or derived an improper benefit from his or her actions as a director.

The Certificate of Incorporation provides that the Company must indemnify and advance expenses to the Company's directors and officers to the fullest extent authorized by the DGCL. The Company also is expressly authorized to maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Company or another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Company would have the power to indemnify such person against such expense, liability or loss under the DGCL. The Company believes that these indemnification and advancement provisions and insurance are useful to attract and retain qualified directors and executive officers.

The limitation of liability, advancement and indemnification provisions in the Certificate of Incorporation may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit the Company and its stockholders. In addition, your investment may be adversely affected to the extent the Company pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Geoffrey Dow, President and Chief Executive Officer of 60 Degrees Pharmaceuticals, Inc. (the "Company"), certify that:

(1) I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods represented in this report;

(4) The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

(5) The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and to the Audit Committee of the Board of Directors (or persons fulfilling the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

April 1, 2024

/s/ Geoffrey Dow
Geoffrey Dow
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Tyrone Miller, Chief Financial Officer of 60 Degrees Pharmaceuticals, Inc. (the "Company"), certify that:

(1) I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods represented in this report;

(4) The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

(5) The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and to the Audit Committee of the Board of Directors (or persons fulfilling the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

April 1, 2024

/s/ Tyrone Miller
Tyrone Miller
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of 60 Degrees Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Geoffrey Dow, President and Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

April 1, 2024

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of 60 Degrees Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Tyrone Miller, Chief Financial Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

April 1, 2024

/s/ Tyrone Miller
Tyrone Miller
Chief Financial Officer
(Principal Financial Officer)

Exhibit 97.1

60 DEGREES PHARMACEUTICALS, INC.

CLAWBACK POLICY

Introduction

The Board of Directors ("Board") of 60 Degrees Pharmaceuticals, Inc. (the "Company") believes that it is in the best interests of the Company and its stockholders to adopt this policy which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the "Policy"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), Rule 10D-1 promulgated under the Exchange Act ("Rule 10D-1"), and Listing Rule 5608 of The Nasdaq Stock Market LLC ("Nasdaq").

Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee of the Board (the "Compensation Committee") or the Audit Committee of the Board (the "Audit Committee"), or any special committee comprised of members of the Compensation Committee or Audit Committee (the "Administrator"). Any determinations made by the Administrator shall be final and binding on all affected individuals. Subject to any limitation at applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Administrator in accordance with Section 10D of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed, and such other senior executives/employees who may from time to time be deemed subject to the Policy by the Administrator (each, a "Covered Executive").

For the purposes of this Policy, "executive officers" shall include persons subject to reporting and short-swing liability provisions of Section 16 under the Exchange Act. This shall include the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company and any person identified under Regulation S-K Item 401(b) in the Company's annual reports and proxy statements. Executive officers of a parent or subsidiary are deemed executive officers of the listed company if they perform such policy-making functions for the listed company or such parent or subsidiary. The policy-making function is not intended to include policy-making functions that are not significant.

Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Administrator will require, as promptly as it reasonably can, reimbursement or forfeiture of any Incentive Compensation, as defined below, received by any Covered Executive during the three (3) completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement (the "Restatement Date"), so long as the Incentive Compensation received by such Covered Executive is in excess of what would have been awarded or vested after giving effect to the accounting restatement. The amount to be recovered will be the excess of Incentive Compensation paid to the Covered Executive based on the erroneous data in the original financial statements over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, without respect to any taxes paid.

The Restatement Date is defined as the earlier of (i) the date the Board, a Board committee, or management (if no Board action is required) concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement.

Incentive Compensation

For purposes of this Policy, "Incentive Compensation" means any of the following; *provided* that, such compensation is granted, earned, or vested based wholly or in part on the attainment of a financial reporting measure:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock.
- Restricted stock units.
- Performance shares.
- Performance units.
- Non-equity incentive plan awards.

Financial reporting measures include any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in-part from such measure. The following examples (and any measures derived therefrom) are non-exhaustive:

- Company stock price.
- Total shareholder return.
- Revenues.
- Net income.
- Operating income.
- Earnings before interest, taxes, depreciation, and amortization (EBITDA).
- Funds from operations and adjusted funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.
- Profitability of one or more reportable segments.
- Financial ratios such as accounts receivable turnover.
- Cost per employee, where cost is subject to any accounting restatement.
- Any of such financial reporting measures relative to a peer group, where the Company's financial reporting measure is subject to an accounting restatement and tax basis income.
- Capital raised through debt or equity financing.
- Reductions in accounts receivables.

For the avoidance of doubt, Incentive Compensation does not include annual salary, compensation awarded based on completion of a specified period of service, or compensation awarded based on subjective standards, strategic measures, or operational measures.

Incentive Compensation includes incentive-based compensation received by a person:

- after beginning service as an executive officer;
- who serves as an executive officer at any time during the performance period for the incentive-based compensation;
- who served as an executive officer while the Company has a class of securities listed on a national securities exchange; and
- who serves as an executive officer during the three (3) fiscal years preceding the Restatement Date.

For the avoidance of doubt, subsequent changes in a Covered Executive's employment status, including retirement or termination of employment, do not affect the Company's rights to recover incentive-based compensation pursuant to this Policy.

Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, as determined by the Administrator. Incentive Compensation is deemed "received" during the fiscal period during which the financial reporting measure specified in the incentive-based compensation award is attained, even if payment or grant of the Incentive Compensation occurs after the end of the period.

If the Administrator cannot determine the amount of excess Incentive Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement.

Method of Recoupment

The Administrator will determine, in its sole discretion, the method for recouping excess Incentive Compensation hereunder, which may include, without limitation:

- requiring reimbursement of cash Incentive Compensation previously paid;
- seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;
- canceling outstanding vested or unvested equity awards; and/or
- taking any other remedial and recovery action permitted by law, as determined by the Administrator.

No Indemnification of Covered Executives

The Company shall not indemnify any current or former Covered Executive against the loss of any incorrectly awarded Incentive Compensation, and shall not pay, or reimburse any Covered Executive for premiums for any insurance policy to fund such executive's potential recovery obligations.

Indemnification of the Administrator

Any members of the Administrator who assist in the administration of this Policy, shall not be personally liable for any action, determination, or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination, or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the Administrator under applicable law or Company policy.

Interpretation

The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Rule 10D-1, Nasdaq Listing Rule 5608, and any other applicable rules or standards adopted by the Securities and Exchange Commission or any national securities exchange on which the Company's securities are then listed.

Effective Date

This Policy shall be effective as of the date it is adopted by the Administrator (the " Effective Date") and shall apply to Incentive Compensation that is approved, awarded, or granted to any Covered Executive on or after that date.

Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect final regulations adopted by the Securities and Exchange Commission under Section 10D of the Exchange Act, Rule 10D-1, and Nasdaq Listing Rule 5608 and to comply with any other rules or standards adopted by a national securities exchange on which the Company's securities are then listed. The Board may terminate this Policy at any time.

Other Recoupment Rights

The Administrator intends that this Policy will be applied to the fullest extent of the law. The Administrator may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

Impracticability

The Administrator shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Administrator in accordance with Rule 10D-1 of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators, or other legal representatives.

Exhibit Filing Requirement

A copy of this Policy and any amendments thereto shall be posted on the Company's website and filed as an exhibit to the Company's Annual Report on Form 10-K.