Filed Pursuant to Rule 424(b)(4)
Registration No. 333-276641

5,260,901 Units, with each Unit consisting of One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

999,076 Pre-Funded Units, with each Pre-Funded Unit consisting of One Pre-Funded Warrant to Purchase One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

6,259,977 Shares of Common Stock Underlying the Warrants

999,076 Shares of Common Stock Underlying the Pre-Funded Warrants

60 Degrees Pharmaceuticals, Inc.

60 Degrees Pharmaceuticals, Inc. is offering on a firm commitment, underwritten basis, 5,260,901 units (the "Units"), each Unit consisting of one share of our common stock, $0.0001 par value per share, and one warrant ("Warrant"), with the right to purchase one (1) share of our common stock, at a public offering price of $0.3850 per Unit. The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. Each Warrant offered hereby is immediately exercisable on the date of issuance at an exercise price of $0.4235 per share (110% of the offering price per Unit) and will expire five years from the date of issuance.

We are also offering 999,076 pre-funded units (the "Pre-Funded Units") to certain purchasers whose purchase of Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering. Each Pre-Funded Unit consists of one pre-funded warrant exercisable for one (1) share of our common stock ("Pre-Funded Warrant") and one Warrant. The purchase price of each Pre-Funded Unit is equal to the price per Unit being sold to the public in this offering, minus $0.01, and the exercise price of each Pre-Funded Warrant included in the Pre-Funded Unit is $0.01 per share. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full.

For each Pre-Funded Unit we sell, the number of Units we are offering will be decreased on a one-for-one basis. The offering also includes the shares of common stock issuable from time to time upon exercise of the Warrants and Pre-Funded Warrants. Without an active trading market, the liquidity of the Warrants and Pre-Funded Warrants will be limited.

The shares of common stock and Pre-Funded Warrants, if any, can each be purchased in this offering only with the accompanying Warrants as part of a Unit or Pre-Funded Unit, as applicable, but the components of the Units or Pre-Funded Unit, as applicable, will be immediately separable and will be issued separately in this offering. See "*Description of Securities*" in this prospectus for more information.

Our common stock is listed on The Nasdaq Capital Market under the symbol "SXTP." The closing price of our common stock on January 29, 2024 as reported by The Nasdaq Capital Market, was $0.5172. There is no established trading market for the Warrants and Pre-Funded Warrants and we do not intend to list the Warrants and the Pre-Funded Warrants on any securities exchange or nationally recognized trading system.

The final public offering price was determined through negotiation between us, the underwriter and the investors based upon a number of factors, including our history and our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers and the general condition of the securities markets at the time of this offering.

We have agreed pursuant to the terms in an underwriting agreement dated the date of this prospectus, to grant WallachBeth Capital LLC, the underwriter, an option, exercisable for 45 days from the date of this prospectus, to purchase up to an additional 789,136 shares of common stock (15.0% of the shares sold as part of the Units in this offering) and/or 938,997 Warrants (15.0% of the Warrants sold as part of the Units and/or Pre-Funded Units in this offering) and/or 149,862 Pre-Funded Warrants (15.0% of the Pre-Funded Warrants sold in this offering).

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

Investing in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 19 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

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

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

	Per Unit	Per Pre-Funded Unit	Total
Public offering price	$ 0.3850	$ 0.3750	$ 2,400,100.39
Underwriting discounts and commissions[(1)]	$ 0.0308	$ 0.03	$ 192,008.03
Proceeds to us (before expenses)[(2)]	$ 0.3542	$ 0.345	$ 2,208,092.36

(1) Represents underwriting discount and commissions equal to $0.0308 per Unit and $0.03 per Pre-Funded Unit. Does not include a non-accountable expense allowance equal to 1.5% of the gross proceeds of this offering, payable to WallachBeth Capital LLC, as representative of the underwriters, or the reimbursement of certain expenses of the underwriters. See *"Underwriting*" beginning on page 128 of this prospectus for additional information regarding underwriting compensation.

(2) The amount of offering proceeds to us presented in this table does not give effect to any exercise of the Warrants or Pre-Funded Warrants.

We have agreed to issue upon the closing of this offering to WallachBeth Capital LLC warrants that will expire on the fifth anniversary of the effective date of the registration statement of which this prospectus is a part, entitling the underwriter to purchase 6.0% of the number of securities sold in this offering (the "Representative Warrants"). The registration statement of which this prospectus is a part also covers the Representative Warrants and the shares of common stock issuable upon the exercise thereof. For additional information regarding our arrangement with the underwriter, please see "*Underwriting*" beginning on page 128.

We anticipate that delivery of the securities against payment therefor will be made on or before January 31, 2024.

Sole Book-Running Manager

WallachBeth Capital LLC

Prospectus dated January 29, 2024

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

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

ABOUT THIS PROSPECTUS

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

- all references to the "Company," "60P," the "registrant," "we," "our," or "us" mean 60 Degrees Pharmaceuticals, Inc., a Delaware corporation, and majority owned subsidiary 60P Australia Pty Ltd, an Australian proprietary company limited by shares;
- "year" or "fiscal year" means the year ending December 31; and
- all dollar or $ references, when used in this prospectus, refer to United States dollars.

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

- no shares of common stock have been issued pursuant to any warrants, including the Warrants and Pre-Funded Warrants;
- no shares of common stock have been issued pursuant to the warrants issued to the representative in our initial public offering; and
- no shares of common stock have been issued pursuant to the Representative Warrants.

TRADEMARKS

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

GLOSSARY OF SELECTED TERMS

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

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

"Agency of Record" refers to a marketing/advertising agency used by a Company to develop marketing collateral for a commercial pharmaceutical product.

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

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

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

"CAR-T" means chimeric antigen receptor therapy.

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

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

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

"EUA" means Emergency Use Authorization.

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

"G6PD" means glucose-6-phosphate dehydrogenase.

"GMP" means Good Manufacturing Practices.

"IND" means investigational new drug application.

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

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

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

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

"NIH" means the National Institutes of Health.

"PDUFA" means The Prescription Drug User Fee Act.

"PMA" means Premarket Approval by the FDA.

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

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

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

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

"Spp" is shorthand use to refer to multiple species of organisms in a particular genus. Thus, *Candida* spp refers collectively to *Candida auris*, *Candida albicans* and other *Candida* species.

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

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

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

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

In connection with presentation of scientific data, this prospectus references "*P*-values" at various points. These values are provided to convey the likelihood of a particular set of data occurring by chance. For example, a *P*-value of 0.12 associated with a stand-alone, pre-conceived hypothesis is generally understood to mean that the likelihood of that particular outcome occurring purely by chance is 12%. It is scientific convention that a particular observation is "proven" if its associated *P* value is lower than 0.05 (i.e., associated with a likelihood of occurring by chance of < 5%). However, clinical observations of interest are routinely reported in the peer-reviewed scientific literature even if their associated *P*-values are > 0.05, because they may represent important therapeutic signals, and motivate additional research.

USE OF PRODUCT VERSUS GENERIC NAMES

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

MARKET DATA

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

PROSPECTUS SUMMARY

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

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 new products relevant to Lyme disease and an antimalarial combination partner for Tafenoquine for *P. vivax* malaria.

Mission

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

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 US sales of Arakoda (not excluding returns) to pharmacies and other outlets was 1,633 boxes (a gross value of $383,755 at a WAC price of $235 per box), a substantial increase from the 572 boxes of Arakoda sold in 2022. Following this offering, targeted marketing efforts will commence to promote the malaria indication as described herein. We are continuing 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. travelers (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.

- 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.

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

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 observations of 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).

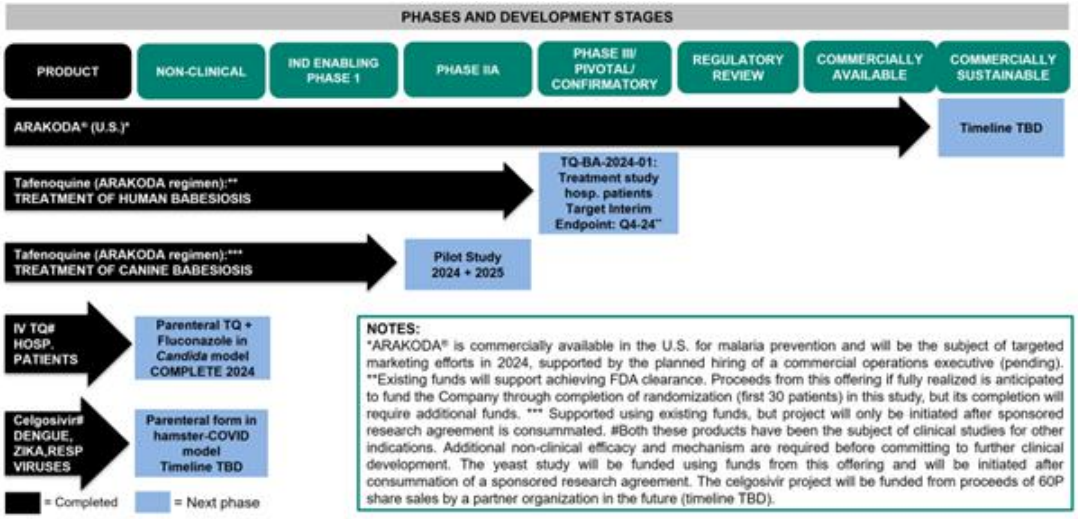
7 https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html.; https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html.

- 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.

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]

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.

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.

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

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

Tafenoquine 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.

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

15 See prescribing information at www.arakoda.com.

16 See prescribing information at www.arakoda.com.

17 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.

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.

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. Following this offering, and depending on net proceeds, we may hire a new Chief Commercial Officer to lead our commercial effort to reintroduce Arakoda for malaria prevention. Prior to implementation of any marketing initiatives, we will conduct the following research and planning activities to be completed in the first half of 2024.

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

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.

Repositioning of Arakoda Relative to Atovaquone-Proguanil. Market research will be conducted to determine whether current pricing and contractual relationships with pharmacy benefit managers ("PBMS") allow optimal positioning of Arakoda relative to its main competitor or require adjustment. 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 the 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 key marketing messages and materials. Our Arakoda website will be revamped 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.

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 17th, 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. The 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 are discussing, with a prominent U.S. university, a plan to support a pilot study of Tafenoquine for treatment of canine babesiosis in the United States under a sponsored research program. Should this potential collaboration be successful, we believe that the data from that study may provide supportive data for the clinical babesiosis development program, and could provide proof of concept for an expanded study to prove utility for veterinary indications.

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.

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 may be conducted under a (pending) sponsored research agreement with a prominent international research university that we are currently pursuing.

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 a hamster-COVID-19 model to evaluate whether parenterally administered castanospermine can ameliorate the pathological effects of SARS CoV-2 via modulation of cytokine response to infection. Following this offering this project will be added to our statement of work for our services agreement with Florida State University Research Foundation ("FSURF"), and will commence when there is 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 this offering to be expended on such a pediatric study will be limited to the minimum required to support protocol preparation and regulatory interactions with the FDA.

Potential In licensing Activities

We may, following this offering, 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

We plan to raise up to $3 million in this financing. If insufficient funds are realized, we intend to raise the balance of the funds following our annual meeting in the second quarter of 2024. 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 to support further commercialization of Arakoda. There is no assurance that funds will be available on acceptable terms.

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*

Title	Patent No.	Country	Status	US Patent Date	Application No.	Estimated/ Anticipated Expiration Date
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	China	Pending		202180029643.7	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections By Administration Of Tafenoquine	Pending	Australia	Pending		2021231743	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	Pending	Hong Kong	Pending		62023078645.6	02-Mar-2041*
Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine	11,633,391	US		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 royalties at the rate of 1.5% of gross sales.

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

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

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

On February 15, 2021, we entered into the Inter-Institutional Agreement 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. Upon succeeding with the qualified IPO, at the end of the quarter and each thereafter the royalty will be calculated, and payment will be made within fifteen days.

Corporate Structure

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

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

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

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

Going Concern

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

Suppliers

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

Recent Developments

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

We continue to monitor the global outbreak and spread of COVID-19 and take steps in an effort to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and the governmental and community reactions thereto. COVID-19 globally resulted in loss of life, business closures, restrictions on travel, and widespread cancellation of social gatherings. The travel restrictions, in particular, hampered our sales and marketing of Arakoda as global travel was significantly curtailed. The extent to which COVID-19 impacts our business in the future will depend on developments such as the following, which are highly uncertain and cannot be predicted at this time:

- new information or strains of the virus may emerge concerning the severity of the disease;
- the duration and spread of the outbreak;
- the severity of travel restrictions imposed by geographic areas in which we operate, mandatory or voluntary business closures;
- regulatory actions taken in response to any future COVID-19 outbreak, which may impact our product offerings;

- other business disruptions that affect our workforce and supply chain;
- the impact on capital and financial markets; and
- actions taken throughout the world, including in markets in which we operate, to contain the COVID-19 outbreak or treat its impact.

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

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

2023 Financings

On May 8, 2023, we issued a note in the amount of $111,111.10 to Cyberbahn Federal Solutions, LLC with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Cyberbahn Federal Solutions, LLC shares of our common stock equal to the number of shares of our common stock calculated using $5.30 a share.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Ariana Bakery Inc with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Ariana Bakery Inc shares of our common stock equal to the number of shares of our common stock calculated using $5.30 a share.

On May 8, 2023, we issued a note in the amount of $333,333.30 to Sabby Volatility Warrant Master Fund, Ltd. with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Sabby Volatility Warrant Master Fund, Ltd. shares of our common stock equal to the number of shares of our common stock calculated using $5.30 a share.

On May 8, 2023, we issued a note in the amount of $55,555.55 to Steel Anderson with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Steel Anderson shares of our common stock equal to the number of shares of our common stock calculated using $5.30 a share.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Bixi Gao & Ling Ling Wang with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Bixi Gao & Ling Ling Wang shares of our common stock equal to the number of shares of our common stock calculated using $5.30 a share.

Summary Risk Factors

Our business is subject to a number of risks. You should be aware of these risks before making an investment decision. These risks are discussed more fully in the section of this prospectus titled "*Risk Factors,*" which begins on page 19 of this prospectus. These risks include, among others, that:

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

- Our intellectual property rights may not preclude competitors from developing competing products and our business may suffer;
- If the manufacture, use or sale of our products infringe on the intellectual property rights of others, we could face costly litigation, which could cause us to pay substantial damages or licensing fees and limit our ability to sell some or all of our products;
- We may not be able to protect our intellectual property rights throughout the world;
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- The earliest Paragraph IV certification date for Arakoda has passed. Generic companies may file an ANDA at any time, and successful challenge of our malaria use patents would negatively impact our business;
- We may not be able to maintain the listing of our common stock on Nasdaq, which could adversely affect our liquidity and the trading volume and market price of our common stock and decrease or eliminate your investment;
- Any failure to maintain effective internal controls over financial reporting could have an adverse impact on us; and
- We are an "emerging growth company" and a "smaller reporting company" under the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

Information Regarding our Capitalization

As of January 29, 2024, we had 5,810,089 shares of common stock issued and outstanding. Additional information regarding our issued and outstanding securities may be found under "*Market for Common Equity and Related Stockholder Matters*" and "*Description of Securities*."

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

Corporate Information

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

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

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

These exemptions include:

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

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

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

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

SUMMARY OF THE OFFERING

Issuer	60 Degrees Pharmaceuticals, Inc.
Units offered by us	5,260,901 Units, with each Unit consisting of one (1) share of common stock and one (1) Warrant to purchase one share of common stock.
Pre-Funded Units offered by us	We are also offering 999,076 Pre-Funded Units to certain purchasers whose purchase of Units in this offering would otherwise result in the purchaser, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering. Each Pre-Funded Unit consists of one Pre-Funded Warrant exercisable for one share of our common stock and one Warrant. The purchase price of each Pre-Funded Unit is equal to the price at which the Units are being sold to the public in this offering, minus $0.01, and the exercise price of each Pre-Funded Warrant included in each Pre-Funded Unit is $0.01 per share. The Pre-Funded Warrants will be exercisable immediately and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any Pre-Funded Warrants sold in this offering.
Underwriter's over-allotment option	We have agreed pursuant to the terms in an underwriting agreement dated the date of this prospectus, to grant WallachBeth Capital LLC, the underwriter, an option, exercisable for 45 days from the date of this prospectus, to purchase up to an additional 789,136 shares of common stock (15.0% of the shares sold as part of the Units in this offering) and/or 938,997 Warrants (15.0% of the Warrants sold as part of the Units and/or Pre-Funded Units in this offering) and/or 149,862 Pre-Funded Warrants (15.0% of the Pre-Funded Warrants sold in this offering).
Description of Warrants	The Warrants will be exercisable from the date of issuance until the fifth anniversary date of issuance date for $0.4235 per share (110% of the public offering price of one Unit), subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock as described herein. A holder may not exercise any portion of a warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of the outstanding common stock after exercise, as such percentage ownership is determined in accordance with the terms of the warrants, except that upon notice from the holder to us, the holder may waive such limitation up to a percentage, not in excess of 9.99%. The terms of the warrants will be governed by the warrant agent agreement entered into between the Company and Equity Stock Transfer, LLC (the "Warrant Agent Agreement"). This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants. See "*Description of Securities–Warrants*."
Common stock outstanding prior to the offering[(1)]	5,810,089 shares
Common stock to be outstanding after the offering[(2)]	11,070,990 shares (assuming that none of the Pre-Funded Warrants and Warrants issued in this offering are exercised).

(1) As of January 29, 2024 and excludes 198,609 shares of common stock reserved for issuance under our 2022 Equity Incentive Plan.

(2) Excludes (i) 198,609 shares of common stock reserved for issuance under our 2022 Equity Incentive Plan; (ii) 3,163,854 shares of common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of $6.17 per share; (iii) 807,924 shares of common stock issuable upon the exercise of outstanding options to purchase common stock at a weighted average exercise price of $1.36 per share; (iv) 256,000 shares of common stock issuable pursuant to fully vested restricted stock units which have not yet been issued as of the date of this prospectus; (v) 16,000 shares of common stock issuable upon the future vesting of outstanding restricted stock units; (vi) 315,655 shares of common stock issuable upon exercise of the Representative Warrants at an exercise price equal to 110% of the public offering price of the Units; and (vii) shares of common stock issuable upon the conversion of 78,803 shares of Series A Preferred Stock.

Offering price	$0.3850 per Unit and $0.3750 per Pre-Funded Unit.
Use of Proceeds	We currently intend to use the net proceeds to us from this offering for general corporate purposes, including working capital. See the section of this prospectus titled "*Use of Proceeds*" beginning on page 54.
Representative Warrants	Upon the closing of this offering, we have agreed to issue to WallachBeth Capital LLC warrants that will expire on the fifth anniversary of the commencement date of sales in this offering, entitling the underwriter to purchase 6.0% of the number of securities sold in this offering. The registration statement of which this prospectus is a part also covers the Representative Warrants and the shares of common stock issuable upon the exercise thereof. For additional information regarding our arrangement with the underwriter, please see "*Underwriting*."
Lock-up agreements	Our executive officers and directors have agreed with the underwriter not to sell, transfer or dispose of any shares or similar securities for six (6) months following the effective date of the registration statement for this offering without the prior written consent of WallachBeth Capital LLC. Any other holders of more than 5% of the outstanding shares of our common stock have also agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for six (6) months following the effective date of the registration statement for this offering without the prior written consent of the underwriters. For additional information regarding our arrangement with the underwriters, please see "*Underwriting*."
Transfer Agent	Equity Stock Transfer, LLC.
Risk Factors	You should carefully consider the information set forth in this prospectus and, in particular, the specific factors set forth in the "*Risk Factors*" section beginning on page 19 of this prospectus before deciding whether or not to invest in shares of our common stock.

RISK FACTORS

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

Risks Related to Our Business

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

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

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

To date, we have financed our operations primarily through the issuance of equity, promissory notes and convertible notes. We incurred annual net losses of $6,177,784 in 2022 and $4,260,299 in 2021, respectively and operating losses were $1,750,445 in 2022 and $1,124,102 in 2021. We had an accumulated deficit of $28,815,148 as of December 31, 2022 ($22,633,428 as of December 31, 2021). For the nine month period ended September 30, 2023, we incurred a net loss of $1,767,583 and an operating loss of $3,260,422 and now have accumulated losses of $30,568,566.

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

There is no assurance that we will be profitable.

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

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

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

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

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

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

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

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

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

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

- the further spread of COVID-19, and the requirements to take action to mitigate the spread of any future COVID-19 outbreak (e.g., hygiene requirements or social distancing or other measures), will impact our ability to carry out our business as usual and may materially adversely impact global economic conditions, our business, results of operations, cash flows and financial condition.

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

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

Sales to the U.S. DoD were important to our revenue stream in the recent past. Although, as of the date of this prospectus, we are not in discussions with the DoD about additional/future procurement, we anticipate that if certain conditions/events described in this paragraph occur, our sales to DoD could develop; however, there is no assurance that such conditions/events will occur. First, the position of Arakoda in the DoD formulary (Tricare, deployed personnel) needs to be improved from second/third tier to at least equivalency with competing products (as is the case for civilian use as recommended by the CDC). We believe that changes in pricing or reimbursement structure may be needed to secure that. Second, the shelf-life of the existing product requires extension, which is known to be technically possible as the shelf-life of Kodatef in Australia is 48 months, but appropriate data must be generated to meet FDA requirements. Finally, a change in the operational footprint of DoD deployments to areas with higher malaria attack rates (e.g., the Liberia deployment to manage the Ebola outbreak in 2014) may lead to a rapid reassessment by DoD of the position of Arakoda in the formulary (advancement of the last approved prophylactic antimalarial to co-equal standard of care took thirteen years). If none of these events transpire, we would not have the opportunity for revenues and such failure would jeopardize our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

It is possible that our Babesiosis trial might fail if we cannot recruit sufficient patients, G6PD testing in a hospital setting cannot be conducted quickly enough to allow Tafenoquine administration with 48 hour of initiation of standard of care therapy, or that Tafenoquine when combined with standard of care azithromycin/atovaquone does not sufficiently accelerate the time to molecular cure to allow statistical demonstration of clinical benefit within resource constraints.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- collaborators may experience financial difficulties.

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

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

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

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

For clinical trials administered in the United States, G6PD testing is provided through commercial pathology companies including Labcorp and Quest Diagnostics. Such testing, while usually available with 72-hour turnaround time, may sometimes take much longer. There is a single FDA-approved point of care test (Abbott's Binax Now). There is also a 510k approved microfluidics test from Baebies which may be adaptable for point of care use in some research settings. However, both the Abbott and Baebies tests must be executed in a CLIA-certified setting, which not all clinical trials sites may have access to.

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

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

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

Several third-party diagnostic test companies are developing point of care G6PD tests (or platforms that would accommodate them) that utilize finger stick blood samples and which may be appropriate for use in the United States. One of these tests is approved in Brazil and Australia.[26] Another is available for use in Europe and was recently approved by the FDA in the United States.[27] A third test is being developed with the NIH grant support for the U.S. and ex U.S. markets and is in clinical development.[28] There is no guarantee that tests will succeed in clinical development or ever become commercially available to the public. Having to take a test at all, or to go to a third-party lab in order to take the test, may be a hindrance to the use of Arakoda, which would negatively impact our sales.

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

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

26 https://www.sdbiosensor.com/product/product_view?product_no=183.
27 Baebies Receives FDA 510(k) Clearance for G6PD Test on FINDER Platform | Baebies.
28 https://ivd.solutions/grant/.

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

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

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

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

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

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

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

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

We plan to proceed with a revised clinical trial of the Arakoda regimen of Tafenoquine for babesiosis (to include high-risk patients and a clinical primary endpoint as requested by FDA). At the time of this offering based on written and verbal feedback from FDA, we believe it is likely that our planned study, if it successfully meets its endpoint, would be pivotal, and therefore support regulatory approval of a supplementary NDA for the babesiosis treatment indication. However, the Company has not received the FDA's formal minutes from the meeting and will not do so until 30 days following January 17th, 2023. It is possible that our recollections of the FDA meeting are incorrect and that the official record of the meeting is different from our recollections. If this risk materializes, it might mean we have to do more than one clinical trial to reach regulatory approval which would harm our business. There is a risk, that in switching to a clinical endpoint as FDA has requested that the sample size of the study required to reach statistical significance is more than planned, which would increase our costs and harm our business. It is possible that, due to the planned change to a clinical endpoint, there may be delays in obtaining necessary ethics or FDA approval, or that the number of patients required to reach an interim endpoint increases. If either of the risks in the prior sentence were realized it may delay the timeline to reach an interim analysis, thereby harming our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the inability of a supplier to provide raw materials;
- equipment malfunctions or failures at the facilities of our collaborators or suppliers;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

State-specific regulatory activities may negatively affect our business.

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

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

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

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

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

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

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

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

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

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

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

- successfully and rapidly complete clinical trials for any product candidates and obtain all requisite regulatory approvals in a cost-effective manner;
- build an adequate sales and marketing infrastructure, raise additional funding, or enter into strategic transactions enabling the commercialization of our products;

- develop competitive formulations of our product candidates;
- attract and retain key personnel; and
- identify and obtain other product candidates on commercially reasonable terms.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our operations could be disrupted by geopolitical conditions, political and social instability, acts of war, terrorist activity or other similar events. In February 2022, Russia initiated significant military action against Ukraine. In response, the U.S. and certain other countries imposed significant sanctions and export controls against Russia, Belarus and certain individuals and entities connected to Russian or Belarusian political, business, and financial organizations, and the U.S. and certain other countries could impose further sanctions, trade restrictions, and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U.S. and other countries in respect thereof as well as any counter measures or retaliatory actions by Russia or Belarus in response, including, for example, potential cyberattacks or the disruption of energy exports, is likely to cause regional instability, geopolitical shifts, and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. In addition, the ongoing conflicts in the Middle East may further impact global economic conditions and market sentiments. This, in turn, could adversely affect the trading price of our shares of common stock and investor interest in us.

The Russia-Ukraine war and conflicts in the Middle East remain uncertain, and while it is difficult to predict the impact of any of the foregoing, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

We could be subject to lawsuits.

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

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

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

Risks Related to Intellectual Property and Other Legal Matters

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to this Offering

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

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

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

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

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

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

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

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

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

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

Existing stockholders may sell significant quantities of common stock.

The existing shareholders will own 52.48% of our common stock following the successful completion of this offering. Notwithstanding that certain of our officers and directors who are shareholders will be locked up for a period of six months, and any greater than 5% holders of our common stock will also be locked up for a period of six months, following the completion of this offering, our existing stockholders may have acquired their shares at a lower price than that of this offering. Accordingly, they may be incentivized to sell all or part of their holdings as soon as any applicable transfer restrictions have ended and such sales could have a negative impact on the market price of our common stock.

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

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

The requirements of being a public company.

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

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

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

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

Risks Relating to Ownership of Our Securities

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

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

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

We may not be able to maintain the listing of our common stock on Nasdaq, which could adversely affect our liquidity and the trading volume and market price of our common stock and decrease or eliminate your investment.

Our common stock is listed on Nasdaq. If we violate the maintenance requirements for continued listing of our common stock, our common stock may be delisted. On November 2, 2023, we received a letter from Nasdaq notifying us that we were no longer in compliance with the $1.00 minimum bid price requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5550(a)(2) the "Bid Price Rule"). Although Nasdaq informed us that we were again compliant with the Bid Price Rule on January 10, 2024, there can be no assurance that we will maintain compliance. Nasdaq could issue us another letter notifying us of our non-compliance if our shares of common stock trade less than $1.00 per share for 30 consecutive business days, and in that event, subsequently make a determination to delist our common stock if we fail to take appropriate action.

Nasdaq requires us to have, among other requirements, including the Bid Price Rule, a minimum amount of shareholders' equity of $2.5 million in order to maintain our listing. Currently, our adjusted, pro forma shareholders' equity is $6,516,250 as of September 30, 2023. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital. Also, our Board may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. An active trading market for our shares may never develop or be sustained.

Any delisting determination by Nasdaq could seriously decrease or eliminate the value of an investment in our common stock and other securities linked to our common stock. While a listing on an over-the-counter exchange could maintain some degree of a market in our common stock, we could face substantial material adverse consequences, including, but not limited to, the following: limited availability for market quotations for our common stock; reduced liquidity with respect to and decreased trading prices of our common stock; a determination that shares of our common stock are "penny stock" under the SEC rules, subjecting brokers trading our common stock to more stringent rules on disclosure and the class of investors to which the broker may sell the common stock; limited news and analyst coverage for our Company, in part due to the "penny stock" rules; decreased ability to issue additional securities or obtain additional financing in the future; and potential breaches under or terminations of our agreements with current or prospective large stockholders, strategic investors and banks. The perception among investors that we are at heightened risk of delisting could also negatively affect the market price of our securities and trading volume of our common stock.

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

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

There is no public market for the Warrants and Pre-Funded Warrants.

There is no public trading market for the Warrants and Pre-Funded Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to list the Warrants and the Pre-Funded Warrants on The Nasdaq Capital Market or any other national securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the Warrants and the Pre-Funded Warrants will be limited.

Holders of the Warrants and the Pre-Funded Warrants will have no rights as holders of common stock until they exercise their Warrants or Pre-Funded Warrants and acquire common stock.

The Warrants offered in this offering do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Until holders of warrants acquire shares of common stock upon exercise of the warrants, holders of the warrants will have no rights with respect to the shares of our common stock issuable upon exercise of such warrants. Specifically, commencing on the date of issuance, holders of the Warrants may exercise their right to acquire the common stock and pay an exercise price of $0.4235 per share (110% of the offering price per Unit), from time to time, until the fifth anniversary from the date of issuance, after which date any unexercised Warrants will expire and have no further value. Holders of the Pre-Funded Warrants may exercise their right to acquire the common stock and pay an exercise price of $0.01 per share, from time to time, until all of the Pre-Funded Warrants have been exercised. In addition, there is no established trading market for the Warrants and Pre-Funded Warrants. Upon exercise of the warrants, the holders thereof will be entitled to exercise the rights of a holder of Common Stock only as to matters for which the record date occurs after the exercise date.

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

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

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

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

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

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

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

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

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

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

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

We will not receive any meaningful amount of additional funds upon the exercise of the Pre-Funded Warrants.

Each Pre-Funded Warrant will be exercisable and will have no expiration date and by means of payment of the nominal cash purchase price upon exercise. Accordingly, we will not receive any or any meaningful additional funds upon the exercise of the Pre-Funded Warrants.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

USE OF PROCEEDS

We will receive net proceeds of approximately $1,852,090 (or approximately $2,186,400 if the Over-Allotment Option is exercised in full) based on a public offering price of $0.385 per Unit and $0.375 per Pre-Funded Unit (assuming that none of the Pre-Funded Warrants and Warrants issued in this offering are exercised), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses of approximately $548,010 payable by us (or approximately $583,100 if the Over-Allotment Option is exercised in full).

The principal purposes of this offering are to increase our capitalization and financial flexibility. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering.

We plan to "relaunch" Arakoda for malaria prevention in the U.S. later in 2024. $500,000 from this offering will be utilized to prepare for that relaunch.

We plan to dedicate $1,250,000 to activities related to execution of a pivotal clinical study of tafenoquine for babesiosis.

We plan to dedicate $160,000 to conduct additional research and development activities including execution of animal studies to further evaluate the activities of Tafenoquine against *Candida* and canine babesiosis.

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

Description	Amount
Working Capital and General Corporate Purposes	$ 384,250
"Relaunch" Preparations for Arakoda	$ 384,250
Research and Development (clinical trials and related activities)	$ 1,083,590
Total	$ 1,852,090

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

DIVIDEND POLICY

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

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock and tradeable warrants are listed on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively. As of January 29, 2024, 5,810,089 shares of our common stock were issued and outstanding and were held by 15 stockholders of record. As of January 29, 2024, we have issued tradeable warrants to purchase up to 1,422,739 shares of our common stock at an exercise price equal to $6.095 per share.

We also have outstanding:

- 78,803 shares of Series A Preferred Stock;
- Representative warrants to purchase up to 84,906 shares of our common stock at an exercise price equal to $5.83 per share issued to our underwriters in our initial public offering;
- Non-tradeable warrants issued in our initial public offering to purchase up to 1,455,739 shares of our common stock at a weighted average exercise price of $6.36 per share;
- Warrants to purchase up to 120,544 shares of our common stock at an exercise price of $5.83 per share;
- Warrants to purchase up to 79,926 shares of our common stock at an exercise price of $4.77 per share issued to related parties;
- Options to purchase up to 807,924 shares of common stock at a weighted average exercise price of $1.36 per share; and
- Restricted stock units related to 272,000 shares of our common stock, a portion of which are fully vested, of which 256,000 shares of common stock are underlying the vested restricted stock units, and the remaining portion of which are not fully vested.

CAPITALIZATION

The following table sets forth our consolidated cash and capitalization, as of September 30, 2023. Such information is set forth on the following basis:

- on an actual basis;
- on a pro forma basis to reflect shares of common stock issued after September 30, 2023 and prior to the date of this prospectus;
- on a pro forma as adjusted basis to reflect the pro forma adjustments discussed in the prior bullet and our receipt of the net proceeds from our sale and issuance of 5,260,901 Units in this offering at an offering price of $0.3850 per Unit and 999,076 Pre-Funded Units in this offering at a public offering price of $0.3750 per Pre-Funded Unit (assuming that none of the Pre-Funded Warrants and Warrants issued in this offering are exercised and no exercise of the over-allotment option), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and after the use of net proceeds therefrom.

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

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

	Actual[1]	Pro Forma[2]	Pro forma, as adjusted[3]
Cash	$ 2,218,540	$ 2,218,540	$ 4,070,630
Total Assets	$ 9,150,212	$ 9,150,212	$ 11,002,302
Total Current Liabilities	2,481,368	2,441,368	2,441,368
Total Long-Term Liabilities	$ 152,594	$ 152,594	$ 152,594
Shareholders' equity:			
Common stock, $0.0001 par value, 150,000,000 shares authorized, 5,799,535 shares issued and outstanding, actual; 150,000,000 shares authorized, 5,810,089 shares issued and outstanding, pro forma; and 150,000,000 shares authorized, 11,070,990 shares issued and outstanding, pro forma as adjusted.	580	581	1,107
Preferred stock, $0.0001 par value, 1,000,000 shares authorized, 78,803 shares issued and outstanding, actual; 1,000,000 shares authorized, 78,803 shares issued and outstanding, pro forma; and 1,000,000 shares authorized, 78,803 shares issued and outstanding, pro forma as adjusted.	9,858,040	9,858,040	9,858,040
Additional Paid-in Capital	27,182,915	27,222,914	29,074,478
Accumulated Deficit	(30,568,566)	(30,568,566)	(30,568,566)
Total Shareholders' Equity	6,516,250	6,556,250	8,408,340
Total Capitalization	$ 9,150,212	$ 9,150,212	$ 11,002,302

(1) As of September 30, 2023.

(2) The number of issued and outstanding shares as of September 30, 2023 on a pro forma basis includes the issuance of 10,554 shares of our common stock in December 2023 as required by the terms of the investment relations consulting agreement with Red Chip.

(3) The number of issued and outstanding shares as of September 30, 2023 on a pro forma as adjusted basis reflects the pro forma adjustments discussed in footnote (2) above and our receipt of the net proceeds of approximately $1,852,090 resulting from our sale and issuance of 5,260,901 Units at an offering price of $0.385 per Unit and 999,076 Pre-Funded Units at an offering price of $0.375 per share for total gross proceeds of $2,400,100, after deducting $548,010 of underwriting discounts and commissions and estimated offering expenses payable by us.

The foregoing table and calculations exclude:

- 3,163,854 shares of common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of $6.17 per share;
- 807,924 shares of common stock issuable upon the exercise of outstanding options to purchase common stock at a weighted average exercise price of $1.36 per share;
- 256,000 shares of common stock issuable pursuant to fully vested restricted stock units which have not yet been issued as of the date of this prospectus;
- 16,000 shares of common stock issuable upon the future vesting of outstanding restricted stock units;
- 315,655 shares of common stock issuable upon exercise of the Representative Warrants at an exercise price equal to 110% of the public offering price of the Units; and
- shares of common stock issuable upon the conversion of 78,803 shares of Series A Preferred Stock.

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

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

Overview

We specialize in the cost-effective development and commercialization of small molecule therapeutics for infectious diseases. We have a single FDA-approved product Arakoda, for malaria prevention in travelers. This product is revenue-generating in the United States and foreign markets, but not yet profitable, primarily due to the lack of an active marketing campaign following its introduction into the U.S. supply chain in late 2019. The COVID-19 pandemic curtailed foreign travel and therefore any ability to raise financing to support an active marketing effort. We believe that the pathway to profitability lies through future investment in an active marketing program and recruitment of a direct sales force to support Arakoda. However, the return on investment for such an effort is likely to be much greater if it can be shown that the pool of potential prescriptions/patients is larger than that for malaria prevention alone. To that end, our primary operational goal is to demonstrate the clinical effectiveness of the already approved dosing regimen of Arakoda in other disease states. Thus, in 2024, our focus will be on executing a Phase II clinical investigation of the efficacy of Arakoda in hospitalized babesiosis patients, and conducting preparatory activities for "relaunch" of Arakoda for malaria prevention. Other supporting activities referenced below and elsewhere in this prospectus, such as improving technical specifications, portfolio development, and support for our overseas distribution partners, will be conducted as resources permit.

Key Factors Affecting our Performance

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

Known Trends and Uncertainties

Inflation

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

Supply Chain

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

Geopolitical Conditions

In February 2022, Russia initiated significant military action against Ukraine. In response, the U.S. and certain other countries imposed significant sanctions and export controls against Russia, Belarus and certain individuals and entities connected to Russian or Belarusian political, business, and financial organizations, and the U.S. and certain other countries could impose further sanctions, trade restrictions, and other retaliatory actions should the conflict continue or worsen. Further, since October 2023, there have been ongoing conflicts in the Middle East. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U.S. and other countries in respect thereof as well as any counter measures or retaliatory actions in response, including, for example, potential cyberattacks or the disruption of energy exports, is likely to cause regional instability, geopolitical shifts, and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. The situation remains uncertain, and while it is difficult to predict the impact of any of the foregoing, the conflict and actions taken in response to the conflict could increase our costs, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

Effects of the COVID-19 Pandemic

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

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

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

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

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

Seasonality

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

Foreign Currency

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

Concentration of Revenues

We received the majority of our revenues from sales of our Arakoda product to the DoD. The DoD has historically been our largest customer. Upon fulfilment of the final purchase of product under the contract, which expired on August 31, 2022, the DoD has not issued any further contracts nor contract modifications to allow additional procurement and, absent events or changes that may not occur and that outside of our control, may never matter. Further information is provided in the "*Product Revenues - net of Discounts and Rebates, Cost of Revenues, Gross Loss, and Gross Margin*" section below. Revenues remain concentrated. The following tables set forth our concentrations of product revenues – net of discounts and rebates for the nine months ended September 30, 2023 and 2022 and the twelve months ended December 31, 2022 and 2021.

Nine Months Ended September 30, 2023, and 2022

Customers (Market)	9/30/2023	9/30/2022	$ Change	% Change
Biocelect (Australia)	$ 54,166	$ 87,840	$ (33,674)	(38)%
ICS AmerisourceBergen (US Commercial)	73,726	154,542	(80,816)	(52)
Scandinavian Biopharma Distribution AB (European Union)	-	18,000	(18,000)	(100)
Product revenues – net of discounts and rebates	$ 127,892	$ 260,382	$ (132,490)	(51)%

Twelve Months Ended December 31, 2022, and 2021

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

Results of Operations

Nine Months Ended September 30, 2023, and 2022

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

	Nine Months Ended September 30,	
Consolidated Statements of Operations Data:	**2023**	**2022**
Product revenues – net of discounts and rebates	$ 127,892	$ 260,382
Cost of revenues	328,293	269,535
Gross loss	(200,401)	(9,153)
Research revenues	82,974	259,669
Net (loss) revenue	(117,427)	250,516
Operating expenses:		
Research and development	591,569	322,106
General and administrative expenses	2,551,426	994,157
Total operating expenses	3,142,995	1,316,263
Loss from operations	(3,260,422)	(1,065,747)
Interest and other income (expense), net:		
Interest expense	(2,281,191)	(2,883,714)
Derivative Expense	(399,725)	(504,613)
Change in fair value of derivative liabilities	95,324	(23,496)
Loss on debt extinguishment	(1,231,480)	-
Change in fair value of promissory note	5,379,269	-
Other income	(69,169)	(29,810)
Total interest and other income (expense), net	1,493,028	(3,441,633)
Loss from operations before provision for income taxes	(1,767,394)	(4,507,380)
Provision for income taxes	189	750
Net loss including noncontrolling interest	(1,767,583)	(4,508,130)
Net loss noncontrolling interest	(14,165)	(1,454)
Net loss - attributed to 60 Degrees Pharmaceuticals Inc	(1,753,418)	(4,506,676)
Comprehensive loss:		
Net loss	(1,767,583)	(4,508,130)
Unrealized foreign currency translation gain (loss)	7,678	(20,850)
Total comprehensive loss	(1,759,905)	(4,528,980)
Net loss – noncontrolling interest	(14,165)	(1,454)
Unrealized foreign currency translation loss from noncontrolling interest	-	(544)
Comprehensive loss - attributed to 60 Degrees Pharmaceuticals, Inc.	$ (1,745,740)	$ (4,526,982)

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

	Nine Months Ended September 30,	
Consolidated Statements of Operations Data:	**2023**	**2022**
Product revenues – net of discounts and rebates	100.00%	100.00%
Cost of revenues	256.70	103.52
Gross loss	(156.70)	(3.52)
Research revenues	64.88	99.73
Net (loss) revenue	(91.82)	96.21
Operating expenses:		
Research and development	462.55	123.71
General and administrative expenses	1,994.99	381.80
Total operating expenses	2,457.54	505.51
Loss from operations	(2,549.36)	(409.30)
Interest and other income (expense), net:		
Interest expense	(1,783.69)	(1,107.49)
Derivative Expense	(312.55)	(193.80)
Change in fair value of derivative liabilities	74.53	(9.02)
Loss on debt extinguishment	(962.91)	-
Change in fair value of promissory note	4,206.12	-
Other income	(54.08)	(11.45)
Total interest and other income (expense), net	1,167.42	(1,321.76)
Loss from operations before provision for income taxes	(1,381.94)	(1,731.06)
Provision for income taxes	0.15	0.29
Net loss including noncontrolling interest	(1,382.09)	(1,731.35)
Net loss noncontrolling interest	(11.08)	(0.56)
Net loss - attributed to 60 Degrees Pharmaceuticals, Inc.	(1,371.01)	(1,730.79)
Comprehensive loss:		
Net loss	(1,382.09)	(1,731.35)
Unrealized foreign currency translation gain (loss)	6.00	(8.01)
Total comprehensive loss	(1,376.09)	(1,739.36)
Net loss – noncontrolling interest	(11.08)	(0.56)
Unrealized foreign currency translation loss from noncontrolling interest	0.00	(0.21)
Comprehensive loss - attributed to 60 Degrees Pharmaceuticals, Inc.	(1,365.01)%	(1,738.59)%

Comparison of the Nine Months Ended September 30, 2023 and 2022

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

	Nine Months Ended September 30,		$	%
	2023	2022	Change	Change
Product revenues – net of discounts and rebates	$ 127,892	$ 260,382	$ (132,490)	(50.88)%
Cost of revenues	328,293	269,535	(58,758)	21.80
Gross loss	$ (200,401)	$ (9,153)	$ (191,248)	(2,089.46)%
Gross margin	(156.70)%	(3.52)%		

Product Revenues - net of Discounts and Rebates

Our product revenues – net of discounts and rebates were $127,892 for the nine months ended September 30, 2023, as compared to $260,382 for the nine months ended September 30, 2022. For the nine months ended September 30, 2023, our Australian distributor accounted for 0% (34% for the nine months ended September 30, 2022), and our U.S. distributor accounted for 100% of our total net product sales (59% for the nine months ended September 30, 2022). While our domestic sales volume increased over the same periods, the decrease is due to a reduction in international sales from $105,840 to none.

For the nine months ended September 30, 2023, discounts and rebates were $124,090 compared to $38,478 for the nine months ended September 30, 2022. This reflects both greater sales volume and the new contract with our 3PL partner at the beginning of 2023 in which both the percentage and fixed fee rebates increased.

Arakoda entered the U.S. civilian supply chain in the third quarter of 2019. For the nine months ended September 30, 2022, 386 boxes were sold to pharmacies and dispensaries. Sales volume increased 174% to 1,059 boxes to pharmacies and dispensaries for the nine months ended September 30, 2023. The increase in commercial sales volume reflects the response to the reduction of our 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.

Kodatef sales to our distributor Biocelect in Australia for the nine months ended September 30, 2023 were none ($87,840 for the nine months ended September 30, 2022). Sales to Biocelect are currently subject to a profit share distribution once the original transfer price has been recouped. As of September 30, 2023, $54,166 was paid ($0 for the nine months ended September 30, 2022).

During the first nine months of 2022, we recorded our first sale of Arakoda/Kodatef to our European distributor Scandinavian Biopharma Distribution AB. We did not record sales of Arakoda/Kodatef to the distributor during the first nine months of 2023. Product will be distributed there on a named patient basis. As in Australia a profit distribution share is possible depending on the retail price established.

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

The cost of goods sold was $328,293 for the nine months ended September 30, 2023, as compared to $269,535 for the nine months ended September 30, 2022. The increase in cost of goods sold is primarily due to a greater allowance for expiring inventory. The Gross Margin % fell to (156.70)% for the nine months ended September 30, 2023 from (3.52)% for the nine months ended September 30, 2022. This is partially due to the fixed part of cost of goods. As the sales volume continues to grow the gross margin will improve as the variable cost of goods of each unit sold is substantially less than the sales price. However, right now the allowance required for expiring inventory provides the largest negative impact to Gross Margin.

Other Operating Revenues

	Nine Months Ended September 30,		$	%
	2023	2022	Change	Change
Research revenues	$ 82,974	$ 259,669	$ (176,695)	(68.05)%

The research revenues earned by us were $82,974 for the nine months ended September 30, 2023, as compared to $259,669 for the nine months ended September 30, 2022. Our research revenues have historically been derived mostly from a single, awarded research grant in the amount of $4,999,814 at the beginning of December 2020 (with an additional $720,000 awarded in February of 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. We also earn research revenues from the Australian Tax Authority for research activities conducted in Australia. The research rebate revenue was $82,974 for the nine months ended September 30, 2023 compared to $14,499 during the nine months ended September 30, 2022.

Operating Expenses

	Nine Months Ended September 30,		$	%
	2023	2022	Change	Change
Research and development	$ 591,569	$ 322,106	$ 269,463	83.66%
General and administrative	2,551,426	994,157	1,557,269	156.64
Total operating expenses	$ 3,142,995	$ 1,316,263	$ 1,826,732	138.78%

Research and Development

Research and development costs increased during the nine months ended September 30, 2023 when compared to the nine months ended September 30, 2022. Research and development costs incurred during the nine months ended September 30, 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 nine months ended September 30, 2023, we incurred initial costs related to our Phase II B clinical trial, which has now been halted. Direct COVID-19-related trial costs are 85% of the costs for the nine months ended September 30, 2023 at $504,711 and 49% of the costs for the nine months ended September 30, 2022 at $157,892.

General and Administrative

For the nine months ended September 30, 2023, our general and administrative expenses increased by 156.64% or $1,557,269 over the nine months ended September 30, 2022. During the nine months ended September 30, 2023 we spent substantially more for legal, accounting and audit fees at $669,010 (up from $186,280 for the nine months ended September 30, 2022). Additionally, during the nine months ended September 30, 2023, we incurred $417,620 of investor outreach expenses, $458,266 of stock-based compensation expense, $64,280 of advertising and promotion expenses, and $198,618 of pharmacovigilance monitoring costs (up from $10,100, $155,000, $5,731, and $48,000 for the nine months ended September 30, 2022, respectively). A going public and a public company are both more expensive than a private company in terms of operating costs and this is reflected in the changes above. For example there is now a board expense when previously there was none. Additionally, some of the increase is non-cash related including the stock-based compensation expense and the pharmacovigilance costs which were paid via share issuance in 2023 vs cash in 2022. However, we anticipate continued higher professional fees as a public company that is undertaking additional funding in the capital markets.

Interest and Other Income (Expense), Net

	Nine Months Ended September 30,		$	%
	2023	2022	Change	Change
Interest expense	$ (2,281,191)	$ (2,883,714)	$ 602,523	(20.89)%
Derivative expense	(399,725)	(504,613)	104,888	(20.79)
Change in fair value of derivative liabilities	95,324	(23,496)	118,820	(505.70)
Loss on debt extinguishment	(1,231,480)	-	(1,231,480)	NA
Change in fair value of promissory note	5,379,269	-	5,379,269	NA
Other expense	(69,169)	(29,810)	(39,359)	132.03
Total Interest and Other Income (Expense), Net	$ 1,493,028	$ (3,441,633)	$ 4,934,661	(143.38)%

Interest Expense

For the nine months ended September 30, 2023, we recognized $2,281,191 of interest expense ($2,883,714 for the nine months ended September 30, 2022). The decrease in interest expense is the result of the settlement or conversion of our outstanding debt obligations upon the closing of our initial public offering on July 14, 2023. Cash paid for interest expense was $176,924 and $731 for the nine months ended September 30, 2023 and September 30, 2022, respectively.

Derivative Expense

For the nine months ended September 30, 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 nine months ended September 30, 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 cash proceeds received.

Change in Fair Value of Derivative Liabilities

For the nine months ended September 30, 2023, we recognized a net change in fair value of derivative liabilities of $95,324 and ($23,496) for the nine months ended September 30, 2022.

Loss on debt extinguishment

For the nine months ended September 30, 2023, we recognized a $1,231,480 net loss on debt extinguishment (none for the nine months ended September 30, 2022). The increase is related, in part to the conversion of the cumulative outstanding debt pursuant to the Knight Debt Conversion Agreement in January 2023, which was accounted for as a debt extinguishment, 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 nine months ended September 30, 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 nine months ended September 30, 2023, we recognized a $5,379,269 gain related to the net change in fair value of the Convertible Knight Loan from the modification date in January 2023 to the conversion of the outstanding debt obligation into our equity shares upon the closing of our initial public offering on July 14, 2023. 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 nine months ended September 30, 2022.

Other Income (Expense), Net

For the nine months ended September 30, 2023, we recognized $69,169 in other expense compared to $29,810 for the nine months ended September 30, 2022. For the nine months ended September 30, 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.

Twelve Months Ended December 31, 2022, and 2021

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

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

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

	Twelve Months Ended December 31,	
Consolidated Statements of Operations Data:	**2022**	**2021**
Product revenues – net of discounts and rebates	86.43%	92.94%
Service revenues	13.57	7.06
Product and service revenues	100.00	100.00
Cost of revenues	193.71	73.32
Gross (loss) profit	(93.71)	26.68
Research revenues	129.03	447.50
Net revenue	35.32	474.18
Operating expenses:		
Research and development	235.46	474.94
General and administrative expenses	584.08	96.12
Total operating expenses	819.54	571.06
Loss from operations	(784.22)	(96.88)
Interest and other income (expense), net:		
Interest expense	(1,787.28)	(273.43)
Derivative expense	(226.07)	-
Change in fair value of derivative liabilities	(4.62)	-
Gain on debt extinguishment	54.07	-
Other income (expense)	(19.37)	3.23
Total interest and other income (expense), net	(1,983.27)	(270.20)
Loss from operations before provision for income taxes	(2,767.49)	(367.08)
Provision for income taxes	0.22	0.09
Net loss including noncontrolling interest	(2,767.71)	(367.17)
Net gain (loss) - noncontrolling interest	1.76	(0.74)
Net loss – attributable to 60 Degrees Pharmaceuticals, Inc.	(2,769.47)	(366.43)
Comprehensive loss:		
Net loss including noncontrolling interest	(2,767.71)	(367.17)
Unrealized foreign currency translation loss	(0.95)	(0.26)
Total comprehensive loss	(2,768.66)	(367.43)
Net gain (loss) – noncontrolling interest	1.76	(0.74)
Unrealized foreign currency translation gain from noncontrolling interest	-	0.14
Comprehensive loss - attributed to 60 Degrees Pharmaceuticals, Inc.	(2,770.42)%	(366.83)%

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

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

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

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

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

We offer discounts and rebates to the civilian U.S. supply chain distribution channel. We record sales when our third-party logistics ("3PL") partner transfers boxes into their title model. Discounts and rebates are offered to our 3PL partner amounting to 2%. Then product is transferred normally to one of the three large U.S. pharmaceutical distributors where rebates range form 10-15%. Lastly, we have relationships with several large pharmacy benefit managers ("PBMs") that allows patients to purchase Arakoda at a discount. The rebate associated with PBMs ranges from 15% to 39.75% depending on the amount of coverage provided. For the twelve months ending December 31, 2022, discounts and rebates were $59,552 compared to none for the twelve months ending December 31, 2021. There were neither discounts nor rebates on direct sales to USAMMDA.

Although, as of the date of this prospectus, we are not in discussions with the DoD about additional/future procurement, we anticipate that if certain conditions/events described in this paragraph occur, our sales to DoD could develop; however, there is no assurance that such conditions/events will occur. First, the position of Arakoda in the DoD formulary (Tricare, deployed personnel) needs to be improved from second/third tier to at least equivalency with competing products (as is the case for civilian use as recommended by the CDC). We believe that changes in pricing or reimbursement structure may be needed to secure that. Second, the shelf-life of the existing product requires extension, which is known to be technically possible as the shelf-life of Kodatef in Australia is 48 months, but appropriate data must be generated to meet FDA requirements. Finally, a change in the operational footprint of DoD deployments to areas with higher malaria attack rates (e.g., the Liberia deployment to manage the Ebola outbreak in 2014) may lead to a rapid reassessment by DoD of the position of Arakoda in the formulary (advancement of the last approved prophylactic antimalarial to co-equal standard of care took thirteen years). If none of these events transpire, we would not have the opportunity for revenues and such failure would jeopardize our business.

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

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

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

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

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

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

Other Operating Revenues

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

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

Operating Expenses

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

Research and Development Expenses

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

General and Administrative Expenses

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

Interest and Other Income (Expense), Net

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

Interest Expense

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

Derivative Expense

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

Change in Fair Value of Derivative Liabilities

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

Gain on debt extinguishment

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

Other Income (Expense), Net

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

Liquidity and Capital Resources

For the nine months ended September 30, 2023 and 2022, our net cash used in operating activities was $4,479,242 and $944,033, respectively and the cash balance was $2,218,540 as of September 30, 2023 ($264,865 as of December 31, 2022). Based on current internal projections, and assuming we receive the full proceeds from this offering as planned, and that no funds are obtained from warrant exercise, we will have sufficient funds to remain viable through August 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.

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

Going Concern

As of September 30, 2023, we had an accumulated deficit of $30,568,566. In their audit report for the fiscal year ended December 31, 2022, 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 twelve months ended December 31, 2022, and December 31, 2021, respectively, included an explanatory note referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. The accompanying consolidated condensed financial statements were prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. To date, we have not yet established an ongoing source of revenues and cash flows sufficient to cover our operating costs and allow us to continue as a going concern. These factors among others raise substantial doubt about our ability to continue as a going concern for at least one year from the date of issuance of the accompanying consolidated condensed financial statements.

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

Borrowings

Since December 10, 2015, we have financed our operations in part through borrowings. The below information is intended to summarize the history of our borrowings, and provisions for debt settlement. As of the date of this prospectus, the only outstanding debt was the SBA loan. The Company retains certain obligations to Knight as conditions of debt extinguishment as described herein.

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

Pursuant to the Knight Debt Conversion Agreement, executed January 9, 2023 and modified on January 13, 2023, and again on January 27, 2023, Knight and us agreed, to:

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

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

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

On July 14, 2023, the Knight debt was extinguished, and Knight was issued preferred and common shares in accordance with the debt conversion agreement. There remains a commitment to pay a milestone fee of $10,000,000 in the event of a change of control, certain royalties on Arakoda and to negotiate a services contract per the terms of the Knight conversion agreement and amendments as described above.

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

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

The extinguishment accounting resulted in a fair value of the Avante Note, including the Amendment of $1,099,578. The discount of $120,683 and costs incurred with third parties directly related to the Amendment of $1,767 was amortized over the remaining life of the debt using the effective interest method. Amortization of the discount on the Avante Note, including the Amendment for the year ended December 31, 2022 was $4,955 ($0 in 2021). Interest expense related to the Note, including the Amendment, for the year ended December 31, 2022 was $115,546 ($104,558 in 2021). Interest expense related to the Note, for the nine months ended September 30, 2023 and September 30, 2022 was $66,558 and $85,242, respectively.

On July 14, 2023, the Avante note was extinguished, and common shares were issued to Xu Yu in accordance with the conversion provisions of the note.

On May 14, 2020, we issued the note to the U.S. Small Business Administration with a principal amount of $150,000 and a per annum interest rate of 3.75%. The current outstanding balance of the COVID-19 Loan is $161,366 as of September 30, 2023.

On May 19, 2022, we issued a Convertible Promissory Note to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 (the "Geoffrey Dow Trust Note"), in the amount of $44,444.44 and a per annum interest rate of 6%. Immediately prior to the closing of our initial public offering, the balance of such note converted into shares of common stock at a price equal to 80% of $5.30.

On May 19, 2022, we issued a Convertible Promissory Note to Mountjoy Trust in the amount of $294,444.42 and a per annum interest rate of 6%. Immediately prior to the closing of our initial public offering, the balance of such note converted into shares of common stock at a price equal to 80% of $5.30.

On May 24, 2022, we issued a note in the amount of $333,333.30 to Bigger Capital Fund, LP. On the date of the pricing of our initial public offering, we delivered to Bigger Capital Fund, LP shares of our common stock based on the offering price of $5.30.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Cavalry Investment Fund, LP. On the date of the pricing of our initial public offering, we delivered to Cavalry Investment Fund, LP shares of our common stock based on the offering price of $5.30.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Walleye Opportunities Master Fund Ltd. On the date of the pricing of our initial public offering, we delivered to Walleye Opportunities Master Fund Ltd shares of our common stock equal to the number of shares of our common stock based on the offering price of $5.30.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Cyberbahn Federal Solutions, LLC with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Cyberbahn Federal Solutions, LLC shares of our common stock based on the offering price of $5.30.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Ariana Bakery Inc with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Ariana Bakery Inc shares of our common stock equal to the number of shares of our common stock based on the offering price of $5.30.

On May 8, 2023, we issued a note in the amount of $333,333.30 to Sabby Volatility Warrant Master Fund, Ltd. with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Sabby Volatility Warrant Master Fund, Ltd. shares of our common stock equal to the number of shares of our common stock based on the offering price of $5.30.

On May 8, 2023, we issued a note in the amount of $55,555.55 to Steel Anderson with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Steel Anderson shares of our common stock equal to the number of shares of our common stock based on the offering price of $5.30.

On May 8, 2023, we issued a note in the amount of $111,111.10 to Bixi Gao & Ling Ling Wang with a 10% original issue discount. On the date of the pricing of our initial public offering, we delivered to Bixi Gao & Ling Ling Wang shares of our common stock equal to the number of shares of our common stock based on the offering price of $5.30.

Contractual Obligations

The following table summarizes our contractual obligations as of September 30, 2023:

	Payments Due By Period				
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Principal obligations on the debt arrangements	$ 150,000	$ -	$ 1,990	$ 6,731	$ 141,279
Interest obligations on the debt arrangements	116,230	8,772	24,326	10,813	72,319
Operating leases	26,800	26,800	-	-	-
Purchase obligations	271,602	271,602	-	-	-
Total	$ 564,632	$ 307,174	$ 26,316	$ 17,544	$ 213,598

Cash Flows

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

Nine Months Ended September 30, 2023, and 2022

	Nine Months Ended September 30,		$	%
	2023	2022	Change	Change
Net cash (used in) provided by:				
Operating activities	$ (4,479,242)	$ (944,003)	$ (3,535,239)	374%
Investing activities	(49,326)	(1,488)	(47,838)	3.215
Financing activities	6,474,565	1,290,335	5,184,230	402
Effect of foreign currency translation on cash flow	7,678	(20,850)	28,528	(137)
Net increase (decrease) in cash and cash equivalents	$ 1,953,675	$ 323,994	$ 1,629,681	503%

Cash Used in Operating Activities

Net cash used in operating activities was $4,479,242 for the nine months ended September 30, 2023, as compared to $944,003 for the nine months ended September 30, 2022. Our net cash used in operating activities increased as a result of higher legal, accounting, and auditing fees totaling $669,010 and investor outreach expenses of $417,620 during the nine months ended September 30, 2023 ($186,268 and $10,100 for the nine months ended September 30, 2022, respectively). In addition, in August 2023 our subsidiary 60P Australia Pty Ltd. incurred start-up costs to open the first three clinical sites for its now halted COVID-19-Tafenoquine Phase IIB treatment study.

Cash Used in Investing Activities

Net cash used in investing activities was $49,326 for the nine months ended September 30, 2023, as compared to $1,488 for the nine months ended September 30, 2022. The increase in net cash used in investing activities was due to higher costs paid for the acquisition of patents ($29,220 and $1,488 for the nine months ended September 30, 2023 and 2022, respectively), and higher cash paid for capitalized website development costs ($18,283 and $0 for the nine months ended September 30, 2023 and 2022, respectively).

Cash Provided by Financing Activities

Net cash provided by financing activities was $6,474,565 for the nine months ended September 30, 2023, as compared to $1,290,335 for the nine months ended September 30, 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.

Effect of foreign currency translation on cash flow

Our foreign operations were small relative to U.S. operations for the nine months ended September 30, 2023 and September 30, 2022, thus effects of foreign currency translation have been minor.

Twelve Months Ended December 31, 2022, and 2021

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

Cash Used in Operating Activities

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

Cash Used in Investing Activities

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

Cash Provided by Financing Activities

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

Effect of foreign currency translation on cash flow

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

Critical Accounting Policies, Significant Judgments, and Use of Estimates

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

Use of Estimates

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

Revenue Recognition

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

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

Derivative Liabilities

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

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

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

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

Original Issue Discount

For certain notes issued, we may provided the debt holder with an original issue discount. The original issue discount was recorded as a debt discount, reducing the face amount of the note, and was amortized to interest expense over the life of the debt.

Debt Issuance Cost

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

Income Taxes

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

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

Off-Balance Sheet Arrangements

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

JOBS Act Accounting Election

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

Recent Accounting Pronouncements

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

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

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

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

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

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.

Mission

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

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 US sales of Arakoda (not excluding returns) to pharmacies and other outlets was 1,633 boxes (a gross value of $383,755 at a WAC price of $235 per box), a substantial increase from the 572 boxes of Arakoda sold in 2022. Following this offering, targeted marketing efforts will commence to promote the malaria indication as described herein. We are continuing 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.[29] Approximately 650 of these cases are hospitalizations.[30] 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.[31] 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.[32] 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.[33] 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%).[34] 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.

- 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.[35] 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.

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29 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).

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

31 According to IDSA guidelines.

32 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.

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

34 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).

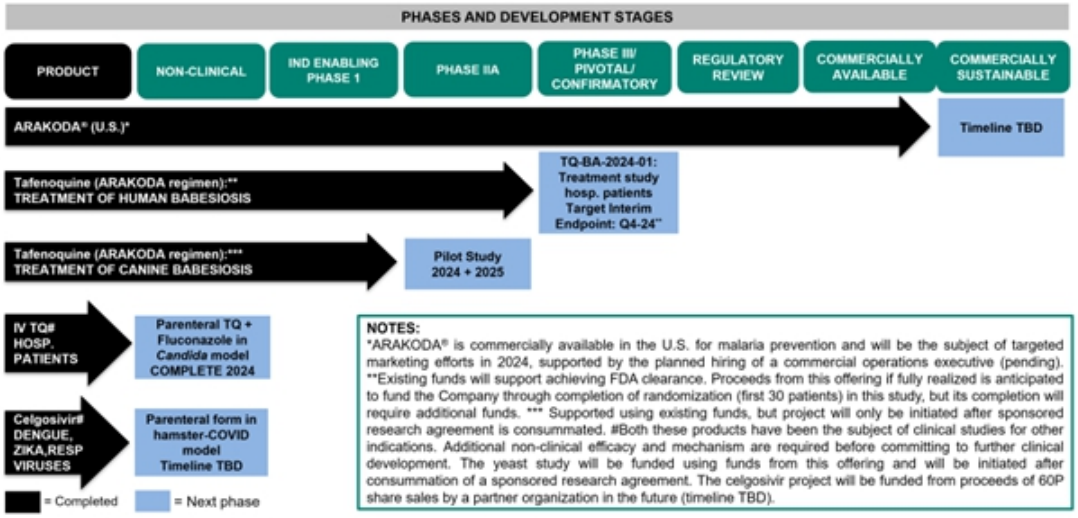
35 https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html.; https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html.

- 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.[36] 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.[37] 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)[38] 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.[39] As outlined in the "*Strategy*" section below, we expect to evaluate Celgosivir in additional non-clinical disease models before making a decision regarding clinical development.

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

Figure A



Products

Arakoda (Tafenoquine) for malaria prevention

We entered into a cooperative research and development agreement with the United States Army in 2014 to complete development of Arakoda for prevention of malaria.[40] 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.[41]

36 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.

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

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

39 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.

40 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.

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

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.[42] Tafenoquine entered the commercial supply chains in the U.S. (as Arakoda) and Australia (as Kodatef) in the third quarter of 2019.

The only limitation of Arakoda is the requirement for a G6PD test prior to administration.[43] 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.[44] 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.[45] Our work followed Legacy Studies that show Tafenoquine is effective for treatment and prevention of *Pneumocystis* pneumonia in animal models.[46] 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.[47] 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.[48] 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.[49] 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).[50] This observation led to the filing and approval of a patent related to Dengue, which we licensed from the National University of Singapore.

42 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.

43 See prescribing information at www.arakoda.com.

44 See prescribing information at www.arakoda.com.

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

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

47 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.

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

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

50 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. Following this offering, and depending on net proceeds, we may hire a new Chief Commercial Officer to lead our commercial effort to reintroduce Arakoda for malaria prevention. Prior to implementation of any marketing initiatives, we will conduct the following research and planning activities to be completed in the first half of 2024.

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

Repositioning of Arakoda Relative to Atovaquone-Proguanil. Market research will be conducted to determine whether current pricing and contractual relationships with pharmacy benefit managers ("PBMS") allow optimal positioning of Arakoda relative to its main competitor or require adjustment. 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 the 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 key marketing messages and materials. Our Arakoda website will be revamped 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.[51] 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.[52] 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.

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 17th, 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 are discussing, with a prominent U.S. university, a plan to support a pilot study of Tafenoquine for treatment of canine babesiosis in the United States under a sponsored research program. Should this potential collaboration be successful, we believe that the data from that study may provide supportive data for the clinical babesiosis development program, and could provide proof of concept for an expanded study to prove utility for veterinary indications.

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 may be conducted under a (pending) sponsored research agreement with a prominent international research university that we are currently pursuing.

51 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

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

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 a hamster-COVID-19 model to evaluate whether parenterally administered castanospermine can ameliorate the pathological effects of SARS CoV-2 via modulation of cytokine response to infection. Following this offering this project will be added to our statement of work for our services agreement with FSURF, and will commence when there is 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.[53] 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 this offering to be expended on such a pediatric study will be limited to the minimum required to support protocol preparation and regulatory interactions with the FDA.

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

Potential In licensing Activities

We may, following this offering, 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

We plan to raise up to $3 million in this financing. If insufficient funds are realized, we intend to raise the balance of the funds following our annual meeting in the second quarter of 2024. 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 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.

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.

Sales and Marketing

In 2024, we plan to "relaunch" Arakoda for malaria prevention in the United States. As described in the "Strategy" section this will consist of (i) subject to feasibility, hiring a Chief Commercial Officer to lead commercialization efforts, (ii) conducting market research to ensure optimal positioning for Arakoda and confirm a forecast and (iii) initiate marketing outreach in the second half of 2024. We plan to phase in hiring of sales staff as sales grow, and we may do so through a contract services organization to ensure greater flexibility and limit overhead if this makes business sense based on to be conducted market research.

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

Under Section 28D of the Industry Research and Development Act 1986[69], research and development activities conducted outside Australia are also potentially eligible if they meet the following criteria: (i) they are approved in advance, (ii) they are linked to a core research and development activity conducted in Australia, (iii) cannot be conducted in Australia for various reasons and (iv) the value of activities conducted overseas is less than the value of activities conducted in Australia.

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.

67 Novitt-Moreno et al. TMAID 2022; 45:102211.
68 See Industry Research and Development Act 1986 (legislation.gov.au).
69 See Australian Government R&D Tax Incentive – Overseas R&D: Information Sheet.

Review and Approval of Drugs in the United States

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

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

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

Preclinical Studies

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

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

The IND and IRB Processes

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

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

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

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

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

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

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

Human Clinical Studies in Support of an NDA

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

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

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

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

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

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

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

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

Submission of an NDA to the FDA

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

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

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

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

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

Fast-Track, Breakthrough Therapy and Priority Review Designations

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

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

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

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

Tropical Disease PRVs

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

70 21 U.S.C. § 360n(a)(1).

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

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

Accelerated Approval Pathway

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

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

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

71 21 U.S.C. § 360n(a)(3).

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

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

The FDA's Decision on an NDA

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

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

Post-Approval Requirements

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

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

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

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

Abbreviated New Drug Applications for Generic Drugs

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

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

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

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

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

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

Hatch-Waxman Patent Certification and the 30-Month Stay

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

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

- the required patent information has not been filed;
- the listed patent has expired;

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

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

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

Pediatric Studies and Exclusivity

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

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

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

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

Orphan Drug Designation and Exclusivity

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

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

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

Patent Term Restoration and Extension

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

Review and Approval of Medical Devices in the United States

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

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

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

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

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

Review and Approval of Drug Products in the European Union

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

Procedures Governing Approval of Drug Products in the European Union

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

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

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

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

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

Clinical Trial Approval

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

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

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

Data and Market Exclusivity in the European Union

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

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

Periods of Authorization and Renewals

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

Orphan Drug Designation and Exclusivity

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

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

Brexit and the Regulatory Framework in the United Kingdom

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

Regulatory Framework in Australia

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

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

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

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

Application

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

Evaluation

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

Approval

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

Registration

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

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

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

Other activities under the control of the TGA include:

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

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

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

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

Healthcare Law and Regulation

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

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

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

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

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

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

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

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

Healthcare Reform

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Human Capital Resources

As of September 30, 2023, we had a total of two employees, both of which are full-time. We also utilize the services of two part-time contractors.

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

Properties

Our corporate headquarters are located at 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036. We do not own any physical property, plant or labs. We currently lease two offices at the above address and, as a result of the renewal of our lease for an additional one-year in January 2023, recognized a Right of Use Asset of $63,570 as of September 30, 2023, with offsetting accumulated depreciation of $37,036 ($63,570 as of December 31, 2022 with no offsetting accumulated depreciation).

Legal Proceedings

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

History

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

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

We own 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.

MANAGEMENT

The following table sets forth the name, age and position of each of our executive officers, directors and director nominees as of January 29, 2024.

Name	Age	Position	Director Since
Geoffrey Dow	50	Chief Executive Officer, President and Director	June 1, 2022
Tyrone Miller	49	Chief Financial Officer	—
Charles Allen	48	Director	July 12, 2023
Cheryl Xu	56	Director	July 12, 2023
Stephen Toovey	70	Director	July 12, 2023
Paul Field	60	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.

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, of 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.

2022 Equity Incentive Plan

On November 22, 2022, the Board and majority stockholder adopted the 60 Degrees Pharmaceuticals, Inc. 2022 Equity Incentive Plan (the "Plan"). The Plan provides for the grant of the following types of stock awards: (i) incentive stock options, (ii) nonstatutory stock options, (iii) stock appreciation rights, (iv) restricted stock awards, (v) restricted stock unit awards and (vi) other stock awards. The Plan is intended to help us secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for our success and any of our affiliates and provide a means by which the eligible recipients may benefit from increases in value of the common stock. The Board reserved 238,601 shares of common stock issuable upon the grant of awards under the Plan.

EXECUTIVE COMPENSATION

The following table illustrates the compensation paid by us to our executive officers. The disclosure is provided for the years ended December 31, 2023, and December 31, 2022.

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, 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.

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. 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.

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. 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.

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

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

2022 Equity Incentive Plan

Overview

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

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

Authorized Shares

Initially, the maximum number of shares of our common stock that may be subject to awards under the Plan is equal to 238,601.

Plan Administration

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

Eligibility

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

Stock Options

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

Stock Appreciation Rights

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

Restricted Stock

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

Restricted Stock Units

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

Performance Awards

Performance awards may be granted under the Plan. Performance awards are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will set objectives or vesting provisions, that, depending on the extent to which they are met, will determine the value 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 Plan generally does not allow for the transfer of awards other than by will or by the laws of descent and distribution and only the recipient of an award may exercise an award during their lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments

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

Dissolution or Liquidation

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

Merger or Change in Control

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

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

Clawback

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

Amendment and Termination

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

Board Compensation

In November and December 2022, we signed agreements with four 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) receives $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 also receives annual equity compensation beginning on 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).

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information, as of January 29, 2024 with respect to the holdings of (1) each person who is the beneficial owner of more than 5% of our voting stock, (2) each of our directors, (3) each executive officer, and (4) all of our current directors and executive officers as a group.

Beneficial ownership of the voting stock is determined in accordance with the rules of the SEC and includes any shares of company voting stock over which a person exercises sole or shared voting or investment power, or of which a person has a right to acquire ownership at any time within 60 days of January 29, 2024. Except as otherwise indicated, we believe that the persons named in this table have sole voting and investment power with respect to all shares of voting stock held by them. Applicable percentage ownership in the following table is based on 5,810,089 shares of common stock issued and outstanding on January 29, 2024 and 11,070,990 shares of common stock after the offering assuming an offering of 5,260,901 Units in this offering (based upon the sale of 5,260,901 Units and 999,076 Pre-Funded Units in this offering and assuming no exercise of the Warrants and Pre-Funded Warrants), plus, for each individual, any securities that individual has the right to acquire within 60 days of January 29, 2024.

To the best of our knowledge, except as otherwise indicated, each of the persons named in the table has sole voting and investment power with respect to the shares of our common stock beneficially owned by such person, except to the extent such power may be shared with a spouse. To our knowledge, none of the shares listed below are held under a voting trust or similar agreement, except as noted. To our knowledge, there is no arrangement, including any pledge by any person of our securities, the operation of which may at a subsequent date result in a change in control of the Company.

Name and Address of Beneficial Owner[1]	Title	Beneficially Owned Before Offering	Beneficially Owned After Offering	Percent of Class Before Offering	Percent of Class After Offering
Officers and Directors					
Geoffrey Dow	President, Chief Executive Officer and Director	773,107[2]	773,107[2]	13.09%	6.92%
Tyrone Miller	Chief Financial Officer	176,928[3]	176,928[3]	3.01%	1.59%
Charles Allen	Director	23,434[4]	23,434[4]	*	*
Cheryl Xu	Director	238,368[5]	238,368[5]	4.09%	2.15%
Stephen Toovey	Director	23,434[6]	23,434[6]	*	*
Paul Field	Director	23,434[7]	23,434[7]	*	*
Officers and Directors as a Group (total of 6 persons)		**1,258,705**	**1,258,705**	**20.86%**	**11.13%**
5%+ Stockholders					
Kentucky Technology Inc.[8]		525,000	525,000	9.04%	4.74%
Knight Therapeutics International S.A.[9]		1,153,897	1,153,897	19.86%	10.42%

* Less than 1%.

(1) Unless otherwise indicated, the principal address of the named directors and directors and 5% stockholders of the Company is c/o 1025 Connecticut Avenue NW Suite 1000, Washington, D.C. 20036.

(2) Includes (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 dated August 27, 2018 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 in the name of Mr. Field, (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.

(8) Kentucky Technology Inc.'s Board of Directors has voting and dispositive control over the shares held by Kentucky Technology Inc. The members of the Board of Directors of Kentucky Technology Inc. are Kevin Adkins, Lisa Cassis, Nancy Cox, Penny Cox, Judy Duncan, John Farris, Taunya Phillips, Gene Strong and George Ward. Because the Board of Directors acts by consensus and majority approval, none of the members of Kentucky Technology Inc.'s Board of Directors has individual voting or dispositive control with respect to such shares. The principal address of Kentucky Technology Inc. is 824 Bull Lea Run, Suite 2100, Lexington, KY 40511.

(9) Knight Therapeutics Inc. wholly owns Knight Therapeutics International S.A. Arvind Utchanah has voting and dispositive control over the shares held by Knight Therapeutics International S.A. The principal address of Knight is 3400 de Maisonneuve W. Suite 1055, Montreal, QC Canada H3Z 3B8.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

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

The above summary description of related part transactions includes some of the general terms and provisions of the agreements related to such transactions. For a more detailed description of those agreements, you should refer to such agreements which are included as exhibits to the registration statement of which this prospectus forms a part.

DESCRIPTION OF SECURITIES

The following description of our securities is only a summary and is qualified in its entirety by reference to the actual terms and provisions of the capital stock contained in our Certificate of Incorporation and our Bylaws.

General

We are authorized to issue one class of stock. The total number of shares of stock which we are authorized to issue is 151,000,000 shares of capital stock, 150,000,000 of which are common stock, $0.0001 par value per share, and 1,000,000 of which are “blank check” preferred stock. As of January 29, 2024, 5,810,089 shares of common stock were issued and outstanding and held by 15 stockholders of record.

Common Stock

The holders of our common stock are entitled to the following rights:

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

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

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

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

Preferred Stock

Our Certificate of Incorporation authorizes 1,000,000 shares of "blank check" preferred stock, par value $0.0001 per share. We have currently authorized 78,803 shares of Series A Preferred Stock with the following terms and rights: (i) 6% dividend, (ii) non-voting; (iii) not redeemable; and (iv) convertible into shares of common stock, solely at the Company's discretion, determined by (A) multiplying the number of shares of Series A Preferred Stock to be converted by $100, (B) adding to the result all accrued and accumulated and unpaid dividends on such shares to be converted, if any, and then (C) dividing the result by a price equal to the lower of (1) $100, (2) the price paid for the shares of common stock in the IPO and (3) the 10-day volume weighted average share price immediately preceding our election to convert the shares of Series A Preferred Stock; provided that the conversion of the shares of Series A Preferred Stock does not result in the holder's ownership of common stock exceeding 19.9%.

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

- the designation of the series;
- the number of shares of the series;
- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate, if any, of the series;
- the dates at which dividends, if any, will be payable;
- the redemption rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;
- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of the affairs of our Company;
- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of our Company or any other entity, and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates and provisions for any adjustments to such prices or rates, the date or dates as of which the shares will be convertible, and all other terms and conditions upon which the conversion may be made;
- the ranking of such series with respect to dividends and amounts payable on our liquidation, dissolution or winding-up, which may include provisions that such series will rank senior to our common stock with respect to dividends and those distributions;
- restrictions on the issuance of shares of the same series or any other class or series; or
- voting rights, if any, of the holders of the series.

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

Warrants Offered in this Offering

Overview

The following summary of certain terms and provisions of the Warrants included in the Units and the Pre-Funded Units offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrant Agent Agreement and the form of Warrant, of which are filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the Warrant Agent Agreement, including the exhibits attached thereto, and the form of Warrant.

The exercise price and number of shares of common stock issuable upon exercise of the Warrant may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation. However, the Warrants will not be adjusted for issuances of common stock at prices below its exercise price.

Exercisability

The Warrants are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. The Warrants may be exercised upon surrender of the Warrant certificate on or prior to the expiration date at the offices of the Company, 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 Warrants, 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.

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 Warrants is $0.4235 per share (110% of the public offering price per Unit). The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Fractional Shares

No fractional shares of common stock will be issued upon exercise of the Warrants. If, upon exercise of the Warrant, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, pay a cash adjustment in respect of such fraction in an amount equal to such fraction multiplied by the exercise price. If multiple Warrants are exercised by the holder at the same time, we shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Transferability

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

Exchange Listing

There is no established public trading market for the Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants on any national securities exchange or other nationally recognized trading system, including The Nasdaq Capital Market. Without an active trading market, the liquidity of the Warrants will be limited.

Warrant Agent; Global Certificate

The Warrants will be issued in registered form under a Warrant Agent Agreement between the warrant agent and us. The Warrants shall initially be represented only by one or more global warrants deposited with the Warrant Agent, as custodian on behalf of The Depository Trust Company ("DTC") and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. Our transfer agent, Equity Stock Transfer, LLC, will serve as the warrant agent (the "Warrant Agent").

Warrant Certificate

The Warrants will be issued in certificated form.

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 are governed by New York law.

Pre-Funded Warrants Offered in this Offering

Overview

The following summary of certain terms and provisions of the Pre-Funded Warrants that are part of the Pre-Funded Units offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the Warrant Agent Agreement and the form of Pre-Funded Warrant, which are filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the Warrant Agent Agreement, including the exhibits attached thereto, and the form of Pre-Funded Warrant.

The term "pre-funded" refers to the fact that the purchase price of our common stock in this offering includes almost the entire exercise price that will be paid under the Pre-Funded Warrants, except for a nominal remaining exercise price of $0.01. The purpose of the Pre-Funded Warrants is to enable investors that may have restrictions on their ability to beneficially own more than 4.99% (or, upon election of the holder, 9.99%) of our outstanding common stock following the consummation of this offering the opportunity to invest capital into our Company without triggering their ownership restrictions, by receiving Pre-Funded Warrants in lieu of our common stock which would result in such ownership of more than 4.99% (or 9.99%), and receive the ability to exercise their option to purchase the shares underlying the Pre-Funded Warrants at such nominal price at a later date.

Duration

The Pre-Funded Warrants offered hereby will entitle the holders thereof to purchase shares of our common stock at a nominal exercise price of $0.01 per share, at any time after its original issuance until exercised in full.

Exercise Limitation

A holder will not have the right to exercise any portion of the Pre-Funded Warrant if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% (or, upon election of the holder, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. However, any holder may increase, but not in excess of 9.99%, or decrease such percentage, provided that any increase will not be effective until the sixty-first (61st) day after such election.

Exercise Price

The Pre-Funded Warrants will have an exercise price of $0.01 per share. 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.

Warrant Agent; Global Certificate

The Pre-Funded Warrants will be issued in registered form under a Warrant Agent Agreement between the Warrant Agent and us. The Pre-Funded Warrants shall initially be represented only by one or more global warrants deposited with the Warrant Agent, as custodian on behalf of The Depository Trust Company ("DTC") and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Transferability

Subject to applicable laws, the Pre-Funded Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

There is no established public trading market for the Pre-Funded Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Pre-Funded Warrants on any national securities exchange or other nationally recognized trading system, including The Nasdaq Capital Market. Without an active trading market, the liquidity of Pre-Funded Warrants will be limited.

Fundamental Transactions

If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Pre-Funded Warrants with the same effect as if such successor entity had been named in the Pre-Funded Warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the Pre-Funded Warrant following such fundamental transaction.

Rights as a Stockholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Pre-Funded Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Pre-Funded Warrant.

Notes Outstanding

On May 14, 2020, we issued the note to the U.S. Small Business Administration with a principal amount of $150,000 and a per annum interest rate of 3.75%. The current outstanding balance of the COVID-19 Loan is $161,366 as of September 30, 2023 ($163,022 as of December 31, 2022).

Warrants

On July 14, 2023, we issued to investors tradeable warrants with an exercise price of $6.095 per share and non-tradeable warrants with an exercise price per share of $6.36 per share. The warrants may be exercised beginning on July 12, 2023 until July 12, 2028.

On May 19, 2022, we issued to Geoffrey Dow a right to receive five-year (5) warrants to purchase a total of 10,482 shares of common stock upon the closing of our initial public offering with an exercise price of $4.77.

On May 19, 2022, we issued to Mountjoy Trust a right to receive five-year (5) warrants to purchase a total of 69,444 shares of common stock upon the closing of our initial public offering with an exercise price of $4.77.

On May 24, 2022, we issued to Bigger Capital Fund, LP a right to receive five-year (5) warrants to purchase a total of 31,447 shares of common stock upon the closing of our initial public offering with an exercise price of $5.83.

On May 24, 2022, we issued to Cavalry Investment Fund, LP a right to receive five-year (5) warrants to purchase a total of 26,205 shares of common stock upon the closing of our initial public offering with an exercise price of $5.83.

On May 24, 2022, we issued to Walleye Opportunities Master Fund Ltd a right to receive five-year (5) warrants to purchase a total of 26,205 shares of common stock upon the closing of our initial public offering with an exercise price of $5.83.

On May 8, 2023, we issued to Cyberbahn Federal Solutions, LLC a right to receive five-year (5) warrants to purchase a total of 10,482 shares of common stock upon the closing of our initial public offering with an exercise price of $5.83.

On May 8, 2023, we issued to Ariana Bakery Inc. a right to receive five-year (5) warrants to purchase a total of 10,482 shares of common stock upon the closing of our initial public offering with an exercise price of $5.83.

On May 8, 2023, we issued to Sabby Volatility Warrant Master Fund, Ltd. a right to receive five-year (5) warrants
to purchase a total of 31,447 shares of common stock upon the closing of our initial public offering with an exercise price of $5.83.

On May 8, 2023, we issued to Steel Anderson a right to receive five-year (5) warrants to purchase a total of 5,241 shares of common stock upon the closing of our initial public offering with an exercise price of $5.83.

On May 8, 2023, we issued to Bixi Gao & Ling Ling Wang a right to receive five-year (5) warrants to purchase a total of 10,482 shares of common stock upon the closing of our initial public offering with an exercise price of $5.83.

Options

In November and December 2022, we signed agreements with Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey. We issued to each of Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey a non-qualified option to purchase a total of 7,547 shares of common stock at an exercise price of $5.30 which were fully vested on the grant date of July 11, 2023, expiring on July 11, 2028, and a non-qualified option to purchase a total of 9,434 shares of common stock at an exercise price of $5.30 which vests in equal monthly installments over a period of 12 months from July 11, 2023, expiring on July 11, 2028.

Section 203 of the Delaware General Corporation Law

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

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

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

- our Board approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction; or
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock.

Potential Effects of Authorized but Unissued Stock

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

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

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock 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*.

Stock Exchange

Our common stock and tradeable warrants are listed on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively. We do not intend to apply for listing of the Warrants and the Pre-Funded Warrants on any exchange or market.

UNDERWRITING

We are offering our securities described in this prospectus through the underwriters named below. WallachBeth Capital LLC is acting as representative of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, each of the underwriters has severally agreed to purchase, and we have agreed to sell to the underwriters, the number of Units and Pre-Funded Units listed next to its name in the following table.

Underwriters	Number of Units	Number of Pre-Funded Units
WallachBeth Capital LLC	5,260,901	999,076
Total	5,260,901	999,076

The underwriting agreement provides that the underwriters must buy all of the securities being sold in this offering if they buy any of them. However, the underwriters are not required to take or pay for the securities covered by the underwriters' option to purchase additional securities as described below.

Our securities are offered subject to a number of conditions, including:

- receipt and acceptance of our common stock and warrants by the underwriters; and
- the underwriters' right to reject orders in whole or in part.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses electronically.

Indemnification

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the securities, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have agreed pursuant to the terms in an underwriting agreement dated the date of this prospectus, to grant WallachBeth Capital LLC, the underwriter, an option, exercisable for 45 days from the date of this prospectus, to purchase up to an additional 789,136 shares of common stock (15.0% of the shares sold as part of the Units in this offering) and/or 938,997 Warrants (15.0% of the Warrants sold as part of the Units and/or Pre-Funded Units in this offering) and/or 149,862 Pre-Funded Warrants (15.0% of the Pre-Funded Warrants sold in this offering)

Underwriting Discount

Securities sold by the underwriters to the public will initially be offered at the Unit offering price or Pre-Funded Unit offering price as applicable set forth on the cover of this prospectus. The underwriters may offer the securities through one or more of their affiliates or selling agents. If all the Units and/or Pre-Funded Units are not sold at the public offering price, WallachBeth Capital LLC may change the offering price and the other selling terms. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the securities at the prices and upon the terms stated therein.

The following table shows the per Unit and Pre-Funded Unit and total underwriting discount we will pay to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 789,136 shares of common stock (15.0% of the shares sold as part of the Units in this offering) and/or 938,997 Warrants (15.0% of the Warrants sold as part of the Units and/or Pre-Funded Units in this offering) and/or 149,862 Pre-Funded Warrants (15.0% of the Pre-Funded Warrants sold in this offering).

	Per Unit	Per Pre-Funded Unit	Total without Over-Allotment Option	Total with Over-Allotment Option
Public offering price	$ 0.3850	$ 0.3750	$ 2,400,100.39	$ 2,769,505.97
Underwriting discounts and commissions (8%)	$ 0.0308	$ 0.03	$ 192,008.03	$ 221,560.48
Proceeds, before expenses to us	$ 0.3542	$ 0.345	$ 2,208,092.36	$ 2,547,945.49

We have agreed to pay WallachBeth Capital LLC a non-accountable expense allowance of 1.5% of the gross proceeds of the offering. We also have agreed to pay WallachBeth Capital LLC's reasonable out-of-pocket fees and expenses up to a maximum amount of $115,000. In accordance with FINRA Rule 5110, the reimbursement fee described in the preceding sentence is deemed underwriting compensation for this offering.

We estimate that the total expenses of the offering payable by us, not including the underwriting discount, will be approximately $320,000. We have also agreed to reimburse the underwriters for certain expenses incurred by them.

Representative Warrants

In connection with this offering, WallachBeth Capital LLC is entitled to receive the Representative Warrants to purchase an aggregate of 315,655 shares of our common stock (equal to 6% of the common stock sold in the offering, including any exercise of any shares in the over-allotment option). The Representative Warrants have a five-year term and an exercise price of 110% of the initial public offering price. The Representative Warrants will expire on the fifth anniversary of the commencement date of sales in this offering in accordance with FINRA Rule 5110(g)(8)(A). In accordance with FINRA Rule 5110(e)(1), WallachBeth Capital LLC has agreed not sell, transfer, assign, pledge or hypothecate, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the Representative Warrants or the shares underling the Representative Warrants for a period of 180 days beginning on the date of commencement of sales of this public offering.

Right of First Refusal

Upon the closing of this offering, for a period of twelve (12) months from such closing, the Company has granted WallachBeth Capital LLC the right of first refusal to act as underwriter and book-running manager and/or placement agent for any and all future public and private equity and equity-linked (excluding commercial bank debt) offerings during such twelve (12) month period of the Company, or any successor to or any subsidiary of the Company. If WallachBeth Capital LLC or one of its affiliates decides to accept any such engagement, the agreement governing such engagement will contain, among other things, provisions for customary fees for transactions of similar size and nature, but in no event will the fees be less than those outlined herein, and the provisions of this Agreement, including indemnification, which are appropriate to such a transaction.

Tail

If we, within the six (6) months following the termination of the Letter of Engagement dated as of January 12, 2024 and effective as of January 12, 2024 (the "Letter of Engagement"), issued by WallachBeth Capital LLC to us, effect a sale of securities with an investor or a transaction with an entity that was introduced by WallachBeth Capital LLC to us for discussions or negotiations regarding an offering, we will pay WallachBeth Capital LLC the following: (i) an aggregate cash discount equal to eight percent (8.0%) of the aggregate sales price of securities sold in any offering plus one and one-half percent (1.5%) of the aggregate sales price of securities sold in any offering as non-accountable expenses; and (ii) a number of warrants equal to six percent (6.0%) of the number of securities of common stock sold in the offering.

Termination Right

We may terminate the right of first refusal or the tail financial fee if we terminate the Letter of Engagement for "Cause," which is defined as a material breach of the Letter of Engagement by WallachBeth or a material failure of WallachBeth to provide services contemplated by the Letter of Engagement.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

Transfer Agent and Registrar

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

Listing

Our common stock and Tradeable Warrants are listed on The Nasdaq Capital Market under the symbols "SXTP" and "SXTPW," respectively. We do not intend to apply for listing of the Warrants and the Pre-Funded Warrants on any exchange or market.

Electronic Distribution

A prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriters of this offering, or by their affiliates. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Price Stabilization, Short Positions

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock during and after this offering, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. These transactions may also include making short sales of our common stock, which involve the sale by the underwriters of a greater number of common stock than they are required to purchase in this offering and purchasing common stock on the open market to cover short positions created by short sales. Short sales may be "covered short sales," which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked short sales," which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are short sales made in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because has repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on The Nasdaq Capital Market, in the over-the-counter market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. Neither we, nor any of the underwriters make any representation that the underwriters will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice.

Affiliations

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and their affiliates may from time to time in the future engage with us and perform services for us or in the ordinary course of their business for which they will receive customary fees and expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of us. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of these securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in these securities and instruments.

Offer Restrictions Outside the United States

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of the common stock the possession, circulation or distribution of this prospectus or any other material relating to us or the common stock in any jurisdiction where action for that purpose is required. Accordingly, the common stock may not be offered or sold, directly or indirectly, and neither this prospectus nor any other material or advertisements in connection with the common stock may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

INTERESTS OF NAMED EXPERTS AND COUNSEL

Sichenzia Ross Ference Carmel LLP, New York, New York, our counsel, owns 100,000 shares of Common Stock.

EXPERTS

RBSM LLP, an independent registered public accounting firm, audited our financial statements for the years ended December 31, 2022 and 2021, respectively. We have included our financial statements in this prospectus and elsewhere in the registration statement in reliance on the reports of RBSM LLP, given their authority as experts in accounting and auditing.

LEGAL MATTERS

Certain legal matters with respect to the validity of the securities being offered by this prospectus will be passed upon by Sichenzia Ross Ference Carmel LLP, New York, New York. TroyGould PC, Los Angeles, California, is acting as counsel for the underwriter with respect to this offering.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

We are subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, are required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at *https://60degreespharma.com/*. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

60 DEGREES PHARMACEUTICALS, INC

CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022

60 DEGREES PHARMACEUTICALS, INC
INDEX TO FINANCIAL STATEMENTS

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED CONDENSED BALANCE SHEETS

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current Assets:		
Cash	$ 2,218,540	$ 264,865
Accounts Receivable	138,009	45,965
Prepaid and Other	5,939,927	200,967
Deferred Offering Costs	-	68,629
Inventory, net (Note 3)	598,319	518,578
Total Current Assets	**8,894,795**	**1,099,004**
Property and Equipment, net (Note 4)	3,836	21,300
Other Assets:		
Right of Use Asset (Note 12)	26,534	12,647
Intangible Assets, net (Note 5)	225,047	164,255
Total Other Assets	**251,581**	**176,902**
Total Assets	**$ 9,150,212**	**$ 1,297,206**
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts Payable and Accrued Expenses	$ 271,602	$ 758,668
Lease Liability (Note 12)	26,800	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)	2,174,194	1,129,840
Derivative Liabilities - Related Parties (Note 9)	-	364,360
Total Current Liabilities:	**2,481,368**	**23,921,211**
Long-Term Liabilities:		
Deferred Compensation (Note 7)	-	255,000
SBA EIDL *(including accrued interest)* (Note 8)	152,594	160,272
Promissory Notes *(including accrued interest)* (Note 8)	-	1,109,783
Total Long-Term Liabilities	**152,594**	**1,525,055**
Total Liabilities	**2,633,962**	**25,446,266**
Commitments and Contingencies (Note 12)		
SHAREHOLDERS' EQUITY (DEFICIT):		
Preferred stock, $0.0001 par value, 1,000,000 shares authorized; 78,803 issued and outstanding as of September 30, 2023 and 0 as of December 31, 2022, respectively (Note 6)	9,858,040	-
Class A common stock, $0.0001 par value, 150,000,000 shares authorized; 5,799,535 and 2,386,009 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively (Note 6)	580	239
Additional Paid-in Capital	27,182,915	5,164,461
Accumulated Other Comprehensive Income	81,386	73,708
Accumulated Deficit	(30,568,566)	(28,815,148)
60P Shareholders' Equity (Deficit):	6,554,355	(23,576,740)
Noncontrolling interest	(38,105)	(572,320)
Total Shareholders' Equity (Deficit)	**6,516,250**	**(24,149,060)**
Total Liabilities and Shareholders' Equity (Deficit)	**$ 9,150,212**	**$ 1,297,206**

See the accompanying notes to the unaudited consolidated condensed financial statements.

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Product Revenues – net of Discounts and Rebates	$ 51,188	$ 168,185	$ 127,892	$ 260,382
Cost of Revenues	71,196	92,281	328,293	269,535
Gross Revenue (Loss)	(20,008)	75,904	(200,401)	(9,153)
Research Revenues	75,566	150,262	82,974	259,669
Net Revenue (Loss)	55,558	226,166	(117,427)	250,516
Operating Expenses:				
Research and Development	263,703	27,655	591,569	322,106
General and Administrative Expenses	1,313,617	413,627	2,551,426	994,157
Total Operating Expenses	1,577,320	441,282	3,142,995	1,316,263
Loss from Operations	(1,521,762)	(215,116)	(3,260,422)	(1,065,747)
Interest Expense	(40,106)	(1,215,978)	(2,281,191)	(2,883,714)
Derivative Expense	-	-	(399,725)	(504,613)
Change in Fair Value of Derivative Liabilities	92,490	(22,495)	95,324	(23,496)
Loss on Debt Extinguishment	(391,593)	-	(1,231,480)	-
Change in Fair Value of Promissory Note	6,105,066	-	5,379,269	-
Other Income (Expense), net	(70,490)	3,172	(69,169)	(29,810)
Total Interest and Other Income (Expense), net	5,695,367	(1,235,301)	1,493,028	(3,441,633)
Income (Loss) from Operations before Provision for Income Taxes	4,173,605	(1,450,417)	(1,767,394)	(4,507,380)
Provision for Income Taxes (Note 10)	63	250	189	750
Net Income (Loss) including Noncontrolling Interest	4,173,542	(1,450,667)	(1,767,583)	(4,508,130)
Net Loss – Noncontrolling Interest	(9,656)	(3,172)	(14,165)	(1,454)
Net Income (Loss) – attributed to 60 Degrees Pharmaceuticals, Inc.	4,183,198	(1,447,495)	(1,753,418)	(4,506,676)
Comprehensive Income (Loss)				
Net Income (Loss)	4,173,542	(1,450,667)	(1,767,583)	(4,508,130)
Unrealized Foreign Currency Translation Gain (Loss)	9,342	(6,417)	7,678	(20,850)
Total Comprehensive Income (Loss)	4,182,884	(1,457,084)	(1,759,905)	(4,528,980)
Net Loss – Noncontrolling Interest	(9,656)	(3,172)	(14,165)	(1,454)
Unrealized Foreign Currency Translation Loss from Noncontrolling Interest	-	(544)	-	(544)
Comprehensive Income (Loss) – attributed to 60 Degrees Pharmaceuticals, Inc.	4,192,540	(1,453,368)	(1,745,740)	(4,526,982)
Cumulative dividends on Series A Preferred Stock	(101,538)	-	(101,538)	-
Net Income (Loss) - attributed to common stockholders	**$ 4,091,002**	**$ (1,453,368)**	**$ (1,847,278)**	**$ (4,526,982)**
Net Income (Loss) per Common Share:				
Basic and Diluted	$ 0.77	$ (0.61)	$ (0.55)	$ (1.92)
Weighted average number of common shares outstanding				
Basic and Diluted	5,319,255	2,386,009	3,344,843	2,361,569

See the accompanying notes to the unaudited consolidated condensed financial statements.

60 DEGREES PHARMACEUTICALS, INC

CONSOLIDATED CONDENSED STATEMENTS OF SHAREHOLDERS' AND MEMBERS' EQUITY (DEFICIT) (UNAUDITED)

	For the Three and Nine Months Ended September 30, 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 Gain	-	-	-	-	-	-	96,556	96,556	-	96,556
Net Income (Loss)	-	-	-	-	-	(912,282)	-	(912,282)	4,835	(907,447)
Balance— March 31, 2022 (unaudited)	**18,855,165**	**$ 4,979,365**	**-**	**$ -**	**$ -**	**$ (23,545,710)**	**$ 172,391**	**$ (18,393,954)**	**$ (571,421)**	**$ (18,965,375)**
Business Combination: June 1, 2022 (60P LLC into 60P, Inc.)	(18,855,165)	(4,979,365)	2,348,942	235	4,979,130	-	-	-	-	-
Issuance of Common Stock	-	-	37,067	4	185,331	-	-	185,335	-	185,335
Net Foreign Translation Loss	-	-	-	-	-	-	(110,989)	(110,989)	-	(110,989)
Net Loss	-	-	-	-	-	(2,146,899)	-	(2,146,899)	(3,117)	(2,150,016)
Balance— June 30, 2022 (unaudited)	**-**	**$ -**	**2,386,009**	**$ 239**	**$ 5,164,461**	**$ (25,692,609)**	**$ 61,402**	**$ (20,466,507)**	**$ (574,538)**	**$ (21,041,045)**
Net Foreign Translation Loss	-	-	-	-	-	-	(5,873)	(5,873)	(544)	(6,417)
Net Loss	-	-	-	-	-	(1,447,495)	-	(1,447,495)	(3,172)	(1,450,667)
Balance— September 30, 2022 (unaudited)	**-**	**$ -**	**2,386,009**	**$ 239**	**$ 5,164,461**	**$ (27,140,104)**	**$ 55,529**	**$ (21,919,875)**	**$ (578,254)**	**$ (22,498,129)**

	For the Three and Nine Months Ended September 30, 2023									
	Series A Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Shareholders' Equity (Deficit)	Noncontrolling	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Attributable to 60P	Interest on 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	-	-	-	-	-
Issuance of common stock	-	-	1,443,000	144	5,378,764	-	-	5,378,908	-	5,378,908
Net Foreign Translation Loss	-	-	-	-	-	-	(1,290)	(1,290)	-	(1,290)
Net Income (Loss)	-	-	-	-	-	(2,600,061)	-	(2,600,061)	2,527	(2,597,534)
Balance— March 31, 2023 (unaudited)	**-**	**$ -**	**2,378,009**	**$ 238**	**$10,543,370**	**$ (31,415,209)**	**$ 72,418**	**$ (20,799,183)**	**$ (569,793)**	**$ (21,368,976)**
Net Foreign Translation Loss	-	-	-	-	-	-	(374)	(374)	-	(374)
Net Loss	-	-	-	-	-	(3,336,555)	-	(3,336,555)	(7,036)	(3,343,591)
Balance— June 30, 2023 (unaudited)	**-**	**$ -**	**2,378,009**	**$ 238**	**$10,543,370**	**$ (34,751,764)**	**$ 72,044**	**$ (24,136,112)**	**$ (576,829)**	**$ (24,712,941)**
Issuance of common stock for payment of deferred compensation	-	-	29,245	3	154,997	-	-	155,000	-	155,000
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
Reclassification of liability-classified warrants to equity-classified	-	-	-	-	838,748	-	-	838,748	-	838,748
Issuance of common stock pursuant to IPO, net of underwriting discounts and offering costs of $1,266,740	-	-	1,415,095	141	6,235,135	-	-	6,235,276	-	6,235,276
Issuance of common stock upon exercise of warrants	-	-	184,447	18	1,131,753	-	-	1,131,771	-	1,131,771
Voluntary conversion of Series A Preferred Stock into common stock	(2,162)	(270,460)	45,560	5	270,455	-	-	-	-	-
Issuance of common stock pursuant to share-based compensation awards	-	-	40,000	4	187,196	-	-	187,200	-	187,200
Share-based compensation expense	-	-	-	-	271,066	-	-	271,066	-	271,066
Prepaid share-based compensation	-	-	-	-	109,148	-	-	109,148	-	109,148
Contribution from noncontrolling interest	-	-	-	-	(548,380)	-	-	(548,380)	548,380	-
Net Foreign Translation Gain	-	-	-	-	-	-	9,342	9,342	-	9,342
Net Income (Loss)	-	-	-	-	-	4,183,198	-	4,183,198	(9,656)	4,173,542
Balance— September 30, 2023 (unaudited)	**78,803**	**$ 9,858,040**	**5,799,535**	**$ 580**	**$27,182,915**	**$ (30,568,566)**	**$ 81,386**	**$ 6,554,355**	**$ (38,105)**	**$ 6,516,250**

See the accompanying notes to the unaudited consolidated condensed financial statements.

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)

For the Nine Months Ended September 30,	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (1,767,583)	$ (4,508,130)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation	19,287	20,747
Amortization	20,606	2,783
Amortization of Debt Discount	669,148	821,154
Amortization of ROU Asset	37,035	33,848
Amortization of Note Issuance Costs	67,728	-
Amortization of Capitalized Services	690,173	-
Stock-based Compensation	670,871	-
Loss on Debt Extinguishment	1,231,480	-
Change in Fair Value of Derivative Liabilities	(95,324)	23,496
Derivative Expense	399,725	504,613
Change in Fair Value of Promissory Note	(5,379,269)	-
Inventory Reserve	(139,946)	-
Changes in Operating Assets and Liabilities:		
Accounts Receivable	(92,044)	(48,679)
Prepaid and Other	(1,512,578)	58,083
Inventory	60,205	(36,415)
Accounts Payable and Accrued Liabilities	(489,337)	(36,199)
Accrued Interest	1,267,703	2,055,810
Reduction of Lease Liability	(37,122)	(34,271)
Deferred Compensation	(100,000)	199,157
Net Cash Used in Operating Activities	**(4,479,242)**	**(944,003)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Capitalization of Patents	(29,220)	(1,488)
Purchases of Property and Equipment	(1,823)	-
Acquisition of Intangibles	(18,283)	-
Net Cash Used in Investing Activities	**(49,326)**	**(1,488)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of Deferred Offering Costs	(150,420)	-
Net proceeds from IPO and Over-Allotment	6,454,325	-
Proceeds from the exercise of warrants	1,131,771	-
Proceeds from issuance of Common Stock	-	185,335
Proceeds from Notes Payable	650,000	800,000
Proceeds from Notes Payable - Related Parties	-	305,000
Repayment of Notes Payable	(1,611,111)	-
Advances from Related Parties	250,000	-
Repayment of Related Party Advances	(250,000)	-
Net Cash Provided by Financing Activities	**6,474,565**	**1,290,335**
Foreign Currency Translation Gain (Loss)	7,678	(20,850)
Change in Cash	1,953,675	323,994
Cash—Beginning of Period	264,865	115,399
Cash—End of Period	**$ 2,218,540**	**$ 439,393**
NONCASH INVESTING/FINANCING ACTIVITIES		
Conversion of Debt into Common Stock	$ 7,989,598	$ -
Conversion of Debt into Series A Preferred Stock	$ 10,128,500	$ -
Conversion of Series A Preferred Stock into Common Stock	$ 270,460	$ -
Common Stock Issued as Prepayment for Services	$ 4,916,556	$ -
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	$ 480,000	$ -
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 the accompanying notes to the unaudited consolidated condensed financial statements

1. NATURE OF OPERATIONS

60 Degrees Pharmaceuticals, Inc. was incorporated in Delaware on June 1, 2022 and merged on the same day with 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company organized on September 9, 2010 ("60P LLC"). 60 Degrees Pharmaceuticals, Inc. and its subsidiaries (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 COVID-19, fungal, tick-borne, and other viral diseases utilizing three of the Company's future products: (i) new products that contain the Arakoda regimen of tafenoquine; (ii) new products that contain tafenoquine; and (iii) celgosivir. 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 payable by the Company (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, which is 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.

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 continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financial requirements, raise additional capital, and the success of its future operations. The financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company not continue as a going concern.

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

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 condensed financial statements pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC"). These financial statements are unaudited and, in our opinion, include all adjustments consisting of normal recurring adjustments and accruals necessary for a fair presentation of our consolidated condensed balance sheets, consolidated condensed statements of operations and other comprehensive income (loss), consolidated condensed statements of shareholders' and member's equity (deficit) and consolidated condensed statements of cash flows for the periods presented. Operating results for the periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 due to various factors. These consolidated condensed financial statements should be read in conjunction with the audited consolidated financial statements for the years ended December 31, 2022 and 2021 and related notes thereto as contained in the Company's Registration Statement. Certain information and footnote disclosures that would substantially duplicate the disclosures contained in the Registration Statement have been omitted.

Principles of Consolidation and Noncontrolling Interest

The Company's consolidated condensed 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 condensed statement 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.

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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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 September 30, 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 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. 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, and 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 incurred 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.

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. 100% of receivables as of September 30, 2023, consisting of two significant customers at 78% and 22%, are outstanding from significant customers. At December 31, 2022, 98% of the Company's receivables, consisting of three customers and two significant at 59% and 39%, were outstanding from significant customers. For the three months ended September 30, 2023, 100% of total net revenues (consisting of one significant customer) were generated by significant customers (100% for the three months ended September 30, 2022 consisting of three significant customers at 48%, 43%, and 9%). For the nine months ended September 30, 2023, 100% of the revenues were generated by the Company from significant customers, consisting of two customers at 72% and 28% (100% for the nine months ended September 30, 2022, consisting of three customers at 65%, 29%, and 6% respectively).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Concentrations (Continued)

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

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

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 during 2022 and near-term receivables and revenues from the government are not anticipated to be significant.

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

As of September 30, 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. The terms of the preferred share conversion with Knight Therapeutics currently limits the Company's ability to access additional credit without their consent.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Concentrations (Continued)

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 $263,703 and $591,569 in research and development costs expense during the three and nine months ended September 30, 2023, respectively ($182,655 and $477,106 for the three and nine months ended September 30, 2022, respectively). During the nine months ended September 30, 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. The agreements with these 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 security laws, the nonemployees can sell the received equity instruments. Kentucky Technology Inc. is expected to render research and development services to identify a combination drug partner for tafenoquine over a period of one year. 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. At September 30, 2023, the Company recorded $2,834,148 current unamortized deferred prepaid research and development costs ($0 at December 31, 2022). Current unamortized deferred prepaid research and development costs are presented as a component of Prepaid and Other on the accompanying consolidated condensed balance sheets.

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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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

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 income in the consolidated statements of operations. Changes in fair value related to credit risk are recognized in other comprehensive income. 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 September 30, 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 September 30, 2023 and December 31, 2022 are as follows:

	September 30, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Promissory Notes (including accrued interest), at fair value	$ -	$ -	$ -	$ -
Derivative Liabilities	-	-	2,174,194	2,174,194
Total	$ -	$ -	$ 2,174,194	$ 2,174,194

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

Foreign Currency Transactions and Translation

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

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

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

	Average Exchange Rate					
	Three Months Ended September 30,		Nine Months Ended September 30,		As of	
Currency	**2023**	**2022**	**2023**	**2022**	**September 30, 2023**	**December 31, 2022**
1 AUD =	0.6545 USD	0.6837 USD	0.6688 USD	0.7074 USD	0.6428 USD	0.6805 USD
1 SGD =	NA	NA	NA	1.0150 AUD*	NA	1.0230 AUD*

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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 income (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 management's 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 straight-line 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 equity instruments when they are granted. The corresponding cost is recognized as an immediate expense or a prepaid asset depending on the specific facts and circumstances of the agreement with the nonemployee.

During the nine months ended September 30, 2023 and 2022, 513,000 and 0 common stock shares, respectively, were issued as fully vested, nonforfeitable equity instruments to nonemployees. 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. 120,000 and 100,000 of the common stock shares issued during the nine months ended September 30, 2023 were issued to Trevally, LLC and Carmel, Milazzo & Feil LLP, respectively. Before March 31, 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. Carmel, Milazzo & Feil LLP is expected to provide legal services before March 31, 2024. As of September 30, 2023, the unamortized balance of prepaid assets related to these share-based payments for which the services are expected to be rendered within one year is $1,063,235 ($0 at December 31, 2022), which is reported in Prepaid and Other on the Consolidated Condensed Balance Sheets.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Net Income (Loss) per Common Share

Net Income (Loss) per Common Share is computed by dividing net income or loss 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 a reduction to net income (loss) in determining basic and diluted net earnings (loss) attributable to common stockholders.

For periods in which a loss is reported, diluted net loss per common share is the same as basic net loss per common share for those periods. For the three months ended September 30, 2023, the diluted net income (loss) per share computation did not include the anti-dilutive effect of the common stock warrants, stock options and unvested restricted stock units granted under the 2022 Plan, as their effect would be anti-dilutive under the treasury stock method.

Related Parties

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

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through November 20, 2023, which is the date the financial statements were issued. See Note 13.

Recently Issued and Adopted 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 condensed 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 condensed financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Recently Issued and Adopted Accounting Pronouncements (Continued)

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 condensed 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 condensed financial statements.

3. INVENTORY

Inventory consists of the following major classes:

	September 30, 2023	December 31, 2022
Raw Material (API)	$ 350,362	$ 397,487
Packaging	73,391	97,486
Finished Goods	108,208	183,943
Clinical Trial Supplies	149,812	63,062
Total Inventory	681,773	741,978
Reserve for Expiring Inventory	(83,454)	(223,400)
Inventory, net	**$ 598,319**	**$ 518,578**

4. PROPERTY AND EQUIPMENT

As of September 30, 2023 and December 31, 2022, Property and Equipment consists of:

	September 30, 2023	December 31, 2022
Lab Equipment	$ 132,911	$ 132,911
Computer Equipment	14,084	12,261
Furniture	3,030	3,030
Property and Equipment, at Cost	150,025	148,202
Accumulated depreciation	(146,189)	(126,902)
Property and Equipment, Net	**$ 3,836**	**$ 21,300**

Depreciation expenses for Property and Equipment for the nine months ended September 30, 2023 and 2022 were in the amount of $19,287 and $20,747, respectively ($5,485 and $6,901 for the three months ended September 30, 2023 and 2022, respectively).

5. INTANGIBLE ASSETS

As of September 30, 2023 and December 31, 2022, Intangible Assets consist of:

	September 30, 2023	December 31, 2022
Patents	$ 174,833	$ 145,613
Website Development Costs	79,248	27,070
Intangible Assets, at Cost	254,081	172,683
Accumulated Amortization	(29,034)	(8,428)
Intangible Assets, Net	**$ 225,047**	**$ 164,255**

During the three months ended September 30, 2023 and 2022, the Company capitalized website development or related costs of $12,283 and $0, respectively ($52,178 and $0 for the nine months ended September 30, 2023 and 2022, respectively), in connection with the upgrade and enhancement of functionality of the corporate website at www.60-p.com. Amortization expense for the nine months ended September 30, 2023, and 2022 was in the amount of $20,606 and $2,783, respectively ($7,414 and $1,831 for the three months ended September 30, 2023 and 2022, respectively).

The following table summarizes the estimated future amortization expense for our patents and website development costs as of September 30, 2023:

Period	Patents	Website Development Costs
2023 (remaining three months)	$ 1,670	$ 6,604
2024	6,681	26,416
2025	6,681	23,303
2026	6,681	3,974
Thereafter	55,656	-
Total	**$ 77,369**	**$ 60,297**

The Company additionally has $83,808 in capitalized patent expenses that will be 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.

6. STOCKHOLDER'S EQUITY (CONTINUED)

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 September 30, 2023, 5,799,535 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. 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 14, 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 25, 2023, the Company issued 45,560 shares of common stock to Knight upon conversion of 2,162 shares of Series A Preferred Stock.

6. STOCKHOLDER'S EQUITY (CONTINUED)

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 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 summarizes the activity for the Company's equity-classified warrants for the three months ended September 30, 2023:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Total outstanding, June 30, 2023	-	$ -	-
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, September 30, 2023	3,163,854	$ 6.17	4.73
Total exercisable, September 30, 2023	3,163,854	$ 6.17	4.73

There were no warrant exercises, forfeitures, or expirations prior to the IPO. During the three months ended September 30, 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.

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.

6. STOCKHOLDER'S EQUITY (CONTINUED)

Series A Preferred Stock (Continued)

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 September 30, 2023, accrued dividends on outstanding shares of Series A Preferred Stock totaled $101,538. As of September 30, 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 is payable contingent upon a future capital raise and is non-interest bearing. On May 5, 2022, the Company agreed to modify their contract with Biointelect. 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 the next five years the Company nets at least $10,000,000 in an IPO or any private financing that secures the retirement and/or conversion to equity of all secured debt excluding the loans advanced by the Small Business Administration. Then before the year ended December 31, 2022, the Company and Latham Biopharma initiated an agreement that converted the entire deferred compensation into 65,000 shares valued at $5 per share. As of December 31, 2022, the Company recognized a contingent liability related to the subsequent agreement of $325,000. On January 11, 2023, the Company issued 65,000 shares to Latham Biopharma 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 bear 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 matures 60 days after the Knight Loans are 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 consummates an IPO. The Amendment also provides the lender the option to convert the outstanding principal and accumulated interest through March 31, 2022 into equity shares of the Company at the maturity date, which option shall expire 30 days after maturity. Cumulative interest after March 31, 2022 will 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 are being amortized over the remaining life of the debt using the effective interest method. Amortization of the discount on the Note for the three months ended September 30, 2023 and 2022 was $3,869 and $0, respectively ($52,628 and $0 for the nine months ended September 30, 2023 and 2022, respectively). Interest expense related to the Note, for the three months ended September 30, 2023 and 2022 was $4,944 and $29,429, respectively ($66,558 and $85,242 for the nine months ended September 30, 2023 and 2022, 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 September 30, 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	$ -	$ -	$ -	$ -

8. DEBT (CONTINUED)

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 bear interest at 10% with a default interest rate of 15% and are 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 bear interest at 10% with a default interest rate of 15% and are 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 condensed statement of operations and comprehensive income (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 contain an original issue discount of 10% ($33,888) and debt issuance costs of $34,289, resulting in net proceeds of $270,711. These notes bear interest at 6% with a default interest rate of 15% and are unsecured. The notes 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.

8. DEBT (CONTINUED)

Related Party Notes (Continued)

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 September 30, 2023 and December 31, 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**	**1**
Interest rate	10%	6%	10%
Default interest rate	15%	15%	15%
Collateral	Unsecured	Unsecured	Unsecured
Conversion rate	**2**	**2**	**2**
Face amount of notes	$ 888,889	$ 338,889	$ -
Less: unamortized debt discount	(407,555)	(155,443)	-
Add: accrued interest on promissory notes	54,567	11,651	-
Balance - December 31, 2022	$ 535,901	$ 195,097	$ -
Face amount of notes	-	-	-
Less: unamortized debt discount	-	-	-
Add: accrued interest on promissory notes	-	-	-
Balance - September 30, 2023	$ -	$ -	$ -

1- earlier of 1 year from date of issuance or closing of IPO.

2- see discussion above for (a) and (b)

For the nine months ended September 30, 2023 and 2022, the Company recorded amortization of debt discounts, including issuance costs, of $670,550 and $453,063, 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.

8. DEBT (CONTINUED)

Knight Debt Conversion (Continued)

- 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 three and nine months ended September 30, 2023:

	Convertible Knight Note, at fair value
Promissory Notes, at fair value at December 31, 2022	$ -
Fair value at modification date - January 9, 2023	21,520,650
Fair value - mark to market adjustment	(339,052)
Accrued interest recognized	634,243
Promissory Notes, at fair value at March 31, 2023	$ 21,815,841
Fair value - mark to market adjustment	1,064,849
Accrued interest recognized	659,306
Promissory Notes, at fair value at June 30, 2023	$ 23,539,996
Fair value - mark to market adjustment	(6,105,066)
Extinguishment of Promissory Notes	(17,434,930)
Promissory Notes, at fair value at September 30, 2023	$ -

8. DEBT (CONTINUED)

Knight Debt Conversion (Continued)

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 $6,106,066 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 ($368,091 during the nine months ended September 30, 2022) and the unamortized original issue discount at September 30, 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 September 30, 2023 and December 31, 2022 consisted of the following:

	September 30, 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 has been extended an additional eighteen months. Thus, the Company was first obligated to start making interest payments of $731 on November 4, 2022. The balance as of September 30, 2023 is $161,366 ($163,022 at December 31, 2022). The current maturity at September 30, 2023 is $8,772 and the long-term liability is $152,594 ($2,750 and $160,272 at December 31, 2022, respectively).

8. DEBT (CONTINUED)

SBA COVID-19 EIDL (Continued)

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

Period	Principal Payments
2023 (remaining three months)	$ -
2024	-
2025	-
2026	-
2027	2,804
Thereafter	147,196
Total	**$ 150,000**

Due to the deferral, the Company is expected to make a balloon payment of $32,383 to be due on 10/12/2050.

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 September 30, 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 three and nine months ended September 30, 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

9. DERIVATIVE LIABILITIES (CONTINUED)

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 three and nine months ended September 30, 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 September 30, 2023 and December 31, 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	4,902	1,689	(1,457)	-	5,134
Derivative liabilities - March 31, 2023	$ 839,254	$ 579,853	$ 80,227	$ -	$ 1,499,334
Fair value - commitment date	680,276	274,449	-	-	954,725
Fair value - mark to market adjustment	8,896	(17,009)	145	-	(7,968)
Derivative liabilities - June 30, 2023	$ 1,528,426	$ 837,293	$ 80,372	$ -	$ 2,446,091
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	-		-	57,052	57,052
Derivative liabilities - September 30, 2023	$ -	$ -	$ -	$ 2,174,194	$ 2,174,194

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 September 30, 2022 and December 31, 2021:

	Bridge Shares	Warrants	Convertible Notes Payable	Total
Derivative liabilities - December 31, 2021	$ -	$ -	$ -	$ -
Fair value - commitment date	823,687	565,007	95,194	1,483,888
Fair value - mark to market adjustment	664	2,932	(2,595)	1,001
Derivative liabilities - June 30, 2022	$ 824,351	$ 567,939	$ 92,599	$ 1,484,889
Fair value - mark to market adjustment	1,352	25,869	(4,726)	22,495
Derivative liabilities - September 30, 2022	$ 825,703	$ 593,808	$ 87,873	$ 1,507,384

Changes in fair value of derivative liabilities (mark to market adjustment) are included in other income (expense) in the accompanying consolidated condensed statements of operations and comprehensive income (loss). During the nine months ended September 30, 2023, the Company recorded a net change in the fair of derivative liabilities of ($95,324). From the commitment date of May 8, 2022 to September 30, 2022, the Company recorded a net change in the fair value of derivative liabilities of $23,496.

9. DERIVATIVE LIABILITIES (CONTINUED)

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, we have remeasured 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

The Company did not record a federal income tax provision or benefit for each of the three and nine months ended September 30, 2023 and 2022 due to losses. The Company recorded a provision for income taxes for DC of $63 and $189 for the three and nine months ended September 30, 2023, respectively, thereby reflecting the minimum statutory tax due ($250 and $750 for the three and nine months ended September 30, 2022, respectively).

11. SHARE-BASED COMPENSATION

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. As of September 30, 2023, the maximum shares available under the 2022 Plan is equal to 238,601.

Stock Grants

On July 11, 2023, the Company recognized $187,196 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 condensed statement of operations.

11. SHARE-BASED COMPENSATION (CONTINUED)

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 vest over periods ranging from one to five years. The Company estimates the fair value of stock options on the grant date by applying the Black-Scholes option pricing valuation model.

The following table summarizes the significant assumptions used in determining the fair value of options granted for the three and nine months ended September 30, 2023:

	2023
Weighted-average grant date fair value	$ 3.42
Risk-free interest rate	4.25% - 4.33%
Expected volatility	105.0% - 110.0%
Expected term (years)	3.18 - 3.76
Expected dividend yield	0.00%

Upon the Closing of the IPO on July 12, 2023, the Company granted an aggregate of 607,924 stock options to directors and executives, with a weighted average exercise price of $4.75. There were no stock options granted, issued, or outstanding prior to the IPO. For the three and nine months ended September 30, 2023, the Company recognized $233,728 of compensation expense related to stock option awards ($0 for the three and nine months ended September 30, 2022).

Restricted Stock Units

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.

Upon the Closing of the IPO on July 12, 2023, the Company granted an aggregate of 32,000 RSUs to directors of the Company. No RSUs were granted, vested, or outstanding prior to the IPO. For the three and nine month periods ended September 30, 2023, the Company recognized $37,338 of compensation expense related to the vesting of 8,000 RSUs ($0 and 0 shares, respectively, for the three and nine months ended September 30, 2022). These shares are excluded from the number of shares outstanding at September 30, 2023 as the shares have not yet been legally issued.

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 until March 31, 2024. The Company applies ASC 842 to its operating leases, which are reflected on the consolidated condensed balance sheets within Right of Use (ROU) Asset and the related current and non-current operating lease liabilities. ROU assets represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments arising from lease agreement. 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.

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%
2023 (remaining three months)	$ 13,992
2024	13,992
Thereafter	-
Total undiscounted minimum future payments	27,984
Imputed interest	(1,184)
Total operating lease payments	26,800
Short-term lease liabilities	26,800
Long-term lease liabilities	$ -

12. COMMITMENTS AND CONTINGENCIES (CONTINUED)

Operating Lease (Continued)

Other information related to our operating lease is as follows:

	September 30, 2023
Weighted average remaining lease term (in years)	0.50
Weighted average discount rate	15.00%

Operating lease costs were in the amount of $13,859 and $12,974 for the three months ended September 30, 2023, and September 30, 2022, respectively ($41,225 and $38,921 for the nine months ended September 30, 2023, and September 30, 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, (ii) a fully vested, non-qualified option to purchase 9,434 shares of common stock at an exercise price of $5.30 per share, (iii) a non-qualified option to purchase 7,547 shares of common stock at an exercise price of $5.30 per share, which vests 100% one year from the date of grant, and (iv) restricted stock units covering 8,000 shares of the Company's common stock which vest in equal quarterly installments over one year from the date of grant. See Note 11 for further details.

Contingencies

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

Contingent Compensation

Prior to 2015 the Company agreed with certain vendors, advisors and employees to deferred compensation that expires on December 31, 2023. The net amount of these contingent payments is $43,581. The Company does not anticipate the trigger for these payments to be reached prior to expiration.

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).

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 September 30, 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 November 20, 2023, which is the date the financial statements were issued.

On October 6, 2023, the Company's Board of Directors decided that its subsidiary, 60P Australia Pty Ltd., will not re-submit its investigational new drug ("IND") application for ACLR8-LR, a Phase IIB study of tafenoquine compared to placebo in patients with mild to moderate COVID-19 disease and low risk of disease progression. The decision was in response to recent comments received from the U.S. Food and Drug Administration ("FDA"). As a result, the Company expects a return of the deposited funds from the contract research organization engaged for the suspended trial of approximately $820,000, of which $419,755 was received on November 9, 2023.

The Company decided it will instead prepare to conduct a Phase IIA study of tafenoquine in hospitalized babesiosis patients. On November 1, 2023, the Company submitted a request for a Type C meeting with FDA under its malaria IND 129656. That meeting is scheduled for January 15, 2024.

On November 2, 2023, the Company received a letter from The Nasdaq Capital Market stating that for the 30 consecutive business days ending on November 1, 2023, 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 April 30, 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 financial statements.

60 DEGREES PHARMACEUTICALS, INC
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 60 Degrees Pharmaceuticals, Inc. (formerly known as 60 Degrees Pharmaceuticals, LLC) and subsidiaries ("the Company") as of December 31, 2022 and 2021, and the related statements of operations and comprehensive loss, shareholders' and members' deficit, and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Change in Reporting Entity

As described in Note 6, the Company operated as a Limited Liability Company, LLC, from January 1, 2022 to May 31, 2022 and converted to a "C" Corporation starting from June 1, 2022 through December 31, 2022. Prior to the Company's conversion from an LLC to a Corporation, the LLC equity structure consisted of "Membership Units.

The Company's Ability to Continue as a Going Concern

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

Basis for Opinion

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

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

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

/s/ RBSM LLP

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

Las Vegas, Nevada

April 3, 2023

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash	$ 264,865	$ 115,399
Accounts Receivable	45,965	146,362
Prepaid and Other	200,967	225,869
Deferred Offering Costs	68,629	-
Inventory (Note 3)	518,578	689,042
Total Current Assets	**1,099,004**	**1,176,672**
Property and Equipment, net (Note 4)	21,300	48,948
Other Assets:		
Right of Use Asset (Note 11)	12,647	58,667
Intangible Assets, net (Note 5)	164,255	109,240
Total Other Assets	**176,902**	**167,907**
Total Assets	**$ 1,297,206**	**$ 1,393,527**
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current Liabilities:		
Accounts Payable and Accrued Expenses	$ 758,668	$ 588,678
Lease Liability (Note 11)	13,000	46,795
Deferred Compensation (Note 7)	325,000	-
Related Party Notes, net *(including accrued interest)* (Note 9)	195,097	-
Debenture (Note 8)	4,276,609	-
SBA EIDL *(including accrued interest)* (Note 8)	2,750	-
Promissory Notes *(including accrued interest)* (Notes 8 and 9)	16,855,887	-
Derivative Liabilities (Note 9)	1,129,840	-
Derivative Liabilities – Related Parties (Note 9)	364,360	-
Total Current Liabilities	**23,921,211**	**635,473**
Long-Term Liabilities:		
Deferred Compensation (Note 7)	255,000	154,743
Lease Liability (Note 11)	-	13,000
Debenture (Note 8)	-	3,388,570
SBA EIDL *(including accrued interest)* (Note 8)	160,272	159,161
Promissory Notes *(including accrued interest)* (Note 8)	1,109,783	15,197,064
Total Long-Term Liabilities	**1,525,055**	**18,912,538**
Total Liabilities	**25,446,266**	**19,548,011**
Commitments and Contingencies (Note 11)		
SHAREHOLDERS' DEFICIT		
Members' Capital	-	4,979,365
Preferred stock, $0.0001 par value, 1,000,000 shares authorized; no shares issued and outstanding	-	-
Class A common stock, $0.0001 par value, 150,000,000 shares authorized; 2,386,009 and no shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively (Note 6)	239	-
Additional Paid-in-Capital	5,164,461	-
Accumulated Other Comprehensive Income	73,708	75,835
Accumulated Deficit	(28,815,148)	(22,633,428)
60P Shareholders' Deficit	(23,576,740)	(17,578,228)
Noncontrolling interest	(572,320)	(576,256)
Total Shareholders' Deficit	**(24,149,060)**	**(18,154,484)**
Total Liabilities and Shareholders' Deficit	**$ 1,297,206**	**$ 1,393,527**

The accompanying notes are an integral part of these audited consolidated financial statements.

60 DEGREES PHARMACEUTICALS, INC
Consolidated Statements of Operations and Comprehensive Loss

For Fiscal Years Ended December 31,	2022	2021
Product Revenues – net of Discounts and Rebates	$ 192,913	$ 1,078,440
Service Revenues	30,295	81,900
Product and Service Revenues	223,208	1,160,340
Cost of Revenues	432,370	850,742
Gross (Loss) Profit	(209,162)	309,598
Research Revenues	288,002	5,192,516
Net Revenue	78,840	5,502,114
Operating Expenses		
Research and Development	525,563	5,510,866
General and Administrative Expenses	1,303,722	1,115,350
Total Operating Expenses	1,829,285	6,626,216
Loss from Operations	(1,750,445)	(1,124,102)
Interest Expense	(3,989,359)	(3,172,712)
Derivative Expense	(504,613)	-
Change in Fair Value of Derivative Liabilities	(10,312)	-
Gain on Debt Extinguishment	120,683	-
Other (Expense) Income	(43,238)	37,515
Total Interest and Other Expense (Income), net	(4,426,839)	(3,135,197)
Loss from Operations before Provision for Income Taxes	(6,177,284)	(4,259,299)
Provision for Income Taxes (Note 10)	500	1,000
Net Loss including Noncontrolling interest	(6,177,784)	(4,260,299)
Net Gain (Loss) – Noncontrolling Interest	3,936	(8,554)
Net Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	(6,181,720)	(4,251,745)
Comprehensive Loss:		
Net Loss	(6,177,784)	(4,260,299)
Unrealized Foreign Currency Translation Gain (Loss)	(2,127)	(3,031)
Total Comprehensive Loss	(6,179,911)	(4,263,330)
Net Gain (Loss) – Noncontrolling Interest	3,936	(8,554)
Unrealized Foreign Currency Translation (Loss) Gain from Noncontrolling Interest	-	1,588
Comprehensive Loss – attributed to 60 Degrees Pharmaceuticals, Inc.	**$ (6,183,847)**	**$ (4,256,364)**
Net loss (June 1 – December 31, 2022) per common share		
Basic and Diluted	$ 1.78	$ -
Weighted average number of common shares outstanding (June 1 – December 31, 2022)		
Basic and Diluted	2,380,986	-

The accompanying notes are an integral part of these audited consolidated financial statements.

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS'AND MEMBERS' DEFICIT

For Fiscal Years Ended December 31, 2022 and 2021

	Members' Equity		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Shareholders' Equity (Deficit) Attributable	Noncontrolling Interest on	Total Shareholders'
	Units	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	to 60P	Shareholders	Deficit
Balance—December 31, 2020	**14,675,500**	**$ 799,700**	**-**	**$ -**	**$ -**	**$ (18,381,683)**	**$ 80,454**	**$ (17,501,529)**	**$ (569,290)**	**$ (18,070,819)**
Conversion of Debt into Member Units	4,179,665	4,179,665	-	-	-	-	-	4,179,665		4,179,665
Foreign Translation (Loss) Gain	-	-	-	-	-	-	(4,619)	(4,619)	1,588	(3,031)
Net loss	-	-	-	-	-	(4,251,745)	-	(4,251,745)	(8,554)	(4,260,299)
Balance—December 31, 2021	**18,855,165**	**$ 4,979,365**	**-**	**$ -**	**$ -**	**(22,633,428)**	**$ 75,835**	**$ (17,578,228)**	**$ (576,256)**	**(18,154,484)**
Net Foreign Translation Loss through May 31, 2022	-	-	-	-	-	-	(28,654)	(28,654)	(611)	(29,265)
Net (Loss) Gain through May 31, 2022	-	-	-	-	-	(1,949,246)	-	(1,949,246)	1,370	(1,947,876)
Business Combination: June 1, 2022 (60P, LLC into 60P, Inc.)	(18,855,165)	(4,979,365)	2,348,942	235	4,979,130	-	-	-	-	-
Issuance of Shares June 30, 2022	-	-	37,067	4	185,331	-	-	185,335	-	185,335
Net Foreign Translation Gain after June 1, 2022	-	-	-	-	-	-	26,527	26,527	611	27,138
Net (Loss) Gain after June 1, 2022	-	-	-	-	-	(4,232,474)	-	(4,232,474)	2,566	(4,229,908)
Balance—December 31, 2022	**-**	**$ -**	**2,386,009**	**$ 239**	**$ 5,164,461**	**$ (28,815,148)**	**$ 73,708**	**$ (23,576,740)**	**$ (572,320)**	**$ (24,149,060)**

The accompanying notes are an integral part of these audited consolidated financial statements.

60 DEGREES PHARMACEUTICALS, INC
CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Years Ended December 31,	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (6,177,784)	$ (4,260,299)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation	27,648	27,528
Amortization	5,118	3,310
Amortization of Debt Discount	1,090,387	604,595
Amortization of ROU Asset	46,020	40,947
Amortization of Note Issuance Costs	74,496	-
Gain on Debt Extinguishment	(120,683)	-
Derivative expense	504,613	-
Change in fair value of derivative liabilities	10,312	-
Inventory Reserve	223,400	38,322
Changes in Operating Assets and Liabilities:		
Accounts Receivable	100,397	713,063
Prepaid and Other	24,902	135,844
Inventory	(52,936)	312,226
Accounts Payable and Accrued Liabilities	169,990	(844,670)
Accrued Interest	2,685,678	2,568,118
Reduction of Lease Liability	(46,795)	(39,820)
Deferred Compensation	425,257	51,730
Net Cash Used in Operating Activities	**(1,009,980)**	**(649,106)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Capitalization of Patents	(33,063)	(32,324)
Purchases of Property and Equipment	-	(3,068)
Acquisition of Intangibles	(27,070)	-
Net Cash Used in Investing Activities	**(60,133)**	**(35,392)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of Deferred Offering Costs	(68,629)	-
Proceeds from Notes Payable	800,000	-
Proceeds from Notes Payable – Related Parties	305,000	683,226
Repayments on Notes Payable – Related Party	-	(72,000)
Proceeds from Advances – Related Party	185,335	-
Net Cash Provided by Financing Activities	**1,221,706**	**611,226**
Foreign Currency Translation Loss	(2,127)	(3,031)
Change in Cash	149,466	(76,303)
Cash—Beginning of Year	115,399	191,702
Cash—End of Year	**$ 264,865**	**$ 115,399**
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid During the Year for Interest	$ 2,193	$ -
Cash paid During the Year for Income Taxes	1,000	750
NONCASH INVESTING/FINANCING ACTIVITIES		
Right-of-use asset obtained in exchange for new operating lease liability	-	99,615
Debt discount recorded in connection with derivative liabilities	1,105,000	-
Conversion of Debt into Shares	185,335	-
Conversion of Debt into Member Units	$ -	$ 4,179,665

The accompanying notes are an integral part of these audited consolidated financial statements.

1. NATURE OF OPERATIONS

60 Degrees Pharmaceuticals, Inc. was incorporated in Delaware on June 1, 2022 and merged on the same day with 60^{o} Pharmaceuticals, LLC which was organized on September 9, 2010 in the District of Columbia. The financial statements of 60 Degrees Pharmaceuticals, Inc. and its subsidiaries (which may be referred to as the "Company", "we", "us", "our", "60P" or "60 Degrees Pharmaceuticals") are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company's headquarters are located in Washington, DC.

60 Degrees Pharmaceuticals, Inc. was formed to develop new medicines for the treatment and prevention of infectious diseases. Since its founding, the Company has developed Arakoda™ for the prevention of malaria. The Company continues to develop its novel products targeting the effects and treatment of diseases such as Coronaviruses.

Going Concern

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

In view of these matters, continuation as a going concern is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financial requirements, raise additional capital, and the success of its future operations. The financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company not continue as a going concern.

Management plans to fund operations of the Company through third-party and related party debt/advances, private placement of restricted securities and the issuance of stock in a public offering until such a time as a business combination or other profitable investment may be achieved. There currently is a plan in place to take the Company public in an IPO transaction in the first half of 2023. Management believes that this plan provides an opportunity for the Company to continue as a going concern.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accounting and reporting policies of the Company and its subsidiaries are presented on a consolidated basis and conform to GAAP after elimination of intercompany transactions and accounts. These consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. The Company has adopted the calendar year as its basis of reporting.

Principles of Consolidation and Non-Controlling Interest

The Company's consolidated financial statements include the financial statements of its majority-owned (87.53%) subsidiary 60P Australia Pty Ltd, as well as the financial statements of 60P Singapore Pty Lte, a wholly owned subsidiary of 60P Australia Pty Ltd. 60P Singapore Pty Lte was closed via dissolution as of March 31, 2022. All significant intercompany accounts and transactions have been eliminated in consolidation. 60P Singapore Pty Lte was originally set up to conduct research in Singapore. The entity had no assets and its liabilities were to both 60P Australia Pty Ltd, its direct owner, and 60P. Through consolidation accounting the closure of the business Unit resulted in a currency exchange gain.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Principles of Consolidation and Non-Controlling Interest (Continued)

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

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents include all cash in banks and short-term highly liquid investments (with original maturities of three months or less) as cash equivalents. The Company's cash is deposited in demand accounts at financial institutions that management believes are creditworthy. The Company's cash and cash equivalents in bank deposit accounts, at times, may exceed federally insured limits. On December 31, 2022, the Company's cash and cash equivalents did not exceed FDIC insured limits (did not exceed FDIC insured limits at December 31, 2021). The Company also held cash at its subsidiaries in Australia and Singapore though the amounts were minimal. The Company has not experienced any losses related to amounts in excess of FDIC limits. The Company does not hold any cash equivalents, which would consist of highly liquid investments with original maturities of three months or less at the time of purchase.

Accounts Receivable and Allowance for Doubtful Accounts

The Company records accounts receivable at net realizable value. This value includes an appropriate allowance for estimated uncollectible accounts to reflect any loss anticipated on the trade accounts receivable balances and charged to the provision for doubtful accounts. Based on the Company's history there has been no need to make a recording to allowance for doubtful accounts. Most of the Company's revenue has been earned via government contracts, and with a large American pharmaceutical distributor. As the Company continues to engage with smaller distributors, we will continue to analyze whether an entry should be recorded in Allowance for Doubtful Accounts. There was no allowance as of December 31, 2022 and December 31, 2021. At the year ended December 31, 2022, the US government accounted for 66% of the outstanding AR balance (84% at December 31, 2021) and the American pharmaceutical distributor accounted for 30% of the outstanding AR balance at the year ended December 31, 2022 (15% at the year ended December 31, 2021).

Inventory

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

Property and Equipment

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Property and Equipment (Continued)

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

Impairment of Long-lived Assets

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

Intangible Assets

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

Website Development Costs

The Company accounts for website development costs in accordance with ASC 350-50 "Website Development Costs". Accordingly, all costs incurred in the planning stage are expensed as incurred, costs incurred in the website application and infrastructure development stage that meet specific criteria are capitalized and costs incurred in the day-to-day operation of the website are expensed as incurred. All costs associated with the websites are subject to straight-line amortization over a three-year period.

For the years ended December 31, 2022 and 2021, the Company capitalized website development or related costs of $27,070 and none, respectively, in connection with the upgrade and enhancement of functionality of corporate website at www.60-p.com.

Derivative Liabilities

The Company assessed the classification of its derivative financial instruments as of December 31, 2022 and December 31, 2021, which consist of bridge shares, convertible notes payable and certain warrants (excluding those for compensation) and has determined that such instruments qualify for treatment as derivative liabilities as they meet the criteria for liability classification under ASC 815.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Derivative Liabilities (Continued)

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

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

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

Original Issue Discount ("OID")

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

Debt Issuance Cost

Debt issuance costs paid to lenders, or third parties are recorded as debt discounts and amortized to interest expense over the life of the underlying debt instrument, in the Consolidated Statements of Operations and Comprehensive Loss.

Income Taxes

60 Degrees Pharmaceuticals, Inc. is a corporation and has accepted the default taxation status of C corporation. The merger does not materially impact tax matters in 2022 as the LLC had elected to be taxed as a C corporation for income tax purposes at the beginning of 2022. Previously, the LLC was taxed as a partnership in which for federal purposes, all income tax benefits of a partnership are passed through to the members. The District of Columbia taxes partnerships on form D-30 (District of Columbia Unincorporated Business Franchise Tax Return) and corporations on form D-20 (District of Columbia (DC) Corporation Franchise Tax Return) and both returns have a minimum tax due of $250 if gross receipts are at $1 million or less and a $1,000 if above. The tax years that remain subject to examination by major tax jurisdictions include the years ended December 31, 2019, 2020 and 2021.

60P Australia Pty Ltd is subject to the taxes of the Australian Taxation Office and the now closed 60P Singapore Pte Ltd was subject to the taxes of the Inland Revenue Authority of Singapore.

Concentrations

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Concentrations (Continued)

Significant customers represent any customer whose business makes up 10% of our receivables or revenues. 96% of receivables (consisting of three customers and two significant at 66% and 30%) and 100% of revenues (consisting of four customers and three significant at 40%, 39% and 14% respectively) were generated by significant customers for the year ended December 31, 2022. 99% of the Company's receivables (consisting of three customers and two significant at 84% and 15%) and 100% of the revenues (consisting of three customers and all of them significant at 95%, 3% and 2% respectively) were generated by the Company from significant customers during the year ended December 31, 2021. Currently, the Company has exclusive relationships with distributors in Australia and Europe. A failure to perform by any of our current distributors would create disruption for patients in those markets. The US government has historically been the Company's largest customer through a purchase support contract and a clinical study. Both of those activities ended as during 2022 and near-term receivables and revenues from the government are not anticipated to be significant.

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

As of December 31, 2022, 85% (93% at December 31, 2021) of the Company's non-related party debt is held by Knight Therapeutics, the senior secured lender and also a publicly traded Canadian company. The amount of senior secured debt with Knight Therapeutics currently limits the Company's ability to access additional credit and management has been informed that additional lending with Knight Therapeutics is not currently possible.

Business Segments

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

Revenue Recognition

The Company recognizes revenue in accordance with the Financial Accounting Standards Board's ("FASB"), Accounting Standards Codification ("ASC") ASC 606, Revenue from Contracts with Customers ("ASC 606"). Revenues are recognized when control is transferred to customers in amounts that reflect the consideration the Company expects to be entitled to receive in exchange for those goods. Revenue recognition is evaluated through the following five steps: (i) identification of the contract, or contracts, with a customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the performance obligations in the contract; and (v) recognition of revenue when or as a performance obligation is satisfied.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Research and Development Costs

The Company accounts for research and development costs in accordance with ASC subtopic 730-10, Research and Development ("ASC 730-10"). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred.

The Company recorded $525,563 in research and development costs during the year ended December 31, 2022 ($5,510,866 for the year ended December 31, 2021).

Fair Value of Financial Instruments

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

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

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

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

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

See Note 9 regarding Derivative Liabilities.

Liabilities measured at fair value at December 31, 2022 and December 31, 2021 are as follows:

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

Foreign Currency Transactions and Translation

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Foreign Currency Transactions and Translation (Continued)

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

translated at the average exchange rates for the period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the dates of the transactions are used. Exchange differences arising, if any, are recognized in other income. Exchange rates along with historical rates used in these financial statements are as follows:

	Average Exchange Rate as of December 31,		December 31,	December 31,
Currency	2022	2021	2022	2021
1 AUD =	0.6948 USD	0.7513 USD	0.6805 USD	0.72644959 USD
1 SGD =	1.015 AUD*	0.9912 AUD	1.023 AUD*	1.02069301 AUD

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

Reclassifications

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

Accumulated Comprehensive Income (Loss)

Other comprehensive loss consists of foreign currency translation adjustments, unrealized gains and losses from cash flow hedges.

2022 Equity Incentive Plan

On November 22, 2022, the Company adopted a 2022 Equity Incentive Plan also referred to as ("2022 Plan"). The maximum shares available under the 2022 Plan is equal to 10% of the currently outstanding shares or 238,601.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through April 3, 2023, which is the date the financial statements were issued.

Recently Issued and Adopted Accounting Pronouncements

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Recently Issued and Adopted Accounting Pronouncements (Continued)

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

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

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

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

Related Parties

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

3. INVENTORY

Inventory consists of the following major classes:

	December 31, 2022	December 31, 2021
Raw Material (API)	$ 397,487	$ 538,320
Packaging	97,486	88,468
Finished Goods	183,943	37,514
Clinical Trial Supplies	63,062	63,062
Total Inventory	**741,978**	**727,364**
Reserve for Expiring Inventory	(223,400)	(38,322)
Inventory, net	**$ 518,578**	**$ 689,042**

4. PROPERTY AND EQUIPMENT

As of December 31, 2022 and December 31, 2021, Property and Equipment consists of:

	December 31, 2022	December 31, 2021
Lab Equipment	$ 132,911	$ 132,911
Computer Equipment	12,261	12,261
Furniture	3,030	3,030
Property and Equipment, at Cost	**148,202**	**148,202**
Accumulated depreciation	(126,902)	(99,254)
Property and Equipment, Net	**$ 21,300**	**$ 48,948**

Depreciation expenses for Lab and Computer Equipment for the years ended December 31, 2022, and 2021 were in the amount of $27,648 and $27,528 respectively.

5. INTANGIBLE ASSETS

As of December 31, 2022 and December 31, 2021, Intangible Assets consist of:

	December 31, 2022	December 31, 2021
Patents	$ 145,613	$ 112,550
Website Development Costs	27,070	-
Intangible Assets, at Cost	172,683	-
Accumulated Amortization	(8,428)	(3,310)
Intangible Assets, Net	**$ 164,255**	**$ 109,240**

Amortization expense for the years ended December 31, 2022, and 2021 was in the amount of $5,118 and $3,310, respectively.

5. INTANGIBLE ASSETS (CONTINUED)

The following table summarizes the estimated future amortization expense related to our patents and website development costs for the years ended December 31:

Year	Patents	Website Development Costs
2023	$ 4,033	$ 9,023
2024	4,033	9,023
2025	4,033	7,520
2026	4,033	-
Thereafter	31,345	-
Total	**$ 47,477**	**$ 25,566**

The Company additionally has $91,644 in capitalized patent expenses that will be amortizable as the patents they are associated with are awarded.

6. CAPITALIZATION AND EQUITY TRANSACTIONS

Business Combination – Subsidiary

On June 1, 2022, 60 Degrees Pharmaceuticals, LLC, a District of Columbia limited liability company ("60P LLC"), entered into the Agreement and Plan of Merger with 60 Degrees Pharmaceuticals, Inc., pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. The value of each outstanding member's membership interest in 60P LLC was correspondingly converted into common stock of 60 Degrees Pharmaceuticals, Inc., par value $0.0001 per share, with a cost basis equal to $5 per share.

On June 30, 2022 the Company issued 37,067 shares of common stock to its Chief Executive Officer for $185,335 ($5/share).

7. DEFERRED COMPENSATION

In 2020, the Company received consulting services from Biointelect Pty Ltd of Australia with a value of $100,000, which is payable contingent upon a future capital raise and is non-interest bearing. On May 5, 2022, the Company agreed to modify their contract with Biointelect Pty Ltd. Previously, Biointelect potentially could earn $60,000 in deferred cash compensation and $400,000 in warrants in connection with a fundraise and other services provided. As the Company considered this compensation unlikely, it agreed to restructure by increasing the cash component to $100,000, tying $155,000 in equity compensation to an IPO/future qualifying transaction while leaving $245,000 in equity compensation with the original triggering events. The Company took a deferred compensation charge for the $155,000 in equity compensation in Q2 of 2022.

7. DEFERRED COMPENSATION (CONTINUED)

Also in 2020, the Company entered into an agreement with Latham Biopharma for contingent compensation. As of June 17, 2022, $57,198 had been earned and was due ($54,743 was earned as of December 31, 2021). On June 17, 2022 the Company and Latham Biopharma agreed to convert the deferred compensation of $57,198 and $12,500 of accrued expense into a 100% contingent deferred compensation amount of $38,900 in cash and $60,000 in shares of the Company if within the next five years the Company nets at least $10,000,000 in an IPO or any private financing that secures the retirement and/or conversion to equity of all secured debt excluding the loans advanced by the Small Business Administration. Then before the end of the year the Company and Latham Biopharma initiated an agreement that converted the entire deferred compensation into 65,000 shares valued at $5 per share. The Company has taken a contingent deferred compensation charge of $226,100 in Q4 of 2022 to reflect this subsequent agreement.

8. DEBT

Promissory Notes

On December 27, 2019 the Company restructured its cumulative borrowing with its senior secured lender, Knight Therapeutics, Inc, into a note for the principal amount of $6,309,823 and accrued interest of $4,160,918 and a debenture of $3,483,851, collectively referred to as the 'Knight Loan'. The Knight Loan matures on December 31, 2023. The Knight Loan bears an annual interest rate of 15% compounded quarterly. Under the Knight Loan, the Company is required to pay the lender 15% of cumulative gross profits of above $7,000,000. At the end of December 31, 2022, the Company had reached cumulative gross profits of $1,583,231 ($1,790,744 at December 31, 2021).

On October 11, 2017 the Company issued a promissory note ("Note") with an individual investor in the amount of $750,000. The Note matures 60 days after the Knight Loan is repaid. The Note bore an interest rate of 5% from inception for the first six months and 10% per annum thereafter both compounded quarterly on a calendar basis. The lender has an option to convert the Note into equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest would have originally been forfeited prior to the Amendment (discussed below), should the lender have elected to convert the Note into equity.

On December 11, 2022, the Company and the individual investor amended the Note ("the Amendment"). The Amendment added a provision to automatically convert the outstanding principal and accumulated interest through March 31, 2022 into common shares in the event the Company consummates an IPO. The Amendment also provides the lender the option to convert the outstanding principal and accumulated interest through March 31, 2022 into equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest after March 31, 2022 will be forfeited should the lender elect to convert the Note into equity. The Company evaluated the Amendment and determined that it constitutes an extinguishment as the option to convert interest through March 31, 2022 is considered the addition of a substantive conversion option. Accordingly, the Amendment resulted in extinguishment accounting and a corresponding extinguishment gain of $120,683, which represents the difference between the carrying value of the Note just prior to the Amendment and the fair value of the Note just after the Amendment. The extinguishment accounting resulted in a fair value of the Note, including the Amendment of $1,099,578. The discount of $120,683 and costs incurred with third parties directly related to the Amendment of $1,767 will be amortized over the remaining life of the debt using the effective interest method. Amortization of the discount on the Note for the year ended December 31, 2022 was $4,955 ($0 in 2021). Interest expense related to the Note, including the Amendment, for the year ended December 31, 2022 was $115,546 ($104,558 in 2021).

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

	Knight Therapeutics	Note, including amendment	Bridge Notes	Total
Promissory Notes and Interest less Discounts	16,319,986	1,109,783	535,901	17,965,670
Less Current Maturities	16,319,986	-	535,901	16,855,887
Long Term Promissory Notes	-	1,109,783	-	1,109,783

8. DEBT (CONTINUED)

Promissory Notes (Continued)

Promissory notes are summarized as follows at December 31, 2021:

	Knight Therapeutics	Note, including amendment	Total
Promissory Notes and Interest less Discounts	14,085,333	1,111,731	15,197,064
Less Current Maturities	-	-	-
Long Term Promissory Notes	14,085,333	1,111,731	15,197,064

Debenture

On April 24, 2019 60P entered into the Knight debenture of $3,000,000 with an original issue discount ("OID") of $2,100,000. The OID is being amortized using the effective interest method. The Company subsequently restructured the Knight Loan (see Subsequent Events footnote 13). $500,103 of the original issue discount was amortized to interest expense during the twelve months ended December 31, 2022 ($431,625 during twelve months ended December 31, 2021) and the unamortized original issue discount at December 31, 2022 was $279,061 ($779,164 at December 31, 2021

	December 31, 2022	December 31, 2021
Original Debenture	$ 3,000,000	$ 3,000,000
Unamortized debt discount	(279,061)	(779,164)
Debenture Prior to Accumulated Interest	2,720,939	2,220,836
Accumulated Interest	1,555,670	1,167,734
Debenture	**$ 4,276,609**	**$ 3,388,570**

SBA COVID-19 EIDL

On May 14, 2020, the Company received COVID-19 EIDL lending from the Small Business Administration (SBA) in the amount of $150,000. The loan bears interest at an annual rate of 3.75% calculated on a monthly basis. The Company was committed to make $731 monthly payments first due June 4, 2021. On March 31, 2021, the SBA announced the deferment period has been extended an additional eighteen months. Thus, the Company was first obligated to start making payments of $731 on November 4, 2022. The current balance is $163,022 for the year ended December 31, 2022 ($159,161 at December 31, 2021). The current maturity is $2,750 and the long-term liability is $160,272. The current future payment obligations of the principal are as follows:

Period	Principal Payments
2023	$ -
2024	-
2025	-
2026	250
2027	3,211
Thereafter	146,539
Total	**$ 150,000**

Due to the deferral, the Company is expected to make a balloon payment of $32,283 to be due on 10/12/2050.

9. DERIVATIVE LIABILITIES

Promissory Notes, Bridge Shares and Warrants

During May 2022, the Company executed promissory notes having a face amount of $888,889. The notes contain an original issue discount of 10% ($88,889) and debt issuance costs of $91,436, resulting in net proceeds of $708,564. These notes bear interest at 10% with a default interest rate of 15% and are unsecured. The notes are due at the earlier of one-year (1) from the issuance date or the closing of an initial public offering ("IPO"). In connection with the issuance of these notes, the Company will also issue common stock to each note holder equivalent to (a) 100% of the face amount of the note divided by the IPO price per share, or (b) if the Company fails to complete the IPO prior to May 24, 2023, the number of shares of the Company's common stock calculated using a $27,000,000 pre-money valuation of the Company and the number of the Company's outstanding shares of common stock on May 24, 2023. Additionally, each of these note holders are entitled to receive five-year (5) fully vested warrants upon the closing of an IPO, with an exercise price of 110% of the IPO price.

Convertible Promissory Notes and Warrants - Related Parties

During May 2022, the Company executed convertible promissory notes with the Company's Chief Executive Officer and a family member related to the Chief Executive Officer, having a face amount of $338,889. The notes contain an original issue discount of 10% ($33,888) and debt issuance costs of $34,289, resulting in net proceeds of $270,711. These notes bear interest at 6% with a default interest rate of 15% and are unsecured. The notes are due at the earlier of one-year (1) from the issuance date or the closing of an IPO. Upon the closing of an IPO, these notes are mandatorily redeemable at the lesser of (a) 20% discount to the IPO price or (b) $27,000,000 pre-money valuation. Additionally, each of these note holders are entitled to receive five-year (5) fully vested warrants upon the closing of an IPO, with an exercise price of 110% of the IPO price. If the IPO is not completed by May 31, 2023, the exercise price is 90% of the IPO price.
Promissory notes and Convertible notes – related parties are summarized as follows at December 31, 2022:

	Promissory Notes	Convertible Notes
Issuance date of promissory notes	May 2022	May 2022
Maturity date of promissory notes	1	1
Interest rate	10%	6%
Default interest rate	15%	15%
Collateral	Unsecured	Unsecured
Conversion Rate	2	2
Balance - December 31, 2021	$ -	$ -
Face amount of notes	888,889	338,889
Less: unamortized debt discount	(407,555)	(155,443)
Add: accrued interest on promissory notes	54,567	11,651
Balance - December 31, 2022	$ 535,901	$ 195,097

For the twelve months ended December 31, 2022, the Company recorded amortization of debt discount of $664,780.

1 - earlier of 1 year from date of issuance or closing of IPO.
2 - see discussion above in (a) and (b)

9. DERIVATIVE LIABILITIES (CONTINUED)

Convertible Promissory Notes and Warrants - Related Parties (Continued)

As noted above, certain of the Company's bridge shares, warrants and convertible notes (containing an embedded conversion feature) are accounted for as derivative liabilities since there is an unknown exercise price associated with each instrument. The exercise price is dependent upon a yet to be completed IPO or a failed IPO. In both cases, the possible exercise prices contain different conditions (related to the success or failure of the IPO) that could result in issuing an undeterminable amount of common stock to settle any conversions.

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

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

Changes in fair value of derivative liabilities (mark to market adjustment) are included in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss.

During the year ended December 31, 2022, the Company recorded a change in fair of derivative liabilities of $10,312. In connection with the valuation of the Company's derivative liabilities, and accounting for these instruments at fair value, the Company computed a fair value on the commitment date of $1,483,888, and upon the initial valuation of these instruments, determined that the fair value of the liabilities exceeded the cash value raised of $979,275. As a result, the Company recorded a debt discount at the maximum amount allowed (the face amount of the debt less the OID and debt issuance costs), which required the excess to be recorded as a derivative expense.

For the year ended December 31, 2022, the Company recorded a derivative expense of $504,613.

Derivative expense is summarized as follows:

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

Notes to the consolidated financial statements

9. DERIVATIVE LIABILITIES (CONTINUED)

Convertible Promissory Notes and Warrants - Related Parties (Continued)

On the commitment date (Day 1 valuation), the fair value of the Company's potential future issuances of common stock related to common stock issued with promissory notes, warrants and embedded conversion features in convertible promissory notes is established with an estimate using the Monte Carlo Simulation Model to compute fair value. The Monte Carlo simulation requires the input of assumptions, including our stock price, the volatility of our stock price, remaining term in years, expected dividend yield, and risk-free rate.

In addition, the valuation model considers the probability of the occurrence or nonoccurrence of an IPO within the terms of our liability-classified financial instruments, as an IPO event can potentially impact the settlement.

Additionally, at each subsequent reporting period, we remeasure the fair value of our liability-classified bridge shares, warrants and embedded conversion features in convertible promissory notes using the Monte Carlo simulation.

The assumptions used to perform the Monte-Carlo Simulation were as follows at the Commitment Date as well as for the year ended December 31, 2022:

Commitment Date	**May 2022**
Stock price	$ 5.00
Volatility	99.7%
Expected term (in years) – Notes	1.00 - 1.03
Expected term (in years) – Warrants	5
Risk-free interest rate	2.76% - 2.84%
Dividend yield	0%
IPO probability (prior to note maturity date)	95%

Mark to Market	**December 31, 2022**
Stock price	$ 5.00
Volatility	101.9%
Expected term (in years) – Notes	0.39 - 0.41
Expected term (in years) – Warrants	4.39
Risk-free interest rate	4.06%
Dividend yield	0%
IPO probability (prior to note maturity date)	95%

10. INCOME TAXES

The Company currently pays taxes at the federal level as a "C Corporation". Previously, for federal income tax purposes, 60 Degrees Pharmaceuticals, LLC filed as a partnership whereby all liability and benefit was attached to the Members' returns through December 31, 2021. The District of Columbia, however, taxed the entity separately as an unincorporated business on a D-30 franchise tax return when income was over $12,000 annually. Additionally, there was a minimum tax of $250 for revenues at and below $1,000,000 and $1,000 for those revenues above.

10. INCOME TAXES (CONTINUED)

	Federal	DC
Taxable loss	$ (5,807,867)	$ (5,807,367)
DC Franchise tax	-	500
Provision (added) used	(1,219,652)	(479,108)
Allowance added (used)	1,219,652	479,108
Net Provision for income tax	**$ -**	**$ 500**

60P, LLC elected to be taxed as a C-Corporation as of January 1, 2022. A final DC return of the LLC (five-month period ended May 31, 2022) will be filed on the District of Columbia's D-20 Corporation Franchise Tax Return, which also has minimum taxes for revenues above $1,000,000 ($1,000) and at or below ($250). As a result of the merger of 60P, LLC into 60P, Inc., all accumulated DC net operating losses incurred prior to January 1, 2022 are not transferable (irreversibly vacated). Prospectively, DC net operating loss will not be considered in deferred tax asset computations as the 12/31/2021 balance of $577,978 has been written off to reflect the relinquished DC net operating loss. The provision for income taxes for the year ended December 31, 2022 consists of the following:

Federally the Company has a cumulative net loss of $5,807,867 as of December 31, 2022 (none as of December 31, 2021). The net tax benefit associated with loss accumulated through the year ending December 31, 2022 is $1,219,652 (none as of December 31, 2021) with the federal tax rate of 21%.

The Company has cumulative net loss in DC of $5,807,367 for the twelve months ended December 31, 2022 ($6,996,799 as of December 31, 2021). The net tax benefit is the cumulative net loss multiplied by the District of Columbia corporate tax rate of 8.25%. The Company's net tax benefit at December 31, 2022 is $479,108 ($577,978) at December 31, 2021.

Australian subsidiary has cumulative losses of AUD9,640,315 at December 31, 2022 (and AUD8,997,499 at December 31, 2021). The Australian subsidiary has also measured a deferred tax benefit associated with the cumulative losses of AUD2,410,079 at December 31, 2022 (and AUD2,249,375 at December 31, 2021). The current tax rate in Australia is now 25% for businesses with an aggregated turnover (ordinary income of the Company and its affiliates) of AUD50 million. The Company projects to continue to qualify for the lower tax rate in the near future.")

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. On the basis of this evaluation, the Company has determined that it is more likely than not that the Company will not recognize the benefits of the foreign and state net deferred tax assets, and, as a result, full valuation allowance has been set against its net deferred tax assets as of December 31, 2022, and December 31, 2021. The amount of the deferred tax asset to be realized could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased.

As of the Period Ended	**December 31, 2022**	**December 31, 2021**
Federal Deferred Tax Asset	$ 1,219,652	$ -
DC Deferred Tax Asset	479,108	577,978
Australian Deferred Tax Asset (USD)	1,640,059	1,634,058
	3,338,819	2,212,036
Allowance	3,338,819	2,212,036
Net Value of Deferred Tax Asset	**$ -**	**$ -**

The Company recognizes the impact of a tax position in the financial statements if that position is more likely than not to be sustained on a tax return upon examination by the relevant taxing authority, based on the technical merits of the position. As of December 31, 2022, and December 31, 2021, the Company had no recognized tax benefits. The Company recognizes interest and penalties related to income tax matters as other expense and non-deductible penalties, respectively. As of December 31, 2022, the Company has recognized a potential tax penalty regarding a US foreign tax reporting form of $30,000 and none at December 31, 2021.

11. COMMITMENTS AND CONTINGENCIES

Operating Lease

On February 3, 2016, the Company entered into the lease agreement with CXI Corp to rent business premises. The contract most recently amended on December 10, 2020 with an additional term of twelve months that was set to expire on March 31, 2023 has been extended for an additional one year term until March 31, 2024. As a result of our adoption of ASC 842, the operating leases are reflected on our balance sheet within operating lease right-of-use (ROU) assets and the related current and non-current operating lease liabilities. ROU assets represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments arising from lease agreement. Lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectation regarding the terms. Variable lease costs such as common area maintenance, property taxes and insurance are expensed as incurred.

When the new accounting standard was adopted on December 31, 2021 the Company had current and long-term operating lease liabilities of $46,795 and $13,000, respectively, and right of use of asset of $58,667.

Future minimum lease payments on a discounted and undiscounted basis under this lease are as follows:

	Undiscounted Cash Flows
Discount rate	15.00%
2023 (January 1 to March 31)	13,326
Total undiscounted minimum future payments	13,326
Imputed interest	(326)
Total operating lease payments	13,000
Short-term lease liabilities	13,000
Long-term lease liabilities	$ -

Other information related to our operating lease is as follows:

	December 31, 2022
Weighted average remaining lease term in years	0.25 years
Weighted average discount rate	15.00%

Rent expenses were in the amount of $51,894 and $51,894 as of the years ended December 31, 2022, and December 31, 2021, respectively.

Board of Directors

In November and December 2022, the Company signed agreements with four director nominees (Cheryl Xu, Paul Field, Charles Allen and Stephen Toovey) which come into effect on the date the Company's S-1 becomes effective. Each director will receive cash compensations of $11,250 quarterly. In addition, the two non-audit committee chairs (Toovey, Field) will receive $1,250 per quarter and the audit committee chair (Allen) will receive an additional $2,000 per quarter. Each director will receive a one-off issuance of common stock of value $50,000 and a non-qualified option to purchase an additional $50,000 of common stock. Each director will receive equity compensation in the form of restricted stock Units valued at $40,000 and a non-qualified option to purchase $40,000 of common stock.

11. COMMITMENTS AND CONTINGENCIES (CONTINUED)

Contingencies

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

Contingent Compensation

Prior to 2015 the Company agreed with certain vendors, advisors and employees to deferred compensation that expires on December 31, 2023. The net amount of these contingent payments is $43,581. The Company does not anticipate the trigger for these payments to be reached prior to expiration.

In 2020, the Company engaged with two vendors to help secure COVID-19 trial funding for the Company's Phase II COVID trial. Ultimately, the efforts were unsuccessful but a tail does remain. If one Australian fund participates in the Company's IPO a maximum of $520,000 would be due as of December 31, 2021. Due to subsequent agreement the maximum amount due would be $305,000 as of December 31, 2022. Currently, the Company is not engaged with the Australian fund to solicit their participation in the Company's IPO.

Litigation, Claims and Assessments

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of December 31, 2022, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the results of the Company's operations.

12. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through April 3, 2023, which is the date the financial statements were issued.

On January 1, 2023 the Company lowered the wholesale acquisition cost [WAC] price of a box of Arakoda™ [16 x 100 mg tablets] from $285 to $235 per box, to better align the cost of utilizing Arakoda™ for malaria prophylaxis with competing products including atovaquone-proguanil.

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

- The Parties agreed to fix Knight's cumulative debt to the value as it stood on March 31, 2022, which consisted of $10,770,037 in principal and $8,096,486 in accumulated interest should the Company execute an IPO that results in gross proceeds of at least $7,000,000 prior to December 31, 2023. Should an IPO not occur by January 1, 2024 then all terms of the original loans would resume including any interest earned after March 31, 2022. From April 1, 2022 through December 31, 2022 the Company has recorded $2,009,133 in accumulated Interest that would be subject to reversal should the IPO be successfully executed.

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

12. SUBSEQUENT EVENTS (CONTINUED)

- The Parties agreed to convert the accrued interest into that number of shares (the "Conversion Preferred Shares" and, together with the Conversion Common Shares, the "Conversion Shares") of a new class of preferred stock (the "Preferred Stock") by dividing the Accrued Interest by [$100.00], then rounding up (resulting in the issuance of 80,965 preferred shares at the IPO). The Preferred Stock shall have the following rights, preferences, and designations: (i) have a 6% [cumulative] dividend accumulated annually on March 31; (ii) shall be non-voting stock; (iii) are not redeemable, (iv) be convertible to shares of Common Stock at a price equal to the lower of (1) the price paid for the shares of Common Stock in the IPO and (2) the 10 day volume weighted average share price immediately prior to conversion; and (v) conversion of the preferred stock to common shares will be at the sole discretion of the Company. Notwithstanding the foregoing, the Company shall not convert the Preferred Stock into shares of Common Stock if as a result of such conversion Lender will own 19.9% or more of the Company's outstanding Common Stock.

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

On January 12, 2023 Geoff Dow signed an updated employment agreement as Chief Executive Officer with a two-year agreement subject to automatic annual renewals unless either party provides notice within 90 days of expiration. Notable provisions are as follows:

- Annual salary will be $228,000 per year with a cash bonus of up to 25% of base pay should performance goals be met.

- Upon the Company becoming public, Geoff Dow will be awarded 300,000 options which will vest at the end of each quarter over five years. The exercise price will be the closing price of the stock on the day of the IPO.

- The Executive will be awarded a two times base salary cash bonus if in a change of control transaction, the Company's share price is two times the closing price on the day of the IPO.

12. SUBSEQUENT EVENTS (CONTINUED)

On January 12, 2023 Tyrone Miller signed an updated employment agreement as Chief Financial Officer with a two-year agreement subject to automatic annual renewals unless either party provides notice within 90 days of expiration. Notable provisions are as follows:

- Annual salary will be $204,000 per year with a cash bonus of up to 25% of base pay should performance goals be met.
- Annual salary will be $204,000 per year with a cash bonus of up to 25% of base pay should performance goals be met.
- Upon the Company becoming public, Tyrone Miller will be awarded 240,000 options which will vest at the end of each quarter over five years. The exercise price will be the closing price of the stock on the day of the IPO.
- The Executive will be awarded a two times base salary cash bonus if in a change of control transaction, the Company's share price is two times the closing price on the day of the IPO.

The Company must meet a NASDAQ listing requirement of a minimum public float of $15 million. As of December 31, 2022, the value of the Company's potentially freely tradable shares was $1,715,246 representing 165,938 shares of value $829,690 owned by Douglas Loock, and an obligation to the three interim investors (Bigger, Calvary and Walleye) to issue common shares of value $885,556 at the IPO. Subsequently the Company issued common shares in exchange for services to the following organizations in the indicated amounts: Carmel, Milazzo & Feil LLP (100,000 shares), Florida State University Research Foundation (405,000 shares), Trevally LLC (120,000 shares), ENA Healthcare Communications LLC (8,500 shares), 4C Pharma Solutions LLC (54,000 shares), Hybrid Financial Inc. (65,000 shares), Method Health Communications LLC (20,000 shares), Kentucky Technology Inc. (525,000 shares), Ludlow Business Services Inc. (37,500 shares), and Delve Innovation Pty Ltd (13,000 shares). We also issued 30,000 shares of our common shares to Elliot Berman in exchange for services provided by Berman Accounting & Advisory P.A. Additionally, the Company issued Latham BioPharm Group LLC 65,000 common shares in exchange for extinguishment of $98,900 in deferred compensation that would otherwise have been payable in the event of an IPO.

On January 16, 2023 the Company and their Australian distributor agreed to settle historical profit share through September 30, 2022 for $24,381 (AUD$35,000) through the issuance of a onetime pandemic credit of $18,637 (AUD$26,640). On March 3, 2023, the Company's Board, with the consent of Geoffrey S. Dow decided to cancel 18,217 common shares issued to the Geoffrey S. Dow Revocable Trust and, with the consent of Tyrone Miller, decided to cancel 2,783 shares issued to Tyrone Miller.

On January 21, 2023, the Company's Board, with the consent of Geoffrey S. Dow decided to cancel 1,240,682 common shares issued to the Geoffrey S. Dow Revocable Trust and, with the consent of Tyrone Miller, decided to cancel 189,318 shares issued to Tyrone Miller.

On March 1, 2023, the Company signed an investment relations consulting agreement with Red Chip. This Agreement obligates the Company to issue Red Chip $40,000 of Rule 144 stock, based on the 30-day average of the publicly traded common shares after the IPO. All shares are deemed earned immediately upon signing, acceptance, and execution of this Agreement.

In March 2023, the Company received $200,000 in paid-in capital from the Geoffrey S. Dow Revocable Trust. As of the day of finalization of these statements, the Board had not made a decision regarding the capitalization of the aforementioned paid-in capital.

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

5,260,901 Units, with each Unit consisting of One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

999,076 Pre-Funded Units, with each Pre-Funded Unit consisting of One Pre-Funded Warrant to Purchase One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

6,259,977 Shares of Common Stock Underlying the Warrants

999,076 Shares of Common Stock Underlying the Pre-Funded Warrants

60 Degrees Pharmaceuticals, Inc.

PROSPECTUS

WallachBeth Capital LLC

January 29, 2024