As confidentially submitted to the Securities and Exchange Commission on October 18, 2022. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. [*]

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

FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware	**2834**	**45-2406880**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

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

Geoffrey S. Dow
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Approximate date of commencement of proposed sale to the public: **As soon as practicable after the effective date of this Registration Statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☐

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

EXPLANATORY NOTE

Pursuant to the applicable provisions of the Fixing America's Surface Transportation (FAST) Act, we are currently omitting our combined unaudited financial statements. We intend to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

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

SUBJECT TO COMPLETION, DATED _____, 2022

PRELIMINARY PROSPECTUS

Shares
Common Stock

60 Degrees Pharmaceuticals, Inc.

This is an initial public offering of shares of 60 Degrees Pharmaceuticals, Inc. common stock, at an assumed offering price of $ per share, the midpoint of a range between $ and $ per share.

Prior to this offering, there has been no public market for our common stock. We will apply to have our common stock listed on The Nasdaq Capital Market under the symbol " ," which listing is a condition to this offering. There can be no assurance that we will be successful in listing our common stock on The Nasdaq Capital Market.

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

Investing in our common stock involves a high degree of risk. See "*Risk Factors*" beginning on page 17 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.

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 Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions[1][2]	$	$
Proceeds, before expenses, to us	$	$

(1) Represents underwriting discount and commissions equal to $ per share.

(2) 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 (the "Representative"), or the reimbursement of certain expenses of the underwriters. See "*Underwriting*" beginning on page 102 of this prospectus for additional information regarding underwriting compensation.

In addition to the underwriting discounts listed above and the non-accountable expense allowance described in the footnote, we have agreed to issue upon the closing of this offering to the Representative, 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 Representative to purchase 6% of the number of shares of common stock sold in this offering (excluding shares of common stock sold to cover over-allotments, if any) (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 underwriters, please see "*Underwriting*" beginning on page 102.

We have granted the Representative an option to purchase from us, at the public offering price, up to additional shares of common stock, less the underwriting discounts and commissions, within 45 days from the date of this prospectus to cover over-allotments, if any. If the Representative exercises the option in full, the total underwriting discounts and commissions payable will be $, and the total proceeds to us, before expenses, will be $.

The underwriters expect to deliver the shares against payment on or about _____, 2022.

Sole Book-Running Manager

WallachBeth Capital LLC

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Through and including _____, 2022 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriter and with respect to their unsold allotments or subscriptions.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment. Neither we, nor the underwriters, 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 underwriters 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 common stock. 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 common stock 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" in this prospectus mean 60 Degrees Pharmaceuticals, Inc., a Delaware corporation, and 60P Australia Pty Ltd, an Australian proprietary company limited by shares, its wholly owned subsidiary;
- assumes an initial public offering price of our common stock of $ per share, the midpoint of the estimated range of $ to $ per share;
- "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 (i) the conversion of certain of our outstanding debt and (ii) certain consultant agreements;
- no shares of common stock have been issued pursuant to any warrants;
- no shares of common stock have been issued pursuant to the Representative's over-allotment option; 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*.

"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 action" 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.

"DMID" means Division of Microbiology and Infectious Diseases.

"EUA" means Emergency Use Authorization.

"G6PD" means glucose-60-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 U.S. Food and Drug Administration.

"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.

"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 U.S. Food and Drug Administration.

"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.

USE OF PRODUCT VERSUS GENERIC NAMES

Solely for convenience, brand names of products owned by 60P (Arakoda and Kodatef) are used where reference is made to the commercial product or use of the commercial product at the FDA (or TGA) for approved dosing in clinical studies. Where the active ingredient of Arakoda and Kodatef, tafenoquine, was tested in cell culture, animals, or at doses in clinical studies which differs from the FDA-approved dose, the molecular name (tafenoquine) is used.

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 as to 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 common stock 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.

Unless the context otherwise requires, references in this prospectus to "60P," the "Company," "we," "us" and "our" refer to 60 Degrees Pharmaceuticals, Inc., a Delaware corporation, and its wholly owned subsidiary.

Overview

We are a growth-oriented 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 COVID-19, fungal, tick-borne, and other viral diseases through Arakoda and Celgosivir.

Mission

Our mission is to address the unmet medical need associated with infectious diseases, through the development and commercialization of new small molecule therapeutics, focusing on synthetic drugs (made by chemists in labs, excluding biologics) with good safety profiles based on prior clinical studies, in order to reduce cost, risk, and capitalize on existing research. We are seeking to expand Arakoda's use 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 developed for COVID-19, RSV and dengue.

Market Opportunity

In 2018, the U.S. Food and Drug Administration ("FDA") approved Arakoda for malaria prevention in individuals 18 years an older, an indication for which there has historically been approximately 485,000 prescriptions (one prescription per three weeks of travel) in the United States each year for the current market-leading product (atovaquone-proguanil). 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. Targeted marketing efforts will commence in 2023 to promote the malaria indication as resources permit, although we expect our primary efforts to be developing Arakoda for other applications.

We are developing Arakoda for non-malaria indications to address several therapeutic indications that have substantial U.S. caseloads, as further described below:

- Treatment of COVID-19. According to *The New York Times*, the lowest daily case rate for the COVID-19 virus since March 2020 based on a seven day average has not typically been below 11,000 cases. Assuming this trend continues, this dynamic translates into a potential market size of at least 4,000,000 cases per year in 2023 and future years. Paxlovid and molunupiravir have received emergency use authorization for the prevention of death and hospitalization in individuals with high risk of disease progression and their use for those purposes continues to be recommended by public health experts. However, to our knowledge, there is not published evidence from randomized controlled clinical trials that either drug reduces the time to sustained clinical recovery for four or more days in standard risk patients infected with contemporary viral strains, and Pfizer has formally abandoned efforts related to this endpoint for paxlovid.[1] If proven effective for early relief of COVID-19 symptoms in standard risk COVID-19 patients, Arakoda could fulfill a patient's need unmet by the approved antivirals.

[1] Press release: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reports-additional-data-paxlovidtm-supporting.

- Treatment and Post-Exposure Prevention of Tick-Borne Diseases. There are approximately 38,000 cases of babesiosis (red blood cell infections caused by deer tick bites) in the United States each year. This estimate is based on the observations of Krugeler[2] who reported that 380,000 cases of Lyme disease occur in U.S. states where babesiosis is endemic and Krause et. al.[3] which reported that approximately 10% of Lyme patients are also infected with *Babesia*. Furthermore, post-exposure prophylaxis following a tick-bite is a recognized indication to prevent Lyme disease, and it is likely that a drug proven to be effective for this indication for babesiosis would also be used in conjunction with Lyme prophylaxis. There may be more than 400,000 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 tickbites based on observations from comparable ex-U.S health systems.[4] 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.

- Prevention of fungal pneumonias. There are 175,000 new medical conditions each year in the United States, including CAR/T therapy and other malignancies, solid organ, autologous and allogeneic hematopoietic stem cell transplants, which are associated with immunosuppression and for which antifungal prophylaxis may be prescribed for vulnerable patients.[5] 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.[6] Arakoda has the potential to be added to existing standard of care regimens for the prevention of fungal pneumonias.

- Treatment of *Candida* infections. According to the Centers for Diseases Control (CDC), there are 50,000 cases of candidiasis (a type of fungal infection) each year in the United States and more than 2,000 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.

Dengue and RSV, both afflictions against which 60P's early clinical candidates (e.g., Celgosivir) show potential in non-clinical studies, are associated with 1.37 million cases globally according to the European CDC[8] and 235,000 hospitalizations 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.[9]

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[2] *Emerg Infect Dis* 2021;27:616-619.

[3] *Clin Infect Dis* 2022;72:185-189.

[4] Marx et. al., MMWR 2021;70:612-616.

[5] Calculated based on information from the Organ Procurement and Transplant Network, National Data: https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#; Heffelfinger J et al, 2009 Nonadherence to Primary Prophylaxis against Pneumocystis jirovecii pneumonia, PLoS One. 10.1371/journal.pone.0005002; Fishman et al 2019, Pneumocystis jiroveci in solid organ transplantation: guidelines from the American Society of Transplantation Infectious Diseases Community of Practice NCCN Guidelines Version 1.2020, Prevention and Treatment of Cancer-related infections.

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

[7] https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html.

[8] Dengue worldwide overview (europa.eu).

[9] RSV Trends and Surveillance | CDC.

Products

Arakoda

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. 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 an NDA to the FDA in 2018. The history of that collaboration has been publicly communicated by the U.S. Army.[10]

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 CDC and independent experts have endorsed Arakoda and noted the features and benefits of the product, including: convenient once weekly dosing following a three day load; the absence of drug resistance; activity of the drug against all species and life cycle stages of the parasite; absence of any black-box safety warnings; and comparable safety profile to placebo with up to 12 months continuous dosing.[11] 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.[12] 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.[13] 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, Qwest Diagnostics, etc). Although these tests have a turn-around time of up 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.

During the COVID-19 pandemic, since our commercial opportunities were limited, we embarked upon an exploratory research and development campaign to identify new indications for Arakoda. In the second quarter and third quarter of 2020, we commissioned cell culture studies that showed that tafenoquine, the active ingredient in Arakoda, inhibited replication of SARS-CoV-2 (the virus that causes COVID-19).[14] Then, we commissioned computer simulations, which showed that the predicted concentration of tafenoquine in the lungs of COVID-19 patients following administration of the first four doses of the approved antimalarial prophylactic regimen of Arakoda exceeded those inhibiting the virus in cell culture. The foregoing provided the rationale for seeking approval from the FDA to conduct a Phase II clinical trial in patients with the COVID-19 disease, for which the FDA granted clearance to proceed in October 2020.

In 2021, with financial support from the US Army, we conducted a Phase II clinical investigation of the safety and efficacy of Arakoda in outpatients with mild-moderate COVID-19 disease. We completed this study in October 2021, and the results of the study were accepted for publication in May 2022.[15] Analysis of secondary and exploratory endpoints in that study suggested that Arakoda reduced clinical recovery time from shortness of breath, cough and fever ($P < 0.02$) and improved aggregate symptom scores five days after treatment ($P < 0.1$).[16] We plan to confirm these observations in our next study (described in "*Prospectus Summary—Strategy*" beginning on page 8).

[10] Zottig et al Military Medicine 2020; 185 (S1): 687.

[11] 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.

[12] See prescribing information at www.arakoda.com.

[13] See prescribing information at www.arakoda.com.

[14] U.S. Patent application # 17/189,544, Dow et. al. bioRxiv 2020.07.12.199059; doi: https://doi.org/10.1101/2020.07.12.199059.

[15] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

[16] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

In 2022, we conducted additional analyses of laboratory endpoint data from the clinical study described above and are preparing a manuscript for publication. That analysis and the scientific literature suggest two possible modes of action for Arakoda: (i) down-regulation of cytokines (immune system inflammatory proteins) associated with severe COVID-19 and a greater risk of hospitalization or death and/or (ii) inhibition of viral entry in the lung or elsewhere in the body, perhaps through inhibition of a host enzyme called TMPRSS2 (which facilitates entry of the virus that causes COVID-19, SARS-CoV-2, into human cells).

Assuming the efficacy of Arakoda is proven in our next study, some of the features of Arakoda that make it ideal for malaria prophylaxis might also make it very useful for COVID-19 related indications. Arakoda is slowly metabolized and has no important drug-drug interactions, so it might be an ideal partner for standard of care oral COVID-19 therapeutics that reduce hospitalization but have no demonstrated effect on the time to clinical recovery in non-hospitalized patients. Arakoda requires fewer tablets (8 in the first ten days versus 30 or 40 for paxlovid and molunpiravir) which should make compliance with medication easier for patients. This is an important consideration in the attractiveness of a regimen in standard risk patients at lower risk of hospitalization, and who may be interested in taking a COVID-19 therapeutic primarily to treat early symptoms and accelerate recovery. The potential for better compliance may also suggest suitability for outbreak control in some settings (including, for example, nursing homes).

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] If added to the standard of care for anti-fungal and yeast infection treatments for general use, Arakoda 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.

Tafenoquine is effective in animal models of babesiosis (tick borne red blood cell infections). Two clinical case studies suggest the potential to improve the existing standard of care for treatment of human babesiosis.[19] Combined with standard of care products, Arakoda 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. Once appropriate clinical studies have been conducted, it is likely that Arakoda would be quickly embraced for post-exposure prophylaxis of babesiosis in patients with tick bites and suspected of being co-infected with Lyme disease.

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 confirmed its safety, but did not determine if the observed trend towards lower viral load was statistically significant.[21] Celgosivir (as with other dengue antivirals) has diminished activity to cure dengue infections in animal models when administered after animals become symptomatic. For Celgosivir, we addressed this problem by administering the same dose of drug split into four doses per day rather than one or two doses per day.[22] This observation led to the filing and approval of a patent related to dengue, which we licensed from the National University of Singapore.

[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.

[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.

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 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. We have a small virtual management team, successfully built productive research partnerships with public and academic entities, and licenses 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 regimen of Arakoda in other therapeutic areas, all of which is expected to foster and continue our existing tradition of inexpensive product development.

Strategy

Our general strategy is to demonstrate clinical proof of concept that Arakoda, at its FDA-approved dosing regimen for malaria prevention, provides clinical benefits in non-malaria therapeutic areas. Our initial focus is on COVID-19, but additional indications have been identified for development, namely babesiosis and fungal infections, pending further data generation. Upon demonstration of clinical proof of concept, we plan to enter into a strategic partnership with a larger entity with commercialization capacity, or raise additional capital to facilitate commercialization of Arakoda, and any additional clinical studies that may be required by regulators, for both travel medicine and broad infectious disease indications. We will continue to develop our portfolio products as resources permit.

In 2023, we plan to execute a randomized, placebo-controlled double blind clinical study to prove that Arakoda accelerates time to sustained clinical recovery in patients with mild-moderate disease with no risk factors. We believe that Arakoda has the potential to reduce the time to sustained clinical recovery by about three days. The study will be conducted in out-patient clinics in Australia and/or the United States. The study will utilize the majority of the proceeds of the offering reserved for research and development activities for this purpose. As of the date of this prospectus, we have completed a clinical study synopsis. Submission of the full protocol to the ethics committees and to Australian or U.S. regulators, and a posting at *clinicaltrials.gov* will follow this initial public offering.

In parallel with the planned clinical study, we plan to conduct additional non-clinical studies to clarify the process by which tafenoquine interacts with COVID-19. Specifically, such studies will attempt to determine whether tafenoquine acts as an immunomodulator (by decreasing the production of immune system molecules that cause inflammation) and/or exhibits and antiviral effect via inhibition of the host protease TMPRSS2. Also, we will attempt to investigate potential synergistic effect of tafenoquine in cell culture in combination with other antivirals used to treat COVID-19 disease (e.g., remdesivir, molunpiravir and paxlovid).

Following completion of our planned COVID-19 clinical study, if warranted based on the data generated, we intend to request a change in prescribing information to facilitate an expansion of use of Arakoda for malaria prevention from six to twelve months (mirroring our recently published post-marketing safety study) and to include reference to the recently generated COVID-19 treatment data. Prior to doing so, we plan to discuss with the FDA additional labeling related to COVID-19 which might be acceptable, as well as other routes to regulatory approval such as emergency use authorization.

We are planning several commercial initiatives for the malaria market in parallel with further clinical development activities. Three routes exist for commercialization of Arakoda for the malaria prevention market are: (i) U.S. civilian travel clinics, travel prescribing centers, and large private sector entities with employees deployed overseas (e.g., mining companies), (ii) the prospect of additional U.S. Department of Defense ("DoD") and government agency procurement in the future and (iii) ex U.S. sales strategy where we currently (or in the future) have exclusive distribution arrangements in overseas markets.

As of the date of this prospectus, we did not have plans to hire a U.S. sales force, but are exploring possible commercial arrangements with contract sales organizations to target U.S. travel clinics for malaria prophylaxis. We intend to consummate a contract with a lobbying firm/contract sales organization to attempt to improve the position of Arakoda in the DoD formulary and to raise awareness of Arakoda amongst other U.S. government agencies. For such agencies, the product is expected to meet many of the requirements for occupational malaria prevention identified by the independent parties that have endorsed the product. We have been successful in securing procurement contracts with U.S. government agencies for Arakoda, and anticipate continued success in the future. In the third quarter of 2022, we made our first sale to our European distributor, and made additional sales to our Australian distributor in the second quarter of 2022. We are actively exploring the possibility of named-patient sales in jurisdictions outside Australia, Europe, and the United States. As resources permit, we will undertake a focused marketing campaign for Arakoda for malaria prevention in 2023. This will consist of promotion at relevant conferences, email promotion to prescribers, and target print and electronic advertisements.

It is expected that a point of care G6PD test might be required to maximize the economic potential of a COVID-19 indication for Arakoda. We do not intend to pursue independent development of such a test as there are well resourced development efforts already underway (see "*Risk Factors—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 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 may not directly control the timing, conduct and expense of such testing*" beginning on page 23). However, we will continue to monitor the progress of development and U.S. commercialization of G6PD tests. We will seek to pursue collaborative commercial partnerships with the companies involved in commercialization efforts, if such activities can be conducted through resource sharing efforts.

We plan to generate additional validation data for our portfolio products if resources permit. Specifically, we will evaluate whether Celgosivir provides therapeutic benefit in a COVID-19 animal model, and complete critical activities related to confirming GMP process feasibility.

We may elect, as resources permit, to undertake a clinical study of tafenoquine in combination with standard of care for hospitalized patients with babesiosis. We have developed such a protocol in partnership with academic collaborators and are planning to submit an IND to the FDA and pursue public and philanthropic funding to support our execution. We plan to seek public funding to support additional non-clinical studies to validate the mechanism of action of tafenoquine against *Candida spp*. and further assess our utility in combination with standard of care agents in cell culture and animal studies.

We have a 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.[23] The FDA has asked us to propose an alternate design, for which we have indicated to the FDA that we plan to respond to the FDA's feedback by the end of the fourth quarter of 2022. 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 2024. 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.

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

Intellectual Property

We have global, and exclusive, rights to use patents, manufacturing information and non-clinical and clinical data licensed from the United States Army for tafenoquine for all indications except *P. vivax* malaria. We have submitted patent applications in the United States and elsewhere for 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 (we have submitted a provisional patent). We have licensed patents for Celgosivir for the treatment and prevention of dengue (from the National University of Singapore), COVID-19 (Florida State University) and have submitted provisional patents related to Celgosivir for RSV. We have licensed or owns manufacturing methods related to Celgosivir.

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 (secondary packaging) and supply/quality/pharmacovigilance agreements in place with Biocelect Pty Ltd, Scandinavian Biopharma, and Knight Therapeutics (to allow supply of Arakoda/Kodatef to Australia, Europe and Canada/Israel/Latin America and Russia, respectively).

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 are monitoring the global outbreak and spread of COVID-19 and 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. The current outbreak of COVID-19 has globally resulted in loss of life, business closures, restrictions on travel, and widespread cancellation of social gatherings. 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;
- regulatory actions taken in response to the pandemic, which may impact our product offerings;
- other business disruptions that affect our workforce;
- 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 outbreak 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. 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 the COVID-19 pandemic*."

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 17 of this prospectus. These risks include, among others, that:

- 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;
- Our financial statements have been prepared on a going-concern basis and our continued operations are in doubt;
- There is no assurance that we will be profitable;
- Our financial condition and results of operations may be adversely affected by the COVID-19 pandemic;
- If we are not able to successfully develop, obtain FDA approval for, and provide for the commercialization of non-malaria indications for Arakoda 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;

- The mechanisms of actions of some of our products, and interactions with other antiviral products are not known, which may restrict regulatory label claims;

- 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 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;

- 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, Celgosivir and our other product candidates, and we can provide no assurance that we will successfully commercialize Arakoda, 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;
- There has been no public market for our common stock prior to this offering, and we cannot assure you that an active trading market will develop in the near future. An active market in which investors can resell their shares may not develop. If there is no viable public market for our common stock, you may be unable to sell your shares at or above the initial public offering price;
- We may not be able to satisfy listing requirements of Nasdaq to maintain a listing of our common stock;
- Our 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 , 2022, we have 2,386,009 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 $1.07 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 for complying 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 irrevocably 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.
Common stock offered by us	shares.
Common stock outstanding prior to the offering[(1)]	2,386,009 shares.
Common stock to be outstanding after the offering[(2)]	shares (shares if the underwriters exercise their option to purchase additional shares in full).
Over-allotment option of common stock offered by us	The underwriters have a 45-day option to purchase up to 15% additional shares of common stock solely to cover over-allotments, if any.
Use of Proceeds	The principal purposes of this offering are to fund the development of new indications for our products, to repay debt associated with prior financing, increase our capitalization and financial flexibility, increase our visibility in the marketplace and create a public market for our common stock. 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. However, we currently intend to use the net proceeds to us from this offering for research and general corporate purposes, including working capital. See "*Use of Proceeds*" beginning on page 51.
Proposed Listing	We will apply to have our common stock listed on The Nasdaq Capital Market under the symbol " ," which listing is a condition to this offering.
Representative Warrants	Upon the closing of this offering, we have agreed to issue to the Representative, warrants that will expire on the fifth anniversary of the commencement date of sales in this offering, entitling the Representative to purchase 6% of the number of shares of common stock 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 underwriters, please see "*Underwriting*."
Lock-up agreements	Our executive officers and directors have agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for six 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 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 17 of this prospectus before deciding whether or not to invest in shares of our common stock.

(1) As of , 2022.

(2) Includes (i) shares of our common stock issued to BioIntelect Pty Ltd ("BioIntelect") pursuant to the Master Consultancy Agreement dated as of May 29, 2013 (the "BioIntelect Agreement"), which provides that in connection with our initial public offering, BioIntelect will be entitled to receive deferred equity compensation in the amount equal to $155,000 (or $245,000 if Australian VC Horizon Biotech participates in the offering), (ii) shares of our common stock issued to Knight Therapeutics (Barbados) Inc. ("Knight") as a result of the conversion of certain of our outstanding debt owed to Knight, (iii) shares of our common stock to Latham BioPharm Group, Inc. ("Latham BioPharm") pursuant to the Consulting Agreement dated as of August 17, 2020, as amended (the "Latham Agreement"), which provides that in connection with our initial public offering, Latham BioPharm will be entitled to receive deferred equity compensation in the amount equal to $60,000, and (iv) shares of our common stock that are to be issued prior to the closing of this offering as a result of the conversion of our convertible promissory notes.

(3) Does not include (i) shares of our common stock issuable pursuant to the Termination Letter dated as of May 20, 2021 (the "Torreya Letter"), issued by Torreya Capital, LLC ("Torreya") to us, which entitles Torreya, among other things, a warrant equal to 2% of a maximum aggregate consideration of $1.5 million of the initial public offering if Horizon 3 Biotech Fund participates in this offering, (ii) shares of our common stock underlying a warrant issued to Bigger Capital Fund, LP, (iii) shares of our common stock underlying a warrant issued to Cavalry Investment Fund, LP, (iv) shares of our common stock underlying a warrant issued to Walleye Opportunities Master Fund Ltd, (v) shares of our common stock underlying a warrant issued to Geoffrey Dow (in the form of his revocable grantor trust, the Geoffrey S. Dow Revocable Trust for which Mr. Dow is the sole trustee), (vi) shares of our common stock underlying a warrant issued to Mountjoy Trust and (vii) shares of our common stock issuable upon the exercise of the Representative Warrants.

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

- a public offering price of $ per share, which is the midpoint of the range of the offering price per share;
- no shares of common stock have been issued pursuant to the (i) conversion of certain of our outstanding debt owed to Knight, (ii) BioIntelect Agreement, (iii) Latham Agreement and (iv) conversion of our convertible promissory notes;
- no shares of common stock have been issued pursuant to any warrants; and
- no shares of common stock have been issued pursuant to the Representative's over-allotment option;
- no shares of common stock have been issued pursuant to the Representative Warrants.

SUMMARY FINANCIAL DATA

The following tables summarize our financial data. We derived the summary financial statement data for the years ended December 31, 2021 and 2020 set forth below from our audited financial statements and related notes contained in this prospectus, and the summary financial statement data for the nine months ended September 30, 2022 and September 30, 2021 set forth below from our unaudited financial statements and related notes contained in this prospectus. The unaudited interim financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the information presented below together with "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," our financial statements, the notes to those statements and the other financial information contained in this prospectus.

Summary of Operations in U.S. Dollars

[*]

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

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 $4,260,299 in 2021 and $3,048,470 in 2020, respectively. We had an accumulated deficit of $[*] as of September 30, 2022.

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.

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.

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.

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 revenues 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 the coronavirus (COVID-19) 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.

The continued global COVID-19 pandemic has created significant volatility, uncertainty and economic disruption. To date, this pandemic 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 the COVID-19 pandemic, 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 the COVID-19 pandemic, 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 the pandemic (e.g., vaccination requirements that have been and continue to be taken in response to the pandemic and enhanced health and 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 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 this "*Risk Factors*" section.

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 we need 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 current COVID-19 trials 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 COVID-19 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, 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 in the clinical development of our product candidates. The three clinical trials we conducted in the past were managed directly by us, but executed 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.

The mechanisms of actions of some of our products, and interactions with other antiviral products are not known, which may restrict regulatory label claims.

The FDA has granted full or limited marketing authority for COVID-19 products based on the clinical benefit demonstrated in clinical trials, for products that have both antiviral and non-antiviral modes of action. However, the FDA may require specific additional evidence to grant a labeling claim of antiviral activity. We are planning to further develop Arakoda for treatment of COVID-19 based on the observation of trends towards accelerated recovery observed in the exploratory endpoints of a Phase II clinical trial we recently completed. We plan to undertake limited research activities to confirm whether tafenoquine provides clinical benefit via an antiviral or other mechanism. However, we cannot guarantee such efforts will confirm a direct antiviral mechanism to the satisfaction of the FDA, or that any data generated will support regulatory claims of antiviral activity in additional to whatever claims related to clinical benefit in COVID-19 treatment that the FDA may allow. Relatedly, the FDA required warning language to be placed on the remdesivir label related to a theoretical drug-drug interaction with other antimalarials based on in vitro (not clinical) data. If an appropriate commercial/academic partner can be found, we plan to conduct in vitro studies to assess whether Arakoda interacts with other products including paxlovid, molnupiravir and remdesivir – we cannot guarantee these studies will be successfully executed or provide data that will discharge any theoretical risks or concerns regulators may have (including the need for disclaimers or warning labels).

We will rely on contract research organizations to conduct substantial portions of our clinical trials, including any future clinical trial of Arakoda 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 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 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, 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 Arakoda 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 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 Arakoda.

For clinical trials administered in the United States, G6PD testing is provided through commercial pathology companies including Labcorp and Qwest 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) but this requires administration in a CLIA-certified laboratory, which not all clinical trial sites have access to.

For many clinical trials, and in particular those involving viral diseases, 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 Arakoda. 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 Arakoda in such a trial.

Arakoda requires administration of a G6PD test. The lack of point of care tests may negatively impair sales of Arakoda.

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.

If it is confirmed that the mode of action of Arakoda in COVID-19 is via a direct antiviral mechanism, it is likely that, as with other antivirals, rapid administration of the product is important to maximize efficacy. Therefore, it is possible that the current lack of an FDA-approved, widely available point of care G6PD test will negatively impact sales of Arakoda for COVID-19, under the assumption that the FDA eventually approves Arakoda for this indication and appropriate G6PD tests are never approved by FDA.

Several third party diagnostic test companies are developing point of care G6PD tests 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.[24] Another is available for use in Europe and undergoing review by the FDA in the United States.[25] 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.[26] 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 a new drug application ("NDA") from the FDA for such drug. We have received an NDA approval for Arakoda for malaria prevention, but have not approval from the FDA for any non-malaria indications for Arakoda 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.

[24] https://www.sdbiosensor.com/product/product_view?product_no=183.

[25] https://baebies.com/near-patient-digital-microfluidics-g6pd-assay/.

[26] 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 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, an 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 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 Arakoda for non-malaria indications or of a Celgosivir NDA in a timely manner.

In pursuing clinical development of Arakoda for a non-malaria indication or Celgosivir for other indications, we will be required to amend existing prescribing information, or prepare a new NDA or EUA (if appropriate). The FDA could approve Arakoda or Celgosivir, but without including some or all of the prescribing information that we have requested. For instance, the FDA could approve Arakoda or Celgosivir for AF 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 Arakoda or Celgosivir and effectively protect our intellectual property rights in Arakoda or Celgosivir.

If we are not able to successfully develop, obtain FDA approval for, and provide for the commercialization of non-malaria indications for Arakoda 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 Arakoda (for a non-malaria 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 Arakoda for non-malaria 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 Arakoda (for non-malaria 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 Arakoda for non-malaria 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, 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 Arakoda for non-malaria 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. 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 ("PBMs") 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 is 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 specially 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 or 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. We intend to pursue additional institutional procurement by U.S. government agencies through a lobbying effort, but may not establish our own sales force while pursuing development of our products.

Future commercialization of Arakoda for non-malaria 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 Arakoda for non-malaria 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, 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, 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, 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, or Celgosivir and other selected product candidates, either directly or through third parties via a strategic transaction, the commercialization of Arakoda for non-malaria 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 active pharmaceutical ingredients ("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 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 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, Celgosivir and our other product candidates, and we can provide no assurance that we will successfully commercialize Arakoda, Celgosivir and other product candidates.

Our future growth depends on our ability to successfully commercialize Arakoda, Celgosivir and our other product candidates, including our ability to:

- conduct additional clinical trials and develop and obtain regulatory approval for Arakoda, Celgosivir or other product candidates;
- successfully partner a companion genetic test (if required by the FDA) with the commercialization of Arakoda and Celgosivir;
- pursue additional indications for Arakoda and Celgosivir and develop other product candidates, including other therapies; and
- obtain commercial quantities of Arakoda 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, Arakoda for non-malaria 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 and Celgosivir. If products with any of these properties are developed, or any of the existing products are better marketed, then Arakoda 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. We are currently engaged in a "gap analysis" to ensure we are compliant or will become compliant with any regulations. 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, 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), 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 ("CCPA"), became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing 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. 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 is in discussion with the FDA regarding future plan 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 is 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 is experiencing 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.

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. Recently, 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. 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, 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.

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, Celgosivir or other product candidates.

We 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, 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 or Celgosivir, the genetic testing we intend to use in connection with Arakoda, 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, 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 reexamination, *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 is July 20, 2018. The five year data exclusivity ending date for Arakoda is 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 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 receive 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 Arakoda for other indications. This potential litigation and the related expenditures 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 share 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, of which none are issued and outstanding. The designations, rights and preferences of our 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 % 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 will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase 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 being a public company and 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 will 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

There has been no public market for our common stock prior to this offering, and we cannot assure you that an active trading market will develop in the near future. An active market in which investors can resell their shares may not develop. If there is no viable public market for our common stock, you may be unable to sell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for our common stock. All investments in securities involve the risk of loss of capital. No guarantee or representation is made that an investor will receive a return of its capital. The value of our common stock can be adversely affected by a variety of factors, including development problems, regulatory issues, technical issues, commercial challenges, competition, legislation, government intervention, industry developments and trends, and general business and economic conditions. We cannot predict the extent to which an active market for our common stock will develop or be sustained after this offering, or how the development of such a market might affect the market price of our common stock.

Our common stock is not quoted in the over-the-counter markets and is not listed on any stock exchange and there is currently no active trading in our securities. We will apply to have our common stock listed on The Nasdaq Capital Market under the symbol " " which listing is a condition to this offering. We cannot assure you that an active trading market for our common stock will develop in the future due to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. We cannot give you any assurance that an active public trading market for our common stock will develop or be sustained. You may not be able to liquidate your shares quickly or at the market price if trading in our common stock is not active.

You may be unable to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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

The initial public offering price for the shares will be determined by negotiations between us and the underwriters and may not be indicative of prices that will prevail in the open market following this offering. The market price of our common stock may decline below the initial offering price, and you may not be able to sell your shares of our common stock at or above the price you paid in the offering, or at all. Following this offering, the public price of our common stock in the secondary market will be determined by private buy and sell transaction orders collected from broker-dealers.

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.

Following this offering, 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.

We may not be able to satisfy listing requirements of Nasdaq to maintain a listing of our common stock.

If our common stock is listed on The Nasdaq Stock Market LLC ("Nasdaq"), we must meet certain financial and liquidity criteria to maintain such listing. If we violate the maintenance requirements for continued listing of our common stock, our common stock may be delisted. In addition, our board may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. 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. Although we expect our common stock will be approved for listing on Nasdaq, an active trading market for our shares may never develop or be sustained following this offering.

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 establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, 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 Treasurer 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 ("Certificate of Incorporation") and our 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 the 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.

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 $1.07 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.

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 estimate that we will receive net proceeds of approximately $ (or approximately $ if the underwriters' option to purchase additional shares is exercised in full) from the sale of the common stock offered by us in this offering, based on an assumed public offering price of $ per share (the midpoint of the price range set forth on the front cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share (the midpoint of the price range set forth on the front cover page of this prospectus) would increase or decrease, as applicable, the net proceeds that we receive from this offering by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of shares of our common stock offered by us would increase or decrease, as applicable, the net proceeds that we receive from this offering by approximately $, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, increase our visibility in the marketplace and create a public market for our common stock. 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. However, we currently intend to use the net proceeds to us from this offering for general corporate purposes, including working capital.

Our strategic priority is to further develop, through clinical studies and related activities, additional/new indications for our products. We anticipate up to $6.5 million will be needed to finance such efforts. Additionally, up to $885,556 of net proceeds from this offering may be used to repay promissory notes issued to (i) Bigger Capital Fund, LP, (ii) Cavalry Investment Fund, LP and (iii) Walleye Opportunities Master Fund Ltd.

We may also retire the following cash commitments to other parties associated with the public offering: $85,000 SD to the National University of Singapore as a license agreement milestone payment, $38,900 to Latham BioPharm, $100,000 to Biointelect and up to $30,000 to Torreya in the event Horizon Biotech is an investor.

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	$ 2,200,000
Debt Repayment	$ 1,300,000
Research and Development (clinical trials and related activities)	$ 6,500,000
Total	$ 10,000,000

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

Prior to this offering, our common stock has not been listed on any stock exchange or quoted on any over-the-counter market or quotation system and there has been no public market for our common stock. We intend to apply to have our common stock listed on The Nasdaq Capital Market under the symbol " ," which listing is a condition to this offering. There can be no assurance that our listing application will be approved. For more information see the section "*Risk Factors*."

As of , 2022, 2,386,009 shares of our common stock were issued and outstanding and were held by three stockholders of record.

CAPITALIZATION

The following table sets forth our consolidated cash and capitalization, as of , 2022. Such information is set forth on the following basis:

- on an actual basis;
- on a pro forma basis to reflect the (i) sale of shares of our common stock by us after , 2022, but prior to this offering, (ii) issuance of shares of our common stock to BioIntelect pursuant to the BioIntelect Agreement, (iii) issuance of shares of our common stock to Knight as a result of the conversion of certain of our outstanding debt owed to Knight, (iv) issuance of shares of our common stock to Latham BioPharm pursuant to the Latham Agreement and (v) issuance of shares of our common stock as a result of the conversion of our convertible promissory notes; and
- 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 our sale and issuance of shares of common stock in this offering at an assumed initial public offering price of $ per share (the midpoint of the price range set forth on the front cover page of this prospectus), 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	Pro Forma	Pro forma, as adjusted[1][2]
Cash	$	$	$
Short term liabilities, including deferred revenue due within one year	$	$	$
Long term debt, including convertible notes payable			
Total liabilities including lease obligations - net of current portion	$	$	$
Stockholders' equity:			
Common stock, $0.0001 par value, 150,000,000 shares authorized, 2,386,009 shares issued and outstanding, actual; 150,000,000 shares authorized, [*] shares issued and outstanding, pro forma; and 150,000,000 shares authorized, [*] shares issued and outstanding, pro forma as adjusted; preferred stock, $0.0001 par value, 1,000,000 shares authorized, [0] shares issued and outstanding, actual; 1,000,000 shares authorized, [0] shares issued and outstanding, pro forma; and 1,000,000 shares authorized, [0] shares issued and outstanding, pro forma as adjusted			
Additional paid-in capital			
Retained earnings (deficit)			
Total stockholders' equity			
Total capitalization	$ —	$ —	$ —

(1) The number of issued and outstanding shares as of , 2022 on a pro forma as adjusted basis includes (i) shares of our common stock issued to BioIntelect pursuant to the BioIntelect Agreement, which provides that in connection with our initial public offering, BioIntelect will be entitled to receive deferred equity compensation in the amount equal to $155,000 (or $245,000 if Australian VC Horizon Biotech participates in the offering), (ii) shares of our common stock issued to Knight as a result of the conversion of certain of our outstanding debt owed to Knight (iii) shares of our common stock issued to Latham BioPharm pursuant to the Latham Agreement, which provides that in connection with our initial public offering, Latham BioPharm will be entitled to receive deferred equity compensation in the amount equal to $60,000 and (iv) shares of our common stock that are to be issued prior to the closing of this offering as a result of the conversion of our convertible promissory notes, and excludes shares of our common stock issuable pursuant to the Torreya Letter, which entitles Torreya, among other things, a warrant equal to 2% of a maximum aggregate consideration of $1.5 million of the initial public offering if Horizon 3 Biotech Fund participates in this offering, shares of our common stock underlying a warrant issued to Bigger Capital Fund, LP, shares of our common stock underlying a warrant issued to Cavalry Investment Fund, LP, shares of our common stock underlying a warrant issued to Walleye Opportunities Master Fund Ltd., shares of our common stock underlying a warrant issued to Geoffrey Dow, shares of our common stock underlying a warrant issued to Mountjoy Trust and shares of our common stock issuable upon the exercise of the Representative Warrants.

(2) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share (the midpoint of the price range set forth on the front cover page of this prospectus) would increase or decrease, as applicable, the amount of our cash, additional paid-in capital and total stockholders' equity by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions payable by us. An increase or decrease of shares of our common stock offered by us would increase or decrease, as applicable, the amount of our cash, additional paid-in capital and total stockholders' equity by $, assuming an initial public offering price of $ (the midpoint of the price range set forth on the front cover page of this prospectus) after deducting estimated underwriting discounts and commissions payable by us.

DILUTION

Purchasers of our common stock in this offering will experience an immediate and substantial dilution in the as adjusted net tangible book value of their shares of common stock. Dilution in as adjusted net tangible book value represents the difference between the public offering price per share and the as adjusted net tangible book value per share of our common stock immediately after the offering.

The historical net tangible book value of our common stock as of September 30, 2022, was $ or $ per share. Historical net tangible book value per share of our common stock represents our total tangible assets (total assets less intangible assets) less total liabilities divided by the number of shares of common stock outstanding as of that date. After giving effect to the issuance of shares of common stock upon the (i) issuance of shares of our common stock to BioIntelect pursuant to the BioIntelect Agreement, (ii) issuance of shares of our common stock to Knight as a result of the conversion of certain of our outstanding debt owed to Knight, (iii) issuance of shares of our common stock to Latham BioPharm pursuant to the Latham Agreement and (iv) issuance of shares of our common stock as a result of the conversion of our convertible promissory notes, our pro forma net tangible book value as of September 30, 2022 would have been $ or approximately $ per share of our common stock.

After giving effect to the pro forma adjustments set forth above and the issuance of shares in this offering at an assumed initial public offering price of $ per share (the midpoint of the price range set forth on the front cover page of this prospectus) for net proceeds of approximately $, our pro forma as adjusted net tangible book value as of September 30, 2022 would have been $ or approximately $ per share of our common stock. This represents an immediate increase in pro forma net tangible book value per share of $ to the existing stockholders and an immediate dilution in pro forma net tangible book value per share of $. The following table illustrates this per share dilution to new investors:

Public offering price per share		$
Pro forma net tangible book value per share as of September 30, 2022	$	
Increase in pro forma net tangible book value per share attributable to the offering		
Pro forma as adjusted net tangible book value (deficit) per share as of September 30, 2022		
Dilution in pro forma as adjusted net tangible book value per share to new investors		$

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share (the midpoint of the price range set forth on the front cover page of this prospectus) would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share to new investors by $, and would increase or decrease, as applicable, dilution per share to new investors in this offering by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of shares of our common stock offered by us would increase or decrease, as applicable, our pro forma as adjusted net tangible book value by approximately $ per share and increase or decrease, as applicable, the dilution to new investors by $ per share, assuming the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

After completion of this offering, our existing stockholders would own approximately % and our new investors would own approximately % of the total number of shares of our common stock outstanding after this offering.

To the extent that outstanding options or warrants, if any, are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

Capitalization Table

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Per Share
Existing stockholders		%			
New Investors		%			
		%			

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share (the midpoint of the price range set forth on the front cover page of this prospectus) would increase or decrease, as applicable, the total consideration paid by new investors and total consideration paid by all stockholders by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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 "Unaudited Condensed Consolidated Financial Information." We assume no obligation to update any of these forward-looking statements.

Overview

[*]

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

Recently, 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. 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;
- 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.

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 fulfillment of the existing contract, the DoD has not issued any further contracts nor contract modifications to allow additional procurement. Further information is provided in the "*Revenue*" section below.

Results of Operations

The following table sets forth our consolidated statements of operations for the years ended December 31, 2021 and 2020.

Twelve Months Ended December 31, 2021 and 2020

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

	Twelve Months Ended December 31,	
Consolidated Statements of Operations Data:	**2021**	**2020**
Revenue	$ 1,160,340	$ 2,181,359
Cost of goods sold	850,742	702,989
Gross profit	309,598	1,478,370
Research Revenue	5,192,516	368,107
Net Revenue	5,502,114	1,846,477
Operating expenses:		
Research and development	5,510,866	806,683
General and administrative	1,115,350	1,457,924
Total operating expenses	6,626,216	2,264,607
Loss from operations	(1,124,102)	(418,130)
Interest and other income (expense), net:		
Interest expense	(3,172,712)	(2,678,435)
Other income (expense)	37,515	49,095
Pretax loss	(4,259,299)	(3,047,470)
Taxes	1,000	1,000
Net loss	(4,260,299)	(3,048,470)
Loss attributable to non-controlling interest	(8,554)	(14,726)
Net loss attributable to 60° Pharmaceuticals, LLC	(4,251,745)	(3,033,744)
Comprehensive loss:		
Net loss	(4,260,299)	(3,048,470)
Unrealized foreign currency translation (loss) gain	(3,031)	(134,254)
Comprehensive loss	(4,263,330)	(3,182,724)
Net loss – non-controlling interest	(8,554)	(14,726)
Unrealized foreign currency translation (loss) gain from non-controlling interest	1,588	(5,587)
Comprehensive loss attributable to 60° Pharmaceuticals, LLC	$ (4,256,364)	$ (3,162,411)

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

	Twelve Months Ended December 31,	
Consolidated Statements of Operations Data:	**2021**	**2020**
Revenue	100.00%	100.00%
Cost of goods sold	73.32	32.23
Gross profit	26.68	67.77
Research Revenue	447.50	16.88
Net Revenue	474.18	84.65
Operating expenses:		
Research and development	474.94	36.98
General and administrative	96.12	66.84
Total operating expenses	571.06	103.82
Loss from operations	(96.88)	(19.17)
Interest and other income (expense), net:		
Interest expense	(273.43)	(122.79)
Other income (expense)	3.23	2.25
Total interest and other income (expense), net	(270.20)	(120.54)
Pretax loss	(367.08)	(139.71)
Taxes	0.09	0.05
Net loss	(367.17)	(139.76)
Loss attributable to non-controlling interest	(0.74)	(0.68)
Net loss attributable to 60° Pharmaceuticals, LLC	(366.43)	(139.08)
Comprehensive loss:		
Net loss	(367.17)	(139.76)
Unrealized foreign currency translation (loss) gain	(0.26)	(6.15)
Comprehensive loss	(367.43)	(145.91)
Net loss – non-controlling interest	(0.74)	(0.68)
Unrealized foreign currency translation (loss) gain from non-controlling interest	0.14	(0.26)
Comprehensive loss attributable to 60° Pharmaceuticals, LLC	(366.83)%	(144.97)%

Comparison of the Twelve Months Ended December 31, 2021 and 2020

Revenue, Cost of Goods Sold, Gross Profit, and Gross Margin

	Twelve Months Ended December 31,			
	2021	**2020**	**$ Change**	**% Change**
Revenue	$ 1,160,340	$ 2,181,359	$ (1,021,019)	(46.81)%
Cost of goods sold	850,742	702,989	147,753	21.02%
Gross profit	$ 309,598	$ 1,478,370	$ (873,266)	(59.07)%
Gross margin	26.68%	67.77%		

Revenue

Sales for 60 Degrees Pharmaceuticals were $1,160,340 for the year ended December 31, 2021, as compared to $2,181,359 for the year ended December 31, 2020. As of December 31, 2021, one government customer accounted for approximately 92% (and 98% as of December 31, 2020) of 60 Degrees Pharmaceuticals' 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, and which ended on August 31, 2022. This contract was executed by our U.S. government research partner to support commercialization efforts.

Although, as of the date of this prospectus, we were not in discussions with the DoD about additional/future procurement, we anticipate that this will be feasible in the future if one or more of the conditions/events described in this paragraph 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). 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).

Arakoda entered the U.S. civilian supply chain in the third quarter of 2019. In 2020, 183 boxes were sold. Sales increased by 72% to 315 boxes in 2021, and are up by 42% relative to 2021 during the first through third quarters of 2022. Increasing civilian sales likely reflect organic growth, since no active marketing efforts were made during the pandemic and the wholesale acquisition cost has not changed since launch in 2019.

Cost of Goods Sold, Gross Profit, and Gross Margin

The cost of goods sold was $850,742 for the year ended December 31, 2021, as compared to $702,989 for the year ended December 31, 2020. The increase in cost of goods sold was primarily due to change in accounting for what we now consider periodic COGS such as storage and serialization that is now charged on a quarterly basis. Previously, these costs were accumulated and assigned to production lots ($122,181 unassigned at the end of 2020). The Gross Margin % fell to 26.68% in 2021 from 67.77%. This is due to the aforementioned government client's purchases which were much more profitable. We were able to sell the lots directly to the government skipping the traditional supply chain entirely thus avoiding many of the costs charged by distribution partners, wholesalers and insurers.

Operating Expenses

	Twelve Months Ended December 31,			
	2021	**2020**	**$ Change**	**% Change**
Research and development	$ 5,510,866	$ 806,683	$ 4,704,183	583%
General and administrative	1,115,350	1,457,924	(342,574)	(23)%
Total operating expenses	$ 6,626,216	$ 2,264,607	$ 4,361,609	193 %

Research and Development Expenses

We considerably expanded research and development costs as we ramped up our Phase II COVID-19 trial in 2021. Direct COVID-19 related trial costs are 86% of the costs in 2021 at $4,721,635 and 12% of the costs in 2020 at $100,378. Research and development costs were expected to be significantly lower in 2022, as the write-up of the clinical study reported was completed. Research and development costs are expected to increase substantially in 2023, potentially up to $6.5 million, as the second COVID-19 clinical trial and supporting activities are initiated.

General and Administrative Expenses

In 2021, our General and Administrative expenses decreased by 23% or $342,574. This decrease is primarily related to a corresponding decrease of guaranteed payments to the then partners of $324,216 ($353,811 in 2021, $678,027 in 2020). In 2020, a former partner was actively employed with us for only the first half of the year and additionally in 2021 guaranteed payments were included in research and development.

Interest and Other Income (Expense), Net

	Twelve Months Ended December 31,			
	2021	2020	$ Change	% Change
COVID-19 related grants and PPP	$ 38,500	$ 49,216	$ (10,716)	(22)%
Interest expense	(3,172,712)	(2,678,435)	(494,277)	18%
Other Income (Expense)	(985)	(121)	(864)	714%
Total Interest and Other Income (Expense), Net	$ (3,135,197)	$ (2,629,340)	$ (505,857)	19%

COVID-19 related grants and PPP

In 2021, we qualified for a fully forgivable PPP loan of $38,500. In 2020, that amount was $41,667 and additionally we received a local COVID-19 grant of $4,549 and an SBA EIDL Grant of $3,000.

Interest Expense

In 2021, we recognized $3,172,712 of interest expense ($2,678,435 in 2020). The increase is primarily related to growing principal and interest balances with the primary lender Knight Therapeutics. Cash paid for interest expense was none in 2021 (none in 2020).

Other Income (Expense), Net

In 2021, we recognized ($985) in Other Income (Expense) compared to ($121) in 2020.

Liquidity and Capital Resources

We had net cash used in operating activities of $649,106 for the twelve months ended December 31, 2021 and the cash balance was $443,227 as of September 30, 2022. We believe our current cash balances coupled with anticipated cash flow from operating activities and proceeds from this offering will be sufficient to meet our working capital requirements for at least one year from the date of issuance of the accompanying consolidated financial statements. We continue to control our cash expenses as a percentage of expected revenue on an annual basis and thus may use our cash balances in the short-term to invest in revenue growth. Based on current internal projections, we believe we have and/or will generate sufficient cash for our operational needs, for at least one year from the date of issuance of the accompanying consolidated financial statements. Our plans for our cash within the twelve months from September 30, 2022 and beyond are to [*]. 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 that we will be able to raise additional capital on acceptable terms, or at all. Subject to the foregoing, management believes that we will have sufficient capital and liquidity to fund our operations for at least one year from the date of issuance of the accompanying consolidated financial statements.

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

Borrowings

On December 10, 2015, we entered into the Loan Agreement and Engagement with Knight Therapeutics (Barbados) Inc., as amended by the First Amendment to the Initial Agreement dated as of July 15, 2016, as amended by the Second Amendment to the Initial Agreement dated as of August 21, 2017, as amended by the Third Amendment to the Initial Agreement dated as of December 12, 2017, as amended by the Fourth Amendment to the Initial Agreement dated as of April 21, 2018, as amended by the Fifth Amendment to the Initial Agreement dated as of September 11, 2018, as amended by the Sixth Amendment to the Initial Agreement dated as of January 29, 2019, as amended by the Seventh Amendment to the Initial Agreement dated as of December 27, 2019, and as amended by the Eighth Amendment to the Initial Agreement dated as of January 26, 2021, in which we originally borrowed $500,000 at a per annum interest rate of 15% (the "Knight Loan"). As of September 30, 2022, the current outstanding balance of the Knight Loan is $18,866,523. A portion of the outstanding balance owed will be converted into shares of common stock immediately prior to the initial public offering.

On October 11, 2017, we issued a $750,000 promissory note, as amended, to Avante International Limited with accrued interest at an annual rate of 5.0% for the first six months, and 10% thereafter. On December 23, 2017, Avante International Limited transferred the note to Xu Yu (the "Xu Yu Note"). The current outstanding balance of the Xu Yu Note is $1,196,973 as of September 30, 2022.

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 "COVID-19 Loan"). The current outstanding of the COVID-19 Loan is $162,954 as of September 30, 2022.

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 on May 19, 2022 (the "Dow Note"), with a principal amount of $44,444 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of such note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 19, 2022, we issued a Convertible Promissory Note to Mountjoy Trust (the "Mountjoy Note") with a principal amount of $294,444 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of such note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 24, 2022, we issued a note in the amount of $330,000 to Bigger Capital Fund, LP (the "Bigger Capital Fund Note"). On the date of the pricing of our initial public offering, we will deliver to Bigger Capital Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 24, 2023.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Cavalry Investment Fund, LP (the "Cavalry Investment Fund Note"). On the date of the pricing of our initial public offering, we will deliver to Cavalry Investment Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 24, 2023.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Walleye Opportunities Master Fund Ltd (the "Walleye Note"). On the date of the pricing of our initial public offering, we will deliver to Walleye Opportunities Master Fund Ltd shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 24, 2023.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2021:

	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	$ 7,209,823	$ 668	$ 5,954	$ 5,942	$ 137,436
Interest obligations on the debt arrangements	9,314,137	1,525	9,312,612		
Operating leases	59,795	46,795	13,000		
Purchase obligations	82,938	82,938			
Total	$ 16,666,693	$ 131,926	$ 9,331,566	$ 5,942	$ 137,436

Cash Flows

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

Twelve Months Ended December 31, 2021 and 2020

	Twelve Months Ended December 31,			
	2021	2020	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (649,106)	$ (167,299)	$ (481,807)	288%
Investing activities	(35,392)	(70,978)	35,586	(50)%
Financing activities	611,226	277,357	333,869	120%
Effect of foreign currency translation on cash flow	(3,031)	(134,254)	131,223	(98)%
Net increase (decrease) in cash and cash equivalents	$ (76,303)	$ (95,174)	$ 18,871	(20)%

Cash Used in Operating Activities

Net cash used in operating activities was $649,106 for the year ended December 31, 2021, as compared to $167,299 for the year ended December 31, 2020. The increase in net cash used in operating activities was primarily due to paying down of accounts payable during the year.

Cash Used in Investing Activities

Net cash used in investing activities was $35,392 for the year ended December 31, 2021, as compared to $70,978 for the year ended December 31, 2020. The decrease in net cash used in investing activities was primarily due to a reduction in the annual capitalization of patents.

Cash Provided by Financing Activities

Net cash provided by financing activities was $611,226 for the year ended December 31, 2021, as compared to $277,357 for the year ended December 31, 2020. The increase in net cash provided by financing activities was primarily due to accrued interest on loans and new investments by Members during 2021.

Going Concern

The accompanying consolidated financial statements for the twelve months ended December 31, 2021 and December 31, 2020, respectively, included an explanatory note referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. Our consolidated financial statements have been 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 a reasonable period of time.

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.

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.

Investments

We do not have any material external investments.

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.

Income Taxes

60 Degrees Pharmaceuticals, LLC is a C-corporation for income tax purposes. 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 do not expect to realize any benefits in 2021 and 2020. 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 2021 and 2020, 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 ("FASB") issued ASU No. 2019-02, leases, that requires organizations that lease assets, referred to as "lessees," to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases with lease terms of more than twelve months. ASU 2019-02 will also require disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases and will include qualitative and quantitative requirements. The new standard for nonpublic entities will be effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022, and early application is permitted. These consolidated financial statements have been prepared to comport with this standard.

The FASB issues ASUs to amend the authoritative literature in Accounting Standards Codification ("ASC"). There have been a number of ASUs to date, including those above, 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.

BUSINESS

Overview

We are a growth-oriented 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 COVID-19, fungal, tick-borne, and other viral diseases through Arakoda and Celgosivir.

Market Opportunity

Arakoda was approved in 2018 by the U.S. Food and Drug Administration ("FDA") for malaria prevention in individuals 18 years an older, an indication for which there has historically been approximately 485,000 prescriptions (one prescription per three weeks of travel) in the United States each year for the current market-leading product (atovaquone-proguanil). 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. Targeted marketing efforts will commence in 2023 to promote the malaria indication as resources permit, although we expect our primary efforts to be developing Arakoda for other applications.

We are developing Arakoda for non-malaria indications to address several therapeutic indications that have substantial U.S. caseloads, as further described below:

- Treatment of COVID-19. According to *The New York Times*, the lowest daily case rate for the COVID-19 virus since March 2020 based on a seven day average has not typically been below 11,000 cases. Assuming this trend continues, this dynamic translates into a potential market size of at least 4,000,000 cases per year in 2023 and future years. Paxlovid and molunupiravir have received emergency use authorization for the prevention of death and hospitalization in individuals with high risk of disease progression and their use for those purposes continues to be recommended by public health experts. However, to our knowledge, there is not published evidence from randomized controlled clinical trials that either drug reduces the time to sustained clinical recovery for four or more days in standard risk patients infected with contemporary viral strains, and Pfizer has formally abandoned efforts related to this endpoint for paxlovid.[28] If proven effective for early relief of COVID-19 symptoms in standard risk COVID-19 patients, Arakoda could fulfill a patient's need unmet by the approved antivirals.

[28] Press release: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reports-additional-data-paxlovidtm-supporting.

- Treatment and Post-Exposure Prevention of Tick-Borne Diseases. There are approximately 38,000 cases of babesiosis (red blood cell infections caused by deer tick bites) in the United States each year. This estimate is based on the observations of Krugeler[29] who reported that 380,000 cases of Lyme disease occur in U.S. states where babesiosis is endemic and Krause et. al.[30] which reported that approximately 10% of Lyme patients are also infected with *Babesia*. Furthermore, post-exposure prophylaxis following a tick-bite is a recognized indication to prevent Lyme disease, and it is likely that a drug proven to be effective for this indication for babesiosis would also be used in conjunction with Lyme prophylaxis. There may be more than 400,000 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 tickbites based on observations from comparable ex-U.S health systems.[31] 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.

- Prevention of fungal pneumonias. There are 175,000 new medical conditions each year in the United States, including CAR/T therapy and other malignancies, solid organ, autologous and allogeneic hematopoietic stem cell transplants, which are associated with immunosuppression and for which antifungal prophylaxis may be prescribed for vulnerable patients.[32] 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.[33] Arakoda has the potential to be added to existing standard of care regimens for the prevention of fungal pneumonias.

- Treatment of *Candida* infections. According to the Centers for Diseases Control (CDC), there are 50,000 cases of candidiasis (a type of fungal infection) each year in the United States and more than 2,000 cases of *C. auris*, for which there are few available treatments, have been reported to date.[34] 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.

Dengue and RSV, both afflictions against which 60P's early clinical candidates (e.g., Celgosivir) show potential in non-clinical studies, are associated with 1.37 million cases globally according to the European CDC[35] and 235,000 hospitalizations 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.[36]

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[29] *Emerg Infect Dis* 2021;27:616-619.

[30] *Clin Infect Dis* 2022;72:185-189.

[31] Marx et. al., MMWR 2021;70:612-616.

[32] Calculated based on information from the Organ Procurement and Transplant Network, National Data: https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#; Heffelfinger J et al, 2009 Nonadherence to Primary Prophylaxis against Pneumocystis jirovecii pneumonia, PLoS One. 10.1371/journal.pone.0005002; Fishman et al 2019, Pneumocystis jiroveci in solid organ transplantation: guidelines from the American Society of Transplantation Infectious Diseases Community of Practice NCCN Guidelines Version 1.2020, Prevention and Treatment of Cancer-related infections.

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

[34] https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html.

[35] Dengue worldwide overview (europa.eu).

[36] RSV Trends and Surveillance | CDC.

Products

Arakoda

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. 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 its program at an FDA advisory committee meeting, and submitted an NDA to the FDA in 2018. The history of that collaboration has been publicly communicated by the U.S. Army.[37]

Arakoda was subsequently approved by the FDA and by Australia's medicinal regulatory agency, Therapeutic Goods Administration (under the brand named Kodatef), for prevention of malaria in travelers in 2018. Prescribing information and guidance for patients can be found at *www.arakoda.com*. The CDC and independent experts have endorsed Arakoda and noted the features and benefits of the product, including: convenient once weekly dosing following a three day load; the absence of drug resistance; activity of the drug against all species and life cycle stages of the parasite; absence of any black-box safety warnings; and comparable safety profile to placebo with up to 12 months continuous dosing.[38] Tafenoquine entered the commercial supply chains in the U.S. (as Arakoda) and Australia (as Kodatef) in the third quarter of 2019, respectively.

The only limitation of Arakoda is the requirement that a G6PD test 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.[39] 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.[40] Because G6PD is one of the most common enzyme deficiencies and is implicated in hemolysis following administration/ingestion of a variety of oxidant drugs/food, and must also be ruled out as a possible cause when diagnosing neonatal jaundice, G6PD testing is widely available in the United States through commercial pathology service providers (e.g., Labcorp, Qwest 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.

During the COVID-19 pandemic, since commercial opportunities for us were limited, an exploratory research and development campaign was embarked upon to identify new indications for Arakoda. In the second quarter and third quarter of 2020, we commissioned cell culture studies that showed that tafenoquine, the active ingredient in Arakoda, inhibited replication of SARS-CoV-2 (the virus that causes COVID-19).[41] Then, we commissioned computer simulations, which showed that the predicted concentration of tafenoquine in the lungs of COVID-19 patients following administration of the first four doses of the approved antimalarial prophylactic regimen of Arakoda exceeded those inhibiting the virus in cell culture. This provided the rationale for seeking approval from the FDA to conduct a Phase II clinical trial in patients with the COVID-19 disease, for which the FDA granted clearance to proceed in October 2020.

In 2021, we, with financial support from the US Army, conducted a Phase II clinical investigation of the safety and efficacy of Arakoda in outpatients with mild-moderate COVID-19 disease. This study was completed in October 2021, and the results of the study were accepted for publication in May 2022.[42] Analysis of secondary and exploratory endpoints in that study suggested that Arakoda reduced clinical recovery time from shortness of breath, cough and fever ($P < 0.02$) and improved aggregate symptom scores five days after treatment ($P < 0.1$).[43] We plan to confirm these observations in its next study (described in "*Prospectus Summary—Strategy*" beginning on page 8).

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[37] Zottig et al Military Medicine 2020; 185 (S1): 687.

[38] 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.

[39] See prescribing information at www.arakoda.com.

[40] See prescribing information at www.arakoda.com.

[41] U.S. Patent application # 17/189,544, Dow et. al. bioRxiv 2020.07.12.199059; doi: https://doi.org/10.1101/2020.07.12.199059.

[42] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

[43] Dow and Smith, New Microbe and New Infect 2022; 47:100986.

In 2022, we conducted additional analyses of laboratory endpoint data from the clinical study described above and are preparing a manuscript for publication. That analysis and the scientific literature suggest two possible modes of action for Arakoda: (i) down-regulation of cytokines (immune system inflammatory proteins) associated with severe COVID-19 and a greater risk of hospitalization or death and/or (ii) inhibition of viral entry in the lung or elsewhere in the body, perhaps through inhibition of a host enzyme called TMPRSS2 (which facilitates entry of the virus that causes COVID-19, SARS-CoV-2, into human cells).

Assuming the efficacy of Arakoda is proven in our next study, some of the features of Arakoda that make it ideal for malaria prophylaxis might also make it very useful for COVID-19 related indications. Arakoda is slowly metabolized and has no important drug-drug interactions, so might make an ideal partner for standard of care oral COVID-19 therapeutics that reduce hospitalization but have no demonstrated effect on time to clinical recovery in non-hospitalized patients. Arakoda requires fewer tablets (8 in the first ten days versus 30 or 40 for paxlovid and molunpiravir) which should make compliance with medication easier for patients. This is an important consideration in the attractiveness of a regimen in standard risk patients at lower risk of hospitalization, and who may be interested in taking a COVID-19 therapeutic primarily to treat early symptoms and accelerate recovery. The potential for better compliance may also suggest suitability for outbreak control in some settings (including, for example, nursing homes).

During the pandemic, we also worked with NIH to evaluate the utility of tafenoquine as an antifungal. It was 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.[44] Our work followed legacy studies that show tafenoquine is effective for treatment and prevention of *Pneumocystis* pneumonia in animal models.[45] If added to the standard of care for anti-fungal and yeast infection treatments for general use, Arakoda 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.

Tafenoquine is effective in animal models of babesiosis (tick borne red blood cell infections). Two clinical case studies suggest the potential to improve the existing standard of care for treatment of human babesiosis.[46] Combined with standard of care products, Arakoda 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. Once appropriate clinical studies have been conducted, it is likely that Arakoda would be quickly embraced for post-exposure prophylaxis of babesiosis in patients with tick bites and suspected of being co-infected with Lyme disease.

Celgosivir

Celgosivir is a host targeted glucosidase inhibitor that was developed separately by other sponsors for HIV then for hepatitis C.[47] Celgosivir was abandoned after completion of Phase II clinical trials involving 700+ patients, because other antivirals in development at the time had superior activity. Development of Celgosivir was initiated independently by the National University of Singapore for dengue fever. A clinical study confirmed its safety, but did not determine if the observed trend towards lower viral load was statistically significant.[48] Celgosivir (as with other dengue antivirals) has diminished activity to cure dengue infections in animal models when administered after animals become symptomatic. For Celgosivir, this problem was addressed by administering the same dose of drug split into four doses per day rather than one or two doses per day.[49] This observation led to the filing and approval of a patent related to dengue, which we licensed from the National University of Singapore.

Earlier in our history, we, in partnership with the National University of Singapore, and Singapore General Hospital, were successful in securing a grant from the government of Singapore for a follow-on clinical trial, but was 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 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.

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

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

[46] 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.

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

[48] Low et. al., Lancet ID 2014; 14:706-715.

[49] Watanabe et al, Antiviral Research 2016; 10:e19.

Strategy

Our general strategy is to demonstrate clinical proof of concept that Arakoda, at its FDA-approved dosing regimen for malaria prevention, provides clinical benefits in non-malaria therapeutic areas. Our initial focus is on COVID-19, but additional indications have been identified for development, namely babesiosis and fungal infections, pending further data generation. Upon demonstration of clinical proof of concept, we plan to enter into a strategic partnership with a larger entity with commercialization capacity, or raise additional capital to facilitate commercialization of Arakoda, and any additional clinical studies that may be required by regulators, for both travel medicine and broad infectious disease indications. We will continue to develop our portfolio products as resources permit.

In 2023, we plan to execute a randomized, placebo-controlled double blind clinical study to prove that Arakoda accelerates time to sustained clinical recovery in patients with mild-moderate disease with no risk factors. We believe that Arakoda has the potential to reduce the time to sustained clinical recovery by about three days. The study will be conducted in out-patient clinics in Australia and/or the United States. The study will utilize the majority of the proceeds of the offering reserved for research and development activities for this purpose. As of the date of this prospectus, we have completed a clinical study synopsis. Submission of the full protocol to the ethics committees and to Australian or U.S. regulators, and a posting at *clinicaltrials.gov* will follow this initial public offering.

In parallel with the planned clinical study, we plan to conduct additional non-clinical studies to clarify the process by which tafenoquine interacts with COVID-19. Specifically, such studies will attempt to determine whether tafenoquine acts as an immunomodulator (by decreasing the production of immune system molecules that cause inflammation) and/or exhibits and antiviral effect via inhibition of the host protease TMPRSS2. Also, we will attempt to investigate potential synergistic effect of tafenoquine in cell culture in combination with other antivirals used to treat COVID-19 disease (e.g., remdesivir, molunpiravir and paxlovid).

Following completion of our planned COVID-19 clinical study, if warranted based on the data generated, we intend to request a change in prescribing information to facilitate an expansion of use of Arakoda for malaria prevention from six to twelve months (mirroring our recently published post-marketing safety study) and to include reference to the recently generated COVID-19 treatment data. Prior to doing so, we plan to discuss with the FDA additional labeling related to COVID-19 which might be acceptable, as well as other routes to regulatory approval such as emergency use authorization.

We are planning several commercial initiatives for the malaria market in parallel with further clinical development activities. Three routes exist for commercialization of Arakoda for the malaria prevention market are: (i) U.S. civilian travel clinics, travel prescribing centers, and large private sector entities with employees deployed overseas (e.g., mining companies), (ii) the prospect of additional DoD and government agency procurement in the future and (iii) ex U.S. sales strategy where we currently (or in the future) have exclusive distribution arrangements in overseas markets.

As of the date of this prospectus, we did not have plans to hire a U.S. sales force, but are exploring possible commercial arrangements with contract sales organizations to target U.S. travel clinics for malaria prophylaxis. We intend to consummate a contract with a lobbying firm/contract sales organization to attempt to improve the position of Arakoda in the DoD formulary and to raise awareness of Arakoda amongst other U.S. government agencies. For such agencies, the product is expected to meet many of the requirements for occupational malaria prevention identified by the independent parties that have endorsed the product. We have been successful in securing procurement contracts with U.S. government agencies for Arakoda, and anticipate continued success in the future. In the third quarter of 2022, we made our first sale to our European distributor, and made additional sales to our Australian distributor in the second quarter of 2022. We are actively exploring the possibility of named-patient sales in jurisdictions outside Australia, Europe, and the United States. As resources permit, we will undertake a focused marketing campaign for Arakoda for malaria prevention in 2023. This will consist of promotion at relevant conferences, email promotion to prescribers, and target print and electronic advertisements.

It is expected that a point of care G6PD test might be required to maximize the economic potential of a COVID-19 indication for Arakoda. We do not intend to pursue independent development of such a test as there are well resourced development efforts already underway (see "*Risk Factors—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 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 may not directly control the timing, conduct and expense of such testing*" beginning on page 23). However, we will continue to monitor the progress of development and U.S. commercialization of G6PD tests. We will seek to pursue collaborative commercial partnerships with the companies involved in commercialization efforts, if such activities can be conducted through resource sharing efforts.

We plan to generate additional validation data for our portfolio products if resources permit. Specifically, we will evaluate whether Celgosivir provides therapeutic benefit in a COVID-19 animal model, and complete critical activities related to confirming GMP process feasibility.

We may elect, as resources permit, to undertake a clinical study of tafenoquine in combination with standard of care for hospitalized patients with babesiosis. We have developed such a protocol in partnership with academic collaborators and are planning to submit an IND to the FDA and pursue public and philanthropic funding to support our execution. We plan to seek public funding to support additional non-clinical studies to validate the mechanism of action of tafenoquine against *Candida spp*. and further assess our utility in combination with standard of care agents in cell culture and animal studies.

We have a 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.[50] The FDA has asked us to propose an alternate design, for which we have indicated to the FDA that we plan to respond to the FDA's feedback by the end of the fourth quarter of 2022. 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 2024. 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.

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 long effective in some parts of Southeast Asia.

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

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 Arakoda, of which the priority is treatment of COVID-19 in ambulatory patients. The main competitor products for this indication are molnupiravir and paxlovid, which have been granted emergency use authorization, and likely full marketing authorization in the future to lower the risk of hospitalization and death, principally in high risk patients. However, neither of these products have been shown to reduce the time to sustained clinical recovery in non-hospitalized standard risk patients. We are targeting this therapeutic niche with Arakoda, for which we will attempt to confirm clinical benefit in a clinical study in 2023.

Intellectual Property

We have global, and exclusive, rights to use patents, manufacturing information and non-clinical and clinical data licensed from the United States Army for tafenoquine for all indications except *P. vivax* malaria. We have submitted patent applications in the United States and elsewhere for 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. We have licensed patents for Celgosivir for the treatment and prevention of dengue (from the National University of Singapore), COVID-19 (Florida State University) and have submitted provisional patents related to Celgosivir for RSV. We have licensed or own manufacturing methods related to Celgosivir.

Sales and Marketing

In 2022 and 2023, we are committed to ensuring continuity of supply of Arakoda in the U.S. market for malaria prevention. As resources permit, we will undertake a focused marketing campaign for Arakoda for malaria prevention in 2023. This effort would consist of promotions at relevant conferences, email promotions to prescribers, and target print and electronic advertisements. The focus of promotional efforts would be on the proven features and benefits of Arakoda, and the recent publication demonstrating the good safety and tolerability of Arakoda for continuous weekly dosing for up to one year.[51] We will attempt to improve the position of Arakoda in the DoD formulary and increase product shelf-life in order to facilitate potential DoD procurement in the future. We are exploring the possibility of entering into contract sales agreements with appropriate organizations to further (i) ex U.S. named patient use and (ii) targeted sales to U.S. travel clinics if it is possible to do so in a resource/profit sharing manner.

Manufacturing

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

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.

[51] Novitt-Moreno et al. TMAID 2022; 45:102211.

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 the 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 the 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 are 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.

Accelerated Approval Pathway

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

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

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

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

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 abbreviated new drug application ("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 by 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 respond 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, the 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, that 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 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 trial 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 pre market 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
- 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, nonprescription 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 preempted 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, nondeductible 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 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 the 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. The 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.

Employees

As of , 2022, we have a total of two employees, both of which are full-time. We also utilize the services of two part-time contractors.

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 recognized a Right of Use Asset of $99,615 as of December 31, 2021 (none at December 31, 2020) with offsetting accumulated depreciation of $40,947. The current lease expires March 1, 2023.

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 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 88% 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 are our executive officers and directors and their respective ages and positions as of , 2022.

Name	Age	Position	Director Since
Geoffrey Dow	49	Chief Executive Officer, President and Director	June 1, 2022
Tyrone Miller	48	Treasurer	—
Bryan Smith	57	Chief Medical Officer	—

Geoffrey Dow is our Chief Executive Officer, President, and is also our sole Director. 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.

Tyrone Miller is our Treasurer. Mr. Miller joined us in 2014 and has held a number of roles since then, including Chief Financial Officer. 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.

Bryan Smith is our Chief Medical Officer. Dr. Smith is a medical doctor with expertise in clinical pharmacology, pharmacovigilance, regulatory strategy development and translational medicine and is a retired military colonel with over 30 years of governmental research and leadership experience. He joined us in 2016 as Chief Medical Officer and works with other members of the senior management team to establish all functional areas, including complying with national and international laws and regulations and developing and overseeing research and development projects and agenda. He also is currently a Senior Medical Director, Clinical and Regulatory Affairs at Fast-Track Drugs & Biologics, LLC since 2019, where he is responsible for developing clinical development plans for therapeutic products, managing clinical and regulatory projects and designing and writing clinical trial protocols. Since 2016, Dr. Smith has been the Chief Medical Officer and member of Amivas LLC, where he establishes all functional areas required to successfully secure FDA approvals. In addition, from 2016 to 2019, he was the Principal Medical Consultant at Clinical Network Services, Inc., where he provided required medical, clinical pharmacology, regulatory, translational medicine review, oversight and consultation as requested for over 25 unique clients in a range of activities and tasks for devices, small molecules and large molecules in a range of therapeutic areas. Dr. Smith received a Bachelor of Science in General Science, with highest honors, from Oregon State University and a Doctor of Medicine from Uniformed Services University of the Health Sciences.

Significant Employees

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

Code of Ethics

Our Board plans to adopt 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 business and affairs are managed under the direction of our Board. Our Board consists of [*] directors, [*] of whom qualify as "independent" under the listing standards of Nasdaq.

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. Based on information provided by each director concerning his background, employment and affiliations, our Board has determined that [*] is an independent director of the Company. However, our common stock is not currently quoted or listed on any national exchange or interdealer quotation system with a requirement that a majority of our Board be independent and, therefore, we are not subject to any director independence requirements.

Committees of the Board of Directors

Our Board has established an audit committee (the "Audit Committee"), a compensation committee (the "Compensation Committee") and 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 is 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 [*]. [*] is the Chairman of the Audit Committee. In addition, our Board has determined that [*] is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act. 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.

In addition, we intend to certify to Nasdaq that the committee has, and will continue to have, at least one member who has past employment experience in finance or accounting, requisite professional certification in accounting, or other comparable experience or background that results in the individual's financial sophistication.

Compensation Committee

We have established the Compensation Committee to consist of [*], each of whom is an independent director. Each member of the Compensation Committee is also 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. [*] is the Chairman of the Compensation Committee. 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 consisting of [*]. [*] is the Chairman of the Nominating and Corporate Governance Committee. 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.

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, 2021 and December 31, 2020.

Name and Principal Position	Year	Guaranteed Payments($)[1]	Stock Award ($)	Total($)
Geoffrey Dow	2021	$ 519,996	$ -	$ 519,996
President and Chief Executive Officer	2020	283,400	-	283,400
(Principal Executive Officer)				
Tyrone Miller	2021	$ 363,996	$ -	$ 363,996
Treasurer	2020	223,872	-	223,872
(Principal Financial and Accounting Officer)				
Bryan Smith[2]	2021	$ [*]	$ -	$ [*]
Chief Medical Officer	2020	[*]	-	[*]

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

(2) Bryan Smith's part time services are acquired through a contractual relationship with his direct employer.

Equity Awards

None.

Employment Agreements

Dow Employment Agreement. We entered into an Employment Agreement dated as of October 1, 2020 with Geoffrey Dow (the "Dow Employment Agreement"), our President and a member of our Board. The term of the Dow Employment Agreement began on November 1, 2020 and will continue for a period of five years, with subsequent automatic one-year renewals. The Dow Employment Agreement provides Dr. Dow an annual base salary of $510,000 and employee benefits that are generally given to our senior executives. Under the Dow Employment Agreement, Dr. Dow may terminate his employment at any time during the course of his employment upon 30 days' written notice. We may remove Dr. Dow from his position for "cause" only. In the event that Dr. Dow's employment is terminated, and subject to certain other requirements, Dr. Dow will normally be entitled to a one-time payment of annual salary plus health insurance benefits in an amount equal to $518,396.

Miller Employment Agreement. We entered into an Employment Agreement dated as of October 1, 2020 with Tyrone Miller (the "Miller Employment Agreement"), our Treasurer. The term of the Miller Employment Agreement began on November 1, 2020 and will continue for a period of five years, with subsequent automatic one-year renewals. The Miller Employment Agreement provides Mr. Miller an annual base salary of $355,000 and employee benefits that are generally given to our senior executives. Under the Miller Employment Agreement, Mr. Miller may terminate his employment at any time during the course of his employment upon 30 days' written notice. We may also terminate Mr. Miller at any time upon 45 days' written notice. In the event that Mr. Miller's employment is terminated by us without "cause" or by Mr. Miller for "good reason," and subject to certain other requirements, Mr. Miller will normally be entitled to a one-time payment of annual salary plus health insurance benefits in an amount equal to $363,996.

Board Compensation

[*]

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information, as of , 2022 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 , 2022. 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 2,386,009 shares of common stock issued and outstanding on , 2022 (excludes shares of common stock to be issued on the conversion of our convertible notes which automatically converts upon the consummation of this offering and shares of common stock to be issued prior to the closing of this offering as a success fee pursuant to the Investment Agreement), and after the offering assuming a common stock offering of shares (excluding shares which may be sold upon exercise of the underwriters' over-allotment option), plus, for each individual, any securities that individual has the right to acquire within 60 days of , 2022.

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	Percent of Class Before Offering	Percent of Class After Offering
Officers and Directors				
Geoffrey Dow	President, Chief Executive Officer and Director	1,926,042[2]	80.72%	[*]%
Tyrone Miller	Treasurer	294,029	12.32%	[*]%
Bryan Smith	Chief Medical Officer	—	—	—
[*]	Director	—	—	—
[*]	Director	—	—	—
[*]	Director	—	—	—
[*]	Director	—	—	—
Officers and Directors as a Group (total of [*] persons)				
			93.04%	[*]%
5% Stockholders				
Douglas Loock		165,938	6.95%	[*]%

* 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 1,926,042 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.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

On May 19, 2022, we issued the Convertible Promissory Note to Mountjoy Trust with a principal amount of $294,444 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of such note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering. 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 110% of the initial public offering price, or if we fail to complete the initial public offering prior to May 31, 2023, 90% of the initial public offering price. John Dow, a relative of Geoffrey Dow, our President, Chief Executive Officer and Director, is the trustee of the Mountjoy Trust.

On December 31st, 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.

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 , 2022, 2,386,009 shares of common stock were issued and outstanding and held by three 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 the 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 preemptive 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, of which none are outstanding. The Board may provide for the issue of any or all of the unissued and undesignated shares of the preferred stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board providing for the issuance of such shares and as may be permitted by law, without stockholder approval. Our Board is able to determine, with respect to any series of preferred stock, the terms and rights of that series, including:

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

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

Notes Outstanding

On April 24, 2018, we issued a Secured Convertible Debenture to Knight Therapeutics (Barbados) Inc. with a principal amount of $3,000,000 and a per annum interest rate of 9% and after the occurrence of an event of default and during the default period, the interest rate will be 14%. The maturity date of the Knight Note is April 23, 2023. In the event of a change of control transaction, the balance of the Knight Note will convert at a conversion rate using the following formula: price per common share = A/B where, A = 33,000,000 and B = the number of shares of common stock calculated on a fully diluted basis as at the date of issuance of the Knight Note, subject to a post-closing adjustment for up to $1,900,000 of equity investment from the date of issuance of the Knight Note up to 12 months following the approval of tafenoquine by the FDA.

On May 14, 2020, we issued a Note to the U.S. Small Business Administration with a principal amount of $150,000 and a per annum interest rate of 3.75%.

On May 19, 2022, we issued a Convertible Promissory Note to Geoffrey Dow with a principal amount of $44,444 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of the Dow Note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 19, 2022, we issued a Convertible Promissory Note to Mountjoy Trust with a principal amount of $294,444 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of the Mountjoy Note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 24, 2022, we issued a note in the amount of $330,000 to Bigger Capital Fund, LP. On the date of the pricing of our initial public offering, we will deliver to Bigger Capital Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 24, 2023.

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 will deliver to Cavalry Investment Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 24, 2023.

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 will deliver to Walleye Opportunities Master Fund Ltd shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of our common stock calculated using a $27 million pre-money valuation and the number of our outstanding shares of common stock on May 24, 2023.

Between September 9, 2010 through December 31, 2021, we issued notes representing a cumulative amount of $2,795,250 in principal and a debenture (value of $596,389 at December 31, 2021) to Geoffrey Dow. These were converted into common shares on December 31, 2021. We also issued convertible notes in the amounts of $20,000 and $32,000 to Tyrone Miller and Douglas Loock on December 31, 2016. These were converted into common shares on December 31, 2021 and August 31, 2021, respectively.

Warrants

On May 19, 2022, we issued to Geoffrey Dow a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to (i) the total number of common stock issued to Geoffrey Dow as a result of the conversion of the Dow Note, which will occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price, or (ii) if we fail to complete the initial public offering prior to May 31, 2023, 90% of the initial public offering price.

On May 19, 2022, we issued to Mountjoy Trust a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to (i) the total number of common stock issued to Mountjoy Trust as a result of the conversion of the Mountjoy Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price, or (ii) if we fail to complete the initial public offering prior to May 31, 2023, 90% of the initial public offering price.

On May 24, 2022, we issued to Bigger Capital Fund, LP a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Bigger Capital Fund, LP as a result of the conversion of the Bigger Capital Fund Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 24, 2022, we issued to Cavalry Investment Fund, LP a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Cavalry Investment Fund, LP as a result of the conversion of the Cavalry Investment Fund Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 24, 2022, we issued to Walleye Opportunities Master Fund Ltd a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Walleye Opportunities Master Fund Ltd as a result of the conversion of the Walleye Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

Options

None.

Section 203 of the Delaware General Corporation Law

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

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

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

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

Potential Effects of Authorized but Unissued Stock

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

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

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

Transfer Agent and Registrar

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

Listing

We will apply to have our common stock listed on The Nasdaq Capital Market under the symbol " ," which listing is a condition to this offering.

SHARES ELIGIBLE FOR FUTURE SALE

There is not currently an established U.S. trading market for our common stock. We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding warrants, in the public market after this offering, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon completion of the sale of shares of common stock pursuant to this offering, we will have shares of common stock issued and outstanding. In the event the underwriters exercise the over-allotment option in full, we will have shares of common stock issued and outstanding. The common stock sold in this offering will be freely tradable without restriction or further registration or qualification under the Securities Act.

All previously issued shares of common stock that were not offered and sold in this offering, are or will be upon issuance, "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if such public resale is registered under the Securities Act or if the resale qualifies for an exemption from registration under Rule 144 under the Securities Act, which are summarized below.

In general, a person who has beneficially owned restricted shares of our common stock for at least six months in the event we have been a reporting company under the Exchange Act for at least ninety (90) days before the sale, would be entitled to sell such securities, provided that such person is not deemed to be an affiliate of ours at the time of sale or to have been an affiliate of ours at any time during the ninety (90) days preceding the sale. A person who is an affiliate of ours at such time would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of shares that does not exceed the greater of the following:

1% of the number of shares of our common stock then outstanding; or

1% of the average weekly trading volume of our common stock during the four calendar weeks preceding the filing by such person of a notice on Form 144 with respect to the sale;

provided that, in each case, we are subject to the periodic reporting requirements of the Exchange Act for at least 90 days before the sale. Rule 144 trades must also comply with the manner of sale, notice and other provisions of Rule 144, to the extent applicable.

Lock-Up Agreements

Our executive officers and directors have agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for six months following the effective date of the registration statement for this offering. 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 months following the effective date of the registration statement for this offering without the prior written consent of the underwriters.

UNDERWRITING

We are offering our common stock 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 common stock listed next to its name in the following table.

Underwriter	Number of Shares
WallachBeth Capital LLC	
Totals:	

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

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

- receipt and acceptance of our common stock 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.

Over-Allotment Option

We have granted to the underwriters an option, exercisable for 45 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table that bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

Underwriting Discount

Shares sold by the underwriters to the public will initially be offered at the initial offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. The underwriters may offer the shares through one or more of their affiliates or selling agents. If all the shares are not sold at the initial 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 shares at the prices and upon the terms stated therein.

The following table shows the per share 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 additional common stock.

	Per Share	Total without Over-Allotment Option	Total with Over-Allotment Option
Public offering price	$	$	$
Underwriting discounts and commissions (8%)	$	$	$
Proceeds, before expenses to us	$	$	$

We have agreed to pay WallachBeth Capital LLC's fees and expenses up to a maximum amount of $145,000. We have paid $10,000 to WallachBeth Capital LLC as an advance to be applied towards reasonable out-of-pocket expenses, or the advance. Any portion of the advance shall be returned back to us to the extent not actually incurred.

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

Right of First Refusal

For a period of one year from the closing of this offering, we will grant to WallachBeth Capital LLC an irrevocable right of first refusal to act as lead underwriter or book-running manager or placement agent for each and every future public and private equity and debt offerings of the Company, or any successor to or any subsidiary of the Company in any stock exchange during such one-year period.

Indemnification

We have agreed to indemnify the several underwriters against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriters may be required to make in respect of those liabilities.

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.

No Public Market

Prior to this offering, there has not been a public market for our securities in the U.S. and the public offering price for our common stock will be determined through negotiations between us and the underwriters. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which our common stock will trade in the public market subsequent to this offering or that an active trading market for our common stock will develop and continue after this offering.

Stock Exchange

We will apply to have our common stock listed on The Nasdaq Capital Market under the symbol " ." There can be no assurance that we will be successful in listing our common stock on The Nasdaq Capital 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.

Determination of Offering Price

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation between us and WallachBeth Capital LLC. The principal factors to be considered in determining the initial public offering price include, but are not limited to:

- the information set forth in this prospectus and otherwise available to WallachBeth Capital LLC;
- our history and prospects and the history and prospects for the industry in which we compete;
- our past and present financial performance;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities market at the time of this offering;
- the recent market prices of, and demand for, publicly traded shares of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

The estimated public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock or that the common stock will trade in the public market at or above the initial public offering price.

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.

EXPERTS

RBSM LLP, an independent registered public accounting firm, audited our financial statements for the years ended December 31, 2021 and 2020, 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 on 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 Carmel, Milazzo & Feil LLP, New York, New York. TroyGould PC, Los Angeles, California, is acting as counsel for the underwriters with respect to the 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 is 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. and Subsidiaries

Consolidated Financial Statements
For The Years Ended December 31, 2021 and December 31, 2020

60 DEGREES PHARMACEUTICALS, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Members of 60^{o} Pharmaceuticals, LLC

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 60^{o} Pharmaceuticals, LLC (the Company) as of December 31, 2021 and 2020, and the related statements of operations, comprehensive loss, members' deficit, and cash flows for each of the years in the two-year period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

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

Basis for Opinion

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

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

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

/s/ RBSM LLP.

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

Las Vegas, Nevada

October 17, 2022

60⁰ PHARMACEUTICALS, LLC
CONSOLIDATED BALANCE SHEETS

As of December 31,	**2021**	**2020**
($ in USD)		
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 115,399	$ 191,702
Accounts Receivable	146,362	859,425
Prepaid Expenses	219,844	352,164
Inventory (Note 3)	689,042	1,039,590
Total Current Assets	**1,170,647**	**2,442,881**
Other Assets:		
Property and Equipment, net (Note 4)	48,948	73,408
Right of Use Asset	58,667	-
Intangible Assets, net (Note 5)	109,240	80,226
Deposits	6,025	9,549
Total Other Assets	**222,880**	**163,183**
Total Assets	**$ 1,393,527**	**$ 2,606,064**
LIABILITIES AND MEMBERS' DEFICIT		
Current Liabilities:		
Accounts Payable and Accrued Expenses	$ 537,452	$ 1,376,998
Lease Liability	46,795	-
Other Current Liabilities (Note 6)	51,226	56,350
Total Current Liabilities	**635,473**	**1,433,348**
Long-Term Liabilities:		
Deferred Compensation (Note 8)	154,743	103,013
Lease Liability – long term	13,000	-
Debenture	3,388,570	2,602,034
Related Party Note, net *(including accrued interest)* (Note 9)	-	3,221,328
SBA EIDL *(including accrued interest)* (Note 9)	159,161	153,312
Promissory Note *(including accrued interest)* (Note 9)	15,197,064	13,163,848
Total Long-Term Liabilities	**18,912,538**	**19,243,535**
Total Liabilities	**19,548,011**	**20,676,883**
Commitments and Contingencies (Note 12)		
MEMBERS' DEFICIT		
Members' Capital (Note 7)	4,979,365	799,700
Other Comprehensive Income (Note 13)	75,835	80,454
Accumulated Deficit	(22,633,428)	(18,381,683)
60P Members' Deficit	(17,578,228)	(17,501,529)
Noncontrolling interest	(576,256)	(569,290)
Total Members' Deficit	**(18,154,484)**	**(18,070,819)**
Total Liabilities and Members' Deficit	**$ 1,393,527**	**$ 2,606,064**

60° PHARMACEUTICALS, LLC

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

For Fiscal Years Ended December 31,	**2021**	**2020**
($ in USD)		
Revenues	$ 1,160,340	$ 2,181,359
Less: Cost of Goods Sold	850,742	702,989
Gross Profit	309,598	1,478,370
Research Revenue	5,192,516	368,107
Net Revenue	5,502,114	1,846,477
Operating Expenses		
Research and Development	5,510,866	806,683
Selling, General and Administrative	1,115,350	1,457,924
Total Operating Expenses	6,626,216	2,264,607
Loss from Operations	(1,124,102)	(418,130)
Interest and Other Expense	3,135,197	2,629,340
Loss from Operations before Provision for Income Taxes	(4,259,299)	(3,047,470)
Provision for Income Taxes (Note 10)	1,000	1,000
Net Loss	(4,260,299)	(3,048,470)
Net Loss – Noncontrolling Interest	(8,554)	(14,726)
Net Loss – attributed to 60° Pharmaceuticals, LLC	(4,251,745)	(3,033,744)
Comprehensive Loss:		
Net Loss	(4,260,299)	(3,048,470)
Unrealized Foreign Currency Translation Loss	(3,031)	(134,254)
Comprehensive Loss	(4,263,330)	(3,182,724)
Net Loss – Noncontrolling Interest	(8,554)	(14,726)
Unrealized Foreign Currency Translation Gain (Loss) from Noncontrolling Interest	1,588	(5,587)
Comprehensive Loss – attributed to 60° Pharmaceuticals, LLC	**$ (4,256,364)**	**$ (3,162,411)**

60⁰ PHARMACEUTICALS, LLC

CONSOLIDATED STATEMENTS OF CHANGES IN MEMBERS' DEFICIT

($ in USD)	Member Units		Other Comprehensive Income/(Loss)	Accumulated Deficit	Noncontrolling Interest	Total Members' Deficit
	Units	**Amount**				
Balance—December 31, 2019	**14,175,000**	**$ 299,200**	**$ 209,121**	**$ (15,347,939)**	**$ (548,977)**	**$ (15,388,595)**
Issuance of Member Units	500,500	500,500				500,500
Foreign Translation Loss			(128,667)	-	(5,587)	(134,254)
Net loss				(3,033,744)	(14,726)	(3,048,470)
Balance—December 31, 2020	**14,675,500**	**799,700**	**80,454**	**(18,381,683)**	**(569,290)**	**(18,070,819)**
Conversion of Debt into Member Units	4,179,665	4,179,665				4,179,665
Foreign Translation (Loss) Gain			(4,619)	-	1,588	(3,031)
Net loss				(4,251,745)	(8,554)	(4,260,299)
Balance—December 31, 2021	**18,855,165**	**$ 4,979,365**	**$ 75,835**	**$ (22,633,428)**	**$ (576,256)**	**$ (18,154,484)**

60⁰ PHARMACEUTICALS, LLC
CONSOLIDATED STATEMENTS OF CASH FLOWS

For Fiscal Years Ended December 31,	2021	2020
($ in USD)		
CASH FLOW FROM OPERATING ACTIVITIES		
Net Loss	$ (4,260,299)	$ (3,048,470)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation of Property	27,528	27,865
Amortization of Intangibles	3,310	-
Amortization of Debt Discount	604,595	425,742
Amortization of ROU Asset	40,947	-
Reduction of Lease Liability	(39,820)	-
Changes in Operating Assets and Liabilities:		
Accounts Receivable	713,063	(660,277)
Prepaid Expenses	132,320	(296,221)
Inventory	350,548	190,778
Deposits	3,524	-
Accounts Payable	(839,546)	796,290
Accrued Interest	2,568,118	2,251,744
Current Liabilities	(5,124)	42,237
Deferred Compensation	51,730	103,013
Net Cash Used in Operating Activities	**(649,106)**	**(167,299)**
CASH FLOW FROM INVESTING ACTIVITIES		
Capitalization of Patents	(32,324)	(70,978)
Purchases of Property and Equipment	(3,068)	-
Net Cash Used in Investing Activities	**(35,392)**	**(70,978)**
CASH FLOW FROM FINANCING ACTIVITIES		
Borrowings from SBA EIDL	-	150,000
Borrowings from Related Party Notes	683,226	278,500
Repayments to Related Party Notes	(72,000)	(151,143)
Net Cash Provided by Financing Activities	**611,226**	**277,357**
Foreign Currency Translation (Loss) Gain	(3,031)	(134,254)
Change in Cash	(76,303)	(95,174)
Cash—Beginning of Year	191,702	286,876
Cash—End of Year	**$ 115,399**	**$ 191,702**
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid During the Year for Interest Expense	$ -	$ -
Cash paid During the Year for Income Taxes	$ 750	$ 1,250
NONCASH INVESTING/FINANCING ACTIVITIES		
Acquisition of Lease Liability	$ 99,615	$ -
Purchase of ROU Asset	(99,615)	-
Conversion of Debt into Member Units	4,179,665	500,500

1. NATURE OF OPERATIONS

60^{o} Pharmaceuticals, LLC was incorporated on September 9th, 2010 in the District of Columbia. The financial statements of 60^{o} Pharmaceuticals, LLC and its majority owned subsidiaries in Australia and Singapore (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 ("U.S. GAAP"). The Company's headquarters are located in Washington, DC.

60^{o} Pharmaceuticals, LLC. was formed to develop new best-in-class medicines for the treatment and prevention of infectious diseases. Since its founding, the Company has developed Arakoda^{R} 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, raise 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, meets 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 advances from existing shareholders, 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 toward the end of 2022. 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 subsidiaries are presented on a consolidated basis and conform to accounting principles generally accepted in the United States of America ("US GAAP") after elimination of intercompany transactions and accounts. These consolidated financial statements are presented in US Dollars, which is the Company's functional currency. The Company has adopted the calendar year as its basis of reporting.

Principles of Consolidation

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 Ltd, a wholly owned subsidiary of 60P Australia Pty Ltd. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with United States 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.

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. As of December 31, 2021, and December 31, 2020, the Company's cash and cash equivalents do not exceed FDIC insured limits. The Company also held cash in the majority owned subsidiaries in Australia and Singapore and the amounts were minimal.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts Receivable are recorded at net realizable value or the amount that the Company expects to collect on customer accounts based on product shipments on the dates presented. Any estimate of losses on receivables is based on historical experience with such sales. Receivables are considered impaired and written-off when it is probable that all contractual payments due will not be collected in accordance with the terms of the sale. As of December 31, 2021, and 2020, the Company determined that reserves were not necessary.

Inventory

Inventories are stated at the lower of cost and 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. Cost originally was calculated using the weighted average method but now is calculated on box price per lot numbers and sales are recognized by 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.

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 special 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 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 years.

Income Taxes

60^{o} Pharmaceuticals, LLC is a limited liability company and has elected to be taxed as a partnership for income tax purposes. Federally, all income tax benefits of a partnership are passed through to the members. The District of Columbia taxes partnerships as a D-30 (District of Columbia Unicorporated Business Franchise Tax Return) and has a minimum tax due $250 if gross receipts are at $1 million or less and a $1,000 if above. Thus, the Company owed DC $1,000 in 2021 and 2020 for income tax purposes and these amounts were paid timely. 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 60P Singapore Pte Ltd is subject to the taxes of the Inland Revenue Authority of Singapore. The tax years that remain subject to examination for both entities include the fiscal years ended June 30, 2019, 2020 and 2021.

Concentration of Credit Risk

The Company maintains its cash with a major financial institution located in the United States of America which it believes to be creditworthy. Balances are insured by the Federal Deposit Insurance Corporation up to $250,000. At times, the Company may maintain balances in excess of the federally insured limits.

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 deferred revenues for any advances and then recognizes revenue upon shipment to the retailer who orders product for a specific customer. The Company records a receivable for any amounts to be received pursuant to such sales. The DoD is the Company's largest customer. The Company recorded sales of Arakoda™ of $1,068,750 and $2,137,500 to the DoD in 2021 and 2020, respectively. The US Army purchased 2.5 full commercial lots (7,500 boxes = 1 lot) of ARAKODA under a purchase contract for which the Company delivered in fractional amounts in 2019, 2020 and 2021. Upon fulfillment of the initial contract the DoD has not issued any further contracts nor contract modifications to allow additional procurement.

Accounts Receivable

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 the 60P will continue to analyze whether an entry should be recorded in Allowance for Doubtful Account, there was no allowance in 2021 and 2020. At the end of December 31, 2021 the US government accounted for 84% of the outstanding AR balance (100% in 2020).

Research and Development Costs

Costs incurred in the research and development of the Company's products are expensed as incurred. The Company recorded $5,510,866 in research and development costs in the year ended December 31, 2021 ($806,683 during the year ended December 31, 2020).

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, restricted cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate 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.

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 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. The exchange rates used in these financial statements are as follows:

	Average Exchange Rate		December 31,	
Currency	**2021**	**2020**	**2021**	**2020**
1 AUD =	0.7513 USD	0.6906 USD	0.72644959 USD	0.76991244 USD
1 SGD =	0.9912 AUD	1.0528 AUD	1.20693010 AUD	0.982578610 AUD

COVID-19

In March 2020, the outbreak and spread of the COVID-19 virus was classified as a global pandemic by the World Health Organization. This widespread disease impacted 60P's business operations, including its employees, customers, vendors, and communities. The COVID-19 pandemic may continue to impact the Company's business operations and financial operating results, and there is substantial uncertainty in the nature and degree of its continued effects over time. The extent to which the pandemic impacts the business going forward will depend on numerous evolving factors management cannot reliably predict, including the duration and scope of the pandemic; governmental, business, and individuals' actions in response to the pandemic; and the impact on economic activity including the possibility of recession or financial market instability. These factors may adversely impact consumer and business spending on products as well as customers' ability to pay for products and services on an ongoing basis. This uncertainty also affects management's accounting estimates and assumptions, which could result in greater variability in a variety of areas that depend on these estimates and assumptions, including investments, receivables, and forward-looking guidance.

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 October 17, 2022, which is the date the financial statements were issued.

Recently Issued and Adopted Accounting Pronouncements

FASB issued ASU No. 2019-02, leases, that requires organizations that lease assets, referred to as "lessees", to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases with lease terms of more than twelve months. ASU 2019-02 will also require disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases and will include qualitative and quantitative requirements. The new standard for nonpublic entities will be effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022, and early application is permitted. These consolidated financial statements have been prepared to comport with this standard.

The FASB issues ASUs to amend the authoritative literature in ASC. There have been a number of ASUs to date, including those above, 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.

3. INVENTORY

Class of Inventory	**2021**	**2020**
Raw Material (API)	$ 538,320	$ 678,124
Packaging	88,468	290,108
Finished Goods	37,514	23,095
Allowance for Expiring Inventory	(38,322)	(17,414)
Clinical Trial Supplies	63,062	65,677
Total Inventory	**$ 689,042**	**$ 1,039,590**

4. PROPERTY AND EQUIPMENT

As of December 31, 2021, and December 31, 2020, Property and Equipment consists of:

As of Year Ended December 31,	**2021**	**2020**
Lab Equipment	$ 132,911	$ 132,911
Computer Equipment	12,261	9,193
Furniture	3,030	3,030
Property and Equipment, at Cost	**148,202**	**145,134**
Accumulated depreciation	(99,254)	(71,726)
Property and Equipment, Net	**$ 48,948**	**$ 73,408**

Depreciation expenses for Lab and Computer Equipment for the fiscal years ended December 31, 2021, and 2020 were in the amount of $27,528 and $27,865 respectively.

5. INTANGIBLE ASSETS

As of December 31, 2021, and December 31, 2020, Intangible Assets consist of:

As of Year Ended December 31,	**2021**	**2020**
Patents	$ 112,550	$ 80,226
Accumulated Amortization	(3,310)	-
Intangible Assets, Net	**$ 109,240**	**$ 80,226**

The following table summarizes the estimated amortization expenses relating to the Company's intangible assets as of December 31, 2021:

Period	Amortization Expense (USD)
2022	$ 3,742
2023	3,742
2024	3,742
2025	3,742
Thereafter	32,803
Total	**$ 47,771**

The Company additionally has $60,894 in capitalized patent expenses that will be amortizeable once the patent is approved.

6. OTHER CURRENT LIABILITIES

The Company's other current liabilities are provided in more detail in the table that follows:

As of Year Ended December 31,	2021	2020
Credit cards payable	$ 47,093	$ 53,306
Discounts, rebates and royalty liability	3,133	2,044
Corporate income tax payable	1,000	1,000
Other current liabilities	**$ 51,226**	**$ 56,350**

7. CAPITALIZATION AND EQUITY TRANSACTIONS

Member Units

Pursuant to the Company's Operating Agreement, as amended on December 31, 2021, as of December 31, 2021, and December 31, 2020 14,675,500 and 18,855,165 member units were outstanding, respectively. The original Operating Agreement was adopted on October 28, 2010 and was previously amended and restated as of April 26, 2013, January 6, 2014, February 5, 2016, September 8, 2017, March 28, 2018, August 9, 2018 and September 26, 2018. The Company has one class of shares and each membership share entitles the holder to one vote.

Net income of the Company, if any, for each Fiscal Year (or portion thereof) shall be allocated as follows and in the following order of priority:

(i) First, to Members and holders of Economic Interests, to the extent of any negative adjusted capital account;

(ii) Second, to Members and holders of Economic Interests, in proportion to the amounts necessary to cause the aggregate amount of Net Income allocated to each Member to equal the aggregate amount of Net Loss allocated to such Member;

(iii) Third, to the Members and holders of Economic Interests, in proportion to, but not in excess of, the amounts received pursuant to distributions during the accounting year; and

(iv) Fourth, the balance of any Net income shall be allocated to Members and holders of Economic Interests in proportion to their respective Interest.

Net loss of the Company is allocated to the Members as follows and in the following order priority:

(i) First: to the extent of, and in proportion to, the Members' positive Adjusted Capital Account Balances; and

(ii) Second: the balance of such Net Loss (if any) shall be allocated to the Members in proportion to their respective Company Interests.

On December 31, 2021, the Company converted related party debt and accrued interest totaling $4,179,665 ($500,500 in 2020) into 4,179,665 (500,500 in 2020) member units at a valuation of $1 per member unit based on the previously declared value of member units dating back to January 2016. (See Debt footnote 9 under Related Party Notes header)

8. 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. Also in 2020, the Company entered into an agreement with Latham Biopharma on contingent compensation. $54,743 was earned as of December 31, 2021 ($3,013 as of December 31, 2020). The Biointelect and Latham agreements have since been amended as detailed in Note 14 Subsequent Events.

9. DEBT

Promissory Notes

On December 27, 2019 the Company restructured its cumulative borrowing with their 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, 2021 the Company had reached cumulative gross profits of $1,790,744 ($1,481,146 at December 31, 2020). The Company is not expected to reach this threshold during 2022.

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 to equity in the Company at the maturity date and will have 30 days from maturity to exercise this option. Cumulative interest will be forfeited should the lender elect to convert the Note into equity. Cumulative accrued unpaid interest is $361,732 and $257,174 at December 31, 2021 and 2020, respectively. Interest expense for the year ended December 31, 2021 was $104,558 ($94,968 in 2020).

Debenture

On April 24, 2019 the Company entered into the Knight debenture of $3,000,000 with an original issue discount 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 14). $431,625 of the original issue discount was amortized to interest expense during the twelve months ended December 31, 2021 ($372,524 during 2020) and the unamortized original issue discount at December 31, 2021 was $779,164 ($1,210,790 at December 31, 2020).

	2021	2020
Original Debenture	$ 3,000,000	$ 3,000,000
Unamortized debt discount	(779,164)	(1,210,790)
Debenture Prior to Accumulated Interest	2,220,836	1,789,210
Accumulated Interest	1,167,734	812,824
Debenture	**$ 3,388,570**	**$ 2,602,034**

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 is first obligated to start making payments of $731 on November 4, 2022. The current future payment obligations are as follows:

Period	Payment
2022	$ 1,462
2023	8,772
2024	8,772
2025	8,772
Thereafter	252,288
Total	**$ 280,066**

Due to the deferral the Company is expecting to make a balloon payment of $38,836 to be due on 11/4/2050.

Related Party Notes

Geoff Dow, the majority member had financed the Company throughout its founding with a combination of equity and debt contributions. On December, 31 2021 the majority member converted cumulative borrowings (including a debenture received) and interest into 3,942,919 member units with a par value of $1.00 and thus all debt owed to majority member was extinguished. Additionally, $236,746 of investments from a minority member made in 2020 and 2021 was also converted on December 31, 2021 under the same terms.

10. INCOME TAXES

Federally, the Company is considered a disregarded entity for taxation purposes and thus all liability and benefit is attached to the Members' returns. The District of Columbia taxes the entity separately on a D-30 franchise tax return when income is over $12,000. Additionally, there is a minimum tax of $250 for incomes at and below $1,000,0000 and $1,000 for those incomes above.

The provision for income taxes for the year ended December 31, 2021, and December 31, 2020, consists of the following:

As of Year Ended December 31,	2021	2020
DC taxable income	$ (2,407,267)	$ 211,386
DC Franchise tax	1,000	1,000
Provision (added) used	(198,599)	17,439
Allowance added (used)	198,599	(17,439)
Net Provision for income tax	**$ 1,000**	**$ 1,000**

The Company has cumulative net loss in DC of $6,996,799 as of December 31, 2021 (4,589,532 as of December 31, 2020). 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, 2021 is $577,236 ($378,636 at December 31, 2020).

The Australian subsidiary has cumulative losses of AUD8,997,499 at December 31, 2021 (and AUD8,448,957 at December 31, 2020). The Australian subsidiary has also measured a deferred tax benefit associated with the cumulative losses of AUD2,249,375 at December 31, 2021 (and AUD2,196,729 at December 31, 2020). 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, 2021, and December 31, 2020. 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 Year Ended December 31,	2021	2020
DC Deferred Tax Asset	$ 577,978	$ 379,379
Australian Deferred Tax Asset (USD)	1,634,058	1,691,289
	2,212,036	2,070,668
Allowance	2,212,036	2,070,668
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, 2021, and December 31, 2020, the Company had no recognized tax benefits.

The Company recognizes interest and penalties related to income tax matters in income tax expense. As of December 31, 2021, and December 31, 2020, the Company had no accrued interest and penalties related to uncertain tax positions.

11. RELATED PARTY

Promissory Notes – See Related Party Notes section under Debt footnote 9.

12. COMMITMENTS AND CONTINGENCIES

Capital Leases

The Company leases office space and 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 these leases are as follows:

	Undiscounted Cash Flows
Discount rate	15.00%
2022	52,670
2023	13,326
Total undiscounted minimum future payments	65,996
Imputed interest	(6,201)
Total operating lease payments	59,795
Short-term lease liabilities	46,795
Long-term lease liabilities	13,000

Other information related to our operating leases is as follows:

	December 31, 2021
Weighted average remaining lease term in years	1.3 years
Weighed average discount rate	15.00%

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 twenty-four months expiring on March 31, 2023.

Rent expenses were in the amount of $51,894 and $91,110 as of December 31, 2021, and December 31, 2020, respectively.

Contingencies

The Company's operations are subject to a variety of local and state regulation. 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. These agreements would trigger if in a financial transaction the Company sold 70% of the issued shares outside the Company's management and related parties.

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 ($0 in 2020) would be due. Due to subsequent agreement the maximum amount due currently would be $305,000. Currently, the Company is not engaged with the Australian fund to solicit their participation in the Company's IPO.

Litigation and Claims

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, 2021, 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. FOREIGN CURRENCY TRANSLATIONS

The reporting currency of the Company is the U.S. dollar. The functional currency of the parent company is the U.S. dollar and the functional currency of the Company's operating subsidiary in Australia is the Australian dollar ("AUD") and in the Singaporean subsidiary it is the Singaporean dollar ("SGD"). For the subsidiaries, whose functional currency are the AUD or SGD, results of operations and cash flows are translated at average exchange rates during the period, assets and liabilities and equity are translated at the exchange rate at the end of the period. As a result, amounts relating to assets and liabilities reported on the statements of cash flows may not necessarily agree with the changes in the corresponding balances on the balance sheets. Translation adjustments resulting from the process of translating the local currency financial statements into U.S. dollars are included in determining comprehensive loss. Transactions denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing on the transaction dates. Assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates, prevailing at the balance sheet date with any transaction gains and losses that arise from exchange rate fluctuations on transactions denominated in a currency other than the functional currency are included in the results of operations as incurred.

The Company did not enter into any material transaction in foreign currencies. Transaction gains or losses have not had, and are not expected to have, a material effect on the results of operations of the Company.

14. SUBSEQUENT EVENTS

The Company has evaluated subsequent events for the period from December 31, 2021 through October 17, 2022, which is the date the financial statements were available to be issued.

In March of 2022, the members filed a check the box election to be taxed as a C-Corporation going forward starting January 1, 2022. No impact is expected to the current financial statements though going forward the Company will be subject to US taxation federally.

In March 2022, the Directors of 60 Degrees Pharmaceuticals LLC, its majority-owned subsidiary 60P Australia Pty LTD and that entity's solely-owned subsidiary, 60P Singapore PTE LTD agreed to dissolve 60P Singapore PTE LTD, with effect as of March 31, 2022. Appropriate articles of dissolution were filed with ACRA in Singapore on May 18, 2022. As a component of winding up 60P Singapore PTE LTD, the immediate and ultimate holding companies agreed to waive any remaining debt.

On April 18, 2022, the Company renegotiated the Knight Loan to convert $18,866,523 in debt and accrued interest into equity and debt into the Company upon a closing of an initial public offering that raises at least $7million. The $6,509,823 and $4,260,214 principal amounts shall be converted, at the closing of the Company's initial public offering, into the Company's common stock at a 15% discount to the Company's IPO price; provided that Knight's ownership interest shall not be greater than 19.9%; and cash is greater than $5 million. Any unconverted principal amount shall be issued in the form of a new two-year convertible note earning 10% interest with a mandatory conversion into common stock of principal and accumulated interest after two years at a 15% discount to the lower of the (I) Company's IPO price or (2) the current 10 day weighted average share price. The notes shall not be converted if it would result in Knight's ownership of common shares exceeding 19.9%.

The $8,096,486 million in accrued interest will be converted into $8,096,486 of preferred (non-voting) stock convertible at the option of the Company. The Company will not convert the preferred stock to equity if it would result in Knight's ownership of common shares exceeding 19.9%. The preferred stock shall earn 6% dividends and convert into the Company's common stock at the lower of the (I) Company's IPO price or (2) the current 10 day weighted average share price.

To compensate for the loss of control on the accrued interest being converted into preferred shares, the Company shall pay Knight royalty payments equal to a 3.5% royalty on the Company's sales for the earlier of ten years or the full conversion or redemption of the preferred stock. Such royalty shall be characterized as a payable owing by the Corporation to Knight.

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 plans to take a deferred compensation charge for the $155,000 in equity compensation in Q2 of 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.

On June 17, 2022 the Company and Latham Biopharma agreed to convert their deferred compensation of $54,743 and $12,500 of accrued expense to 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.

The Company raised an additional $185,335 in paid in capital between January 1, 2022 and April 30, 2022 from existing investors, which will be capitalized as common shares. On May 19, 2022, the Company further raised $338,888 in convertible debt from related parties – these notes attract a per annum interest rate of 6% and are to be converted at an IPO at a price equal to 80% of the price per share of the common stock sold in the public offering from related and unrelated parties between May 23rd and June 1, 2022. On May 24, 2022, the Company raised $885,555.56 (10% annualized interest, 10% OID, principal repayable at the earlier of one year from the effective date or an IPO) from unrelated parties (Bigger Capital Fund, Cavalry Investments Fund, LP and Walleye Opportunities Master Fund Ltd) and, as part of the financing agreed to deliver shares of the Company's common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if the Company fails to complete the initial public offering prior to May 24, 2023, the number of shares of the Company's common stock calculated using a $27 million pre-money valuation for the Company and the number of the Company's outstanding shares of common stock on May 24, 2023. Together, these additional funds are sufficient to cover operational costs between 2022-01-1 and a planned IPO.

In July 2022, the Company renegotiated the timing of a license fee of $85,000 SD, payable to the National University of Singapore, such that payment would be due at the earlier of (i) enrolment of a patient in a Phase II clinical trial involving celgosivir, (ii) two years from the agreement date or (iii) an IPO. The agreement between the Parties currently consists of email concurrence in principle – an agreement modification has not yet been executed.

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

Shares
Common Stock

60 Degrees Pharmaceuticals, Inc.

PRELIMINARY PROSPECTUS

WallachBeth Capital LLC

_____, 2022

Through and including, _____, 2022, (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Part II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission ("SEC") registration fee and the Financial Industry Regulatory Authority, Inc. ("FINRA") filing.

	Amount
Securities and Exchange Commission registration fee	$ [*]
FINRA filing fee	[*]
NASDAQ listing fee	[*]
Accountants' fees and expenses	[*]
Legal fees and expenses	[*]
Printing and engraving expenses	[*]
Miscellaneous	[*]
Total expenses	$ [*]

Item 14. Indemnification of Directors and Officers.

Section 102 of the General Company Law of the State of Delaware ("DGCL") permits a company to eliminate the personal liability of directors of a company to the company or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our charter provides that none of our directors shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a company has the power to indemnify a director, officer, employee, or agent of the company, or a person serving at the request of the company for another company, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the company, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the company, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the company unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our charter provides that we will indemnify to the fullest extent permitted from time to time by the DGCL or any other applicable laws as presently or hereafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, including, without limitation, an action by or in the right of the Company, by reason of his acting as a director or officer of the Company or any of its subsidiaries (and the Company, in the discretion of the Board, may so indemnify a person by reason of the fact that he is or was an employee or agent of the Company or any of its subsidiaries or is or was serving at the request of the Company in any other capacity for or on behalf of the Company) against any liability or expense actually and reasonably incurred by such person in respect thereof.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933 (the "Securities Act"), against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding securities issued by us within the last three years which were not registered under the Securities Act of 1933, as amended.

(a) Issuance of Capital Stock.

- 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., a Delaware corporation, pursuant to which 60P LLC merged into 60 Degrees Pharmaceuticals, Inc. (the "Company"). The value of each outstanding members' membership interest in 60P LLC was automatically converted into common stock of the Company, par value $0.0001 per share, with a cost-basis equal to $5.00 per share.

- 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.

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

(b) Warrants.

On May 19, 2022, we issued to Geoffrey Dow a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to (i) the total number of common stock issued to Geoffrey Dow as a result of the conversion of the Dow Note, which will occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price, or (ii) if we fail to complete the initial public offering prior to May 31, 2023, 90% of the initial public offering price.

On May 19, 2022, we issued to Mountjoy Trust a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to (i) the total number of common stock issued to Mountjoy Trust as a result of the conversion of the Mountjoy Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price, or (ii) if we fail to complete the initial public offering prior to May 31, 2023, 90% of the initial public offering price.

On May 24, 2022, we issued to Bigger Capital Fund, LP a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Bigger Capital Fund, LP as a result of the conversion of the Bigger Capital Fund Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 24, 2022, we issued to Cavalry Investment Fund, LP a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Cavalry Investment Fund, LP as a result of the conversion of the Cavalry Investment Fund Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

On May 24, 2022, we issued to Walleye Opportunities Master Fund Ltd a Common Stock Purchase Warrant to purchase a number of shares of our common stock equal to 50% of the total number of common stock issued to Walleye Opportunities Master Fund Ltd as a result of the conversion of the Walleye Note, which is to occur on the pricing date of our initial public offering, at the exercise price equal to 110% of the initial public offering price.

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

(c) Option Grants.

None.

(d) Issuance of Notes.

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%.

On May 19, 2022, we issued the Convertible Promissory Note to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018 on May 19, 2022 (the "Dow Note"), with a principal amount of $44,444 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of the Dow Note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 19, 2022, we issued the Convertible Promissory Note to Mountjoy Trust (the "Mountjoy Note") with a principal amount of $294,444 and a per annum interest rate of 6%. Upon the occurrence of our initial public offering, the balance of the Mountjoy Note will convert immediately prior to the initial public offering at a price equal to 80% of the price per share of the common stock sold in the initial public offering.

On May 24, 2022, we issued a note in the amount of $330,000 to Bigger Capital Fund, LP (the "Bigger Capital Fund Note"). On the date of the pricing of our initial public offering, we will deliver to Bigger Capital Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of common stock calculated using a $27 million pre-money valuation and the number of outstanding shares of common stock on May 24, 2023.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Cavalry Investment Fund, LP (the Cavalry Investment Fund Note"). On the date of the pricing of our initial public offering, we will deliver to Cavalry Investment Fund, LP shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of common stock calculated using a $27 million pre-money valuation and the number of outstanding shares of common stock on May 24, 2023.

On May 24, 2022, we issued a note in the amount of $277,777.78 to Walleye Opportunities Master Fund Ltd (the "Walleye Note"). On the date of the pricing of our initial public offering, we will deliver to Walleye Opportunities Master Fund Ltd shares of our common stock equal to (i) 100% of the face value of the note divided by the initial public offering price per share or (ii) if we fail to complete the initial public offering prior to May 24, 2023, the number of shares of common stock calculated using a $27 million pre-money valuation and the number of outstanding shares of common stock on May 24, 2023.

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

Item 16. Exhibits and Financial Statement Schedules.

(a) ***Exhibits***: Reference is made to the Exhibit Index following Item 17 of Part II hereto, which Exhibit Index is hereby incorporated into this Item.

(b) ***Financial Statement Schedules***: All schedules are omitted because the required information is inapplicable or the information is presented in the financial statements and the related notes.

Item 17. Undertakings.

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

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

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

EXHIBIT INDEX

Exhibit No.	Description
1.1*	Form of Underwriting Agreement
3.1*	Certificate of Incorporation of the Registrant
3.2*	Bylaws of the Registrant
4.1*	Form of Representative Warrant
5.1*	Opinion of Counsel to the Registrant
10.1*	Securities Purchase Agreement dated as of May 19, 2022, by and between the Registrant and Geoffrey Dow
10.2*	Common Stock Purchase Warrant dated as of May 19, 2022, issued by the Registrant to Geoffrey Dow, as assigned to the Geoffrey S. Dow Revocable Trust dated August 27, 2018
10.3*	Convertible Promissory Note dated as of May 19, 2022, issued by the Registrant to Geoffrey Dow
10.4*	Securities Purchase Agreement dated as of May 19, 2022, by and between Registrant and Mountjoy Trust
10.5*	Common Stock Purchase Warrant dated as of May 19, 2022, issued by the Registrant to Mountjoy Trust
10.6*	Convertible Promissory Note dated as of May 19, 2022, issued by the Registrant to Mountjoy Trust
10.7*	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Bigger Capital Fund, LP
10.8*	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Bigger Capital Fund, LP
10.9*	Promissory Note dated as of May 24, 2022, issued by the Registrant to Bigger Capital Fund, LP
10.10*	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Cavalry Investment Fund, LP
10.11*	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Cavalry Investment Fund, LP
10.12*	Promissory Note dated as of May 24, 2022, issued by the Registrant to Cavalry Investment Fund, LP
10.13*	Securities Purchase Agreement dated as of May 24, 2022, by and between Registrant and Walleye Opportunities Master Fund Ltd
10.14*	Common Stock Purchase Warrant dated as of May 24, 2022, issued by the Registrant to Walleye Opportunities Master Fund Ltd
10.15*	Promissory Note dated as of May 24, 2022, issued by the Registrant to Walleye Opportunities Master Fund Ltd
10.16*	Secured Convertible Debenture dated as of April 24, 2018, issued by the Registrant to Knight Therapeutics (Barbados) Inc.
10.17*	Services Agreement dated as of February 3, 2018, by and between the Registrant and CXI Corp., as amended
10.18*	First Amended and Restated License and Supply Agreement dated as of January 21, 2019, by and between the Registrant to Knight Therapeutics (Barbados) Inc.
10.19*	Letter dated as of May 20, 2021, issued by Torreya Capital, LLC to the Registrant
10.20*	Inter-Institutional Agreement dated as of February 15, 2021, by the Registrant and Florida State University Research Foundation
10.21*	Exclusive License Agreement dated as of September 15, 2016, between National University of Singapore and Singapore Health Services Pte Ltd and the Registrant
10.22*	Pharmacovigilance Agreement dated as of October 31, 2021, between the Registrant and Biocelect Pty Ltd
10.23*	Master Consultancy Agreement dated as of May 29, 2013, by and between the Registrant and BioIntelect Pty Ltd
10.24+*	Employment Agreement dated as of October 1, 2020, between the Registrant and Geoffrey Dow
10.25+*	Employment Agreement dated as of October 1, 2020, between the Registrant and Tyrone Miller
10.26*	Subscription Agreement dated as of October 11, 2017, by and between the Registrant and Avante International Limited
10.27*	Promissory Note dated as of October 11, 2017, issued by the Registrant to Avante International Limited
10.28*	Loan Agreement and Engagement dated as of July 15, 2016, by and between the Registrant and Knight Therapeutics (Barbados) Inc., as amended
10.29*	Convertible Promissory Note dated as of December 31, 2016, issued by the Registrant to Geoffrey Dow

10.30*	Agreement to Consolidate and Convert Existing Debt dated as of December 31, 2021, between the Registrant and Geoffrey Dow
10.31*	Agreement to Convert Debt to Equity dated as of December 31, 2021, issued by the Registrant to Geoffrey Dow
10.32*	Convertible Promissory Note dated as of December 31, 2016, issued by the Registrant to Tyrone Miller
10.33*	Agreement to Consolidate and Convert Existing Debt dated as of December 31, 2021, between the Registrant and Tyrone Miller
10.34*	Agreement to Convert Debt to Equity dated as of December 31, 2021, issued by the Registrant to Tyrone Miller
10.35*	Convertible Promissory Note dated as of December 31, 2016, issued by the Registrant to Douglas Loock
10.36*	Agreement to Consolidate and Convert Existing Debt dated as of December 31, 2021, between the Registrant and Douglas Loock
10.37*	Agreement to Convert Debt to Equity dated as of December 31, 2021, issued by the Registrant to Douglas Loock
10.38*	Consulting Agreement dated as of August 17, 2020, by and between the Registrant and Latham BioPharma, Inc., as amended
21.1*	List of Subsidiaries of the Registrant
23.1*	Consent of RBSM LLP dated as of [*], 2022
23.2*	Consent of Counsel to the Registrant (included in Exhibit 5.1)
24.1*	Power of Attorney (included in signature page)
99.1*	Consent of Director Nominee [Name 1]
99.2*	Consent of Director Nominee [Name 2]
99.3*	Consent of Director Nominee [Name 3]
107*	Filing Fee Table

*To be filed by amendment.
+ Management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Washington, District of Columbia, on , 2022.

60 DEGREES PHARMACEUTICALS, INC.

By: _____
Geoffrey Dow
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Geoffrey Dow and Tyrone Miller his or her true and lawful attorney-in-fact, with full power of substitution and re-substitution for him or her and in his or her name, place and stead, in any and all capacities to sign any and all amendments including pre- and post-effective amendments to this registration statement, any subsequent registration statement for the same offering which may be filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and pre- or post-effective amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his or her substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

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

Name	Position	Date
Geoffrey Dow	President, Chief Executive Officer and Director (Principal Executive Officer)	, 2022
Tyrone Miller	Treasurer (Principal Financial and Accounting Officer)	, 2022