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

**Post-Effective Amendment No. 3
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

HedgePath Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

30-0793665
(IRS Employer
Identification No.)

**4830 W. Kennedy Blvd., Suite 600
Tampa, Florida 33609
(813) 509-2417**

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

**Mr. Nicholas J. Virca
President and Chief Executive Officer
4830 W. Kennedy Blvd., Suite 600
Tampa, Florida 33609
Phone: (813) 509-2417
Fax: (813) 830-7489**

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

Copies to:

**Barry I. Grossman, Esq.
Lawrence A. Rosenbloom, Esq.
Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas
New York, New York 10105
Phone: (212) 370-1300
Fax: (212) 370-7889**

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.

If delivery of the Prospectus is expected to be made pursuant to Rule 434, check the following box.

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

Large accelerated filer
Non-accelerated filer

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.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to Be Registered	Amount to Be Registered (1)	Proposed Maximum Offering Price per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Shares of common stock (2)	30,600,000	\$—	\$—	\$(2)
Shares of common stock (3)	27,115,000	\$—	\$—	\$(3)
Shares of common stock underlying warrants (3)	27,115,000	\$—	\$—	\$(3)
Shares of common stock underlying warrants (3)	466,000	\$—	\$—	\$(3)
Total	85,296,000	—	\$—	\$—

- (1) Pursuant to Rule 416 of the Securities Act of 1933, as amended, or the Securities Act, the shares of common stock offered hereby also include such presently indeterminate number of shares of the registrant's common stock as a result of stock splits, stock dividends or similar transactions.
- (2) Represents (i) 20,000,000 shares of common stock purchased in our June 2014 private placement with Hedgepath, LLC; (ii) 10,000,000 shares of common stock issued to Hedgepath, LLC upon conversion of its shares of Series A Convertible Preferred Stock; and (iii) 600,000 shares of common stock issued to an outside law firm for services rendered. The share amounts listed in this table reflect the number of shares originally registered by the registrant and do not reflect any subsequent sales or the deregistration of any shares. Accordingly, all registration fees have been previously paid.
- (3) Represents (i) 27,115,000 shares of common stock purchased in our "best efforts/no minimum" private placement offering to accredited investors that began in April 2016 and closed in May 2016, referred to herein as the 2016 Private Placement, (ii) 27,115,000 shares of common stock underlying warrants purchased in the 2016 Private Placement and (iii) 466,000 shares of common stock underlying warrants issued to FINRA-member agents that assisted in securing investors for the 2016 Private Placement. The share amounts listed in this table reflect the number of shares originally registered by the registrant and do not reflect any subsequent sales or the deregistration of any shares. Accordingly, all registration fees have been previously paid.

Pursuant to Rule 429 under the Securities Act, the prospectus contained in this Post-Effective Amendment No. 3 to Form S-1 Registration Statement (referred to herein as the Registration Statement) will be used as a combined prospectus in connection with this Registration Statement and Registration Statement No. 333-198800, or the Prior Registration Statement, which was filed on September 17, 2014, amended on July 22, 2015 and became effective on August 10, 2015. This Registration Statement constitutes Post-Effective Amendment No. 3 to this Registration Statement and also constitutes Post-Effective Amendment No. 4 to the Prior Registration Statement. Such Post-Effective Amendment will become effective concurrently with the effectiveness of this Registration Statement in accordance with Section 8(c) 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 or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said Section 8(a) may determine.

EXPLANATORY NOTE

Pursuant to Rule 429 under the Securities Act, the prospectus included in this Registration Statement is a combined prospectus relating to:

- the resale of 27,115,000 shares of common stock and 27,155,000 shares of common stock underlying warrants purchased in the 2016 Private Placement as described in further detail in the prospectus, such shares being initially registered herein;
- the resale of 466,000 shares of common stock underlying warrants issued to FINRA-member agents that assisted in securing investors for the 2016 Private Placement as described in further detail in the prospectus, such shares being initially registered herein; and
- the resale of 20,000,000 shares of common stock purchased in our June 2014 private placement with Hedgepath, LLC, (ii) 10,000,000 shares of common stock issued to Hedgepath, LLC upon conversion of its shares of Series A Convertible Preferred Stock and (ii) 600,000 shares of common stock issued to an outside law firm for services rendered, each as described in further detail in the prospectus and previously registered on Registration Statement No. 333-198800, filed on Form S-1 and declared effective on August 10, 2015.

This Registration Statement, which constitutes Post-Effective Amendment No. 3 to this Registration Statement, also constitutes Post-Effective Amendment No. 4 to Registration Statement No. 333-198800, and such post-effective amendment shall hereafter become effective concurrently with the effectiveness of this Registration Statement and in accordance with Section 8(c) of the Securities Act.

The information in this preliminary 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 preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**Subject to Completion, dated April 26, 2019
Preliminary Prospectus**



85,296,000 Shares of Common Stock

This prospectus relates to the resale of up to an aggregate of 85,296,000 shares of common stock, par value \$0.0001 per share, of HedgePath Pharmaceuticals, Inc. held by selling stockholders, consisting of the following: (i) 27,115,000 shares of common stock and 27,115,000 shares of common stock underlying warrants purchased in our “best efforts/no minimum” private placement offering to accredited investors that began in April 2016 and closed in May 2016, referred to herein as the 2016 Private Placement (our license and manufacturing partner and majority stockholder Mayne Pharma Ventures Pty Ltd., or Mayne Pharma, participated in the 2016 Private Placement but is not registering any of its securities herein); (ii) 466,000 shares of common stock underlying warrants issued to FINRA-member agents that assisted in securing investors for the 2016 Private Placement; (iii) 20,000,000 shares of common stock issued in connection with our June 24, 2014 private placement with Hedgepath, LLC, a Florida limited liability company and a principal stockholder of our company, and previously registered on Registration Statement No. 333-198800 which was declared effective on August 10, 2015 (which we refer to as the Prior Registration Statement); (iv) 10,000,000 of the shares issued to Hedgepath LLC in August 2014 upon its conversion of its shares of our Series A Convertible Preferred Stock, par value \$0.0001 per share and previously registered on the Prior Registration Statement; and (v) 600,000 shares of common stock issued to an outside law firm for services rendered to us by such firm and previously registered on the Prior Registration Statement.

This registration does not mean that the selling stockholders named herein will actually offer or sell any of these shares. We will not receive any proceeds from the resale of the above shares of our common stock by the selling shareholders. However, we may receive proceeds from the exercise of the warrants exercised other than pursuant to any applicable cashless exercise provisions of the warrants. We are not offering any securities pursuant to this prospectus.

The number of shares available for resale under this prospectus may have changed since the Securities and Exchange Commission declared this registration statement effective. See “[Selling Stockholders](#)” beginning on page 80 for an updated list of the shares still available for sale under this prospectus to the extent that we are aware of any such changes.

Our common stock is listed for quotation on the OTCQB Market operated by OTC Markets Group, Inc. (which we refer to here as the OTCQB) under the ticker symbol “HPPI.” On April 25, 2019, the closing price of our common stock was \$0.053.

Following the effectiveness of the registration statement of which this prospectus forms a part, the sale and distribution of securities offered hereby may be effected in one or more transactions that may take place on the OTCQB or any future exchange or quotation system on which our common stock is listed or quoted, including ordinary brokers’ transactions, privately negotiated transactions or through sales to one or more dealers for resale of such securities as principals, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling stockholders. The selling stockholders and intermediaries through whom such securities are sold may be deemed “underwriters” within the meaning of the Securities Act of 1933, as amended, or the Securities Act, with respect to the securities offered hereby, and any profits realized or commissions received may be deemed underwriting compensation.

Investing in our common stock is highly speculative and involves a significant degree of risk. See “[Risk Factors](#).” beginning on page 8 of this prospectus for a discussion of information that should be considered before making a decision to purchase our common stock.

Neither the Securities and Exchange Commission 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.

The date of this prospectus is _____, 2019.

TABLE OF CONTENTS

	<u>Page</u>
Prospectus Summary	1
Risk Factors	8
Cautionary Note Regarding Forward-Looking Statements	34
Use of Proceeds	35
Dividend Policy	35
Determination of Offering Price	36
Market for Common Equity and Related Stockholder Matters	36
Management's Discussion and Analysis of Financial Condition and Results of Operations	38
Business	42
Management	63
Certain Relationships and Related Party Transactions	71
Principal Stockholders	76
Description of Securities to be Registered	77
Selling Stockholders	80
Plan of Distribution	82
Legal Matters	84
Experts	84
Where You Can Find More Information	84
Index to Financial Statements	F-1

Please read this prospectus carefully. It describes our business, our financial condition and our results of operations. We have prepared this prospectus so that you will have the information necessary to make an informed investment decision. You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with any information or to make any representations about us, the securities being offered pursuant to this prospectus or any other matter discussed in this prospectus, other than the information and representations contained in this prospectus. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us.

The information contained in this 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. Neither the delivery of this prospectus nor any distribution of securities in accordance with this prospectus shall, under any circumstances, imply that there has been no change in our affairs since the date of this prospectus. This prospectus will be updated and made available for delivery to the extent required by the federal securities laws.

This prospectus includes estimates, statistics and other industry data that we obtained from industry publications, research, surveys and studies conducted by third parties and publicly available information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. This prospectus also includes data based on our own internal estimates. We caution you not to give undue weight to such projections, assumptions and estimates.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. To understand this offering fully, you should read the entire prospectus carefully, including the "Risk Factors" section, the financial statements and the notes to the financial statements. Unless the context otherwise requires, references contained in this prospectus to the "we," "us," or "our" or similar terminology refers to HedgePath Pharmaceuticals, Inc., a Delaware corporation.

Overview

We are a pharmaceutical development company that is seeking to discover, develop and ultimately commercialize innovative therapeutics for patients with certain cancers and non-cancerous proliferation disorders. We also have explored and expect to continue to explore acquiring or licensing other innovative preclinical and clinical stage therapeutics addressing unmet needs and orphan indications for the treatment of cancer and other diseases.

Our current primary focus is on the development of therapies initially for prostate and also lung cancers in the United States utilizing SUBA®-Itraconazole, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole to which we hold an exclusive U.S. license in the licensed field from our majority stockholder, Mayne Pharma Ventures Pty Ltd. (which we refer to herein collectively with its affiliates as Mayne Pharma). We previously conducted a Phase 2(b) study of SUBA-Itraconazole for the treatment of Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome, and which product opportunity we call SUBA-Itraconazole BCCNS), and Mayne Pharma assumed control of the clinical and regulatory development of this indication in December 2018 as described below.

Our current regulatory strategy for clinical development is driven by the so called 505(b)(2) regulatory pathway, under which a drug (in our case, itraconazole) that has already been approved for use in humans in the United States by the U.S. Food and Drug Administration (or FDA) is developed for one or more new medical

Table of Contents

indications (such as an anti-cancer agent). Due to the history of safe and efficacious use of itraconazole in humans for anti-fungal applications, we believe the 505(b)(2) pathway will be available to us for other indications based upon concurrence by FDA with our previous SUBA-Itraconazole BCCNS clinical program. We believe that our utilization of the 505(b)(2) pathway when available creates the potential for significantly reducing the risk and time to achieve FDA approval of our other cancer therapies compared to the program required for new chemical entities.

SUBA-Itraconazole

SUBA-Itraconazole is currently exclusively licensed to us in the United States by Mayne Pharma in the fields of (i) any prostate cancer, prostatic intraepithelial neoplasia and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia, and (iii) familial adenomatous polyposis, colorectal polyps and Barrett's esophagus (we refer to these fields herein collectively as the licensed field). We believe that the dosing of oral capsules of SUBA-Itraconazole can affect the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as prostate cancer and lung cancer. Itraconazole has been approved by the FDA for, and has been extensively used to treat, fungal infections and has an extensive history of safe and effective use in humans.

"SUBA" technology is designed to enhance the bioavailability of orally administered drugs that are poorly soluble. In studies conducted by Mayne Pharma relating to the anti-fungal use of SUBA-Itraconazole, SUBA-Itraconazole demonstrated improved absorption and significantly reduced variability within and between patients compared to the branded and generic forms of itraconazole in human studies. We believe this technology is well-suited for the exploration of the potential anti-cancer effects of itraconazole, and we believe that SUBA-Itraconazole could be well-suited for chronic use in treating cancer and non-cancerous proliferation disorders due to its more predictable therapeutic levels and lower toxicity. We were able to validate these assumptions in our Phase 2(b) clinical trial for SUBA-Itraconazole BCCNS.

Our Supply and License Agreement, Mayne Pharma had the right to assume control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS if we were unable to have the SUBA-Itraconazole BCCNS New Drug Application (or NDA) accepted by FDA for filing by December 31, 2018 (subject to a possible maximum extension of 30 days if the NDA was filed in December). As a result of unexpected FDA guidance, we determined that we would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus we commenced negotiations with Mayne Pharma to allow Mayne Pharma to assume such control of the SUBA-Itraconazole BCCNS program on an expedited basis in December 2018 in exchange for (among other consideration) a 9% quarterly cash royalty on future net sales, if any, of SUBA-Itraconazole BCCNS in the United States. See "Certain Relationships and Related Party Transactions" for further information.

University of Connecticut Itraconazole Analogue Technology

In July 2018, we signed an exclusive option agreement with the University of Connecticut (which we refer to as UConn) related to patents and patent applications covering certain chemical analogues of itraconazole (such analogues represent separate intellectual property from SUBA-Itraconazole). We believe that having access to UConn's itraconazole analogue technology could create the potential for us to expand our developmental pipeline of clinical stage itraconazole-based treatments for certain cancers. The option agreement, which went into effect on August 1, 2018, grants us an exclusive option period of twelve (12) months until July 31, 2019. The optioned field of use includes all therapeutic, prophylactic, and diagnostic uses for cancerous and non-cancerous cell proliferation disorders in humans. During the term of exclusivity, UConn will not offer third parties the opportunity to license the patent portfolio within this field of use. During the option period, we are permitted to use the UConn technology for internal research and evaluation purposes, and we have the right during the option period to negotiate a customary license from UConn for its technology and know-how related to the subject technology. Should pre-clinical testing results look promising related to efficacy and safety, we would expect to proceed with negotiations to license the technology. Pursuant to the option agreement, we have made payments to UConn of \$20,000 in order to secure the option.

The Hedgehog Pathway

Based on the results of physician-sponsored studies conducted by others (including in vitro, animal and human studies), and our direct testing in our Phase 2(b) trial in patients with SUBA-Itraconazole BCCNS, we believe that

Table of Contents

itraconazole affects the Hedgehog signaling pathway in cells, which in turn impacts the development and growth of certain cancers. The studies, conducted at prominent medical institutions, primarily in the United States, were published in the *Journal of Thoracic Oncology*, *The Oncologist* and *the Journal of Clinical Oncology* between May 2013 and February 2014. Based on these studies, as well as our own observations and results in our Phase 2(b) trial conducted to test SUBA-Itraconazole BCCNS, it appears that itraconazole has notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and will continue to be the subject of on-going research. These studies and our own work in the clinic formed the basis of our continued interest in the clinical development of itraconazole for treatment of human cancers.

We believe that the targeted inhibition of Hedgehog signaling is or may be effective in the treatment and prevention of many types of human cancers. We also believe that the discovery and synthesis of specific Hedgehog pathway inhibitors may have significant clinical implications regarding the development of novel cancer therapies. Several synthetic Hedgehog antagonists are now being studied, some of which are undergoing clinical evaluation. The orally available compound, Erivedge®, vismodegib, developed by Curis and sold to Genentech, Inc. (a subsidiary of Roche), is the first Hedgehog inhibitor based-therapy and Odomzo®, sonidegib (developed by Novartis and sold to Sun Pharma by Novartis) is the second orally available compound, that has been approved for treatment of advanced stages of basal cell carcinoma by the FDA. Most recently, in 2018, Daurismo®, glasdegib oral capsules developed by Pfizer, was approved by FDA for use in combination with low-dose cytarabine for patients with newly-diagnosed acute myeloid leukemia (AML), aged 75 or older who are too frail to be treated with intensive chemotherapy.

Repurposing Itraconazole for Treating Cancer

We are implementing clinical and regulatory plans to enable the repurposing of itraconazole, via the use of SUBA-Itraconazole oral capsules, for the treatment of a variety of cancers. This strategy is intended to significantly reduce the risk and time to potential FDA approvals for marketing in the United States. Target applications under our license agreement with Mayne Pharma include therapies for prostate and lung cancers and certain other non-cancerous proliferation disorders.

Itraconazole appears to have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of ongoing research. These anti-cancer effects have been demonstrated in various animal models and, subsequently in human studies over the last few years, including our own Phase 2(b) trial of SUBA-Itraconazole BCCNS. Those models and studies continue to be the basis of our interest in the clinical development of SUBA-Itraconazole for treatment of human cancers and non-cancerous proliferation disorders. We believe that our development of SUBA-Itraconazole as an anti-cancer therapy has demonstrated its potential effective use as an inhibitor of the Hedgehog pathway, thereby retarding the progression of a cancer, as demonstrated in our SUBA-Itraconazole BCCNS trial.

Our Potential Market

The following table depicts our current estimate of the total available market opportunity for our proposed anti-cancer therapies based upon independent market research, scientific and industry publications and management's knowledge of the U.S. oncology market. Our estimates (including estimated product pricing) are based on current assumptions and are subject to change.

HedgePath Pharmaceuticals, Inc. – Summary Estimated U.S. Market Opportunity

<u>Cancer Type</u>	<u>Therapy Indication</u>	<u>Potential for SUBA-Itraconazole</u>	<u>Target Patient Population</u>	<u>U.S. Total Available Market*</u>
Prostate (1)	Patients with metastatic castrate resistant prostate cancer (mCRPC) and rising PSA levels no longer responding to androgen deprivation therapy (ADT)	Delay the progression of metastatic disease	23,000 high-risk men with metastatic prostate cancer who are no longer responding to ADT due to biochemical resistance	\$215Million at Yr 5 (\$843M cumulative from launch) based on HedgePath estimates of ~ \$4,000 - \$5,000 monthly cost of 2 nd line therapy

Table of Contents

Cancer Type	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market*
Lung (2)	Patients with advanced non-squamous cell, non-small cell lung cancer (NSCLC) who will be placed on Platinum Doublet/Pemetrexed IV Therapy	Improve the current median 8 - 10 month survival achieved with best supportive care for patients who are not eligible for treatment with tyrosine kinase or checkpoint inhibitors	45,000 men and women with late-stage disease who may be treated with chemotherapy if not eligible for other therapies	\$270Million at Yr 5 (\$945M cumulative from launch based on HedgePath estimates of ~ \$4,000 - \$5,000 monthly cost of 2 nd or 3 rd line therapy
Skin (3)	Patients with BCC (basal cell carcinoma) lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring surgery Potential for follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures	Less toxic therapy than vismodegib or sonidegib for Gorlin Patients to delay surgeries; low toxicity therapy to delay or minimize surgical intervention for head and neck BCC tumors	10,000 Gorlin patients needing chronic BCC therapy; 65,000 BCC patients pending surgical treatment for facial tumors that require excision and potential plastic surgery	\$300M for Gorlin patients for which HPPI receives a 9% royalty on net sales in the US based upon licensing the indication to Mayne Pharma; and \$600M for patients with BCC facial lesions requiring surgery based upon HedgePath/Mayne Pharma estimates of ~ \$4,000 - \$5,000 monthly cost of therapy for target populations

* **Estimated**

References:

- (1) *J. Urology, 2003; Oncology, 2004; American J. Hematologic Oncology, 2014; NIH NCI SEER 2014; Medscape, 2015; Future Oncology 2015; Global Data 2015; Pennside Partners 2017*
- (2) *STATS MGU, 2009; Global Industry Analysts, 2010; World Health Organization, 2015; Cost of Treating Lung Cancer, 2012; LUNGevity Foundation 2017; NEJM 2015; Pennside Partners 2017*
- (3) *J Am Academy Dermatology, 2006; Skin Cancer Foundation, 2009; International Medicine News, 2011; Seeking Alpha, 2017; BCCNS Life Support Network 2017, Genetics Home Reference 2015; Pennside Partners 2016*

Our Strategy

Our goal is to be a leader in the development and commercialization of itraconazole-based therapeutics for the treatment of cancer patients and patients with non-cancerous proliferation disorders. We believe that we can accomplish this goal by implementing the following key elements of our business strategy:

- *Rapidly Advance the Clinical Development of Our Therapies.* With the history of safe use of itraconazole in humans for anti-fungal indications, we bypassed each of the required pre-clinical animal studies for toxicity and Phase 1 human trials to establish safety for SUBA-Itraconazole BCCNS, and therefore are able to move directly into Phase 2 human trials. We would expect to replicate this outcome with SUBA-Itraconazole Prostate and other SUBA-Itraconazole treatments.

Table of Contents

- *Seek FDA Programs to Expedite Drug Approvals.* The FDA has various programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. These expedited programs help ensure that therapies for serious conditions are available as soon as it can be concluded that the therapies' benefits justify their risks, taking into account the seriousness of the condition and the availability of alternative treatments. These programs include breakthrough therapy designation, fast track designation, accelerated approval, and priority review. We believe that SUBA-Itraconazole for the treatment of cancer may qualify for one of these designations, which could help expedite the regulatory review process.
- *Commercialize and Market with Exclusivity.* We are developing specific clinical trial designs to address different forms of cancer and non-cancerous proliferation disorders in order to pursue FDA approvals for multiple indications. Further, we believe SUBA-Itraconazole can be commercialized in a way that maximizes benefits for patients, based on our specific therapy regimens, while eliminating generic substitution and providing us with market exclusivity protections through our intellectual property rights.

In addition, we have explored and expect to continue to explore acquiring or licensing other innovative pre-clinical and clinical stage therapeutics addressing unmet needs and orphan indications for the treatment of cancer and other diseases. This activity (an example of which is our option agreement with UConn) is aimed at expanding our product candidate portfolio.

We continue to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- proceeds from public and private financings (including, most recently, financing from our majority shareholder, Mayne Pharma) and, potentially, from strategic transactions;
- advances from Mayne Pharma of potential future royalties on the SUBA-Itraconazole BCCNS product available under the Supply and License Agreement;
- royalty revenue from Mayne Pharma from sales of SUBA-Itraconazole BCCNS upon and assuming approval by FDA (after earned royalties have been applied to any advances due under the Supply and License Agreement);
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including potentially, warrants held by our Mayne Pharma, our majority stockholder);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and/or
- seeking government or private foundation grants or loans which would be awarded to us to further develop our current and future anti-cancer therapies.

Risks Associated with Our Business

Our business is subject to many significant risks, as more fully described in the section entitled “Risk Factors” immediately following this prospectus summary. You should read and carefully consider these risks, together with the risks set forth under the section entitled “Risk Factors” and all of the other information in this prospectus, including the financial statements and the related notes included elsewhere in this prospectus, before deciding whether to invest in our common stock. If any of the risks discussed in this prospectus actually occur, our business, financial condition or operating results could be materially and adversely affected. In particular, our risks include, but are not limited to, the following:

- We are a pre-revenue pharmaceutical development company and are thus subject to the risks associated with early stage businesses in that industry.
- Our limited operating history makes it difficult for you to evaluate our business to date and to assess our future viability.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We are highly dependent on our collaboration with our majority stockholder Mayne Pharma, and the loss of this collaboration would materially impair our business plan and viability.
- Mayne Pharma holds a majority equity stake in our company and thus effectively controls our company. Mayne Pharma also has certain contractual rights such as the right to nominate a member of our Board of Directors and the right to invest in future offerings of our securities.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We may also be subject to healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.
- We have licensed or expect to license certain intellectual property from third parties, and such licenses may not continue to be available or may not be available on commercially reasonable terms.

Corporate History

We were founded under the name “Commonwealth Biotechnologies, Inc.” in Virginia in 1992, and completed an initial public offering in October 1997 (we refer to our company prior to our emergence from bankruptcy as CBI). CBI previously provided, on a contract basis, specialized life sciences services to the pharmaceutical and biotechnology sector. On January 20, 2011, CBI filed a voluntary petition for bankruptcy. We recommenced our business operations in August 2013 as a Delaware corporation following the emergence of CBI from its voluntary bankruptcy.

Principal Offices

We were reincorporated under the laws of the State of Delaware on August 12, 2013 upon consummation of our reincorporation merger. We maintain an address at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609 and our telephone number is (813) 509-2417.

The Offering

Common Stock Outstanding:	370,446,185 shares as of April 25, 2019
Common Stock Offered by Selling Stockholders:	85,296,000 shares (1)
Use of Proceeds:	We will not receive any proceeds from the sale of the common stock by the selling stockholders. We would, however, receive proceeds upon the exercise of the warrants held by the selling stockholders which, if such warrants are exercised in full for cash, would be approximately \$3.3 million. Proceeds, if any, received from the exercise of such warrants will be used for general corporate purposes and working capital or for other purposes that our Board of Directors, in their good faith, deem to be in the best interest of our company. No assurances can be given that any of such warrant will be exercised. As of the date of this prospectus, we have received approximately \$0.6 million in proceeds from the exercise of such warrants.
Quotation of Common Stock:	Our common stock is listed for quotation on the OTCQB market under the symbol “HPPI.”
Risk Factors:	An investment in our company is highly speculative and involves a significant degree of risk. See “Risk Factors” and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

(1) Includes 27,581,000 shares of common stock underlying warrants with an exercise price of \$0.12 per share and 30,600,000 shares of common stock that were previously registered on the Prior Registration Statement. See “Selling Stockholders.”

RISK FACTORS

An investment in our common stock involves substantial risks, including the risks described below. You should carefully consider the risks described below before purchasing our common stock. The risks highlighted here are not the only ones that we may face. For example, additional risks presently unknown to us or that we currently consider immaterial or unlikely to occur could also impair our operations. If any of the risks or uncertainties described below or any such additional risks and uncertainties actually occur, our business, prospects, financial condition or results of operations could be negatively affected, and you might lose all or part of your investment.

Risks Relating to Our Business

We are a pre-revenue pharmaceutical development company and are thus subject to the risks associated with early stage businesses in that industry.

We are a pharmaceutical development company with no history of revenue-generating operations. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties inherent in an early stage pharmaceutical development company. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in their pre-revenue generating stages, particularly those in the pharmaceutical field. Potential investors should carefully consider the risks and uncertainties that a new company with no operating history will face. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, or that our business plan is sound;
- maintain our management team or board of directors (including, without limitation, as a result of Mayne Pharma's position as our controlling stockholder and its result rights to remove and replace our directors);
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan;
- determine that the processes and technologies that we have developed are commercially viable; and/or
- attract, enter into or maintain contracts with potential commercial partners such as licensors of technology and suppliers.

If we cannot execute any one of the foregoing, our business may fail, in which case you may lose the entire amount of your investment in our company.

In addition, we have in the past and expect that we may in the future encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be able to reach such point of transition or make such a transition, which would have a material adverse effect on our company.

Table of Contents

Our limited operating history makes it difficult for you to evaluate our business to date and to assess our future viability.

Currently, our sole line of business is the development and potential marketing of our itraconazole anti-cancer therapies, and we acquired the assets related to this business opportunity on August 13, 2013 as part of our emergence from bankruptcy. Our pre-bankruptcy historic business operations ceased contemporaneously with our becoming subject to bankruptcy proceedings in 2011, and all assets supporting our earlier lines of business have been disposed of. Accordingly, we only recommenced active operations on August 13, 2013, the date we emerged from bankruptcy.

Our operations are presently limited to planning and conducting of pre-clinical testing and clinical trials, arranging for the raising of capital, developing our technology or seeking technology licenses or acquisitions, and identifying potential commercial partners. We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for product commercialization. Consequently, any predictions you make about our future viability or ability to accomplish our business goals may not be as accurate as they could be if we had a longer operating history.

We are highly dependent on our collaboration with our majority stockholder Mayne Pharma, and the loss of this collaboration would materially impair our business plan and viability.

Under our Supply and License Agreement with Mayne Pharma, we have secured rights to commercialize oral SUBA-Itraconazole capsules for the treatment of patients with certain cancers and non-cancerous proliferation disorders in the United States. Mayne Pharma is our sole source supplier of SUBA-Itraconazole, and under such agreement, we must obtain all required supply of SUBA-Itraconazole capsules for our clinical trials and commercialization of the product from Mayne Pharma, except in the limited circumstance where Mayne Pharma has established a secondary supplier and is unable to supply the product.

Also, our ability to achieve any royalty revenue from future sales by Mayne Pharma of SUBA-Itraconazole BCCNS is dependent on Mayne Pharma's ability to complete clinical testing of and receive FDA approval for SUBA-Itraconazole BCCNS, and thereafter to successfully generate sales of SUBA-Itraconazole BCCNS, none of which may ever occur. In addition, Mayne Pharma is presently our majority stockholder, and as such has the power to exert significant control over our company.

As such, our agreement and collaboration with Mayne Pharma are critical to our business. In the event that the Supply and License Agreement is terminated, we may lose the ability to commercialize SUBA-Itraconazole, and our business prospects and overall viability as a company would be materially damaged.

Mayne Pharma is our majority stockholder and has, and may in the future, exert significant influence over our business and affairs. Moreover, the corporate governance rights afforded to Mayne Pharma under the Equity Holders Agreement may adversely affect the management of our company.

As of the date of this prospectus, Mayne Pharma beneficially owns approximately 59.1% of our outstanding voting securities (including shares of our common stock and Series B Convertible Preferred Stock which we refer to as our Series B Preferred Stock). Under the terms of our Amended and Restated Equity Holders Agreement, as amended by Amendment No. 1 to Amended and Restated Equity Holders' Agreement, or the Equity Holders Agreement (which we refer to as the Equity Holders Agreement), Mayne Pharma has the right to designate one director to our Board of Directors (and to designate a second director if the size of the Board of Directors is increased to seven directors) until the earlier to occur of: (i) the date that the Supply and License Agreement is terminated or expires, or (ii) the date on which Mayne Pharma along with its affiliates ceases to own ten percent (10%) or more of our issued and outstanding common stock on a fully diluted basis. During this time frame, Mayne Pharma, through its representative on the Board of Directors, holds a veto right in the event that we want to increase or decrease the size of the Board of Directors or replace or remove our President and Chief Executive Officer (such veto right being the result of each of the foregoing Board of Director actions requiring the unanimous consent of the Board of Directors).

Table of Contents

Mayne Pharma's significant ownership of our voting securities plus the existence of these additional rights will for the foreseeable future enable Mayne Pharma to exert significant influence over our company and matters requiring stockholder approval including the election of directors (although required under our Equity Holders Agreement to maintain a majority of independent directors until a single shareholder owns greater than 90% of our common stock), financing activities or a merger or sale of our assets. An example of Mayne Pharma's exercise of its stockholder rights occurred in November 2016, when Mayne Pharma acted by written consent to remove two sitting members of our Board of Directors and replace such directors with appointees of Mayne Pharma's choosing. Mayne Pharma may elect in its discretion to exercise these or similar rights at any time. Additionally, these rights may limit the ability of our Board of Directors and our management team to make necessary personnel decisions, including adding independent directors to our Board of Directors, which may adversely affect the management of our company, particularly if disputes arise between us and Mayne Pharma (which disputes in and of themselves could have a material adverse effect on our ability to conduct business).

The right of Mayne Pharma to participate in future financings of ours could impair our ability to raise capital.

Pursuant to our agreements with Mayne Pharma, Mayne Pharma and its affiliates have been granted certain rights to purchase a pro rata share of any new securities issued by us, which pro rata share would be determined based upon the number of shares of our common stock held by Mayne Pharma and its affiliates on a fully diluted basis as compared to the number of shares of common stock outstanding immediately prior to the offering of the new securities on a fully diluted basis. The existence of such right of participation, or the exercise of such rights, may deter potential investors from providing us needed financing, or may deter investment banks from working with us, which would have a material adverse effect on our ability to finance our company.

We may be unable to acquire or license additional technologies to expand our product development pipeline.

The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary technologies related to pharmaceutical therapies. The licensing and acquisition of third-party intellectual property rights is a competitive practice and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire or license the rights to additional product candidates that we may seek to acquire.

Additionally, as in the case with our option agreement with UConn, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically (as with UConn), these institutions provide companies like ours with an option to negotiate a license to institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a full license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue the applicable program.

All of foregoing could lead to our lack of an evolved product development pipeline, which would leave us at continued risk of dependence on SUBA-Itraconazole and our relationship with Mayne Pharma and would decrease our ability to grow into a viable pharmaceutical development company.

We are dependent upon our officers and directors and their loss could adversely affect our ability to operate.

Our operations are dependent upon a very small group of individuals and, in particular, our current officers and directors, including most notably Nicholas J. Virca. We believe that our ability to implement our business plans depends on the continued service of these individuals and/or other officers and directors. The unexpected loss of the services of one or more of our directors or officers could have a detrimental effect on us.

The requirements of being a public company may strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (which we refer to as 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 (including activities previously undertaken in a private company context) more difficult, time-consuming or costly and increase demand on our systems and resources. 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 adversely affect our ability to implement our business plans. We may need to hire more employees in the future or engage outside consultants 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 business development 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 their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

Our business and operations would suffer in the event of system failures.

Our internal computer systems and those of our current and any future partners, contractors, and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. This is particularly true in the case of collecting and analyzing clinical data, which is a key component of our business. System failures, accidents, or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercialization activities, development programs and our business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the commercialization of any potential product candidate could be delayed.

Risks Related to Our Financial Position and Need For Additional Capital

We will require substantial additional funding to progress our business. If we are unable to raise additional capital, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts and our business could fail.

As of the date of this prospectus, we have cash on hand and commitments for advances of royalties from our majority stockholder sufficient to run our planned operations into the quarter ending September 30, 2020. We expect that we will be required to incur significant expenses in connection with our ongoing activities, particularly as we engage in efforts to develop and ultimately commercialize our itraconazole or other therapies.

Table of Contents

Accordingly, we will need to obtain long term additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts, and our business might fail.

In addition, our future capital requirements will be significant and will depend on many factors, including:

- the progress and results of our development efforts for SUBA-Itraconazole;
- the progress and results of our pre-clinical development efforts with product candidates other than SUBA-Itraconazole;
- the progress and results of Mayne Pharma's efforts to commercialize SUBA-Itraconazole BCCNS for which we will receive a quarterly cash royalty of 9% of net sales if such sales are achieved;
- the costs, timing and outcome of clinical trials of our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- competing technological and market developments;
- market acceptance of our product candidates as a treatment;
- the costs and timing of our potential future acquisitions or licenses of additional pharmaceutical technologies;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidate for which we receive marketing approval;
- the revenue, if any, received from commercial sales or licensing royalty from a commercial partner of any product candidate for which we may receive marketing approval;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

Developing, acquiring or licensing pharmaceutical products, conducting preclinical testing and clinical trials and seeking regulatory approval of such products is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidate, if approved (of which no assurances may be given), may not achieve any level of commercial success. Our commercial revenues, if any, will be derived from sales of a product that we do not expect to be commercially available for at least one year, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We may have difficulty in raising capital and may consume resources faster than expected.

We currently do not generate any revenue from product sales, royalties, or otherwise, and we therefore have a limited source of cash to meet our future capital requirements. We do not expect to generate revenues or receive

Table of Contents

royalty revenue for the foreseeable future, and we may not be able to raise funds in the future, which would leave us without resources to continue operations and force us to resort to stockholder investments or loans, which may not be available to us. We may have difficulty raising needed capital in the near or longer term as a result of, among other factors, the clinical stage nature of our business, Mayne Pharma's status as our majority stockholder, the rights of Mayne Pharma and Hedgepath, LLC (an investment vehicle associated with our former Executive Chairman) to participate in our future financings and our lack of revenues as well as the inherent business risks associated with our company and present and future market conditions. Also, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. Our inability to raise funds could lead to decreases in the price of our common stock and the failure of our business.

Raising additional capital or issuing new securities in connection with strategic transactions may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Since we will be unable to generate any revenue from actual sales of products and expect to be in the development stage for the foreseeable future (other than capital due to us by Mayne Pharma in the form of royalty advances or royalties on future sales of SUBA-Itraconazole BCCNS in the U.S. assuming FDA approval), we will need to seek equity or debt financing to provide the capital required to execute our business plan. We will need significant funding for developing, acquiring or licensing our intellectual property, conducting clinical trials and entering into collaborations with third-party partners as well as for working capital requirements and other operating and general corporate purposes.

There can be no assurance that we will be able to raise sufficient capital on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be adversely affected to a significant extent.

If we raise additional capital by issuing equity securities, the percentage and/or economic ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock.

Debt financing, if obtained, may involve agreements that include liens on our assets, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, increases in our expenses and requirements that our assets be provided as a security for such debt. Debt financing would also be required to be repaid regardless of our operating results.

If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidate, or to grant licenses on terms that are not favorable to us.

Funding from any source may be unavailable to us on acceptable terms, or at all. If we do not have sufficient capital to fund our operations and expenses, our business could fail.

Moreover, we may issue equity securities in connection with potential strategic transactions such as acquisitions or licenses of other companies or technologies. Such issuances could be in significant amounts and would also cause dilution to our stockholders and grant the recipients of such securities varying amounts of control over our company and our business.

Risks Related to the Clinical Development of Our Product Candidate

We are early in our development efforts and currently have no clinical-stage product candidates. If we are unable to clinically develop and ultimately commercialize SUBA-Itraconazole or other product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and have no clinical-stage product candidates as of the date of this prospectus. We have the exclusive U.S. rights to develop SUBA-Itraconazole for the treatment of cancer and non-cancerous proliferation disorders in the licensed field, and while itraconazole has previously been approved by the FDA for use as an anti-fungal agent, the use of itraconazole to treat cancer and non-cancerous proliferation disorders has not been approved and has been subject to limited clinical testing by others and by us in our previous Phase 2(b) clinical trial with SUBA-Itraconazole BCCNS. We are presently planning on filing an IND for SUBA-Itraconazole Prostate, and we hope to begin human testing for this indication in 2019, although no assurance can be given that we will be able to achieve this goal.

Therefore, our ability to generate product or royalty revenues, which we do not expect will occur for several years, if ever, will depend heavily on our ability to develop and eventually commercialize our product candidate. The positive development of our product candidate will depend on several factors, including the following:

- positive commencement and completion of clinical trials;
- successful preparation of regulatory filings and receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and potential regulatory exclusivity for our product candidate and protecting our rights in our intellectual property portfolio;
- maintaining our agreement with Mayne Pharma to produce product needed for clinical testing and, potentially if approvals are obtained, for commercial sale;
- launching commercial sales of our product, if and when approved for one or more indications, whether alone or in collaboration with others;
- acceptance of the product for one or more indications, if and when approved, by patients, the medical community and third-party payors;
- protection from generic substitution based upon our own or licensed intellectual property rights;
- effectively competing with other therapies;
- obtaining and maintaining adequate reimbursement from healthcare payors; and
- maintaining a continued acceptable safety profile of our product following approval, if any.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to clinically develop and commercialize SUBA-Itraconazole as a therapy for cancer and non-cancerous proliferation disorders, which would materially harm our business.

In addition, given our current limited financial resources, we are currently focusing our efforts on one key cancer indication, namely prostate cancer. We are thus faced with the risk that SUBA-Itraconazole could be ineffective in addressing this particular cancer indication, and if our efforts to demonstrate the efficacy of SUBA-Itraconazole in prostate cancer are not positive, we may lack the resources to expand our efforts into other cancer indications.

If we are unable to convince physicians as to the benefits of SUBA-Itraconazole as a therapy for cancer and non-cancerous proliferation disorders, if and when it is approved, we may incur delays or additional expense in our attempt to establish market acceptance.

Use of SUBA-Itraconazole as a cancer therapy and a therapy for non-cancerous proliferation disorders will require physicians to be informed regarding the intended benefits of the product for a new indication. The time and cost of such an educational process may be substantial. Inability to carry out this physician education process may

Table of Contents

adversely affect market acceptance of SUBA-Itraconazole as a therapy for cancer and non-cancerous proliferation disorders. We may be unable to timely educate physicians in sufficient numbers regarding our intended application of SUBA-Itraconazole to achieve our marketing plans or to achieve product acceptance. Any delay in physician education or acceptance may materially delay or reduce demand for our product candidate. In addition, we may expend significant funds toward physician education before any acceptance or demand for SUBA-Itraconazole as a therapy for cancer and non-cancerous proliferation disorders is created, if at all.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidate.

The risk of failure for product candidates in clinical development is high. It is impossible to predict when our sole product candidate, SUBA-Itraconazole for the treatment of cancer and certain non-cancer proliferation disorders, will prove effective and safe in humans or will receive regulatory approval for the treatment of any disease, the indication for which is licensed to us. Before obtaining marketing approval from regulatory authorities for the sale of SUBA-Itraconazole as a cancer therapy, we must conduct one or more clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, the outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidate, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, which would be time consuming and costly;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of materials necessary to conduct clinical trials of our product candidate may be insufficient or inadequate;
- our product candidate may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials; and
- interactions with other drugs.

Table of Contents

If we are required to conduct additional clinical trials or other testing of our product candidate beyond those that we currently contemplate, if we are unable to complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidate for one or more indications;
- not obtain marketing approval at all for one or more indications;
- obtain approval for indications or patient populations that are not as broad as intended or desired (particularly, in our case, for different types of cancer);
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know which, if any, of our clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the right to commercialize our product candidate or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate and may harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in any future clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue future clinical trials for our present or future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidate, and patients who would otherwise be eligible for our future clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for any future clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate, which would cause the value of our company to decline and otherwise materially and adversely affect our company.

Table of Contents

If serious adverse or unacceptable side effects are identified during the development of our product candidate, we may need to abandon or limit such development, which would adversely affect our company.

If clinical testing of our product candidates results in undesirable side effects or demonstrates characteristics that are unexpected, we may need to abandon such development or limit such development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

For the foreseeable future, we expect to expend our limited resources primarily to pursue a particular product candidate, leaving us unable to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of clinical and commercial development.

Because we have limited financial and managerial resources, we will focus for the foreseeable future primarily on the clinical development of SUBA-Itraconazole for the treatment of prostate cancer. As a result, we may forego or be unable to pursue opportunities with other product candidates or for indications other than those we intend to pursue 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. Our spending on research and development programs related to SUBA-Itraconazole for the treatment of cancer may not yield any commercially viable therapies. Because of this concentration of our efforts, our business will be particularly subject to significant risk of failure of our one current product candidate.

We expect to rely on collaborations with third parties for key aspects of our business. If we are unable to secure or maintain any of these collaborations, or if these collaborations do not achieve their goals, including most notably our collaboration with Mayne Pharma, our business would be adversely affected.

We presently have very limited capabilities for drug development and do not yet have any capability for manufacturing, sales, marketing or distribution. Accordingly, we expect to enter into collaborations with other companies that we believe can provide such capabilities. These collaborations may also provide us with important funding for our development programs. One such collaboration was entered into in September 2013 with Mayne Pharma for SUBA-Itraconazole under an exclusive Supply and License Agreement.

There is a risk that we may not be able to maintain our current collaboration or to enter into additional collaborations on acceptable terms or at all, which would leave us unable to progress our business plan. We will face significant competition in seeking appropriate collaborators. Our ability to 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. If we are unable to maintain or reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of our product candidate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Moreover, even if we are able to maintain and/or enter into such collaborations, such collaborations may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of our product candidate, might lead to additional responsibilities for us with respect to such product candidate, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

Table of Contents

- collaborators could independently develop or be associated with products that compete directly or indirectly with our product candidate;
- collaborators could have significant discretion in determining the efforts and resources that they will apply to our arrangements with them;
- should our product candidate achieve regulatory approval, a collaborator with marketing and distribution rights to our product candidate may not commit sufficient resources to the marketing and distribution of such product;
- 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 intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and we do not have the right to sue infringers of the rights granted to us by Mayne Pharma under the Supply and License Agreement; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to either find alternative collaborators (which we may be unable to do) or raise additional capital to pursue further development or commercialization of our product candidate on our own.

Our business could be materially harmed if any of the foregoing or similar risks comes to pass with respect to our key collaborations.

We have contracted with Mayne Pharma and may contract with other third parties, for the manufacture of our product candidates for clinical testing and expect to continue to do so for commercialization. This reliance on third parties, and in particular Mayne Pharma, increases the risk that we will not have sufficient quantities of our product candidate(s) or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing capabilities, nor do we have the right to manufacture or have SUBA-Itraconazole manufactured except under agreement with Mayne Pharma. We will rely on Mayne Pharma for the manufacture of our product candidate, SUBA-Itraconazole, for clinical testing, as well as for commercial manufacture if our product candidate ultimately receives marketing approval. This reliance on Mayne Pharma leaves us exposed to the risk that we will not have sufficient quantities of our product candidate or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. In addition, the possibility of a business interruption event with Mayne Pharma or any other manufacturer may occur, such as bankruptcy, factory contamination or natural disaster, which may result in the inability to obtain product, which would cause our business prospects to be adversely impacted.

Moreover, we may be unable to maintain our agreement with Mayne Pharma or establish any agreements with other third-party manufacturers or to do so on acceptable terms should we have the ability and the need to do so. Even though we have established an agreement with Mayne Pharma or if we are able to establish agreements with other third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third-party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

[Table of Contents](#)

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidate or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidate or products.

In addition, our product candidate and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Also, any performance failure on the part of Mayne Pharma could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If Mayne Pharma cannot perform as agreed, we may not be able to continue developing SUBA-Itraconazole.

Risks Related to the Commercialization of Our Product Candidate

Even if any of our product candidates receive marketing approval for any indication, they 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.

Even if SUBA-Itraconazole for the treatment of cancer and non-cancerous proliferation disorders (or other product candidates we may acquire or license) receives marketing approval for any indication, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments such as chemotherapy, immunotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of SUBA-Itraconazole for the treatment of cancer and non-cancerous proliferation disorders, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Table of Contents

If we are unable to establish sales, marketing and distribution capabilities, we may not be able to commercialize our product candidate if and when it is approved.

We currently do not have a sales or marketing infrastructure. To achieve any level of commercial success for any product for which we have obtained marketing approval, we will need to establish a sales and marketing organization or outsource sales and marketing functions to third parties.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If approved, factors that may inhibit our efforts to commercialize our product on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to or choose not to establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may be unable to enter into arrangements with third parties to sell, market and distribute our product candidate or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product effectively. If we do not establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be able to commercialize our product candidate, which would have a material adverse effect on our company.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidate and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of cancer. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove

Table of Contents

to be significant competitors, particularly through collaborative arrangements with large and established companies. 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 technologies complementary to, or necessary for, our programs, and we may be unable to effectively compete with these companies for these or other reasons.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals.

Our ability to commercialize any product candidate also will depend in part on the extent to which coverage and adequate reimbursement for our product candidate will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to commercialize any product candidate for which we obtain marketing approval.

In addition, there may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidate in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot defend ourselves against claims that our product candidate or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- damage to our reputation and significant negative media attention;

Table of Contents

- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently do not have product liability insurance coverage, which leaves us exposed to any product-related liabilities that we may incur. We may be unable to obtain insurance on reasonable terms or at all. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products (particularly itraconazole, and the formulation of SUBA-Itraconazole in particular, as an anti-cancer therapy), or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to commercialize our technology and products may be impaired.

Our business plan depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products, and in particular, the rights to develop SUBA-Itraconazole as a therapy for cancer and non-cancerous proliferation disorders. We seek to protect our proprietary position through our exclusive license for SUBA-Itraconazole with Mayne Pharma, through our sublicense of other itraconazole-related rights from Mayne Pharma, our own patents for treating cancer with SUBA-Itraconazole and by filing patent applications in the United States related to our novel technologies and product candidate and also our expectation to license additional applicable patents from third parties. We will also need to obtain and maintain patent protection for any technologies we may acquire or license (including the UConn technology to which we currently have an option).

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances (particularly in collaboration scenarios such as our agreement with Mayne Pharma), we may not have the right to control (in whole or in part) the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions

Table of Contents

claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Specifically, United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances. From time to time, the United States Supreme Court, other federal courts, the United States Congress, or interpretation by the United States Patent and Trademark Office or USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. Some cases decided by the United States Supreme Court have involved questions of when claims reciting abstract ideas, laws of nature, natural phenomena and/or natural products are eligible for a patent, regardless of whether the claimed subject matter is otherwise novel and inventive. These cases include *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), also known as the Myriad decision; *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014), also known as the Alice decision; and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, also known as the Prometheus decision, 566 U.S. 66 (2012). The full impact of these decisions is not yet known. In view of these and subsequent court decisions, the USPTO has issued materials to patent examiners providing guidance for determining the patent eligibility of claims reciting laws of nature, natural phenomena, or natural products.

In addition, patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. Accordingly, since we have patent applications pending and plan to file for additional patents in the future, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. 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 and financial condition.

Moreover, we may be subject to a thirdparty pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of our product candidate, patents protecting such candidate might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

[Table of Contents](#)

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our owned or licensed patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Furthermore, we do not have the right to sue infringers of the rights granted to us by Mayne Pharma under the Supply and License Agreement, so we will be reliant upon them to take any action necessary to protect these patents. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

We have licensed or expect to license certain intellectual property from third parties, and such licenses may not continue to be available or may not be available on commercially reasonable terms.

We have and/or expect to enter into licenses with third parties that hold intellectual property, including patent rights, that are important or necessary to the development of itraconazole, and SUBA-Itraconazole in particular, as an anti-cancer therapy, and it may be necessary for us to use the patented or proprietary technology of third parties, such as Mayne Pharma, to commercialize itraconazole as an anti-cancer therapy, in which case we have or would be required to obtain a license from these third parties on commercially reasonable terms, or else our business could be harmed, possibly materially. Even though we have obtained exclusive rights to additional patents from Mayne Pharma and have had patents issued for our own inventions in the United States in November 2015 and May 2018, if we were not able to maintain our current license or obtain additional licenses, or were not able to maintain or obtain such licenses on commercially reasonable terms, our business could be harmed, possibly substantially.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our business will depend upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our primary product candidate or other products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose rights that are important to our business.

We are and expect to be party to one or more license or similar agreements that may impose due diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future licenses, our counterparties may have the right to terminate these agreements, in which case we might not be able to develop, manufacture or market any product that is covered by these agreements (particularly SUBA-Itraconazole as an anti-cancer therapy) or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal and Compliance Matters

If we fail to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidate, and our ability to generate revenue and the viability of our company will be materially impaired.

Our product candidates and the activities associated with their clinical development and commercialization, including matters relating to design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA (including under the Federal Food, Drug and Cosmetic Act) and other regulatory agencies in the United States and by the European Medicines Agency (known as the EMA) and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product candidates will prevent us from commercializing the product candidate. We have not received approval to market SUBA-Itraconazole or any other product from regulatory authorities in any jurisdiction.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use of our product. In particular, new cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. Even if our product candidate receives marketing approval for one or more indications, of which no assurances may be given, the accompanying labels may limit the approved use of our drug, which could limit sales of the product.

The process of obtaining marketing approvals in the United States is very expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in marketing approval policies during the development

Table of Contents

period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We experienced unexpected complexities of this nature in the regulatory development of SUBA-Itraconazole BCCNS (which ultimately led to Mayne Pharma to assume control of that product), and may experience similar complexities in the future, which could harm our prospects.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of our product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidate, the commercial prospects for our product candidate will be harmed and our ability to generate revenues, and the viability of our company generally, will be materially impaired.

We may also be subject to healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Although we currently do not directly market or promote any products, we may also be subject to several healthcare regulations and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal HIPAA and HITECH laws, which govern the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

We will likely seek approval of SUBA-Itraconazole under an expedited procedure, which may not be available to us.

It is our intention to seek to avail ourselves of the FDA's 505(b)(2) approval procedure where it is appropriate to do so, particularly for SUBA-Itraconazole as a therapy to treat cancer and non-cancerous proliferation disorders since itraconazole has previously been approved for another indication. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act permits an applicant to file an NDA with the FDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a

Table of Contents

right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain preclinical testing or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product.

If this approval pathway is not available to us with respect to our product candidate, the time and cost associated with developing and commercializing such candidate may be prohibitive and our business strategy could be materially and adversely affected.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We have the opportunity to seek "fast track" designation for our product candidate for one or more indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe that SUBA-Itraconazole may be eligible for this designation, we cannot assure you that the FDA would decide to grant it should we apply for this designation. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

We were denied breakthrough therapy status by the FDA for our initial proposed therapy, and a breakthrough therapy designation by the FDA for our product candidates, even if ultimately granted, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that SUBA-Itraconazole meets the criteria for designation as a breakthrough therapy for one or more indications, the FDA may disagree and instead determine not to make such designation. In fact, in January 2017, our initial breakthrough request related to SUBA-Itraconazole BCCNS was denied by FDA.

Moreover, even if such designation is granted for one or more of our proposed therapies, of which no assurances may be given, the receipt of a breakthrough therapy designation for any product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if SUBA-Itraconazole qualifies as a breakthrough therapy for one or more indications, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened, which would deny us the benefits of such designation.

Orphan designation for our product candidates may be difficult to obtain, and if our competitors are able to obtain orphan drug exclusivity for their products that are the same drug or a similar medicinal product as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities may designate drugs for relatively small patient populations as "orphan" drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the

Table of Contents

indication for which it has such designation, the product is entitled to a period of market exclusivity, which, subject to certain exceptions, precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable market exclusivity period is seven years in the United States. We previously secured orphan drug designation for SUBA-Itraconazole BCCNS (our previous product candidate).

Obtaining orphan drug exclusivity for our product candidates may be important to our commercial strategy. If a competitor obtains orphan drug exclusivity for and approval of a product with the same indication as our product candidates before we do, and if the competitor's product is the same drug or a similar medicinal product as ours, we could be excluded from the market. Even if we obtain orphan drug exclusivity after FDA approval, we may not be able to maintain it. For example, if a competitive product that is the same drug or a similar medicinal product as our product candidate is shown to be clinically superior to our product candidate, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. In addition, orphan drug exclusivity will not prevent the approval of a product that is the same drug as our product candidate if the FDA finds that we cannot assure the availability of sufficient quantities of the drug to meet the needs of the persons with the disease or condition for which the drug was designated. If one or more of these events occur, it could have a material adverse effect on our company.

Even if we obtain marketing approval for our product candidates, we could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems.

Even if we obtain marketing approval for our product candidates, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, we will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. In addition, even if marketing approval of our product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. New drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If our product candidates receive marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the products.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our products. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we or any third party partners of ours do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our product, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product, our manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of the product;
- restrictions of product distribution use;
- requirements to conduct post-marketing studies or clinical trials;

Table of Contents

- the need to utilize warning letters;
- suspension or withdrawal of marketing approvals;
- withdrawal of the product from the market or product recalls;
- refusal by regulatory authorities to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenues;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

We may face similar issues in connection with non-compliance with non-U.S. regulatory requirements.

Risks Related to an Investment in Our Securities

An active trading market for our common stock may not develop or be sustained.

An investment in our company will likely require a long-term commitment, with no certainty of return. Although our common stock is listed for quotation on the OTCQB marketplace operated by OTC Markets Group, Inc., trading has been very limited, and we cannot predict whether an active market for our common stock will ever develop in the future. In the absence of an active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;
- market visibility for shares of our common stock may be limited; and
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock.

The OTCQB market is a relatively unorganized, inter-dealer, over-the-counter market that provides significantly less liquidity than NASDAQ or the NYSE American (formerly known as the American Stock Exchange). This illiquid trading market for our common stock may make it difficult for you to dispose of your common stock at desirable prices or at all. Moreover, there is a risk that our common stock could be delisted from the OTCQB, in which case it might be quoted on the OTC Pink Market, which is even more illiquid than the OTCQB.

The lack of an active market impairs your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

Moreover, while we may seek to have our common stock listed on the NASDAQ Stock Market, there is a risk that we will be unable to do so, which would leave our common stock listed on the OTCQB and subject to the foregoing risks of illiquidity.

We may not maintain qualification for OTCQB inclusion, and therefore you may be unable to sell your shares.

Our common stock is eligible for quotation on the OTCQB. However, trading of our common stock could be suspended. If for any reason our common stock does not become eligible or maintain eligibility for quotation on the OTCQB or a public trading market does not develop, purchasers of shares of our common stock may have difficulty selling their shares should they desire to do so. If we are unable to satisfy the requirements for quotation on the OTCQB, any quotation in our common stock could be conducted on the OTC Pink Market, which is an unorganized and often illiquid market. As a result, a purchaser of our common stock may find it more difficult to dispose of, or to obtain accurate quotations as to the price of their shares. This would materially and adversely affect the liquidity of our securities.

Even if a market for our common stock develops, the market price of our common stock may be significantly volatile, which could result in substantial losses for purchasers.

The market price for our common stock may be significantly volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices for securities of biotechnology companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- changes in our relationship with Mayne Pharma
- any delay in or the results of our clinical trials;
- the announcements of clinical trial data, and the investment community's perception of and reaction to those data;
- the results of clinical trials conducted by others on products that would compete with our product candidate;
- any delay or failure to receive NDA acceptance and approval by FDA and other regulatory agencies or bodies;
- our inability to commercially launch our product or market and generate sales of our product;
- failure of our product, even if approved for marketing, to achieve any level of commercial success;
- our failure to obtain or maintain patent protection for any of our technologies and product or the issuance of third-party patents that cover our technologies or product;
- developments or disputes concerning our product's intellectual property rights;
- our competitors' technological innovations;

Table of Contents

- general and industry-specific economic conditions that may affect our expenditures;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents;
- failure to adequately manufacture our product through third parties for purposes of clinical trials or actual sales;
- future sales of our common stock or other securities;
- period-to-period fluctuations in our financial results; and
- low trading volume of our common stock;

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be significant impact on the market price of our common stock. Additionally, as we approach the announcement of anticipated significant information and as we announce such information, we expect the price of our common stock to be particularly volatile, and negative results would have a substantial negative impact on the price of our common stock.

In some cases, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

Our management and two significant stockholders collectively own a substantial majority of our common stock and voting power.

Collectively, our officers, our directors and two significant stockholders (Hedgepath, LLC and Mayne Pharma) own or exercise voting and investment control of approximately 79.9% of our common stock as of the date of this prospectus. As a result, investors may be prevented from affecting matters involving our company, including:

- the composition of our Board of Directors and, through it, any determination with respect to our business direction and policies, including the appointment and removal of officers;
- any determinations with respect to mergers or other business combinations;
- our acquisition or disposition of assets; and
- our corporate financing activities.

Furthermore, this concentration of voting power could have the effect of delaying, deterring or preventing a change of control or other business combination that might otherwise be beneficial to our stockholders. This significant concentration of share ownership may also adversely affect the trading price for our common stock because investors may perceive disadvantages in owning stock in a company that is controlled by a small number of stockholders.

Future sales of our common stock in the public market could lower the price of our common stock and impair our ability to raise funds in future securities offerings.

Significant blocks of our stock are held by Hedgepath, LLC and Mayne Pharma, and these entities also hold warrants to purchase our common stock. Future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for us to raise funds in the future through a public offering of our securities.

Our Series B Preferred Stock held by Mayne Pharma ranks senior to our common stock in the event of a bankruptcy, liquidation or winding up of our assets.

As of the date of this prospectus, Mayne Pharma, our majority stockholder, owns 5,797,102 shares of our Series B Preferred Stock, which we issued in connection with two tranches of our financing with Mayne Pharma which closed in January 2018 and July 2018. In the event of our bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Series B Preferred Stock in preference to the holders of our common stock. There is therefore a risk that in such a case, our common stockholders may see no return on their investment if our assets can only satisfy our obligations to Mayne Pharma as the holder of our Series B Preferred Stock.

Our common stock is considered a “penny stock,” and thereby is subject to additional sale and trading regulations that may make it more difficult to sell.

Our common stock is considered a “penny stock” as it does not qualify for one of the exemptions from the definition of “penny stock” under Section 3a51-1 of the Exchange Act. Our common stock will be a “penny stock” for so long as it meets one or more of the following conditions: (i) the stock trades at a price less than \$5 per share; (ii) it is not traded on a “recognized” national exchange; or (iii) is issued by a company (such as ours) that has been in business less than three years with net tangible assets less than \$5 million.

The principal result or effect of being designated a “penny stock” is that securities broker-dealers participating in sales of our common stock will be subject to the “penny stock” regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act. For example, Rule 15g-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor’s account. Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to: (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor’s financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

FINRA sales practice requirements may also limit your ability to buy and sell our common stock, which could depress the price of our shares.

FINRA rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares, have an adverse effect on the market for our shares, and thereby depress our share price.

You may face significant restrictions on the resale of your shares due to state “blue sky” laws.

Each state has its own securities laws, often called “blue sky” laws, which (1) limit sales of securities to a state’s residents unless the securities are registered in that state or qualify for an exemption from registration, and (2) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or it must be exempt from registration. The applicable broker-dealer must also be registered in that state.

We do not know whether our securities will be registered or exempt from registration under the laws of any state. A determination regarding registration will be made by those broker-dealers, if any, who agree to serve as market makers for our common stock. We have not yet applied to have our securities registered in any state and will not do so until we receive expressions of interest from investors resident in specific states after they have viewed this prospectus. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our common stock to be limited, as you may be unable to resell your shares without the significant expense of state registration or qualification.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company.

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. Given the size of our company and the limited number of fulltime employees that we have employed, there may be certain limitations on the effectiveness of our internal controls. Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all errors and all fraud, if any. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially and adversely impact us.

Because we became public by means other than a traditional initial public offering, we may not be able to attract the attention of major brokerage firms.

Our business was created when certain operating assets were contributed to our company in August 2013 as our company was a “shell company” emerging from bankruptcy. Since our current business became a public company by means other than a traditional initial public offering, investors and securities analysts may be reluctant to invest in or provide research coverage of us. This stigma could impair our fundraising opportunities and our reputation generally.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our company and may affect the trading price of our common stock.

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders.

Table of Contents

In addition, our certificate of incorporation, as amended (which we refer to as the certificate of incorporation), and second amended and restated bylaws (which we refer to as the bylaws) may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. In particular, our certificate of incorporation and bylaws, among other matters:

- permit our Board of Directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our Board of Directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice; and
- do not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election;

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

We do not intend to pay dividends on our common stock.

We have never declared or paid any cash dividend on our common stock. We currently intend to retain any future earnings and do not expect to pay any dividends for the foreseeable future. Therefore, you should not invest in our common stock in the expectation that you will receive dividends.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains a number of "forward-looking statements". Specifically, all statements other than statements of historical facts included in this prospectus regarding our financial position, business strategy and plans and objectives of management for future operations are forward-looking statements. These forward-looking statements are based on the beliefs of management at the time these statements were made, as well as assumptions made by and information currently available to management. When used in this prospectus and the documents incorporated by reference herein, the words "anticipate," "believe," "estimate," "expect," "may," "will," "continue" and "intend," and words or phrases of similar import, as they relate to our financial position, business strategy and plans, or objectives of management, are intended to identify forward-looking statements. These statements reflect our current view with respect to future events and are subject to risks, uncertainties and assumptions related to various factors.

Table of Contents

You should understand that the following important factors, in addition to those discussed in our periodic reports to be filed with the SEC under the Exchange Act, could affect our future results and could cause those results to differ materially from those expressed in such forward-looking statements:

A variety of factors, some of which are outside our control, may cause our operating results to fluctuate significantly. They include:

- acceptance of our business model (namely the repurposing of a specialty formulation of the drug itraconazole for the treatment of cancer, and the potential acquisition or license of other pharmaceutical technologies) by investors and potential commercial collaborators;
- our future capital requirements and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our product candidate and obtain approval from the FDA or other regulatory agencies in different jurisdictions;
- matters associated with the fact that Mayne Pharma is our majority stockholder and key licensor;
- our ability to secure and maintain key development and commercialization partners for our product candidate;
- our ability to obtain, maintain or protect the validity of our patents and other intellectual property;
- our ability to internally develop new inventions and intellectual property;
- our ability to retain key executive members; and
- interpretations of current laws and the passages of future laws, rules and regulations applicable to our business.

Although we believe that our expectations (including those on which our forward-looking statements are based) are reasonable, we cannot assure you that those expectations will prove to be correct. Should any one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, actual results may vary materially from those described in our forward-looking statements as anticipated, believed, estimated, expected or intended.

Except for our ongoing obligations to disclose material information under the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or any other reason. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus and the documents incorporated by reference herein might not occur.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the common stock by the selling stockholders. However, we may receive proceeds from the sale of securities upon the exercise of the warrants issued to the selling stockholders which, if such warrants are exercised in full for cash, would be approximately \$3.3 million. As of the date of this prospectus, we have received approximately \$0.6 million of proceeds from such exercises.

Any net proceeds we receive have been and will be used for general corporate and working capital or other purposes that our Board of Directors deems to be in the best interest of our company. Accordingly, we will retain broad discretion over the use of these proceeds, if any.

DIVIDEND POLICY

We have never declared or paid any cash dividend on our common stock. We do not anticipate paying any cash dividends in the foreseeable future and we intend to retain all of our earnings, if any, to finance our growth and operations and to fund the expansion of our business. Payment of any dividends will be made in the discretion of our Board of Directors, after its taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion. Any dividends that may be declared or paid on our common stock, must also be paid in the same consideration or manner, as the case may be, on our shares of preferred stock, if any.

DETERMINATION OF OFFERING PRICE

The selling stockholders will offer common stock at the prevailing market prices or privately negotiated price.

The offering price of our common stock does not necessarily bear any relationship to our book value, assets, past operating results, financial condition or any other established criteria of value. The facts considered in determining the offering price were our financial condition and prospects, our limited operating history and the general condition of the securities market.

In addition, there is no assurance that our common stock will trade at market prices in excess of the offering price as prices for common stock in any public market will be determined in the marketplace and may be influenced by many factors, including the depth and liquidity.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Holder of Common Stock

As of the date of this prospectus, we have approximately 66 holders of record of our common stock. The number of record holders does not include persons, if any, who hold our common stock in nominee or "street name" accounts through brokers.

Market for Common Stock

Our common stock is listed for quotation on the OTCQB market under the symbol "HPPI", but an established public trading market for our common stock does not exist. The range of reported high and reported low sales prices per share for our common stock for each fiscal quarter during 2018 and 2017 and the quarter ended March 31, 2019, as reported by the OTC Markets Group, is set forth below.

Quarterly common stock Price Ranges

<u>Fiscal Year 2019, Quarter Ended:</u>	<u>High</u>	<u>Low</u>
March 31, 2019	\$0.18	\$0.04
<u>Fiscal Year 2018, Quarter Ended:</u>		
March 31, 2018	\$0.36	\$0.22
June 30, 2018	\$0.36	\$0.26
September 30, 2018	\$0.38	\$0.27
December 31, 2018	\$0.32	\$0.04
<u>Fiscal Year 2017, Quarter Ended:</u>		
March 31, 2017	\$0.41	\$0.24
June 30, 2017	\$0.46	\$0.27
September 30, 2017	\$0.47	\$0.30
December 31, 2017	\$0.42	\$0.19

These sales prices were obtained from the OTC Market Group, Inc. and do not necessarily reflect actual transactions, retail markups, mark downs or commissions. As of April 25, 2019, the last reported sales price of a share of our common stock on the OTCQB was \$0.053. No assurance can be given that an established public market will develop in our common stock, or if any such market does develop, that it will continue or be sustained for any period of time.

Table of Contents

Transfer Agent

Our stock transfer agent is American Stock Transfer & Trust Company, LLC, which is located at 6201 15th Avenue, Brooklyn, New York 11219, Telephone: (347) 977-3223.

Securities Authorized for Issuance under Equity Compensation Plans

The following table indicates as of the date of this prospectus the shares of common stock authorized for issuance under our 2014 Equity Incentive Plan (or EIP), subject to approval by our majority stockholders:

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u> (a)	<u>Weighted average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
Equity compensation plans approved by security holders (1)	6,384,527 (2)	\$ 0.19 (2)	10,457,210

- (1) The EIP was adopted by the Board of Directors and approved by a majority of our stockholders on September 30, 2014. The Board of Directors approved an increase to the number of shares available for issuance under the EIP of 11,000,000 shares which was subsequently approved by our majority shareholder in December 2018.
- (2) Outstanding securities issued pursuant to our EIP are 6,384,527 stock options. 650,000 stock options were issued on July 1, 2016 with an exercise price of \$0.24 per share and vested upon a change in control in November 2016. 1,862,000 stock options were issued on March 13, 2018 with an exercise price of \$0.2722 per share. 758,000 of those March 13, 2018 options vested on the grant date with the balance vesting on March 13, 2019. 912,000 stock options were issued on June 15, 2018 with an exercise price of \$0.33 per share and vest on June 15, 2019. 2,960,527 stock options were issued on February 3, 2019 with an exercise price of \$0.076 per shares and vest on February 3, 2020.

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

The following discussion and analysis is based on, and should be read in conjunction with our financial statements, which are included elsewhere in this prospectus. Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. These statements are based on current expectations and assumptions that are subject to risk, uncertainties and other factors. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Actual results could differ materially because of the factors discussed in "Risk Factors" elsewhere in this prospectus, and other factors that we may not know.

Background of Our Company

We are a pharmaceutical development company that is seeking to discover, develop and ultimately commercialize innovative therapeutics for patients with certain cancers and non-cancerous proliferation disorders. We also have explored and expect to continue to explore acquiring or licensing other innovative pre-clinical and clinical stage therapeutics addressing unmet needs and orphan indications for the treatment of cancer and other diseases.

Our current primary focus is on the development of therapies initially for prostate and also lung cancers in the United States utilizing SUBA-Itraconazole, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole to which we hold an exclusive U.S. license from our majority stockholder, Mayne Pharma, for certain

Table of Contents

cancers and non-cancerous proliferation disorders. We previously conducted a positive Phase 2(b) study of SUBA-Itraconazole for the treatment of Basal Cell Carcinoma Nevus Syndrome, and Mayne Pharma assumed control of the clinical and regulatory development of this indication in December 2018 as described elsewhere in this prospectus.

SUBA-Itraconazole was developed and is licensed to us by our majority stockholder Mayne Pharma under a Supply and License Agreement, originally dated September 3, 2013, and most recently amended and restated in December 2018. Mayne Pharma is an Australian specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes directly or through distribution partners and provides contract development and manufacturing services. In addition to being our licensor and supplier, under the Supply and License Agreement and related agreements, Mayne Pharma holds a majority equity stake in our company and holds important rights with respect to our company, such as the right (in its discretion) to appoint and remove members of our Board of Directors.

We were founded under the name “Commonwealth Biotechnologies, Inc.” in Virginia in 1992, and completed an initial public offering in October 1997. CBI previously provided, on a contract basis, specialized life sciences services to the pharmaceutical and biotechnology sector. On January 20, 2011, CBI filed a voluntary petition for bankruptcy. We recommenced our current operations in August 2013 as a Delaware corporation following the emergence of CBI from its voluntary bankruptcy proceedings.

Critical Accounting Policies and Estimates

Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Revenue Recognition

We currently have no ongoing source of revenues. Any miscellaneous income is recognized when earned. Deferred revenue represents cash received for royalties in advance of being earned. Such payments are reflected as deferred revenue until recognized under our revenue recognition policy. Deferred revenue would be classified as current if management believes we will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date. Deferred revenue will be recognized when the product is sold and the royalty is earned. Since all deferred revenue on our balance sheet is related to the BCCNS product which is yet to be approved by FDA, we have determined that 100% of the advances of the royalty received by Mayne Pharma should be classified as non-current.

Cash and Cash Equivalents

We consider all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, we may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts which is up to \$250,000 for substantially all depository accounts. As of December 31, 2018, we had approximately \$0.8 million in excess of the amount covered by Federal Deposit Insurance Corporation with one financial institution.

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties who conduct research and development activities on our behalf as well as purchased in-process research and development.

Stock-Based Compensation

We account for stock-based awards to employees and non-employees using Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 718 – Accounting for Share-Based Payments,

[Table of Contents](#)

which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of RSUs issued are determined based predominantly on the trading price of the common stock on the date of grant. Fair value of each common stock option is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of a peer group's common stock and other factors estimated over the expected term of the options. The expected term of the options granted is derived using the "simplified method" which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

In applying the Black-Scholes option pricing model for options issued in March 2018 that vested on the grant date, the assumptions were as follows: expected price volatility of 113.67%; risk-free interest rate of 2.64%; weighted average expected life in years of 5; and no dividend yield. In applying the Black-Scholes option pricing model for options issued in March 2018 that will vest on the anniversary of the grant date, the assumptions were as follows: expected price volatility of 116.59%; risk-free interest rate of 2.64%; weighted average expected life in years of 6; and no dividend yield. In applying the Black-Scholes option pricing model for options issued in June 2018 that will vest on the anniversary of the grant date, the assumptions were as follows: expected price volatility of 112.6%; risk-free interest rate of 2.81%; weighted average expected life in years of 6; and no dividend yield. The value of these awards is based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

Income taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. We have evaluated the guidance relating to accounting for uncertainty in income taxes and determined that we had no uncertain income tax positions that could have a significant effect on the consolidated financial statements for the years ended December 31, 2018 or 2017. Deferred tax assets consist primarily of in-process research and development, net operating loss carryforward, and share-based compensation. We recorded a 100% valuation allowance against the deferred tax assets as we have determined such amounts will not be currently realizable.

Recent accounting pronouncements

In May 2014, FASB issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of ASC Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. We have evaluated the impact of adoption of this standard on our financial statements, which was effective January 1, 2018, and determined it had no material impact.

In February 2016, the FASB issued ASU 2016-02, "Leases," which created a new Topic, ASC Topic 842 and established the core principle that a lessee should recognize the assets, representing rights-of-use, and liabilities to make lease payments that arise from leases. For leases with a term of 12 months or less, a lessee is permitted to make an election under which such assets and liabilities would not be recognized, and lease expense would be recognized generally on a straight-line basis over the lease term. This standard is effective for us beginning in 2019, and early application is permitted. We have evaluated the potential impact of this guidance and do not believe it will have a material impact on our financial statements.

In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing." ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. This ASU applies to all companies that enter into contracts with customers to

transfer goods or services. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2017. We have evaluated the potential impact of this guidance, which was effective January 1, 2018, and determined it had no material impact on our financial statements.

Results of Operations

For the Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017

Research and Development Expenses. We recognized \$2,633,567 and \$2,227,589 in research and development expenses during the years ended December 31, 2018 and 2017, respectively. The increase of approximately \$0.4 million was due primarily to an increase in consulting associated with the Phase 2(b) BCCNS trial that we were conducting prior to the December 2018 transaction with Mayne Pharma.

General and Administrative Expenses. We recognized \$1,930,690 and \$2,891,442 in general and administrative expenses during the years ended December 31, 2018 and 2017, respectively. The decrease of approximately \$1.0 million was due primarily to a reduction of \$1.2 million in stock-based compensation following the vesting in 2017 of a significant number of RSUs that were fully expensed in 2017. Compensation expense increased by approximately \$0.2 million primarily due to contractual pay increases and bonuses.

Interest Income. We recognized interest income during the year ended December 31, 2018 and 2017 of \$14,027 and \$17,866, respectively, for interest earned on cash balances in our money market account.

Liquidity and Capital Resources

We are presently developing and conducting our clinical and regulatory business plans and are exploring the potential acquisition or license of additional product candidates. Our current cash on hand is insufficient to develop our full clinical and regulatory business plan as currently anticipated or to acquire or license additional product candidates. A continued lack of cash resources resulting from an inability to generate cash flow from operations and royalties or to raise capital from external sources would force us to substantially curtail or cease operations and would, therefore, have a material adverse effect on our business and overall viability.

We intend to finance our research and development, commercialization and distribution efforts, any acquisitions or investments and our working capital needs primarily through:

- public and private financings and, potentially, other strategic transactions (including, most recently, financings from our majority shareholder, Mayne Pharma);
- advances from Mayne Pharma of potential future royalties on the SUBA-Itraconazole BCCNS product available under the Supply and License Agreement;
- royalty revenue from Mayne Pharma from sales of SUBA-Itraconazole BCCNS upon approval by FDA (after earned royalties have been applied to any advances due under the Supply and License Agreement)
- proceeds from the exercise of outstanding warrants previously issued in private financings (including, potentially, warrants held by our majority shareholder, Mayne Pharma);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and
- seeking government or private foundation grants which would be awarded to us to further develop our current and future anti-cancer therapies.

However, there is a risk that none of these plans will be implemented in a manner necessary to sustain us for an extended period of time and we will be unable to obtain additional financing when needed on commercially reasonable terms, if at all. If adequate funds are not available when needed, we may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require us to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on us.

Table of Contents

Contractual Obligations and Commercial Commitments

There are no non-cancellable contractual obligations as of December 31, 2018.

Off Balance Sheet Arrangements

We are not a party to any off-balance sheet arrangements.

BUSINESS

Overview

We are a pharmaceutical development company that is seeking to discover, develop and ultimately commercialize innovative therapeutics for patients with certain cancers and non-cancerous proliferation disorders. We also have explored and expect to continue to explore acquiring or licensing other innovative preclinical and clinical stage therapeutics addressing unmet needs and orphan indications for the treatment of cancer and other diseases.

Our current primary focus is on the development of therapies initially for prostate and also lung cancers in the United States utilizing SUBA-Itraconazole, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole to which we hold an exclusive U.S. license in the licensed field from our majority stockholder, Mayne Pharma. We previously conducted a Phase 2(b) study of SUBA-Itraconazole BCCNS for the treatment of Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome), and Mayne Pharma assumed control of the clinical and regulatory development of this indication in December 2018 as described below.

Our current regulatory strategy for clinical development is driven by the so called 505(b)(2) regulatory pathway, under which a drug (in our case, itraconazole) that has already been approved for use in humans in the United States by the FDA is developed for one or more new medical indications (such as an anti-cancer agent). Due to the history of safe and efficacious use of itraconazole in humans for anti-fungal applications, we believe the 505(b)(2) pathway will be available to us for other indications based upon concurrence by FDA with our previous SUBA-Itraconazole BCCNS clinical program. We believe that our utilization of the 505(b)(2) pathway when available creates the potential for significantly reducing the risk and time to achieve FDA approval of our other cancer therapies compared to the program required for new chemical entities.

SUBA-Itraconazole

SUBA-Itraconazole is currently exclusively licensed to us in the United States by Mayne Pharma in the fields of (i) any prostate cancer, prostatic intraepithelial neoplasia and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia, and (iii) familial adenomatous polyposis, colorectal polyps and Barrett's esophagus (we refer to these fields herein collectively as the licensed field). We believe that the dosing of oral capsules of SUBA-Itraconazole can affect the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as prostate cancer and lung cancer. Itraconazole has been approved by the FDA for, and has been extensively used to treat, fungal infections and has an extensive history of safe and effective use in humans.

Table of Contents

SUBA technology is designed to enhance the bioavailability of orally administered drugs that are poorly soluble. In studies conducted by Mayne Pharma relating to the anti-fungal use of SUBA-Itraconazole, SUBA-Itraconazole demonstrated improved absorption and significantly reduced variability within and between patients compared to the branded and generic forms of itraconazole in human studies. We believe this technology is well-suited for the exploration of the potential anti-cancer effects of itraconazole. The predicted benefits of the SUBA-Itraconazole formulation are as follows:

- polymer drug dispersion technology (which is utilized in SUBA-Itraconazole) has been demonstrated to deliver itraconazole with 90% bioavailability;
- Itraconazole absorption is not dependent on an acidic stomach;
- SUBA-Itraconazole is released in the lower pH conditions found in the intestine, thus improving drug delivery and bioavailability;
- SUBA-Itraconazole levels have been demonstrated to be more consistent within patients and between patients compared to generic or branded itraconazole;
- SUBA-Itraconazole can be taken with or without food or acidic beverages; and
- there are no restrictions regarding achlorhydric patients (low acid stomach) or patients with acid reflux (requiring proton-pump inhibitors).

The foregoing characteristics led us to believe that SUBA-Itraconazole could be well-suited for chronic use in treating cancer and non-cancerous proliferation disorders due to its more predictable therapeutic levels and lower toxicity, and we were able to validate these assumptions in our Phase 2(b) clinical trial for SUBA-Itraconazole BCCNS.

In contrast, we believe that the use of the non-SUBA formulation of itraconazole to treat cancer and non-cancerous proliferation disorders would be more challenging due to the following characteristics of branded and generic formulations:

- poor drug delivery resulting in bioavailability of only 55%;
- inconsistent blood plasma levels in individual patients and between patients;
- the need to eat a meal and take acidic beverages with drug dosing to control pH;
- the need for achlorhydric (low acid stomach) patients to maximize bioavailability with acidic beverages; and
- many patients require proton-pump inhibitor drugs to control acid reflux, resulting in gastric conditions that are not favorable for absorption from non-SUBA formulations of itraconazole.

SUBA-Itraconazole was developed and is licensed to us by our majority stockholder Mayne Pharma under a Supply and License Agreement, most recently updated in December 2018. Mayne Pharma is an Australian specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes directly or through distribution partners and also provides contract development and manufacturing services. In addition to being our licensor and supplier under the Supply and License Agreement and related agreements, Mayne Pharma holds a majority equity stake in our company and holds important rights with respect to our company, such as the right to appoint members to our Board of Directors.

We commenced our Phase 2(b) clinical trial for SUBA-Itraconazole BCCNS in the third quarter of 2015, and we announced positive interim trial data in 2016 and 2017. In October 2017, we announced that we had completed enrollment for this Phase 2(b) trial. In September 2018, we held a face-to-face meeting with representatives of FDA to discuss the requirements for our proposed NDA for SUBA-Itraconazole BCCNS. During the meeting, FDA confirmed that it has agreed with our interpretation of 8 of the 11 NDA requirements discussed at the meeting. For the remaining three items, FDA provide us with guidance on items which, if lacking from the NDA submission, would lead the FDA to not accept the filing. First, FDA instructed us to update our efficacy and safety information to include more recent data than our proposed cutoff date of December 2017 in order to provide additional data on the ten remaining patients who were still being treated beyond December 2017. FDA also indicated that we were required to provide an analysis of basal cell carcinoma tumor burden responses via independent analysis of tumor photographs (which we had already taken) to confirm results reported by the clinical investigators. FDA also requested that we submit an Integrated Safety Summary that would include data not only from our clinical trial, but all human trials of SUBA-Itraconazole regardless of strength and indication. To satisfy this request, we learned that we were required to include data from trials that had been conducted by Mayne Pharma using SUBA-Itraconazole, including pharmacokinetic studies in healthy human volunteers and clinical studies in other indications using lower dosing levels with and shorter dosing periods.

Table of Contents

Based on this meeting with FDA, we concluded that our estimated timeline for submitting the SUBA-Itraconazole BCCNS NDA would need to be revised from sometime during the fourth quarter of 2018 to sometime during the first quarter of 2019. However, under our Supply and License Agreement, Mayne Pharma had the right to assume control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS if we were unable to have the SUBA-Itraconazole BCCNS NDA accepted by FDA for filing by December 31, 2018 (subject to a possible maximum extension of 30 days if the NDA was filed in December). As a result of unexpected FDA guidance, we determined that we would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus we commenced negotiations with Mayne Pharma to allow Mayne Pharma to assume such control of the SUBA-Itraconazole BCCNS program on an expedited basis in December 2018 in exchange for (among other consideration) a 9% quarterly cash royalty on future net sales, if any, of SUBA-Itraconazole BCCNS in the United States. See “Certain Relationships and Related Party Transactions” for further information.

In May 2016, we received notice from FDA of Orphan Drug Designation for SUBA-Itraconazole BCCNS. The FDA, through its Office of Orphan Products Development, grants orphan status to drugs and biologic products that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S. Orphan drug designation provides a drug developer with certain benefits and incentives, including a period of marketing exclusivity if regulatory approval is ultimately received for the designated indication.

University of Connecticut Itraconazole Analogue Technology

In July 2018, we signed an exclusive option agreement with UConn related to patents and patent applications covering certain chemical analogues of itraconazole (such analogues represent separate intellectual property from SUBA-Itraconazole). We believe that having access to UConn’s itraconazole analogue technology could create the potential for us to expand our developmental pipeline of clinical stage itraconazole-based treatments for certain cancers.

The UConn itraconazole analogues have modifications to particular regions of the itraconazole scaffold. The patents and patent applications include compositions of matter claims covering the itraconazole analogues and method claims covering their use for the treatment of cancer. Data suggest that certain of these analogues maintain potent Hedgehog Pathway inhibition while exhibiting improved pharmacokinetic parameters and reduced off-target side effects sometimes associated with itraconazole.

The option agreement, which went into effect on August 1, 2018, grants us an exclusive option period of twelve (12) months until July 31, 2019. The optioned field of use includes all therapeutic, prophylactic, and diagnostic uses for cancerous and non-cancerous cell proliferation disorders in humans. During the term of exclusivity, UConn will not offer third parties the opportunity to license the patent portfolio within this field of use. During the option period, we are permitted to use the UConn technology for internal research and evaluation purposes, and we have the right during the option period to negotiate a customary license from UConn for its technology and know-how related to the subject technology. Should pre-clinical testing results look promising related to efficacy and safety, we would expect to proceed with negotiations to license the technology. Pursuant to the option agreement, we have made payments to UConn of \$20,000 in order to secure the option.

Intellectual Property

We strive to protect the intellectual property that we believe will be important to our business, including seeking our own patent protection (or seeking licenses to patents) intended to cover the composition of matter of our product candidates, their methods of use, related technology and other inventions that are important to our business.

We have developed, licensed, optioned to license, and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole-based compounds. Under our Supply and License Agreement with Mayne Pharma, we have exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole Capsules for the treatment of certain cancers and non-cancerous proliferation disorders via oral administration.

Table of Contents

On September 2, 2015, we entered into the Sublicense Agreement with an affiliate of Mayne Pharma pursuant to which such affiliate sublicensed to us the exclusive U.S. rights to two patents regarding the use of itraconazole for treatment of cancer, namely US patent No 8,980,930 entitled “Angiogenesis Inhibitors”, issued on March 17, 2015, and US patent No 8,653,083 entitled “Hedgehog Pathway Antagonists to Treat Disease”, issued on February 28, 2014 in the licensed filed. Such affiliate is the sublicensee of the patents from Accelas Holdings, a British Virgin Islands company, who in turn is the licensee from The Johns Hopkins University, the owner of the patents. The patents relate to the use of itraconazole as a treatment for cancer and age-related macular degeneration.

The following is a summary of intellectual property in the form of issued U.S. patents we own, or for which we have exclusive licenses, regarding the use of itraconazole, and more specifically SUBA-Itraconazole, as an anti-cancer therapy.

Johns Hopkins University Patents Sublicensed to Accelas Holdings/Mayne Pharma/HedgePath: we have worked in concert with Mayne Pharma to sublicense rights to the following two Johns Hopkins University (JHU) patents for the use of itraconazole as a treatment for cancer as a Hedgehog Pathway Inhibitor and as an Angiogenesis Inhibitor:

Johns Hopkins University US Patent 8,653,083
Hedgehog Pathway Antagonists to Treat Disease
Issued: 02-18-2014; Expires: 04-09-2028

Johns Hopkins University US Patent 8,980,930
Angiogenesis Inhibitors
Issued: 03-17-2015; Expires: 02-04-2029

Mayne Pharma Intellectual Property Licensed to HedgePath: Four issued patents have been licensed to us by Mayne Pharma concerning the manufacturing and composition of matter for SUBA-Itraconazole, for which we are implementing clinical and regulatory programs to enable the repurposing of itraconazole to treat cancer. This strategy is intended to significantly reduce the risk and time to potential FDA approvals for marketing in the United States as evidenced via the clearance by FDA for us to proceed directly into a Phase 2(b) human trial which we commenced in August 2015 and agreement by FDA that, based upon the results demonstrated in the Phase 2(b) trial, we could follow the 505(b)(2) regulatory pathway. The patents that are licensed to us by Mayne Pharma are as follows:

Mayne Pharma US Patent 6,881,745
Pharmaceutical Compositions for Poorly Soluble Drugs
Issued: 04-19-2005; Expires: 12-22-2020

Mayne Pharma US Patent 8,771,739
Pharmaceutical Compositions for Poorly Soluble Drugs
Issued: 07-08-2014; Expires: 12-16-2022

Mayne Pharma US Patent 8,921,374
Itraconazole Compositions and Dosage Forms and Methods Using Same
Issued: 12-30-2014; Expires: 06-21-2033

Mayne Pharma US Patent 9,272,046
Itraconazole Compositions and Dosage Forms and Methods Using Same
Issued: 03-01-2016; Expires: 06-21-2033

HedgePath Intellectual Property: We were issued a patent by the US Patent and Trademark Office (or USPTO) on November 24, 2015 (US Patent 9,129,609, *Treatment and Prognostic Monitoring of Proliferation Disorders Using Hedgehog Pathway Inhibitors*, expires 02-05-2034). On May 8, 2018, we were issued a patent by

Table of Contents

the USPTO for US Patent 9,962,381, *Treatment and Prognostic Monitoring of Cancerous Proliferation Disorders Using Hedgehog Pathway Inhibitors*, expires 02-05-2034; and on May 15, 2018, we were issued a patent by the USPTO for US Patent 9,968,600, *Treatment and Prognostic Monitoring of Non-Cancerous Proliferation Disorders Using Hedgehog Pathway Inhibitors*, expires 02-05-2034.

In addition, as described above, we have an option to be the exclusive licensee of certain chemical analogues of itraconazole owned by UConn.

We also plan to continue to expand our intellectual property estate and are filing patent applications directed to dosage forms, methods of treatment, therapies for other cancers and additional Hedgehog inhibitor compounds and their derivatives. We will also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The Hedgehog Pathway

Based on the results of physician-sponsored studies conducted by others (including in vitro, animal and human studies), and our direct testing in our Phase 2(b) trial in patients with SUBA-Itraconazole BCCNS, we believe that itraconazole affects the Hedgehog signaling pathway in cells, which in turn impacts the development and growth of certain cancers. The studies, conducted at prominent medical institutions, primarily in the United States, were published in the *Journal of Thoracic Oncology*, *The Oncologist* and the *Journal of Clinical Oncology* between May 2013 and February 2014. Based on these studies, as well as our own observations and results in our Phase 2(b) trial conducted to test SUBA-Itraconazole BCCNS, it appears that itraconazole has notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and will continue to be the subject of on-going research. These studies and our own work in the clinic formed the basis of our continued interest in the clinical development of itraconazole for treatment of human cancers.

The Hedgehog signaling pathway is a major regulator of many fundamental cellular processes in vertebrates, including primarily at the embryonic stage of development but also as it relates to stem cell maintenance, cell differentiation, tissue polarity and cell proliferation. Based on published research and our experience in human testing, we believe that inhibiting the Hedgehog pathway can delay or possibly prevent the development of certain cancers in patients. Research has shown that activation of the Hedgehog pathway can lead to the formation of cancerous tumors (a process known as tumorigenesis) such as the most common form of skin cancer known as basal cell carcinoma which was the first form of cancer we studied in our Phase 2(b) trial with SUBA-Itraconazole BCCNS. A variety of other human cancers, including brain, gastrointestinal, lung, breast and prostate cancers, also demonstrate inappropriate activation of this pathway. Hedgehog signaling from the tumor to the surrounding cell structures has been shown to sometimes promote further tumorigenesis as well. This pathway has also been shown to regulate proliferation of cancer stem cells and to increase tumor invasiveness.

We believe that the targeted inhibition of Hedgehog signaling is or may be effective in the treatment and prevention of many types of human cancers. We also believe that the discovery and synthesis of specific Hedgehog pathway inhibitors may have significant clinical implications regarding the development of novel cancer therapies. Several synthetic Hedgehog antagonists are now being studied, some of which are undergoing clinical evaluation. The orally available compound, Erivedge®, vismodegib, developed by Curis and sold to Genentech, Inc. (a subsidiary of Roche), is the first Hedgehog inhibitor based-therapy and Odomzo®, sonidegib (developed by Novartis and sold to Sun Pharma by Novartis) is the second orally available compound, that has been approved for treatment of advanced stages of basal cell carcinoma by the FDA. Most recently, in 2018, Daurismo®, glasdegib oral capsules developed by Pfizer, was approved by FDA for use in combination with low-dose cytarabine for patients with newly-diagnosed acute myeloid leukemia (AML), aged 75 or older who are too frail to be treated with intensive chemotherapy.

Repurposing Itraconazole for Treating Cancer

We are implementing clinical and regulatory plans to enable the repurposing of itraconazole, via the use of SUBA-Itraconazole oral capsules, for the treatment of a variety of cancers. This strategy is intended to significantly reduce the risk and time to potential FDA approvals for marketing in the United States. Target applications under our license agreement with Mayne Pharma include therapies for prostate and lung cancers and certain other non-cancerous proliferation disorders.

Table of Contents

Itraconazole appears to have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of ongoing research. These anti-cancer effects have been demonstrated in various animal models and, subsequently in human studies over the last few years, including our own Phase 2(b) trial of SUBA-Itraconazole BCCNS. Those models and studies continue to be the basis of our interest in the clinical development of SUBA-Itraconazole for treatment of human cancers and non-cancerous proliferation disorders. We believe that our development of SUBA-Itraconazole as an anti-cancer therapy has demonstrated its potential effective use as an inhibitor of the Hedgehog pathway, thereby retarding the progression of a cancer, as demonstrated in our SUBA-Itraconazole BCCNS trial.

In animal models, itraconazole has also demonstrated an anti-angiogenic effect (i.e., inhibiting the formation of new blood vessels), which may be important in controlling the proliferation of cancerous cells and tumors in humans based upon its interaction with certain cell-based growth factors. Itraconazole also appears to induce changes related to the mTOR pathway, an important regulator of cell growth, proliferation and survival which, when unregulated, can also lead to cancer. These effects have been demonstrated in a physician-based study conducted to test the effects of itraconazole on late-stage lung cancer.

We also believe that the use of SUBA-Itraconazole to treat each of our target patient populations has the potential to benefit from various FDA programs designed to expedite the approval process.

Prostate Cancer

Itraconazole has already been tested as a treatment for men with metastatic castrate resistant prostate cancer (mCRPC) in a multi-institutional Phase 2 trial led by Johns Hopkins University and completed in 2011 and published in 2013, which showed that, at a specified dose, there was a significant correlation to slowing the progression of cancer and extending survival. Based on those encouraging results in metastatic disease, we are planning to test SUBA-Itraconazole in high-risk men with mCRPC (who are castrate resistant based on prior drug therapy or surgery) who are no longer responding to androgen deprivation therapy (ADT) to study the effect of itraconazole therapy in combination with chemotherapy in delaying disease progression. We refer to this product opportunity as SUBA-Itraconazole Prostate. Recommended therapy for these men is the drug docetaxel which is dosed in combination with prednisone. We believe that the addition of SUBA-Itraconazole to this regimen may have a significant effect on disease progression based upon the inhibition of the Hedgehog pathway which is up-regulated in this patient population, as well as the enhancement of the chemotherapy which has been previously reported in animal models for prostate cancer.

Our 2019 goals for SUBA-Itraconazole Prostate are to submit and receive clearance from FDA for an Investigational New Drug Application (“IND”) (including a clinical trial design) for SUBA-Itraconazole Prostate and to commence the human testing of SUBA-Itraconazole Prostate in conjunction with chemotherapy for the treatment of late-stage prostate cancer.

Lung Cancer

Physicians treating patients with advanced non-squamous non-small cell lung cancer (NSCLC, most often caused by cigarette smoking) have a variety of options when considering therapies to extend survival, particularly based upon recent approvals of immunotherapies, known as checkpoint inhibitors for PD-L1 (programmed death ligand 1) such as Keytruda®, pembrolizumab marketed by Merck and approved by FDA in 2017 and potentially useful in about 25% of patients. However, if patients are not candidates for immunotherapy based on genetic marker testing (PD-L1 positive) or do not have mutations for EGFR (epidermal growth factor receptor, 15% of patients), ALK (anaplastic lymphoma kinase, 3-5% of patients), ROS1 (c-ros oncogene 1, 1-2% of patients) or BRAF (proto-oncogene B-Raf, 1-3% of patients) in order to be treated with tyrosine kinase inhibitors, they will be given chemotherapy, in particular, platinum based doublet therapy with pemetrexed (Alimta®). With a median survival of only 8-10 months while on these approved chemotherapy regimens, we believe that new therapies for these patients are needed. We believe that the pre-clinical data and reported human data between 2011 and 2018 on the use of itraconazole in conjunction with chemotherapy reflects positively on the use of itraconazole as an anti-cancer therapy for this form of lung cancer in patients who do not present with markers that enable their treatment with the agents mentioned above. If these data prove to be applicable to human treatment by improving survival, while dosing SUBA-Itraconazole in combination with chemotherapy therapy (the combination of platinum-based chemotherapy drugs in conjunction with pemetrexed), the treatment may qualify for one or more FDA accelerated programs, such as a breakthrough therapy or fast track status.

Table of Contents

Our 2019 goals for SUBA-Itraconazole for the treatment of NSCLC are to prepare for a pre-IND Meeting Request with FDA in 2020 should we have adequate funding to undertake a second clinical study in addition to our SUBA-Itraconazole Prostate Program.

Basal Cell Carcinoma

Utilizing SUBA-Itraconazole to treat BCC in patients with Gorlin Syndrome was the first indication that we studied in a Phase 2(b) trial which was launched in August of 2015. We began recruiting and dosing subjects during the fourth quarter of 2015, and we completed enrollment in the fourth quarter of 2017. Individuals who were enrolled in this trial must have been diagnosed with Gorlin Syndrome and had numerous BCC tumors as well as met well-defined inclusion criteria in order to qualify for enrollment and treatment with SUBA-Itraconazole.

Gorlin Syndrome is caused by a mutation in a gene called PTCH1. This mutation causes PTCH to lose its ability to inhibit SMO (a protein receptor of the Hedgehog pathway) which controls Hedgehog Pathway signaling. With SMO not being inhibited, BCCNS patients develop multiple BCC tumors over weeks, months and years on a continued basis. SUBA-Itraconazole is therefore being tested to study its ability to bind to SMO (itraconazole has demonstrated SMO binding in animal and human studies), thus inhibiting Hedgehog pathway activity which leads to the formation of the BCC tumors in these patients. The key objective of our Phase 2(b) trial was to demonstrate patient benefit by reducing tumor burden that requires on-going intervention for tumor growth via surgery and/or use of more toxic Hedgehog inhibitor therapies. Mayne Pharma assumed control of the SUBA-Itraconazole BCCNS program in December 2018 in exchange for (among other consideration) a 9% quarterly cash royalty on future net sales, if any, of SUBA-Itraconazole BCCNS in the United States. See “Certain Relationships and Related Party Transactions” for further information.

Our Potential Market

The following table depicts our current estimate of the total available market opportunity for our proposed anti-cancer therapies based upon independent market research, scientific and industry publications and management’s knowledge of the U.S. oncology market. Our estimates (including estimated product pricing) are based on current assumptions and are subject to change.

HedgePath Pharmaceuticals, Inc. – Summary Estimated U.S. Market Opportunity

<u>Cancer Type</u>	<u>Therapy Indication</u>	<u>Potential for SUBA-Itraconazole</u>	<u>Target Patient Population</u>	<u>U.S. Total Available Market*</u>
Prostate (1)	Patients with metastatic castrate resistant prostate cancer (mCRPC) and rising PSA levels no longer responding to androgen deprivation therapy (ADT)	Delay the progression of metastatic disease	23,000 high-risk men with metastatic prostate cancer who are no longer responding to ADT due to biochemical resistance	\$215Million at Yr 5 (\$843M cumulative from launch) based on HedgePath estimates of ~ \$4,000 - \$5,000 monthly cost of 2 nd line therapy
Lung (2)	Patients with advanced non-squamous cell, non-small cell lung cancer (NSCLC) who will be placed on Platinum Doublet/Pemetrexed IV Therapy	Improve the current median 8 - 10 month survival achieved with best supportive care for patients who are not eligible for treatment with tyrosine kinase or checkpoint inhibitors	45,000 men and women with late-stage disease who may be treated with chemotherapy if not eligible for other therapies	\$270Million at Yr 5 (\$945M cumulative from launch based on HedgePath estimates of ~ \$4,000 - \$5,000 monthly cost of 2 nd or 3 rd line therapy

Table of Contents

Cancer Type	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market*
Skin (3)	Patients with BCC (basal cell carcinoma) lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring surgery Potential for follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures	Less toxic therapy than vismodegib or sonidegib for Gorlin Patients to delay surgeries; low toxicity therapy to delay or minimize surgical intervention for head and neck BCC tumors	10,000 Gorlin patients needing chronic BCC therapy; 65,000 BCC patients pending surgical treatment for facial tumors that require excision and potential plastic surgery	\$300M for Gorlin patients for which HPPI receives a 9% royalty on net sales in the US based upon licensing the indication to Mayne Pharma; and \$600M for patients with BCC facial lesions requiring surgery based upon HedgePath/Mayne Pharma estimates of ~ \$4,000 - \$5,000 monthly cost of therapy for target populations

* **Estimated**

References:

- (1) *J. Urology, 2003; Oncology, 2004; American J. Hematologic Oncology, 2014; NIH NCI SEER 2014; Medscape, 2015; Future Oncology 2015; Global Data 2015; Pennside Partners 2017*
- (2) *STATS MGU, 2009; Global Industry Analysts, 2010; World Health Organization, 2015; Cost of Treating Lung Cancer, 2012; LUNGevity Foundation 2017; NEJM 2015; Pennside Partners 2017*
- (3) *J Am Academy Dermatology, 2006; Skin Cancer Foundation, 2009; International Medicine News, 2011; Seeking Alpha, 2017; BCCNS Life Support Network 2017, Genetics Home Reference 2015; Pennside Partners 2016*

Our Strategy

Our goal is to be a leader in the development and commercialization of itraconazole-based therapeutics for the treatment of cancer patients and patients with non-cancerous proliferation disorders. We believe that we can accomplish this goal by implementing the following key elements of our business strategy:

- *Rapidly Advance the Clinical Development of Our Therapies.* With the history of safe use of itraconazole in humans for anti-fungal indications, we bypassed each of the required pre-clinical animal studies for toxicity and Phase 1 human trials to establish safety for SUBA-Itraconazole BCCNS, and therefore were able to move directly into Phase 2 human trials. We would expect to replicate this outcome with SUBA-Itraconazole Prostate and other SUBA-Itraconazole treatments.
- *Seek FDA Programs to Expedite Drug Approvals.* The FDA has various programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. These expedited programs help ensure that therapies for serious conditions are available as soon as it can be concluded that the therapies’ benefits justify their risks, taking into account the seriousness of the condition and the availability of alternative treatments. These programs include breakthrough therapy designation, fast track designation, accelerated approval, and priority review. We believe that SUBA-Itraconazole for the treatment of cancer may qualify for one of these designations, which could help expedite the regulatory review process.
- *Commercialize and Market with Exclusivity.* We are developing specific clinical trial designs to address different forms of cancer and non-cancerous proliferation disorders in order to pursue FDA approvals for multiple indications. Further, we believe SUBA-Itraconazole can be commercialized in a way that maximizes benefits for patients, based on our specific therapy regimens, while eliminating generic substitution and providing us with market exclusivity protections through our intellectual property rights.

Table of Contents

In addition, we have explored and expect to continue to explore acquiring or licensing other innovative pre-clinical and clinical stage therapeutics addressing unmet needs and orphan indications for the treatment of cancer and other diseases. This activity (an example of which is our option agreement with UConn) is aimed at expanding our product candidate portfolio.

We have and expect to continue to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- proceeds from public and private financings (including, most recently, financing from our majority shareholder, Mayne Pharma) and, potentially, from strategic transactions;
- advances from Mayne Pharma of potential future royalties on the SUBA-Itraconazole BCCNS product available under the Supply and License Agreement;
- royalty revenue from Mayne Pharma from sales of SUBA-Itraconazole BCCNS upon and assuming approval by FDA (after earned royalties have been applied to any advances due under the Supply and License Agreement);
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including potentially, warrants held by our Mayne Pharma, our majority stockholder);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and/or
- seeking government or private foundation grants or loans which would be awarded to us to further develop our current and future anti-cancer therapies.

Background on Cancer

Cancer is a heterogeneous group of diseases characterized by uncontrolled cell division and growth. Cancerous cells that arise in the lymphatic system and bone marrow are referred to as hematological tumors. Cancer cells that arise in other tissues or organs are referred to as solid tumors. Researchers believe that exposure to some chemicals, viruses and various forms of radiation can cause genetic alterations that cause cancer. Genetic predispositions also can increase the risk of cancer in some people.

Cancer is the second leading cause of death in the United States, exceeded only by heart disease. The American Cancer Society estimates that in 2017 there were approximately 1.7 million new cases of cancer and approximately 601,000 deaths from cancer in the United States.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy. A cancer patient often receives treatment with a combination of these methods. Surgery and radiation therapy are particularly effective in patients in whom the disease is localized (not spread beyond the initial site of disease). Physicians generally use systemic drug therapies in situations in which the cancer has spread beyond the primary site or cannot otherwise be treated through surgery. The goal of drug therapy is to damage and kill cancer cells or to interfere with the molecular and cellular processes that control the development, growth and survival of cancer cells or tumors. In many cases, drug therapy entails the administration of several different drugs in combination. Over the past several decades, drug therapy has evolved from non-specific drugs that damage both healthy and cancerous cells, to drugs that target specific molecular pathways involved in cancer and more recently to therapeutics that target the specific oncogenic “drivers” of cancer.

Cytotoxic Chemotherapies. The earliest approach to pharmacological cancer treatment was to develop drugs, referred to as cytotoxic drugs, which kill rapidly proliferating cancer cells through non-specific mechanisms, such as disrupting cell metabolism or causing damage to cellular components required for survival and rapid growth. While these kinds of drugs have been effective in the treatment of some cancers, many unmet medical needs for the treatment of cancer remain. Also, cytotoxic drug therapies act in an indiscriminate manner, acting upon the

metabolism of healthy as well as cancerous cells. Due to their mechanism of action, many cytotoxic drugs have a narrow dose range above which the toxicity causes unacceptable or even fatal levels of damage and below which the drugs are not effective in eradicating cancer cells.

Targeted Therapies. The next approach to pharmacological cancer treatment was to develop drugs, referred to as targeted therapeutics, that target specific biological molecules in the human body that play a role in rapid cell growth and the spread of cancer. Targeted therapeutics include vascular disruptors, also referred to as angiogenesis inhibitors, which prevent the formation of new blood vessels and restrict a tumor's blood supply. Other targeted therapies affect cellular signaling pathways that are critical for the growth of cancer. While these drugs have been effective in the treatment of some cancers, most do not address the underlying cause of the disease. These drugs focus on inhibiting processes that help the cancer cell survive, but not the oncogenes that are the drivers or cause of the cancer itself.

Oncogenic Therapies. A more recent approach to pharmacological cancer treatment is to develop drugs that affect the drivers that cause uncontrolled growth of cancer cells because of a specific genetic alteration. In some cases, these agents were identified as therapeutics without knowledge of the underlying genetic change causing the disease. To date, the shortcoming of this research approach has been that it often follows a conventional trial and error approach to drug discovery. In this approach, clinical development involves the treatment of large populations from which a defined subpopulation that responds to treatment is identified. As a result, this approach can be time-consuming and costly, with success often uncertain. Another major concern of these newly discovered drugs, some of which have been recently approved, is that resistance to them occurs as the cancer finds new ways to circumvent the genetic pathway.

Immunotherapies. Immunotherapy is the use of medicines to stimulate a person's own immune system to recognize and destroy cancer cells more effectively. Immunotherapy can be used to treat many different types of cancer, including lung cancer, melanoma, renal, liver, cervical and gastric cancers. An important part of the immune system is its ability to keep itself from attacking normal cells in the body. To do this, it uses "checkpoints" – molecules on immune cells that need to be turned on (or off) to start an immune response. Cancer cells sometimes use these checkpoints to avoid being attacked by the immune system. But newer drugs that target these checkpoints are demonstrating a lot of promise as cancer treatments. These drugs target PD-1, a protein on immune system T cells that normally helps keep these cells from attacking other cells in the body. By blocking PD-1, these drugs boost the immune response against cancer cells. This can shrink many types of tumors or slow their growth. The new drugs can also target PD-L1, a protein related to PD-1 that is found on some tumor cells and immune cells. Blocking this protein can also help boost the immune response against cancer cells. These drugs can be used in people with certain types of cancer which starts growing again after chemotherapy or other drug treatments. They are also used as a first treatment (instead of chemo) in some people and are given as an intravenous (IV) infusion every 2 or 3 weeks.

The Itraconazole Approach to Treating Cancer

We are focusing our developments on Hedgehog pathway inhibitor therapeutics for patients with certain cancers. Our initial product candidate is based on SUBA-Itraconazole, which employs a patented drug delivery technology that enhances its bioavailability. Previous formulations of itraconazole have exhibited anti-cancer properties in human trials and therefore, based on pre-clinical research regarding specific indicators of Hedgehog pathway inhibition and our most recent Phase 2(b) clinical trial, we have compelling evidence for the significant potential of Hedgehog inhibitors for treatment of cancer in humans. We have exclusive U.S. rights to use and develop SUBA-Itraconazole from Mayne Pharma through the Supply and License Agreement in the licensed field.

Background of Itraconazole. Itraconazole is FDA approved for and used to treat serious fungal or yeast infections. This medicine works by killing the fungus or yeast and preventing its growth. Itraconazole is a prescription-based medication, available as an IV solution, oral liquid, capsule or tablet.

Cancer and Hedgehog Inhibitors. The Hedgehog (also known as Hh) proteins comprise a group of secreted proteins that regulate cell growth, differentiation and survival. They are involved in organogenesis (the formation of organs), and have been shown to promote adult stem cell proliferation. Inappropriate activation of the Hh signaling pathway has been implicated in the development of several types of cancers including prostate, lung, pancreas,

Table of Contents

breast, brain and skin. Hedgehog pathway inhibitors are a relatively new class of therapeutic agents that act by targeting the proteins involved in the regulation of the Hh pathway. Many of these newly discovered inhibitors are currently undergoing preclinical testing and some have entered clinical studies as anti-cancer agents for a variety of cancers. Vismodegib was approved for treatment of locally advanced and metastatic basal cell carcinoma in early 2012, sonidegib was approved for locally advanced BCC in mid-2015 and gladegib was approved in late 2018 for treatment of acute myeloid leukemia

Similarly, itraconazole has also been shown to suppress growth of brain tumors in animal models. It has also been shown to have anti-cancer effects in basal cell carcinoma, lung cancer and prostate cancer in human clinical trials. Itraconazole acts as a SMO (a protein receptor of the Hh pathway) antagonist (blocker), in a manner distinct from its anti-fungal activity which targets a compound found in fungi and yeast known as ergosterol (a steroid found in the cell walls of fungi and yeast that functions in a fashion similar to cholesterol in humans) as well as having anti-angiogenic properties.

Manufacturing and Product Supply and Relationship with Mayne Pharma

We do not have any production facilities or manufacturing personnel. We currently have a Supply and License Agreement in place with Mayne Pharma, our majority stockholder, for the U.S. rights to its SUBA-Itraconazole. The agreement provides for the supply to us of specially formulated capsules of SUBA-Itraconazole, manufactured by Mayne Pharma under cGMP (current good manufacturing practice) standards, for use by us in our clinical trials and for the future commercial supply following FDA approvals, if obtained.

Pursuant to the Supply and License Agreement, Mayne Pharma is obligated to supply us with its patented formulation of SUBA-Itraconazole in a particular oral dose formulation for the treatment of human patients with certain cancers and non-cancerous proliferation disorders. We are required to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer in the United States. See "Certain Relationships and Related Party Transactions" for further information on the Supply and License Agreement and related agreements between us and Mayne Pharma.

Sales and Marketing

We are currently a pharmaceutical development company with no FDA approved products, and thus have not yet established a sales, marketing or product distribution infrastructure because our product candidates are still in development. We may either license commercialization rights to our product candidate to larger third-party partners, who will be responsible for sales, distribution and marketing efforts, or we may (assuming adequate resources are available) retain commercial rights for our product candidates, in which case we would seek to access the oncology market through a focused, specialized sales force of our own or in conjunction with a marketing partner under a co-promotion agreement.

Competition

The pharmaceutical industry is highly competitive and subject to rapid and substantial regulatory and technological changes, and particularly in the oncology field. Developments by others may render our itraconazole therapies, or any proposed product candidates and formulations under development, non-competitive or obsolete, or we may be unable to keep pace with anti-cancer therapy developments or other market factors. Anti-cancer therapy competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

Below are some examples of companies with approved and potentially competitive anti-cancer therapies or related products, though the examples are not all-inclusive. Many of these entities have significantly greater research and development capabilities than do we, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' research, financial, marketing, manufacturing and other resources. Such potential competitive anti-cancer therapies may ultimately prove to be safer, more effective or less costly than any product candidates that we are currently developing or may be able to develop. Additionally, our competitive position may be materially

Table of Contents

affected by our ability to develop or commercialize our drugs and technologies before any such competitor. Other external factors may also impact the ability of our products to meet expectations or effectively compete, including pricing pressures, healthcare reform and other government interventions.

The chart below lists products or products in development that we believe may compete directly with our proposed SUBA-Itraconazole therapy:

<u>Names</u>	<u>Company</u>	<u>Description</u>	<u>Status</u>
Trexall® methotrexate	Teva	Antimetabolite therapy to slow cancer cell growth	Approved before 1984
Taxotere® docetaxel	Sanofi-Aventis	Anti-tumor agent for MCRPC and late-stage NSCLC	Approved 2004; and new generics
Gemzar® gemcitabine	Lilly	Cytotoxic chemotherapy agent for NSCLC in combination with platinum drugs	Approved for multiple cancers since 1996
Avastin® bevacizumab	Genentech	Angiogenesis inhibitor for NSCLC except squamous cell lung cancer	Approved for multiple cancers since 2004
Jevtana® cabazitaxel	Sanofi-Aventis	MCRPC following docetaxel failure	Approved 2010
Provenge® sipuleucel-T	Dendreon/Valeant	Immunotherapy for asymptomatic MCRPC	Approved 2010
Zytiga® abiraterone	Janssen Biotech	Androgen synthesis inhibitor for metastatic and non-metastatic CRPC	Approved 2011
Xalkori® crizotinib	Pfizer	Selective inhibitor for late-stage NSCLC patients who express the ALK gene	Approved in 2011
Xtandi® enzalutamide	Astellas	Androgen receptor inhibitor for MCRPC previously on docetaxel	Approved 2012
Erivedge® vismodegib	Roche Genentech	Hedgehog inhibitor for advanced and metastatic BCC	Approved 2012
Odomzo® - sonidegib	Sun Pharma	Hedgehog inhibitor for advanced and metastatic BCC	Approved 2015
Avastin® bevacizumab	Genentech	Angiogenesis inhibitor for NSCLC except squamous cell lung cancer	Approved for multiple cancers since 2004
Tarceva® erlotinib	Astellas	Epidermal growth factor inhibitor treatment for NSCLC – maintenance therapy after chemo or metastatic disease after chemo	Approved in 2013
Gilotrif® afatinib	Boehringer	NSCLC with mutations in EGFR	Approved 2013
Zykadia® certinib	Novartis	ALK-positive metastatic NSCLC for patients who progressed on Xalkori	Approved 2014
Cyrazma® ramucirumab	Lilly	VEGF antagonist NSCLC	Approved 2014
Opdivo® nivolumab	BMS	Metastatic squamous NSCLC	Approved 2015

Table of Contents

<u>Names</u>	<u>Company</u>	<u>Description</u>	<u>Status</u>
Portrassa® necitumumab	Lilly	Metastatic squamous NSCLC	Approved 2015
Tagrisso® osimertinib	AstraZenica	EGFR mutation positive NSCLC	Approved 2015
Keytruda® pembrolizumab	Merck Oncology	Metastatic NSCLC expressing PD-L1	Approved 2015
Alecensa® alectinib	Genentech	Metastatic NSCLC ALK positive who could not tolerate crizotinib	Approved 2015
Iressa® gefitinib	AstraZeneca	Metastatic NSCLC with EGFR deletion	Approved 2015
Tecentriq® atezolizumab	Takeda	Anti-PDL-1 for Metastatic NSCLC not responding to EGFR or ALK gene therapy or platinum-based chemotherapy	Approved 2016
Alunbrig® brigatinib	Genentech	ALD positive metastatic NSCLC	Approved 2017
Erlada™ apalutamide	Janssen	AR inhibitor for non-MCRPC	Approved 2018

Abbreviations: MCRPC (metastatic castrate resistant prostate cancer), NSCLC (non-small cell lung cancer), BCC (basal cell carcinoma), EGFR (epidermal growth factor receptor) ALK (anaplastic lymphoma kinase), PD-L1 (programmed death ligand 1).

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (or IRB) at each clinical site before each trial may be initiated;
- performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;

Table of Contents

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices (of cGMP) and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance; and
- FDA review and approval of the NDA.

Preclinical Studies. Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

We successfully avoided pre-clinical studies or any Phase 1 studies to demonstrate safety based on the fact that itraconazole has an established history of safe and effective use in humans for anti-fungal indications and the fact that human data are already available and published regarding use of itraconazole in humans for anti-cancer indications, such as basal cell carcinoma, lung cancer and prostate cancer.

Clinical Trials. Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at 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 continue to oversee the clinical trial while it is being conducted. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically 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. In 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.

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. 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 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. We moved directly into Phase 2 trials with SUBA-Itraconazole BCCNS based upon the previous, well-established safety profile of itraconazole use in humans for treatment of anti-fungal indications and based upon the previous human data regarding the use of itraconazole for anti-cancer indications such as basal cell carcinoma, lung cancer and prostate cancer.

Table of Contents

Marketing Approval. Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, 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 product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (or PDUFA) guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application.

The FDA also may require submission of a risk evaluation and mitigation strategy (or REMS) plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. We believe that a REMS program, which includes intellectual property related to SUBA-Itraconazole and itraconazole, and the specific use of SUBA-Itraconazole for anti-cancer indications, may likely provide additional protection of our proposed therapies from generic substitution.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are 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 reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA typically refers a question regarding a novel drug to an external advisory committee. 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.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance 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 trial sites to assure compliance with GCP.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a 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 under a REMS (Risk Evaluation Mitigation Strategy) 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-marketing studies or surveillance programs. After approval, some 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.

Special FDA Expedited Review and Approval Programs. The FDA has various programs, including fast track designation, accelerated approval, priority review and breakthrough designation, that are intended to expedite or

Table of Contents

simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten-month review periods are measured from the “filing” date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We believe that we may qualify for one or more of these expedited approvals since our itraconazole anti-cancer therapies offer significant improvements in therapy for all of our targeted anti-cancer indications should they be approved by FDA.

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.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their

Table of Contents

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 mandatory 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 marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies generally are required to promote their drug products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (or PDMA), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations. In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the biopharmaceutical industry. These laws include anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

[Table of Contents](#)

The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (which we refer to collectively as the PPACA), which, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. PPACA also created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses. The federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA) created new federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act (or HITECH) and its implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to “business associates,” defined as independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Coverage and Reimbursement. The commercial success of our product candidate and our ability to commercialize any approved product candidate will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our therapeutic product candidates and related companion diagnostics. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

[Table of Contents](#)

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidate in whole or in part.

Impact of Healthcare Reform on Coverage, Reimbursement, and Pricing. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (or MMA) imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Part D plans include both standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, any negotiated prices for our future products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The United States is considering enacting or has enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, PPACA, which became law in March 2010 and substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the PPACA establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we are able to charge for our product candidates, once approved, or the amounts of reimbursement available for our product candidates once they are approved.

Exclusivity and Approval of Competing Products

Hatch-Waxman Patent Exclusivity. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application (or ANDA), or a 505(b)(2) NDA.

Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and these drugs can often be substituted by pharmacists under prescriptions written for the original listed drug. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage form or indication. The 505(b)(2) regulatory pathway appears to be available for our proposed application of itraconazole as an anti-cancer therapy based upon our communications with FDA to date.

The ANDA or 505(b)(2) NDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. 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.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed drug. A certification that the proposed 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 indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA 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 application 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 notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

Hatch-Waxman Non-Patent Exclusivity. Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

Table of Contents

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals annually in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. We obtained orphan drug designation for SUBA-Itraconazole BCCNS in May 2016.

Foreign Regulation. Although it is not presently our intention to seek approval of our product candidates outside of the United States, in the future we may do so, either directly or in conjunction with a marketing partner. In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. We do however intend to include sites outside the United States for our clinical trials in order to be able to recruit more patients for testing at a greater number of locations and in less time than if we were to focus only on US-based sites. For example, in the European Union, we would need to obtain authorization of a clinical trial application in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Employees

As of March 31, 2019, we have two full-time employees. One is involved in our clinical development program and operations and one handles our administration and accounting. Neither of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our clinical development and administrative functions. We currently have contracted a regulatory consultant, two advisory firms, a scientific advisor and a Contract Research Organization to spearhead our efforts on clinical development. We consider relations with our employees to be good. Each of our employees has entered into confidentiality, intellectual property assignment and non-competition agreements with us.

Facilities

We lease our corporate offices in Tampa, Florida, for which we currently pay rent of approximately \$3,500 per month.

Corporate History

We were founded under the name “Commonwealth Biotechnologies, Inc.” in Virginia in 1992, and completed an initial public offering in October 1997 (we refer to our company prior to our emergence from bankruptcy as CBI). CBI previously provided, on a contract basis, specialized life sciences services to the pharmaceutical and biotechnology sector. On January 20, 2011, CBI filed a voluntary petition for bankruptcy. We recommenced our business operations in August 2013 as a Delaware corporation following the emergence of CBI from its voluntary bankruptcy.

MANAGEMENT

Set forth below is information regarding our current directors and executive officers. Each director holds his office until he resigns or is removed and his successor is elected and qualified.

Name	Age	Position
W. Mark Watson, CPA	68	Chairman of the Board and Director
Nicholas J. Virca	72	President and Chief Executive Officer
Garrison J. Hasara, CPA	49	Chief Financial Officer, Treasurer, Chief Compliance Officer and Secretary
E. Brendan Magrab	53	Director
Stefan J. Cross	46	Director
Dr. R. Dana Ono	66	Director
Robert D. Martin	71	Director

Mayne Pharma has the right to designate one director to our Board of Directors and to designate a second director if the size of the Board of Directors is increased to seven directors until the earlier to occur of: (i) the date that the Supply and License Agreement is terminated or expires or (ii) the date on which Mayne Pharma ceases to own ten percent (10%) or more of our issued and outstanding common stock on a fully diluted basis. Mayne Pharma’s current designee to our Board of Directors is Stefan J. Cross. In addition, as our current majority shareholder, Mayne Pharma maintains the right to alter the composition of our Board of Directors.

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

To the best of our knowledge, during the past ten years, none of the following occurred with respect to a present director or executive officer of the Company: (1) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; (4) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated; (5) being subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree or finding relating to an alleged violation of the federal or state securities, commodities, banking or insurance laws or regulations or any settlement thereof or involvement in mail or wire fraud in connection with any business entity not subsequently reversed, suspended or vacated and (6) being subject of, or a party to, any disciplinary sanctions or orders imposed by a stock, commodities or derivatives exchange or other self-regulatory organization.

W. Mark Watson, CPA, age 68, has been Chairman of the Board of Directors since April 2019 and is Chairman of the Audit Committee of our Board of Directors. Mr. Watson has been a director since June 2014. Mr. Watson is a Certified Public Accountant with over 40 years of experience in public accounting and auditing, having spent his entire career from January 1973 to June 2013 at Deloitte Touche Tohmatsu and its predecessor, most recently as Central Florida Marketplace Leader. Among other industries, he has a particular expertise in the healthcare and life sciences sector, having played a significant role in the development of Deloitte’s audit approach

Table of Contents

for health and life sciences companies and leading its national healthcare regulatory and compliance practice. He has served as lead audit partner and lead client service partner on the accounts of many public companies ranging from middle market firms to Fortune 500 enterprises. Mr. Watson was elected to the Board of Directors of Sykes Enterprises Inc. in May 2018 and serves on its Audit Committee. Mr. Watson was elected to the Board of Directors of BioDelivery Sciences International, Inc. in December 2017 and was appointed Chairman of its Audit Committee. Mr. Watson is a member of American Institute of Certified Public Accountants and the Florida Institute of Certified Public Accountants. Mr. Watson is qualified to serve on our Board of Directors due to his expertise in public accounting and his experience with life science and pharmaceutical companies. He received his undergraduate degree in Accounting from Marquette University.

Nicholas J. Virca, age 72, has been our President and Chief Executive Officer since August 2013 and has been working on our business opportunity with Hedgepath, LLC since April 2012. From 2008 until April 2012, Mr. Virca served as the Chief Operating Officer for LamdaGen Corporation, a privately held company focused on monitoring assays for biopharmaceutical development and manufacturing applications, as well as high-sensitivity detection for human diagnostic biomarkers, such as oncoproteins related to cervical cancer. From 2005 to 2008, Mr. Virca was Vice President for Global Biotechnology at Pall Life Sciences where he was responsible for growth strategies and programs in the biotechnology arena, including new technology and product initiatives, joint ventures, licensing and acquisitions. He also founded the first Scientific Advisory Board for Pall's Biopharmaceuticals Division. From 1997 to 2004, Mr. Virca was COO, and later CEO and President of Adventrx Pharmaceuticals focusing on anti-cancer drug development in human clinical trials. He was instrumental in transitioning the company from a private corporation to a listing on the American Stock Exchange. Mr. Virca held various marketing and general management positions at Damon Biotech, Promega Corporation, Nicolet Imaging Systems, Ortho Diagnostic Systems, Fisher Scientific, Waters, Ross Laboratories and Pfizer Diagnostics. Mr. Virca previously served on the Life Sciences Advisory Board of Entegris, Inc. from 2007 to 2011 and on the board of Panoptix Events from 2007 through 2017. He previously served on the boards of Adventrx Pharmaceuticals between 2001 and 2004, and Diametrix Detectors between 1991 and 1997. He earned a bachelor's degree in Biology from Youngstown State University, is the co-inventor of packaging technology for enzyme research reagents as well as co-inventor of three patents using itraconazole therapy for treatment of cancer and non-cancerous proliferations disorders and is a member of numerous biotechnology organizations for which he has been a speaker and organizer over the last several decades.

Garrison J. Hasara, CPA, age 49, has been our Chief Financial Officer and Treasurer since September 2013 and has subsequently become our Chief Compliance Officer and Secretary. From January 2011 to September 2013, he was the Acting Chief Financial Officer, Principal Financial Officer and Principal Accounting Officer of Accentia Biopharmaceuticals, Inc., a biotechnology company focused on discovering, developing and commercializing innovative therapies that address the unmet medical needs of patients by utilizing therapeutic clinical products. He also served as Accentia's Controller, a position that he held since June 2005. From November 2003 to June 2005, Mr. Hasara served as Accentia's Compliance Specialist. Prior to that time, from 2000 to 2003, Mr. Hasara was the Chief Financial Officer of Automotive Service Centers, Inc., a franchisee of Midas, Inc. In addition, from 1996 to 1999, Mr. Hasara served in various accounting roles at KForce Inc., a publicly traded staffing services company. Mr. Hasara has been a licensed Certified Public Accountant since 1993 and received his B.S. from the University of South Florida in 1991.

E. Brendan Magrab, age 53, is a director of our company and served as Chairman of the Board from December 2016 to April 2019. He has served as the President and CEO of Transpharmative Advisors, LLC since March 2013. Mr. Magrab has more than 20 years of experience in pharmaceutical development and marketing, including formulation development, clinical development, regulatory affairs, government affairs, marketing, managed care, legal and patents. Previously, from June 2012 to February 2013, he served as the President and CEO of URL Pharma, which was sold to Sun Pharmaceuticals in 2013. From October 2004 to June 2012, he held various positions of increasing responsibility at URL Pharma, including General Counsel and Executive Vice President of Commercial Operations. Prior to joining URL Pharma, from August 2000 to September 2004, Mr. Magrab served as Vice President of Intellectual Property at Alpharma, Inc. Prior to joining Alpharma, Inc., he served as an associate at a Washington D.C law firm, as a law clerk for the U.S. Court of Appeals for the Federal Circuit, and as a Patent Examiner at the U.S. Patent and Trademark Office. Mr. Magrab received his Bachelor's Degree in Biochemistry and Art History from the University of Virginia and his Juris Doctor from Georgetown University Law Center. Mr. Magrab is qualified to serve on our Board of Directors because of his extensive business experience in the

Table of Contents

pharmaceutical industry. On February 11, 2019, Mr. Magrab notified our Board of Directors that he had executed an agreement to become the Chief Executive Officer of a privately-held biotechnology company (Epalex Corporation) and that, pursuant to such agreement, Mr. Magrab was afforded a period of six (6) months to transition off our Board of Directors. In his notification, Mr. Magrab did not resign from our Board of Directors. In light of Mr. Magrab's notification, during the contemplated transition period, the Board of Directors or its designated committee will be evaluating options in light of the potential vacancy on the Board of Directors. It is expected that Mr. Magrab will continue to serve as a director of our company until the earlier of July 1, 2019 or when a new board member is identified.

Stefan J. Cross, age 46, is a director of our company and the appointee of Mayne Pharma to our Board of Directors. Mr. Cross has been a director since June 2014. Mr. Cross is currently serving as President, International Operations of Mayne Pharma Group Limited (ASX:MYX). Previously, Mr. Cross served as the President of the U.S. subsidiaries of Mayne Pharma Group Limited from November 2013 to January 2017. Mr. Cross has more than 20 years of experience in the pharmaceutical industry. He served since 2012 as the Vice President, Business and Corporate Development of Mayne Pharma's non-U.S. operations, where he was responsible for all in-licensing and out-licensing programs and research and development partnerships. Prior to joining Mayne Pharma, Mr. Cross was, from 2007 to 2012, Head of Marketing (Asia Pacific) for Hospira Inc., a leading global provider of pharmaceuticals and medical devices, where he was responsible for expansion of the new product portfolio and on-market product growth across all markets in the region. Prior to Hospira, Mr. Cross spent most of the period from 1991 to 2007 working in the pharmaceutical sector in the areas of strategy, business development/mergers and acquisitions, sales and marketing, human resources, finance and information technology. Mr. Cross is qualified to serve on our Board of Directors because of his extensive business experience in the pharmaceutical industry. Mr. Cross holds a Masters in Business in Administration from Swinburne University of Technology, Australia, and a degree in Business Information Systems from the University of South Australia.

Dr. R. Dana Ono, age 66, is a director of our company and Chairman of the Nominating and Corporate Governance Committee of our Board of Directors. Dr. Ono has been a director since June 2014. Dr. Ono is a co-founder of the VIMAC Milestone Medica Fund LP, a Boston-based early-stage life sciences fund co-sponsored by VIMAC Ventures LLC and RBC Technology Ventures, Inc. Dr. Ono has over 35 years of experience in managing public and private life science companies as well as in venture capital. Presently, Dr. Ono is an executive-in-residence at several universities in the United States advising their licensing offices in spin-outs and new company formation from promising technologies. Throughout his career, he has been engaged in the strategic planning, product management, technology acquisition, and commercial development of life science start-ups and has been involved in a number of pioneering milestones in biotechnology. He has founded several biotech companies in the U.S., including in the areas of drug discovery and development, nutraceuticals and cosmeceuticals. He is a founding director of the Massachusetts Biotechnology Council, Inc. and served on the Board of Trustees of the Marine Biological Laboratory in Woods Hole, Massachusetts. He is a Fellow of the Linnean Society of London and a National Member of the Explorers Club. Dr. Ono is qualified to serve on our Board of Directors because of his medical and business expertise, particularly in the pharmaceutical industry. Dr. Ono received his AB in Earth & Planetary Sciences from The Johns Hopkins University and his AM and PhD in Biology from Harvard University, where he also completed a program in business administration.

Robert D. Martin, age 71, is a director of our company and Chairman of the Compensation Committee of our Board of Directors. Mr. Martin has been a director since December 2016. Mr. Martin has over 30 years of finance and operations experience. Most recently, Mr. Martin was appointed President and Chief Operating Officer of Specicare, a company that arranges for storage of cancer patients' live tumor tissue from surgery to be used for specialized and precision treatment. Since 2006, Mr. Martin has been part of The Interlochen Group, LLC, a firm that provides chief financial officer personnel on a contract basis. Among other assignments, he was assigned to serve as Interim Chief Financial Officer of Tandy Brands Accessories Inc. from January 2011 to June 2011. Also, during 2015, he was a consultant/financial advisor to Intezyme Inc, a clinical stage biotechnology company. From 2004 to 2006, Mr. Martin served as President of RDMartin, LTD., a financial consulting firm, and from 2000 to 2004, Mr. Martin served as Senior Vice President and Chief Financial Officer of Russell Corporation, when it was a New York Stock Exchange listed company. Mr. Martin also previously served as divisional Chief Financial Officer of Sunbeam and in various finance roles, including divisional Chief Financial Officer, at Sara Lee Apparel. Mr. Martin earned a Masters of Business Administration from the University of North Carolina, Chapel Hill and a Bachelor's degree in Industrial Engineering from Georgia Tech. Mr. Martin qualifies for our Board of Directors because of his business expertise, particularly with publicly traded companies.

Board Committees and Director Independence

Director Independence

Of our current directors, we have determined that Robert D. Martin, Dr. R. Dana Ono, and W. Mark Watson are “independent” as defined by NASDAQ Stock Market rules. Accordingly, a majority of our Board of Directors is “independent.”

Board Committees

Our Board of Directors has established three standing committees — Audit, Compensation, and Nominating and Corporate Governance. All standing committees operate under a charter that has been approved by our Board of Directors.

Audit Committee

Our Board of Directors has an Audit Committee, composed of W. Mark Watson, Robert D. Martin and Dr. R. Dana Ono. All members are independent directors as defined in accordance with Rule 10A-3 of the Exchange Act and the rules of the NASDAQ Stock Market. Mr. Watson serves as chairman of the committee. The Board of Directors has determined that Mr. Watson is an “audit committee financial expert” as defined in Item 407(d)(5)(ii) of Regulation S-K.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually) and performs several functions. The Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance any non-audit service and fees therefor to be provided by the independent auditor;
- monitors the independence of the independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and reviews of our quarterly financial statements;
- provides oversight assistance in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the Board of Directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our Board of Directors has a Nominating and Corporate Governance Committee composed of Robert D. Martin, Dr. R. Dana Ono, and W. Mark Watson. Dr. Ono serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the Board of Directors for consideration. The Nominating and Corporate Governance Committee has a charter which is reviewed annually. All members are independent directors in accordance with the rules of the NASDAQ Stock Market. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders.

Table of Contents

Compensation Committee

Our Board of Directors also has a Compensation Committee, which reviews or recommends the compensation arrangements for our management and employees and assists the Board of Directors in reviewing and approving matters such as company benefit and insurance plans, including monitoring the performance thereof. The Compensation Committee has a charter (which is reviewed annually) and is composed of three members: Dr. R. Dana Ono, W. Mark Watson, and Robert D. Martin. Mr. Martin serves as chairman of this committee. All members are independent in accordance with rules of the NASDAQ Stock Market.

Code of Ethics

We have adopted a formal code of ethics that applies to our directors and principal executives and financial officers or persons performing similar functions. A copy of our Code of Ethical Conduct can be found on our website under “Investors” at <http://www.hedgepathpharma.com/>.

Executive Compensation

The following table sets forth all compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2018 and 2017. Individuals we refer to as our “named executive officers” include our Chief Executive Officer and our most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded \$100,000 during the fiscal year ended December 31, 2018.

Name and principal position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Nicholas J. Virca	2018	\$300,000	\$67,500	—	\$68,200	—	—	\$ 23,587 (2)	\$459,287
President and Chief Executive Officer (1)	2017	\$262,500	—	—	—	—	—	\$ 16,665 (2)	\$279,165
Garrison J. Hasara, CPA	2018	\$225,000	\$56,500	—	\$57,200	—	—	\$ 21,822 (4)	\$360,522
Chief Financial Officer, Secretary, and Treasurer (3)	2017	\$212,500	—	—	—	—	—	\$ 18,999 (4)	\$231,499

- (1) Nicholas J. Virca was hired as Chief Executive Officer on August 1, 2013.
- (2) Includes: \$23,587 and \$16,665 of health insurance premiums paid in 2018 and 2017, respectively.
- (3) Garrison J. Hasara was hired as Chief Financial Officer on August 1, 2013.
- (4) Includes: \$21,822 and \$18,999 of health insurance premiums paid in 2018 and 2017, respectively.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

Except as set forth below, we currently have no written employment agreements with any of our officers, directors, or key employees.

Nicholas J. Virca, President and Chief Executive Officer. During the fiscal years ended December 31, 2017 and 2018, Mr. Virca was employed pursuant to an employment agreement that was originally entered into on June 24, 2014 and subsequently amended on May 15, 2015 and February 16, 2017 (the “Prior Virca Employment Agreement”). The Prior Virca Employment Agreement expired on December 31, 2018 and was replaced by the New Virca Employment Agreement (as defined below). Pursuant to the terms of the Prior Virca Employment Agreement, Mr. Virca earned a base salary of \$300,000 per annum effective as of July 1, 2017 and was eligible for a bonus in cash or in kind of up to 75% of his base salary based upon his achievement of certain goals as established by Mr. Virca and approved by the Board of Directors or a committee of the Board of Directors.

Table of Contents

On December 31, 2018, we entered into a new employment letter agreement with Mr. Virca (the “New Virca Employment Agreement”) which formalized revised terms and conditions of Mr. Virca’s employment with us. Pursuant to the New Virca Employment Agreement, Mr. Virca will continue to act as our President and Chief Executive Officer on an “at will” basis for a term beginning on January 1, 2019 and ending on June 30, 2019. If, during the term of the New Virca Employment Agreement, we achieve each of (i) completion of all Transfer Activities (as defined in the Supply and License Agreement), and the resulting receipt by us of \$3 million in advances (as defined in the Supply and License Agreement) from Mayne Pharma and (ii) the filing by us of an IND application with FDA related to the study of SUBA-Itraconazole for the treatment of prostate cancer and the FDA’s clearance of the IND, we will consider extending Mr. Virca’s employment and negotiating in good faith an employment agreement with Mr. Virca that would be on substantially similar terms as the Prior Virca Employment Agreement (subject to the mutual agreement of Mr. Virca and us).

Pursuant to the New Virca Employment Agreement, Mr. Virca will earn a base salary of \$300,000 per annum (his prior salary level), payable in accordance with our regular payroll practices. Mr. Virca will also receive a cash bonus for the fiscal year ended December 31, 2018 (\$90,000 approved in February 2019 and payable by March 15, 2019), the amount of such bonus to be determined by our Compensation Committee of the Board of Directors in accordance with the bonus potential under the Prior Virca Employment Agreement and the Compensation Committee’s determination of corporate objectives met. Mr. Virca is also eligible for a bonus in cash and/or equity awards for the period covered by the New Virca Employment Agreement, any such bonus to be granted at the discretion of the Board of Directors or the Compensation Committee. Pursuant the New Virca Employment Agreement, Mr. Virca will continue to receive customary benefits. The New Virca Employment Agreement may be terminated by us or by Mr. Virca, in each case on 30 days’ notice, and we may terminate the New Virca Employment Agreement immediately for Cause (as such term is defined in the New Virca Employment Agreement). We will have no severance payment obligation to Mr. Virca in the event of any termination of the New Virca Employment Agreement. The New Virca Employment Agreement also provides that Mr. Virca may not compete against us or solicit employees or customers from us for a period of six (6) months after termination of his employment for any reason.

Garrison J. Hasara, Chief Financial Officer, Secretary, Treasurer and Chief Compliance Officer. During the fiscal years ended December 31, 2017 and 2018, Mr. Hasara was employed pursuant to an employment agreement that was originally entered into on June 24, 2014 and subsequently amended on February 16, 2017 (the “Prior Hasara Employment Agreement”). The Hasara Employment Agreement expired on December 31, 2018 and was replaced by the New Hasara Employment Agreement (as defined below). Pursuant to the terms of the Prior Hasara Employment Agreement, Mr. Hasara earned a base salary of \$225,000 per annum effective as of July 1, 2017 and was eligible for a bonus in cash or in kind of up to 75% of his base salary based upon his achievement of certain goals as established by Mr. Hasara and approved by the Board of Directors or a committee of the Board of Directors.

On December 31, 2018, we entered into a new employment letter agreement with Mr. Hasara (“New Hasara Employment Agreement”) which formalized revised terms and conditions of Mr. Hasara’s employment with us. Pursuant to the New Hasara Employment Agreement, Mr. Hasara will continue to act as our Chief Financial Officer, Secretary, Treasurer and Chief Compliance Officer on an “at will” basis for a term beginning on January 1, 2019 and ending on June 30, 2019. If, during the term of the New Hasara Employment Agreement, we achieve each of (i) completion of all Transfer Activities (as defined in the Supply and License Agreement), and the resulting receipt by us of \$3 million in advances (as defined in the Supply and License Agreement) from Mayne Pharma and (ii) the filing by us of an IND with FDA related to the study of SUBA-Itraconazole for the treatment of prostate cancer and the FDA’s clearance of the IND, we will consider extending Mr. Hasara’s employment and negotiating in good faith an employment agreement with Mr. Hasara that would be on substantially similar terms as the Prior Hasara Employment Agreement (subject to the mutual agreement of Mr. Hasara and us).

Pursuant to the New Hasara Employment Agreement, Mr. Hasara will earn a base salary of \$225,000 per annum (his prior salary level), payable in accordance with our regular payroll practices. Mr. Hasara will also receive a cash bonus for the fiscal year ended December 31, 2018 (\$67,500 approved in February 2019 and payable by March 15, 2019), the amount of such bonus to be determined by our Compensation Committee of the Board of Directors in accordance with the bonus potential under the Prior Hasara Employment Agreement and the Compensation Committee’s determination of corporate objectives met. Mr. Hasara is also eligible for a bonus in

[Table of Contents](#)

cash and/or equity awards for the period covered by the New Hasara Employment Agreement, any such bonus to be granted at the discretion of the Board of Directors or the Compensation Committee. Pursuant the New Hasara Employment Agreement, Mr. Hasara will continue to receive customary benefits. The New Hasara Employment Agreement may be terminated by the Company or by Mr. Hasara, in each case on 30 days’ notice, and we may terminate the New Hasara Employment Agreement immediately for Cause (as such term is defined in the New Hasara Employment Agreement). We shall have no severance payment obligation to Mr. Hasara in the event of any termination of the New Hasara Employment Agreement. The New Hasara Employment Agreement also provides that Mr. Hasara may not compete against us or solicit employees or customers from us for a period of six (6) months after termination of his employment for any reason.

Outstanding equity awards

The following table summarizes outstanding unexercised options held by each of our named executive officers, as of December 31, 2018. There were no outstanding unvested stock or equity incentive plan awards held by our named executive officers, as of December 31, 2018.

Name	OPTION AWARDS					STOCK AWARDS			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Options Exercise Prices (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Been Issued (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Been Issued (\$)
Nicholas J. Virca	310,000	—	—	\$0.2722	March 13, 2028	—	—	—	—
Garrison J. Hasara, CPA	260,000	—	—	\$0.2722	March 13, 2028	—	—	—	—

2014 Equity Incentive Plan

In July 2014, our Board of Directors adopted the 2014 Equity Incentive Plan, or the EIP. On September 30, 2014, the EIP was approved by the majority of stockholders pending delivery of required notice to all Company stockholders. The EIP is comprised of 32,583,475 shares of our common stock (ranking pari passu with our issued and outstanding common stock) to be available in the form of incentive stock options, non-qualified stock options, restricted stock, restricted stock units, performance awards and other customary equity incentives.

The purpose of our EIP is to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial achievements. The EIP is administered by the Compensation Committee of our Board of Directors or by the full Board of Directors, which may determine, among other things, (a) the persons who are to receive awards, (b) the type or types of awards to be granted to such persons, (c) the number of shares of common stock to be covered by, or with respect to which payments, rights, or other matters are to be calculated in connection with the awards, (d) the terms and conditions of any awards, (e) whether, to what extent, and under what circumstances awards may be settled or exercised in cash, shares of common stock, other securities, other awards or other property, or canceled, forfeited, or suspended and the method or methods by which awards may be settled, exercised, canceled, forfeited, or suspended, (f) whether, to what extent, and under what circumstances the delivery of cash, shares of common stock, other securities, other awards or other property and other amounts payable with respect to an award, (g) interpret, administer, reconcile any inconsistency in, settle any controversy regarding, correct any defect in and/or complete any omission in the EIP and any instrument or agreement relating to, or award granted under, the EIP, (h) establish, amend, suspend, or waive any rules and regulations and appoint such agents as the Compensation Committee deems appropriate for the proper

Table of Contents

administration of the EIP, (i) accelerate the vesting or exercisability of, payment for or lapse of restrictions on, awards and (j) make any other determination and take any other action that the compensation committee deems necessary or desirable for the administration of the EIP.

The EIP provides that in the event of a change of control event, (i) all of the then outstanding options and stock appreciation rights granted pursuant to the EIP will immediately vest and become immediately exercisable as of a time prior to the change in control, (ii) any performance goal restrictions related to an award will expire as of a time prior to the change in control and (iii) any performance periods that relating to an award which have not yet expired on the date the change in control occurs will end on such date, and the compensation committee will (a) determine the extent to which performance goals with respect to each such performance period have been met based upon such audited or unaudited financial information or other information then available as it deems relevant and (b) cause the relevant participant to receive partial or full payment of awards for each such performance period based upon the compensation committee's determination of the degree of attainment of the performance goals, or assuming that the applicable "target" levels of performance have been attained or on such other basis determined by the compensation committee.

In addition, subject to our Equity Holders Agreement, our Board of Directors may amend our EIP at any time. However, without stockholder approval, our EIP may not be amended in a manner that would:

- increase the number of shares that may be issued under our EIP;
- materially modify the requirements for eligibility for participation in our EIP;
- materially increase the benefits to participants provided by our EIP; or
- otherwise disqualify our EIP for coverage under Rule 16b-3 promulgated under the Exchange Act.

Awards previously granted under our EIP may not be impaired or affected by any amendment of our EIP, without the consent of the affected grantees.

Option Exercises and Stock Vested

There were no options exercised by the executive officers during the years ended December 31, 2018 or 2017.

All previously outstanding RSUs vested upon the change in control as a result of Mayne Pharma's November 2016 warrant exercise, in connection with which Mayne Pharma became our majority stockholder. On March 8, 2017, 26,541,738 previously vested but unpaid RSUs were settled by issuing shares of common stock. Upon settlement of the RSUs, we issued 15,739,594 shares of common stock to employees (including our executive officers), current and former Board members, and contractors. Additionally, 10,802,144 shares of common stock, valued at approximately \$3.7 million, were withheld from issuance representing estimated income taxes due from the RSU recipients as the fair value of the shares is considered taxable income upon issuance. We subsequently remitted to the appropriate taxing authorities in cash both our tax withholdings and the RSU recipient portions of the tax withholdings in the amount of approximately \$3.7 million.

Pension Benefits

None of our employees participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our Compensation Committee may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our company's best interest.

Non-qualified Deferred Compensation

None of our employees participate in or have account balances in non-qualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our Compensation Committee may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified compensation benefits in the future if it determines that doing so is in our company's best interest.

Compensation of Directors

The following table sets forth all compensation paid to our Board members during the year ended December 31, 2018:

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$) ⁽¹⁾	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Stefan J. Cross	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
E. Brendan Magrab	\$ 75,000	—	\$ 156,810	—	—	\$ —	\$ 231,810
Robert D. Martin	\$ 42,500	—	\$ 127,314	—	—	\$ —	\$ 169,814
Dr. R. Dana Ono	\$ 45,000	—	\$ 127,314	—	—	\$ —	\$ 172,314
W. Mark Watson, CPA	\$ 50,000	—	\$ 131,714	—	—	\$ —	\$ 181,714

(1) Options awarded to directors during the twelve months ending December 31, 2018 included compensation for 2017 and 2018.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We are a party to a number of key related party transactions with Mayne Pharma, which are described below.

On December 17, 2018 (or the Effective Date), we entered into the following related agreements (collectively, we refer to these agreements as the Transaction Documents): (i) an agreement (which we refer to as the Agreement), by and among us, Mayne Pharma and Mayne Pharma International Pty Ltd (which we refer to as Mayne Pharma International), (ii) Third Amended and Restated Supply and License Agreement, dated December 17, 2018, by and between us and Mayne Pharma (referred to in this “Certain Relationships and Related Party Transactions” as the Third Amended SLA) and (iii) Amended and Restated Sublicense Agreement, by and between the us and Mayne Pharma International, which amends and restates that certain Sublicense Agreement, dated August 31, 2015, between us and Mayne Pharma International, as amended (referred to in this “Certain Relationships and Related Party Transactions” as the Amended and Restated Sublicense Agreement). In addition, pursuant to the terms of the Agreement, we and Mayne Pharma agreed to the terms and provisions of an Amended and Restated Certificate of Designation of Series B Convertible Preferred Stock of Company (referred to in this “Certain Relationships and Related Party Transactions” as the Amended and Restated COD), which amends and restates the Certificate of Designation of Series B Convertible Preferred Stock of the Company, dated January 8, 2018 (as corrected, the Original COD), to remove certain features thereof as described below. As of the Effective Date, all outstanding shares of Series B Preferred Stock are held by Mayne Pharma. Mayne Pharma owns approximately 54.1% of our equity securities on a fully-diluted basis and beneficially owned 59.1% of our outstanding voting securities (including shares of our common stock and Series B Preferred Stock) as of the date of this prospectus.

The Transaction Documents resulted from negotiations regarding the existing right of Mayne Pharma under the Second Amended and Restated Supply and License Agreement with Mayne Pharma, dated as of May 15, 2015 (as amended through the Effective Date, the Second Amended SLA) to elect to assume control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS after December 31, 2018 in exchange for a royalty on any future net sales if a NDA for SUBA-Itraconazole BCCNS was not accepted for filing by the FDA by December 31, 2018 (subject to limited extension if the NDA were filed in December 2018). Based on unforeseen requirements imposed by FDA in September 2018, we determined that it would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus we commenced negotiations with Mayne Pharma to transfer SUBA-Itraconazole BCCNS in advance of December 31, 2018 on negotiated terms deemed beneficial to our company.

The Transaction Documents were negotiated and approved on behalf of the Company by a special committee of disinterested, independent members of our Board of Directors which was formed on October 26, 2018 for such purpose. The special committee consisted of W. Mark Watson (serving as Chairman), R. Dana Ono and Robert Martin, who are each disinterested with respect to Mayne Pharma.

Table of Contents

Agreement

Pursuant to the terms of the Agreement, on December 18, 2018, Mayne Pharma (in its capacity as the holder of more than 50% of our outstanding voting securities) executed and delivered to us a written stockholder consent in lieu of a special meeting of the stockholders of our company (which we refer to as the Stockholder Consent) which consented to the taking of the following actions:

- the adoption of the Amended and Restated COD;
- the election of each E. Brendan Magrab, W. Mark Watson, Dr. R. Dana Ono, Stefan J. Cross and Robert D. Martin (each a current member of our Board of Directors) to serve on the Board of Directors for a one-year term that expires at the next annual meeting of our stockholders or until his earlier death, resignation or removal; and
- the approval of an increase in the size of the EIP by 11,000,000 shares of common stock from 32,583,475 shares to 43,583,475 shares.

In addition, pursuant to the Agreement, for the period beginning on the Effective Date and ending three (3) years from the Effective Date, in the event that we asks our stockholders (whether at a meeting of stockholders or pursuant to a written consent of stockholders) to vote on or approve a proposal to effect a reverse split of our capital stock for the purpose of uplisting our common stock to a U.S. national securities exchange (which we refer to as a Reverse Stock Split Proposal), Mayne Pharma (on behalf of itself and its affiliates) has agreed to vote or cause to be voted (in person, by proxy or by action by written consent, as applicable) all shares of our voting capital stock that either Mayne Pharma then owns or over which Mayne Pharma has voting control in favor of the adoption and approval of any such Reverse Stock Split Proposal. The Agreement further provides that the Reverse Stock Split Proposal may take the form of an authorization based on a range of ratios for the reverse stock split, with authority being granted to our Board of Directors (or a designated committee thereof) to determine the final ratio of the reverse stock split, provided such range is reasonable in connection with the uplisting of the common stock to a U.S. national securities exchange. No assurances are given that we will seek an uplisting to a U.S. national securities exchange or implement a reverse stock split of our common stock.

Also, pursuant to the Agreement, Mayne Pharma consented and agreed (under the terms of agreements previously executed with us) to an increase in the number of shares of common stock that the Company may issue under the EIP to 17,624,000 shares from the current limit of 6,624,000 shares, with the agreement and understanding that such increase will be utilized by us during the period from the Effective Date through December 31, 2021.

Third Amended and Restated Supply and License Agreement

Pursuant to the Third Amended SLA, as of the Effective Date, Mayne Pharma has assumed control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS and immediately assumed responsibility for all expenses related to exploiting the SUBA-Itraconazole product for basal cell carcinoma nevus syndrome, provided that we continue to be responsible for all liabilities related to the product in the United States prior to the Effective Date. The Third Amended SLA continues in effect on an exclusive basis in United States on substantially the same terms as were provided for under the Second Amended SLA, except as described below.

In connection with the transfer of the SUBA-Itraconazole BCCNS clinical data and regulatory rights to Mayne Pharma:

- Mayne Pharma has agreed to pay us a 9% quarterly cash royalty on future net sales, if any, of SUBA-Itraconazole BCCNS in the United States (which we refer to as the Royalty), from which certain royalties owed by us to Mayne Pharma for access to certain patents would be funded.
- Mayne Pharma has agreed to advance funds to us in an aggregate amount of up to \$5 million (each, referred to as an Advance, and collectively, the Advances) on the following terms and conditions:
 - on the Effective Date, Mayne Pharma made an Advance to us of \$500,000;

Table of Contents

- within three (3) business days following the completion of the agreed upon activities associated with transferring the SUBA-Itraconazole BCCNS product to Mayne Pharma, Mayne Pharma made an Advance to the Company of \$1,000,000 (subsequently received in January 2019);
- if, and only if, our SUBA-Itraconazole BCCNS Phase 2(b) clinical trial data have been provided to Mayne Pharma in all material respects so as to allow Mayne Pharma to assume control of SUBA-Itraconazole BCCNS in the United States, upon the earlier of June 30, 2019 or the acceptance for filing by FDA of an NDA for the SUBA-Itraconazole BCCNS, Mayne Pharma must make an Advance to the Company of \$1,500,000; and
- If we raise aggregate gross proceeds of more than \$3 million from the sale of new common stock, preferred stock equity subordinate to the preferred stock held by Mayne Pharma or warrants (which we refer to as New Securities) to third parties in one or more equity financings by June 30, 2021 (which we refer to as the Equity Funding Achievement), we may request additional Advances of up to an amount equal to \$2 million less the amount of aggregate gross proceeds received by us from Mayne Pharma from the sale of New Securities if Mayne Pharma elects to participate in such equity financings pursuant to contractual pro rata participation rights contained in the Third Amended SLA.
- The field covered by the Third Amended SLA was amended to specifically include only the following indications: (i) any prostate cancer, prostatic intraepithelial neoplasia and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia, and (iii) familial adenomatous polyposis, colorectal polyps and Barrett's esophagus (the licensed field). Our continued right to work on these indications will no longer be tied to the achievement of clinical or commercial target dates as they were under the Second Amended SLA.
- Mayne Pharma will continue to provide quantities of SUBA-Itraconazole drug and placebo oral capsules without charge for our SUBA Itraconazole prostate clinical studies and for future indications as agreed to by the parties.
- Pursuant to the Third Amended SLA, unlike under the Second Amended SLA, Mayne Pharma has licensed to the Company the right to use all pre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to the Product anywhere in the world for its activities under the Third Amended SLA.

The Advances are structured as advances against the future Royalty, if any, owed by Mayne Pharma to us; provided that if SUBA-Itraconazole BCCNS is not approved in the U.S. by December 31, 2023, Mayne Pharma may convert such Advances into shares of our common stock based on a ten percent (10%) discount to the then current market value of the common stock. With respect to each Advance made by Mayne Pharma prior to the receipt of FDA approval of an NDA for SUBA-Itraconazole BCCNS, each \$0.75 increment of each such Advance will be credited and set off against each \$1.00 increment of Royalty owed to us, and with respect to each Advance made by Mayne Pharma following the receipt of FDA approval of an NDA for SUBA-Itraconazole BCCNS, each \$0.85 increment of each such Advance will be credited and set off against each \$1.00 increment of Royalty owed to us.

In addition, if, prior to June 30, 2021, we have not fulfilled the Equity Funding Achievement, Mayne Pharma will have the right to satisfy all of its remaining Royalty obligations by making a single lump sum payment to us in an amount equal to seventy percent (70%) of the fair market value of the remaining royalties payable to us as determined by an independent appraisal process.

Also, for so long as the Third Amended SLA is in effect, we must seek the prior written consent of Mayne Pharma before we dispose of the whole or a substantial part of our assets, operations or business, such consent not to be unreasonably withheld, conditioned or delayed. In addition, we must notify Mayne Pharma before we undergo any change in its direct or indirect Control (as defined below). If, acting reasonably, Mayne Pharma considers that such change will have a material, negative impact on its rights under the Third Amended SLA, Mayne Pharma may terminate the Third Amended SLA by giving written notice to us; provided, however, that we will not be deemed to have undergone a change in its direct or indirect Control if Mayne Pharma ceases to own more than 50% of the outstanding voting power of our company solely as a result of (i) our issuance of securities in an equity financing with respect to which Mayne Pharma has preemptive or similar contractual rights to participate on the same terms and conditions as investors in the financing and (ii) Mayne Pharma's election not to participate in such financing on the same terms and conditions as investors in the financing. For purposes of the Third Amended SLA, the term

Table of Contents

“Control” means having the power to exercise or control the right to vote attached to 50% or more of the issued voting equity in that party, to appoint one half or more of the directors to the board of directors, or the managers as applicable, of the party, or to determine substantially the conduct of the party’s business activities.

The Third Amended SLA also gives Mayne Pharma the right to convert the rights licensed to us from Mayne Pharma under the Third Amended SLA to a non-exclusive license, and to take a non-exclusive license to our pre-clinical or clinical trial or other data to exploit in the licensed field in the United States, if the FDA has not approved an NDA filed by us for SUBA-Itraconazole in part of the licensed field within eight (8) years from the Effective Date.

Amended and Restated Sublicense Agreement

The Amended and Restated Sublicense Agreement amends and replaces a similar agreement entered into between us and Mayne Pharma International, dated as of May 15, 2015, under which Mayne Pharma International sublicensed to us the exclusive U.S. rights to two certain third-party patents relating to the use of itraconazole as a treatment for cancer and age-related macular degeneration. The Amended and Restated Sublicense Agreement amends the required payments to Mayne Pharma for certain development-related milestone payments related to SUBA-Itraconazole BCCNS and allows for the termination of the Amended and Restated Sublicense Agreement if the Third Amended SLA expires or is terminated.

January 2018 Series B Preferred Stock Purchase Agreement

On January 8, 2018, we entered into a definitive securities purchase agreement (referred to in this “Certain Relationships and Related Party Transactions” referred to in this “Certain Relationships and Related Party Transactions” as the Purchase Agreement) with Mayne Pharma, pursuant to which Mayne Pharma agreed to purchase from us, and we agreed to issue to Mayne Pharma (over three closings as described further below, each referred to as a Closing):

- (i) up to 7,246,377 shares of our Series B Preferred Stock at \$0.69 per share of Series B Preferred Stock (with each share of Series B Preferred Stock being convertible into three (3) shares of our common stock for an effective price per share of common stock of \$0.23), for potential gross proceeds of \$5,000,000;
- (ii) Series A warrants (referred to as the Series A Warrants) to purchase up to an aggregate 5,434,783 shares of common stock, with a two-year term from the date of issuance and an exercise price per share of \$0.23; and
- (iii) Series B warrants (referred to as the Series B Warrants) to purchase up to an aggregate of 5,434,783 shares of common stock, with a five-year term from the date of issuance and an exercise price per share of \$0.275 (which we refer to together with the Series A Warrants as, the “Warrants”).

The transactions contemplated by the Purchase Agreement are referred to herein as the Financing. The Financing contemplated three Closings, as follows:

- (i) \$2.4 million was funded at an initial closing of the Financing that occurred on January 10, 2018;
- (ii) \$1.6 million was funded on July 5, 2018; and
- (iii) \$1.0 million may be funded on or before December 31, 2018 (referred to as the Third Closing) did not occur.

The funding of the Third Closing was conditioned upon the acceptance of filing by the FDA of our NDA for SUBA Itraconazole BCCNS. We entered into the Agreement, Third Amended SLA and Amended and Restated Sublicense Agreement because this milestone was not going to be achieved.

Under the Purchase Agreement, Mayne Pharma has been afforded certain demand and “piggyback” rights to cause us to register the shares of common stock underlying the Series B Preferred Stock and the Warrants for public resale; provided, however, that such rights shall only become effective and exercisable from and after the termination of the Second Amended SLA.

Table of Contents

The Warrants are divided equally between the Series A Warrants and the Series B Warrants (i.e., with each being exercisable for an aggregate of 5,434,783 shares of common stock if all Closings occur), which represents fifty percent (50%) warrant coverage on the shares of common stock underlying the Series B Preferred Stock. The Warrants will be issued, pro rata in relation to the total investment in the Series B Preferred Stock, at each Closing. The Warrants are substantially identical in form, except that: (i) the exercise price per share of the Series A Warrants shall be \$0.23 per share and the exercise price per share of the Series B Warrants shall be \$0.275 per share (which we refer to collectively as the Warrant Exercise Price) and (ii) The Series A Warrants shall have a term of two (2) years from the date of issuance and the Series B Warrants shall have term of five (5) years from the date of issuance. The Warrant Exercise Price shall be subject to customary stock-based, but not price-based, anti-dilution protection. The Warrants will not be eligible for “cashless” exercise.

Mayne Pharma owns approximately 54.1% of our equity securities on a fully-diluted basis and beneficially owns approximately 59.1% of our outstanding voting securities (including shares of our common stock and Series B Preferred Stock) as of the date of this filing.

Equity Holders Agreement

On June 24, 2014, we, Mayne Pharma, Hedgepath, LLC, Dr. Francis O’Donnell and Mr. Virca (who for these purposes we refer to together as the Equity Holder Parties) entered into an Amended and Restated Equity Holders Agreement. On May 15, 2015, the Equity Holder Parties entered into the Amendment No. 1 to the Amended and Restated Equity Holders Agreement. The Equity Holders Agreement governs the rights and obligations of each of the parties as they pertain to our securities and to the present and future governance of our company. Pursuant to the Equity Holders Agreement:

- Mayne Pharma and its affiliates have been granted a right of first refusal to purchase a pro rata share of any new securities issued by us, such pro rata share to be determined based upon the number of shares of common stock held by Mayne Pharma on a fully diluted basis as compared to the number of shares of common stock outstanding immediately prior to the offering of the new securities on a fully diluted basis;
- Mayne Pharma has the right to designate one director to our Board of Directors and to designate a second director if the size of the board is increased to seven directors until the earlier to occur of: (i) the date that the Supply and License Agreement is terminated or expires, or (ii) the date on which the Mayne Pharma or its affiliates ceases to own ten percent (10%) or more of the issued and outstanding common stock on a fully diluted basis (which we call the Voting Rights Termination Date);
- The Equity Holder Parties agree to use diligent good faith efforts to ensure that the Board of Directors continues to consist of a majority of “Independent Directors” (as defined in the Equity Holders Agreement) until such time as (i) a single stockholder (not acting as part of a “group”) of our company owns greater than ninety percent (90%) of our common stock or (ii) only for so long as Mayne Pharma holds at least forty percent (40%) of our outstanding common stock, there is a material breach of any document relating to the transactions by and among the Equity Holder Parties on May 15, 2015 other than by Mayne Pharma, and Mayne Pharma has not otherwise nominated, designated, elected or appointed a majority of the directors on the Board of Directors (we collectively refer to this breach as the Material Breach Condition);
- Mayne Pharma was granted a right of first refusal to purchase any shares of our common stock being transferred or sold by the individual account of Dr. O’Donnell or Mr. Virca except for certain exempt transfers as described in the Equity Holders Agreement;

The Equity Holders Agreement terminates (i) if we receive an adjudication of bankruptcy, we execute an assignment for the benefit of creditors, a receiver is appointed for us or we are voluntarily or involuntarily dissolved or (ii) if we, Hedgepath, LLC and Mayne Pharma expressly agree in writing. Additionally, certain limited provisions of the Equity Holders Agreement terminate at such time as the Mayne Pharma and its affiliates collectively own less than ten percent (10%) of our common stock on a fully diluted basis.

PRINCIPAL STOCKHOLDERS

The following table sets forth as of the date of this prospectus certain information concerning the ownership of our common stock as of the date of this prospectus with respect to: (i) each person known to us to be the beneficial owner of more than five percent of our common stock; (ii) all directors; (iii) all named executive officers; and (iv) all directors and executive officers as a group. Beneficial ownership is determined in accordance with the rules of the SEC that deem shares to be beneficially owned by any person who has voting or investment power with respect to such shares. Shares of common stock subject to options or warrants that are exercisable as of the date of this prospectus or are exercisable within 60 days of such date are deemed to be outstanding and to be beneficially owned by the person holding such options for the purpose of calculating the percentage ownership of such person but are not treated as outstanding for the purpose of calculating the percentage ownership of any other person.

Name and address of beneficial owners	Amount and nature of beneficial ownership of Common Stock	Approximate percentage of outstanding common stock (1)
Mayne Pharma Ventures Pty Ltd. (2)	248,244,247	59.1%
Hedgepath, LLC (3)	89,877,638	23.6%
Nicholas J. Virca (4)	9,037,519	2.4%
Garrison J. Hasara, CPA(5)	4,219,044	1.1%
Stefan J. Cross (6)	—	*
Dr. R. Dana Ono(7)	1,121,000	*
W. Mark Watson, CPA (8)	2,291,600	*
E. Brendan Magrab(9)	695,000	*
Robert D. Martin(10)	578,000	*
All directors and executive officers as a group (7 persons)	17,942,163	4.8%

* Less than 1%

- (1) Applicable percentages are based on 370,446,185 shares outstanding as of the date of this filing. This table is based upon information supplied by officers, directors, and principal stockholders and Schedule 13D(s) and Schedule 13G(s) filed with the SEC. Unless indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.
- (2) Includes 198,653,051 shares of our common stock, 17,391,306 shares of common stock upon conversion of Series B Preferred Stock, and warrants to purchase 32,199,890 shares of our common stock. The address for Mayne Pharma Ventures Pty Ltd is Level 14, 474 Flinders Street, Melbourne Vic 3000, Australia.
- (3) Includes 79,627,069 shares of our common stock and a warrant to purchase 10,250,569 shares of our common stock. Our former Corporate Secretary, James A. McNulty, CPA, has sole voting and dispositive power over the securities held by Hedgepath, LLC. The address for Hedgepath, LLC is 324 S. Hyde Park Avenue, Suite 350, Tampa, FL 33606.
- (4) Mr. Virca is our Chief Executive Officer and President. Includes 8,727,519 shares of our common stock and 310,000 vested stock options. Mr. Virca's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.
- (5) Mr. Hasara is our Chief Financial Officer and Treasurer. Includes 3,959,044 shares of our common stock and 260,000 vested stock options. Mr. Hasara's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.
- (6) Mr. Cross is a director of our company. Mr. Cross' address is c/o Mayne Pharma at Level 1, 99 King Street, Melbourne, Victoria 3000, Australia.
- (7) Dr. Ono is a director of our company. Includes 453,000 shares of our common stock and 668,000 vested stock options. Dr. Ono's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.
- (8) Mr. Watson is a director of our company. Includes 1,053,600 shares of our common stock, warrants to purchase 500,000 shares of our common stock, and 738,000 vested stock options. Mr. Watson's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.

Table of Contents

- (9) E. Brendan Magrab is the Chairman and a director of our company. Includes 65,000 shares of our common stock and 630,000 vested stock options. Mr. Magrab's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.
- (10) Robert D. Martin is a director of our company. Includes 60,000 shares of our common stock and 518,000 vested stock options. Mr. Martin's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.

DESCRIPTION OF SECURITIES TO BE REGISTERED

General

Our certificate of incorporation authorizes the issuance of up to 500,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share. As of the date of this prospectus, we had 370,446,185 shares of common stock issued and outstanding, and 5,797,102 shares of Series B Preferred Stock issued and outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders is determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Other matters are decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our Board of Directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Warrants

As of the date of this prospectus, warrants to purchase 64,868,959 shares of common stock were issued and outstanding. Warrants, issued in the amount of 10,250,569 to Hedgepath, LLC on June 24, 2014, have a term of 5 years and an exercise price of \$0.0878.

Further, upon closing of the 2016 Private Placement, 55,945,236 warrants were issued and 45,922,736 are outstanding as of the date of this prospectus with the following terms:

Exercisability. The warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of the first closing of this offering. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. In no event shall we be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of common stock underlying the warrants.

Table of Contents

Exercise Price. The initial exercise price per share of common stock purchasable upon exercise of the warrants is \$0.12 per share.

Certain Adjustments. The exercise price of the warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Delaware Anti-Takeover Law and Provisions of Certificate of Incorporation and By-Laws

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding specified shares; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation to or with the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any person that is:

- the owner of 15% or more of the outstanding voting stock of the corporation;
- an affiliate or associate of the corporation who was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately prior to the relevant date; or

Table of Contents

- the affiliates and associates of the above.

Under specific circumstances, Section 203 makes it more difficult for an “interested stockholder” to effect various business combinations with a corporation for a three-year period, although the stockholders may, by adopting an amendment to the corporation’s certificate of incorporation or bylaws, elect not to be governed by this section, effective 12 months after adoption.

Our certificate of incorporation and bylaws do not exclude us from the restrictions of Section 203. We anticipate that the provisions of Section 203 might encourage companies interested in acquiring us to negotiate in advance with our Board of Directors since the stockholder approval requirement would be avoided if a majority of the directors then in office approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder.

Certificate of Incorporation and Second Amended and Restated Bylaws

On May 15, 2015, our Board of Directors approved and adopted our second amended and restated bylaws. Provisions of our bylaws and our certificate of incorporation may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our certificate of incorporation and bylaws:

- permit our Board of Directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our Board of Directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder’s notice;
- do not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election.

SELLING STOCKHOLDERS

The shares of common stock being offered by the selling stockholders listed below (or their successors and assigns) were issued as follows:

- 27,115,000 shares of common stock and 27,115,000 shares of common stock underlying warrants purchased in the 2016 Private Placement to accredited investors that began in April 2016 and closed in May 2016;
- 466,000 shares of common stock underlying warrants issued to FINRA-member agents that assisted in securing investors for the 2016 Private Placement;
- 20,000,000 shares of common stock issued in connection with our June 24, 2014 private placement with Hedgepath, LLC;
- 10,000,000 of the shares issued to Hedgepath LLC in August 2014 upon its conversion of its Series A Convertible Preferred Stock; and
- 600,000 shares of common stock issued to an outside law firm for services rendered to us by such firm and previously registered on the Prior Registration Statement.

Summary of Offerings

2016 Private Placement

The 2016 Private Placement was a “best efforts/no minimum” private placement offering to accredited investors of units (each a Unit) at a price of \$0.10 per Unit, with each Unit consisting of: (i) one (1) share of common stock and (ii) a five-year warrant to purchase one (1) share of common stock at an exercise price of \$0.12 per share. No actual Units were issued, and each investor received shares of common stock and warrants only. During the course of the 2016 Private Placement, which began on March 30, 2016, we sold all 55,000,000 Units reserved for the 2016 Private Placement for aggregate gross proceeds of \$5,500,000. We conducted the first closing of the 2016 Private Placement on April 11, 2016.

In connection with the final closing, and pursuant to an existing right of our license and manufacturing partner and significant stockholder Mayne Pharma to purchase its pro rata share, on a fully-diluted basis, of new securities issuances of our company (we refer to this as the Mayne Right of First Refusal), we entered into a definitive securities purchase agreement (in substantially the same form as the purchase agreement executed by other investors in the 2016 Private Placement) with Mayne, and in connection therewith issued an aggregate of 27,885,000 Units to Mayne, consisting of an aggregate of 27,885,000 shares of common stock and a warrant to purchase up to an aggregate of 27,885,000 shares of common stock, for aggregate gross proceeds to us of \$2,788,500.

In connection with the 2016 Private Placement, we engaged certain FINRA-member agents to help it secure investors for the offering. Such agents’ secured investors for an aggregate of \$582,500 for the offering and received commissions equal to an aggregate of \$46,600 in cash and warrants (in substantially the form of the warrants issued in the offering) to purchase 466,000 shares of common stock. Pursuant to the Mayne Right of First Refusal, we issued and sold to Mayne Pharma a warrant to purchase 479,236 shares of common stock for a purchase price of \$47,924, which constituted Mayne Pharma’s pro rata share, on a fully-diluted basis, of all warrants issued in connection with the finder’s arrangements.

June 2014 Private Placement

On the June 24, 2014, we entered into a Stock Purchase Agreement with Hedgepath, LLC. Pursuant to such agreement, Hedgepath, LLC purchased 20,000,000 shares of our common stock at a purchase price of \$0.075 per share for an aggregate purchase price of \$1,500,000.

Table of Contents

Selling Stockholder Table

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of common stock by each of the selling stockholders. The table below sets forth information as of the date of this prospectus, to our knowledge, about the beneficial ownership of our common stock by the selling stockholders both before and immediately after this offering.

The selling stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior to Offering (1)	Maximum Number of Shares of Common Stock Offered by this Prospectus	Number of Shares of Common Stock Owned After Offering	Percentage of Common Stock Owned After Offering Assuming All Shares are Sold (2)
Camille Lamar Roberts (3)	3,000,000	3,000,000	—	—
R. David Yost (3)	4,000,000	4,000,000	—	—
Koo Family Limited Partnership, LLLP(4)	5,000,000	5,000,000	—	—
Robert F Henderson (3)	3,000,000	3,000,000	—	—
Chance Juenger (3)	2,000,000	2,000,000	—	—
BIF Family Trust (3)(5)	6,000,000	6,000,000	—	—
Tova Hanna Feinberg (3)	500,000	500,000	—	—
Rivka Lara Feinberg (3)	700,000	700,000	—	—
W. Mark Watson (3)(6)	1,553,600	1,000,000	553,600	*
David Kennedy (3)	4,000,000	4,000,000	—	—
Todd and Nancy Stewart Joint Revocable Living Trust (3)(7)	1,680,000	1,680,000	—	—
D.R.J.R. 2 Family Partners, LTD. (8)	4,000,000	4,000,000	—	—
Jeffrey A. Mullen (3)	500,000	500,000	—	—
JEB Partners, L.P. (3)(9)	5,000,000	5,000,000	—	—
Todd J. Stewart MD (3)	4,100,000	4,100,000	—	—
Cresswell Advisors Inc. (3)(10)	1,000,000	1,000,000	—	—
Charles W. Antrim (3)	600,000	600,000	—	—
George A. Paletta Jr. Revocable Trust (3)(11)	2,000,000	2,000,000	—	—
Ronald B. McNeil (3)	4,000,000	4,000,000	—	—
Freddie Garcia, Jr. (3)	500,000	500,000	—	—
Robert Waldon (3)	825,000	825,000	—	—
Concordia Capital Partners (3)(12)	825,000	825,000	—	—
Merriman Capital, Inc. (3)(13)	266,000	266,000	—	—
Craig Pierson (19)	85,000	85,000	—	—
Tom Masterson	85,000	85,000	—	—
Newbridge Securities (14)	30,000	30,000	—	—
Hedgepath, LLC (15)	89,877,638	7,440,000	82,437,638	22.3%
MOAB Investments, LP (16)(17)	6,000,000	6,000,000	—	—
Hopkins Capital Group II, LLC (16)(18)	14,060,000	14,060,000	—	—
Ellenoff Grossman & Schole LLP	600,000	600,000	—	—

* less than 1%

- (1) The number of shares owned prior to resale by each selling stockholder includes (i) all shares of common stock held by such selling stockholder and (ii) the shares of common stock issuable upon exercise of the any warrants held by such selling stockholder. No other securities have been included in this column.
- (2) Based upon 370,446,185 shares of common stock outstanding as of April 25, 2019.

Table of Contents

- (3) The number of shares of common stock offered pursuant to this prospectus by the selling stockholder consists of an equal number of (i) shares of common stock and (ii) shares of common stock underlying warrants to purchase common stock. Both the common stock and warrants were issued in connection with the 2016 Private Placement.
- (4) Michelle Koo has voting and investment power over the securities held by Koo Family Limited Partnership, LLLP.
- (5) Barry I. Feinberg has voting and investment power over the securities held by BIF Family Trust
- (6) W. Mark Watson is a director of the company.
- (7) Todd Stewart has voting and investment power over the securities held by Todd and Nancy Stewart Joint Revocable Living Trust
- (8) David Raskas has voting and investment power over the securities held by D.R.J.R. 2 Family Partners, LTD.
- (9) James Bessler has voting and investment power over the securities held by JEB Partners, L.P.
- (10) David Allan has voting and investment power over the securities held by Cresswell Advisors Inc.
- (11) George A. Paletta has voting and investment power over the securities held by George A. Paletta Jr. Revocable Trust
- (12) Michael Liss has voting and investment power over the securities held by Concordia Capital Partners
- (13) Merriman Capital, Inc. is a registered broker-dealer that served as a finder in the 2016 Private Placement. Jon Merriman, the chief executive officer of Merriman Capital, Inc. has voting and investment power over the securities held by Merriman Capital, Inc.
- (14) Robert Spitler has voting and investment power over the securities held by Newbridge Securities Corporation.
- (15) Hedgepath, LLC is a Florida limited liability company and a principal stockholder of our company which is controlled by Black Robe Capital LLC, of which James A. McNulty (our former Secretary and Chief Compliance Officer) is the manager.
- (16) The selling stockholder was transferred the shares of common stock offered pursuant to this prospectus by Hedgepath LLC.
- (17) Elizabeth A. Olish, president of the General Partner of MOAB Investment, LP, has voting and investment power over the securities held by MOAB Investments, LP
- (18) James A. McNulty (our former Secretary and Chief Compliance Officer) has sole voting and investment power over the securities held by Hopkins Capital Group II, LLC.
- (19) Consists of 50,000 shares of common stock underlying warrants to purchase common stock issued in connection with the 2016 Private Placement.

PLAN OF DISTRIBUTION

We are registering the shares of common stock to permit the resale of these shares of common stock by the holders thereof (and such holders' successors and assigns) from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

Table of Contents

- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- sales pursuant to Rule 144;
- broker-dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

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

The selling stockholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or reallocated or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

Table of Contents

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, estimated to be approximately \$33,000 in total, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that a selling stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the related registration rights agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

LEGAL MATTERS

Certain legal matters with respect to the shares of common stock offered hereby will be passed upon by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The financial statements of our company appearing in this prospectus have been included herein in reliance upon the report of Cherry Bekaert LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of Cherry Bekaert LLP as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the Securities and Exchange Commission (SEC) for our common stock offered in this offering. This prospectus does not contain all of the information set forth in the registration statement. You should refer to the registration statement and its exhibits for additional information. Whenever we make references in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for the copies of the actual contract, agreement or other document.

Our fiscal year ends on December 31. We are a reporting company and file annual, quarterly, and current reports, and other information with the SEC. Our SEC filings are also available to the public on the SEC's Internet site at <http://www.sec.gov>. We maintain a website at www.hedgepathpharma.com. Information contained in or accessible through our website is not and should not be considered a part of this prospectus and you should not rely on that information in deciding whether to invest in our common stock.

HEDGEPATH PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm – Cherry Bekaert LLP	F-2
Balance Sheets as of December 31, 2018 and 2017	F-3
Statements of Operations for the years ended December 31, 2018 and 2017	F-4
Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017	F-5
Statements of Cash Flows for the years ended December 31, 2018 and 2017	F-6
Notes to Financial Statements	F-7

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of HedgePath Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of HedgePath Pharmaceuticals, Inc. (the “Company”) as of December 31, 2018 and 2017 and the related statements of operations, stockholders’ equity and cash flows for each of the years then ended, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

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 of the United States of America (“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 standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to fraud or error. 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 supporting 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 financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ Cherry Bekaert LLP

We have served as the Company’s auditors since 2013.

Tampa, Florida
March 7, 2019

HEDGEPATH PHARMACEUTICALS, INC.
BALANCE SHEETS
DECEMBER 31, 2018 AND 2017

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,108,713	\$ 344,113
Prepaid expenses	41,296	61,655
Deposit	—	250,000
Total current assets	1,150,009	655,768
Other long-term assets	82,992	112,284
Total assets	<u>\$ 1,233,001</u>	<u>\$ 768,052</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 384,829	\$ 534,956
Dividends payable, related party	99,945	—
Other liabilities	215,876	66,533
Total current liabilities	700,650	601,489
Deferred revenue, related party	500,000	—
Total liabilities	<u>1,200,650</u>	<u>601,489</u>
Commitments and contingencies	—	—
Stockholders' equity:		
Series A Preferred Stock, \$0.0001 par value; 500,000 shares authorized; no shares issued and outstanding	—	—
Series B Convertible Preferred Stock, \$0.0001 par value; 7,246,377 shares authorized; 5,797,102 and -0- shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	3,960,866	—
Undesignated Preferred Stock, \$0.0001 par value; 2,253,623 shares authorized; no shares issued or outstanding (Note 5)	—	—
Common stock, \$0.0001 par value; 500,000,000 shares authorized; 370,084,064 and 369,599,266 shares issued and outstanding in 2018 and 2017, respectively	37,008	36,960
Additional paid-in capital	49,015,120	48,403,523
Accumulated deficit	(52,980,643)	(48,273,920)
Total stockholders' equity	<u>32,351</u>	<u>166,563</u>
Total liabilities and stockholders' equity	<u>\$ 1,233,001</u>	<u>\$ 768,052</u>

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2018 AND 2017

	Year Ended December 31,	
	2018	2017
Revenues:	\$ —	\$ —
Total revenues	—	—
Expenses:		
Research and development	2,633,567	2,227,589
General and administrative	1,930,690	2,891,442
Total expenses	4,564,257	5,119,031
Loss from operations	(4,564,257)	(5,119,031)
Interest income	14,027	17,866
Net loss	\$ (4,550,230)	\$ (5,101,165)
Preferred stock dividend	(156,493)	—
Net loss applicable to common shareholders	(4,706,723)	(5,101,165)
Basic and diluted loss per share	\$ (0.01)	\$ (0.01)
Weighted average common shares outstanding	369,812,939	366,622,107

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2018 AND 2017

	<u>Preferred Stock – Series B</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balances, January 1, 2017	—	—	353,447,172	\$35,345	\$50,167,372	\$(43,172,755)	\$ 7,029,962
Issuance of common stock upon warrant exercise	—	—	412,500	41	49,459	—	49,500
Issuance of common stock in payment of vested restricted stock units, net	—	—	15,739,594	1,574	(3,679,301)	—	(3,677,727)
Stock-based compensation	—	—	—	—	1,865,993	—	1,865,993
Net loss	—	—	—	—	—	(5,101,165)	(5,101,165)
Balances, December 31, 2017	—	—	369,599,266	\$36,960	\$48,403,523	\$(48,273,920)	\$ 166,563
Sale of Preferred Stock and common stock warrants to related party, net	5,797,102	3,960,866	—	—	—	—	3,960,866
Issuance of common stock upon warrant exercise	—	—	100,000	10	11,990	—	12,000
Issuance of common stock for payment of dividends on Preferred Stock	—	—	184,798	18	56,529	—	56,547
Stock based compensation	—	—	75,000	7	543,091	—	543,098
Issuance of common stock in payment of vested restricted stock units, net	—	—	125,000	13	(13)	—	—
Preferred stock dividends	—	—	—	—	—	(156,493)	(156,493)
Net loss	—	—	—	—	—	(4,550,230)	(4,550,230)
Balances, December 31, 2018	<u>5,797,102</u>	<u>\$3,960,866</u>	<u>370,084,064</u>	<u>\$37,008</u>	<u>\$49,015,120</u>	<u>\$(52,980,643)</u>	<u>\$ 32,351</u>

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2018 AND 2017

	Year Ended	
	December 31,	
	2018	2017
Operating activities:		
Net loss	\$(4,550,230)	\$(5,101,165)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Stock-based compensation	543,098	1,865,993
Changes in assets and liabilities:		
Prepaid expenses and other assets	299,651	28,734
Accounts payable and other current liabilities	(785)	293,356
Net cash flows used in operating activities	<u>(3,708,266)</u>	<u>(2,913,082)</u>
Financing activities:		
Net settlement in connection with the issuance of shares associated with underlying Restricted Stock Units	—	(3,677,727)
Advances of royalties, related party	500,000	—
Proceeds from exercise of common stock warrants	12,000	49,500
Proceeds from the sale of Preferred Stock and common stock warrants, related party, net	3,960,866	—
Net cash provided by (used in) from financing activities	<u>4,472,866</u>	<u>(3,628,227)</u>
Net increase(decrease) in cash and cash equivalents	764,600	(6,541,309)
Cash and cash equivalents at beginning of year	344,113	6,885,422
Cash and cash equivalents at end of year	<u>\$ 1,108,713</u>	<u>\$ 344,113</u>
Supplemental disclosure of non-cash financing activities:		
Fair value of shares withheld with net settlement transaction (Note 5)	<u>\$ —</u>	<u>\$ 3,677,727</u>
Issuance of common stock for payment of Preferred Stock dividend	<u>\$ 56,547</u>	<u>\$ —</u>
Accrued, but unpaid dividends	<u>\$ 99,946</u>	<u>\$ —</u>

See notes to financial statements

1. Corporate overview:

Overview

The accompanying audited financial statements of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the “Company”, “HPPI”, “we”, “us” or similar terminology) as successor to Commonwealth Biotechnologies, Inc., a Virginia corporation (“CBI”), have been prepared by the Company as a going concern, and in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

As used herein, the term “common stock” means the Company’s common stock, \$0.0001 par value per share.

Nature of the Business

The Company is a pharmaceutical development company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers and certain non-cancerous proliferation disorders. The Company may also explore acquiring or licensing other innovative therapeutics addressing unmet needs and orphan indications beyond cancer. The Company’s current focus is on the development of therapies for lung and prostate cancers in the U.S. market after licensing its initial indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome to Mayne Pharma in December 2018.

The Company’s primary proposed therapy is based upon the use of SUBA-Itraconazole, which is a patented, oral formulation of the currently marketed anti-fungal drug itraconazole. SUBA-Itraconazole is licensed to the Company on an exclusive basis in the United States in the field of certain cancers (including prostate and lung cancer) and certain non-cancerous proliferation disorders. The licensor of this technology is the Company’s majority stockholder, Mayne Pharma Ventures Pty Ltd (“Mayne Pharma”).

The Company demonstrated in its previous Phase 2(b) trial in Basal Cell Carcinoma Nevus Syndrome (“BCCNS”) that the dosing of oral capsules of SUBA-Itraconazole affects the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration (“FDA”) for, and has been extensively used to, treat fungal infections and has an extensive history of safe and effective use in humans. The Company has developed, optioned and licensed intellectual property and know-how related to the treatment of cancer patients using itraconazole and certain itraconazole analogues.

Overview of December 2018 Transactions with Mayne Pharma

On December 17, 2018 (the “Effective Date”), the Company entered into the following related agreements (collectively, the “Transaction Documents”):

- An agreement, by and among the Company, and Mayne Pharma, and Mayne Pharma International, an affiliate of Mayne Pharma (the “Agreement”);
- The Third Amended and Restated Supply and License Agreement with Mayne Pharma (the “Third Amended SLA”), which amended and restated the Company’s Second Amended and Restated Supply and License Agreement with Mayne Pharma, dated as of May 15, 2015 (as amended immediately prior to the Effective Date, the “Second Amended SLA”); and
- Amended and Restated Sublicense Agreement, by and between the Company and Mayne Pharma International, which amends and restates that certain Sublicense Agreement, dated August 31, 2015, between the Company and Mayne Pharma International, as amended.

1. Corporate overview (continued):

In addition, pursuant to the terms of the Agreement, the Company and Mayne Pharma agreed to vote in favor of the adoption of an Amended and Restated Certificate of Designation (“the Amended and Restated COD”) for the Company’s Series B Convertible Preferred Stock (the “Series B Preferred Stock”), which amended and restated the terms of the Series B Preferred Stock (originally issued to Mayne Pharma on January 8, 2018) to remove the redemption rights of the Series B Preferred Stock as described below. As of the Effective Date and at December 31, 2018, all 5,797,102 outstanding shares of the Series B Preferred Stock are held by Mayne Pharma.

The Transaction Documents resulted from negotiations regarding the existing right of Mayne Pharma under the Second Amended SLA to elect to assume control of the regulatory and clinical development program for SUBA-Itraconazole for the treatment of BCCNS (such product candidate “SUBA-Itraconazole BCCNS”) in exchange for a royalty on any future net sales of SUBA-Itraconazole BCCNS by Mayne Pharma in the United States if and FDA New Drug Application (“NDA”) was not accepted for filing by FDA by December 31, 2018 (subject to limited extension if the NDA were filed in December 2018). Based on unforeseen requirements imposed by FDA in September 2018, the Company determined that it would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus the Company commenced negotiations with Mayne Pharma to transfer SUBA-Itraconazole BCCNS in advance of December 31, 2018 on negotiated terms deemed beneficial to the Company.

The Transaction Documents were negotiated and approved on behalf of the Company by a special committee of disinterested, independent members of the Company’s Board of Directors (the “Board”) which was formed on October 26, 2018 for such purpose. The special Board committee consisted of three members of the Board who were each disinterested with respect to Mayne Pharma.

December 2018 Agreement with Mayne Pharma

Pursuant to the terms of the Agreement, on the Effective Date, Mayne Pharma (in its capacity as the holder of more than 50% of the outstanding voting securities of the Company) executed and delivered to the Company a stockholder consent which consented to the taking of the following actions: (a) the adoption of the Amended and Restated COD; (b) the election of each E. Brendan Magrab, W. Mark Watson, Dr. R. Dana Ono, Stefan J. Cross and Robert D. Martin (each a current member of the Board) to serve on the Board for a one-year term that expires at the next annual meeting of the Company’s stockholders or until his earlier death, resignation or removal; and (c) the approval of an increase in the size of the Company’s 2014 Equity Incentive Plan (the “EIP”) by 11,000,000 shares of common stock from 32,583,475 shares to 43,583,475 shares.

In addition, pursuant to the Agreement, for the period beginning on the Effective Date and ending three (3) years from the Effective Date, in the event that the Company asks its stockholders (whether at a meeting of stockholders or pursuant to a written consent of stockholders) to vote on or approve a proposal to effect a reverse split of the Company capital stock for the purpose of uplisting the common stock to a U.S. national securities exchange (a “Reverse Stock Split Proposal”), Mayne Pharma (on behalf of itself and its affiliates) agreed to vote or cause to be voted (in person, by proxy or by action by written consent, as applicable) all shares of the Company’s voting capital stock that either Mayne Pharma then owns or over which Mayne Pharma has voting control in favor of the adoption and approval of any such Reverse Stock Split Proposal. No assurances are given that the Company will seek an uplisting to a U.S. national securities exchange or implement a reverse stock split of its common stock.

Also, pursuant to the Agreement, Mayne Pharma consented and agreed (under the terms of agreements previously executed with the Company) to an increase in the number of shares of common stock that the Company may issue under the EIP to 17,624,000 shares from the current limit of 6,624,000 shares, with the agreement and understanding that such increase will be utilized by the Company during the period from the Effective Date through December 31, 2021.

1. **Corporate overview (continued):**

December 2018 – Third Amended and Restated Supply and License Agreement with Mayne Pharma

Pursuant to the Third Amended SLA, as of the Effective Date, Mayne Pharma assumed control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS and immediately assumed responsibility for all expenses related to exploiting the SUBA-Itraconazole product in the BCCNS field, provided that the Company continues to be responsible for all liabilities related to the product in the United States prior to the Effective Date. The Third Amended SLA will continue in effect on an exclusive basis in the United States on substantially the same terms as were provided for under the Second Amended SLA, except as described below.

In consideration of the transfer to Mayne Pharma of the SUBA-Itraconazole BCCNS clinical data and regulatory rights, the Company will receive the following consideration:

- (a) a 9% quarterly cash royalty (the “Royalty”) on future net sales, if any, of SUBA-Itraconazole product in the BCCNS field in the United States, from which certain royalties owed by the Company to Mayne Pharma for access to certain patents would also be funded.
- (b) Mayne Pharma’s agreement to advance funds to the Company in an aggregate amount of up to \$5 million on the following terms and conditions:
 - (i) As of the Effective Date, Mayne Pharma shall make an Advance to the Company of \$500,000; the Company received this first Advance on December 18, 2018;
 - (ii) Within three (3) business days following the completion of the agreed upon activities associated with transferring the SUBA-Itraconazole BCCNS product to Mayne Pharma, Mayne Pharma must make an Advance to the Company of \$1 million; the Company received this Advance in January 2019;
 - (iii) If, and only if, the Company’s Phase 2(b) clinical trial data have been provided to Mayne Pharma in all material respects so as to allow Mayne Pharma to assume control of SUBA-Itraconazole BCCNS in the United States, upon the earlier of June 30, 2019 or the acceptance for filing by FDA of an NDA for the SUBA-Itraconazole BCCNS, Mayne Pharma must make an Advance to the Company of \$1,500,000; and
 - (iv) If the Company raises aggregate gross proceeds of more than \$3 million from the sale of new common stock, preferred stock equity subordinate to the Series B Preferred Stock held by Mayne Pharma or warrants to third parties (“New Securities”) in one or more equity financings by June 30, 2021 (the “Equity Funding Achievement”), the Company may request additional Advances of up to an amount equal to \$2 million less the amount of aggregate gross proceeds received by the Company from Mayne Pharma from the sale of New Securities if Mayne Pharma elects to participate in such equity financings pursuant to contractual pro rata participation rights contained in the Third Amended SLA.
- (c) The field covered by the Third Amended SLA was amended to specifically include only the following indications: (i) any prostate cancer, prostatic intraepithelial neoplasia and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia, and (iii) familial adenomatous polyposis, colorectal polyps and Barrett’s esophagus (the “Field”). The Company’s work on these indications will no longer be tied to the achievement of clinical or commercial target dates as they were under the Second Amended SLA.
- (d) Mayne Pharma will continue to provide quantities of SUBA-Itraconazole drug and placebo oral capsules without charge for the Company’s SUBA-Itraconazole Prostate clinical studies and for future indications as agreed to by the parties.
- (e) Pursuant to the Third Amended SLA, Mayne Pharma has licensed to the Company the right to use all pre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to SUBA-Itraconazole anywhere in the world for its activities under the Third Amended SLA.

1. Corporate overview (continued):

With respect to each Advance made by Mayne Pharma prior to the receipt of FDA approval of an NDA for SUBA-Itraconazole BCCNS, each \$0.75 increment of each such Advance will be credited and set off against each \$1.00 increment of Royalty owed to the Company, and with respect to each Advance made by Mayne Pharma following the receipt of FDA approval of an NDA for SUBA-Itraconazole BCCNS, each \$0.85 increment of each such Advance will be credited and set off against each \$1.00 increment of Royalty owed to the Company. In addition, if, prior to June 30, 2021, the Company has not fulfilled the Equity Funding Achievement, Mayne Pharma shall have the right to satisfy all of its remaining Royalty obligations by making a single lump sum payment to the Company in an amount equal to seventy percent (70%) of the fair market value of the remaining royalties payable to the Company as determined by an independent appraisal process. The Third Amended SLA also gives Mayne Pharma the right to convert the Company's rights licensed from Mayne Pharma under the Third Amended SLA to anon-exclusive license if the FDA has not approved an NDA filed by the Company for the Product in part of the Field within eight (8) years from the Effective Date.

December 2018 Amended and Restated Sublicense Agreement

The Amended and Restated Sublicense Agreement amends and replaces a similar agreement entered into between the Company and Mayne Pharma International, dated as of May 15, 2015, under which Mayne Pharma International sublicensed to the Company the exclusive U.S. rights to two certain third-party patents relating to the use of itraconazole as a treatment for cancer and age-related macular degeneration. The Amended and Restated Sublicense Agreement amends the required payments to Mayne Pharma for certain development-related milestone payments related to SUBA-Itraconazole BCCNS and allows for the termination of the Amended and Restated Sublicense Agreement if the Third Amended SLA expires or is terminated.

January Series B Preferred Stock Purchase Agreement

On January 8, 2018, the Company entered into a Securities Purchase Agreement with Mayne Pharma (the "Securities Purchase Agreement"), pursuant to which Mayne Pharma agreed to purchase from the Company, and the Company agreed to issue to Mayne Pharma (over three closings as described further below):

- (i) up to 7,246,377 shares of the Company's then newly designed Series B Preferred Stock at \$0.69 per share of Series B Preferred Stock (with each share of Series B Preferred Stock being convertible into three (3) shares of the Company's common stock for an effective price per share of common stock of \$0.23), for potential gross proceeds of \$5,000,000;
- (ii) Series A Warrants to purchase up to an aggregate 5,434,783 shares of common stock, with a two-year term from the date of issuance and an exercise price per share of \$0.23; and
- (iii) Series B Warrants to purchase up to an aggregate of 5,434,783 shares of common stock, with a five-year term from the date of issuance and an exercise price per share of \$0.275 (together with the Series A Warrants, the "Warrants").

The transactions contemplated by the Purchase Agreement are referred to herein as the "Financing." The Financing contemplated three closings (each, a "Closing"), as follows:

- (i) \$2.4 million was funded at an initial closing of the Financing that occurred on January 10, 2018 (the "Initial Closing");
- (ii) \$1.6 million was funded in July 2018 (the "Second Closing"); and
- (iii) \$1.0 million that was to be funded on or before December 31, 2018 (or the "Third Closing") did not occur.

The funding of the Third Closing was conditioned upon the acceptance of filing by the FDA of the Company's NDA for SUBA-Itraconazole BCCNS, which did not occur.

1. Corporate overview (continued):

Terms of the Series B Preferred Stock

The Series B Preferred Stock carries the following provisions:

Price Per Share. The purchase price for each share of Series B Preferred Stock was \$0.69 (which is equal to three times (3x) the Conversion Price (as defined below)) (the "Per Share Price"). An applicable number of shares of Series B Preferred Stock was issued at the Initial and Second Closing based on the Per Share Price.

Dividends. The shares of Series B Preferred Stock accrue dividends at a rate of 5% of the Per Share Price per annum per share. Dividends are paid semi-annually as of June 30 (with a payment date of July 15) and December 31 (with a payment date of January 15) each year. The Company has the option in its discretion to pay dividends in cash or shares of common stock. If the Company elects to pay dividends in shares of common stock, the number of shares to be paid being calculated by dividing (i) the principal value of the dividend to be paid by (ii) the 6-month volume-weighted average price of the common stock prior to the measurement date (being 31 December, or 30 June) of the applicable year.

Voluntary and Mandatory Conversion. The shares of Series B Preferred Stock issued with the Initial and Second Closing will be convertible as provided for below into an aggregate of 17,391,306 shares of common stock based on a conversion price per share of \$0.23 (the "Conversion Price"). Each share of Series B Preferred Stock is convertible into three (3) shares of common stock at any time at the election of Mayne Pharma at a price per share equal to the Conversion Price. The Conversion Price is subject to customary stock-based, but not price-based, anti-dilution protection. Each share of Series B Preferred Stock automatically converts into three (3) shares of common stock based on the Conversion Price upon the approval by the FDA of an NDA for any SUBA-based therapeutic under the Third Amended SLA, pursuant to the Amended and Restated COD.

Liquidation Preference. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, Mayne Pharma (with respect to its holdings of Series B Preferred Stock only) will be entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payment will be made to the holders of all other capital stock of the Company (including the common stock) an amount per share of Series B Preferred Stock equal to the Per Share Price plus any dividends accrued but unpaid thereon.

Seniority. So long as the shares of Series B Preferred Stock are outstanding, the Company shall not, without the prior written approval of from the holders of a majority of the then outstanding shares of Series B Preferred Stock: (i) establish any security nor incur any secured or unsecured indebtedness (other than trade debt in the ordinary course of business) or (ii) establish and security that is pari passu or senior (or reclassify any junior security so as to make it pari passu or senior) in liquidation preference or senior to the Series B Preferred Stock.

Voting. With respect to its shares of Series B Preferred Stock, Mayne Pharma shall be entitled to vote together with the holders of common stock as a single class the number of votes Mayne Pharma would have if the Series B Preferred Stock were converted into common stock.

Redemption. On or after the five (5) year anniversary of the Initial Closing, Mayne Pharma had the right to cause the Company to redeem all (but not less than all) of the outstanding shares of Series B Preferred Stock for a price per share equal to the Per Share Price plus any accrued but unpaid dividends on such shares. However, pursuant to the Amended and Restated COD, the redemption rights were removed.

Terms of the Warrants

The Warrants are divided equally between the Series A Warrants and the Series B Warrants (i.e., with each being exercisable for an aggregate of 5,434,783 shares of common stock if all Closings had occurred), which

1. Corporate overview (continued):

represents fifty percent (50%) warrant coverage on the shares of common stock underlying the Series B Preferred Stock. The Warrants were issued, pro rata in relation to the total investment in the Series B Preferred Stock, at each Closing. Since the Third Closing did not occur, only 4,347,827 were issued of each the Series A Warrants and the Series B Warrants.

The Warrants are substantially identical in form, except that: (i) the exercise price per share of the Series A Warrants shall be \$0.23 per share and the exercise price per share of the Series B Warrants shall be \$0.275 per share (collectively, the “Warrant Exercise Price”) and (ii) The Series A Warrants shall have a term of two (2) years from the date of issuance and the Series B Warrants shall have term of five (5) years from the date of issuance. The Warrant Exercise Price shall be subject to customary stock-based, but not price-based, anti-dilution protection. The Warrants will not be eligible for “cashless” exercise.

2. Liquidity and management’s plans:

At December 31, 2018, the Company had approximately \$1.1 million in cash and cash equivalents. In December 2018, the Company entered into an agreement with Mayne Pharma which will provide \$3.0 million in funding by June 30, 2019 and up to an additional \$2.0 million if certain conditions are met by June 30, 2021 as discussed in Note 1 above. Based on the Company’s current operational plan and budget, the Company expects that it has sufficient cash to manage its business into approximately the third quarter of 2020. This estimation assumes the Company does not accelerate the development of existing product candidates, acquire other drug development opportunities, or otherwise face unexpected events, costs or contingencies, any of which could affect the Company’s cash requirements. Available resources may be consumed more rapidly than anticipated, potentially resulting in the need for additional funding. The Company intends to finance additional research and development, commercialization and distribution efforts, and its working capital needs primarily through the following:

- Proceeds from public and private financings (including, most recently, financings from the Company’s majority shareholder, Mayne Pharma) and, potentially, from strategic transactions;
- advances from Mayne Pharma of potential future royalties on the SUBA-Itraconazole BCCNS product available under the Third Amended SLA;
- royalty revenue from Mayne Pharma from sales of SUBA-Itraconazole BCCNS upon approval by FDA (after earned royalties have been applied to any advances due under the Third Amended SLA)
- proceeds from the exercise of outstanding warrants previously issued in private financings (including, potentially, warrants held by our majority shareholder, Mayne Pharma);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and
- seeking government or private foundation grants which would be awarded to us to further develop our current and future anti-cancer therapies.

However, there is a risk that none of these plans will be implemented in a manner necessary to sustain the Company for an extended period of time and that the Company will be unable to obtain additional financing when needed on commercially reasonable terms, if at all. If adequate funds are not available when needed, the Company may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require the Company to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on the Company.

3. Summary of Significant Accounting Policies:

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of Accounting Standards Codification ("ASC") Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard, as updated in 2015, will be effective for the Company in the first quarter for the year ending December 31, 2018 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. The Company will evaluate the impact of adoption of the new standard on its financial statements upon commencement of revenue generating activities.

In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing." ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. These ASUs apply to all companies that enter into contracts with customers to transfer goods or services. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, but not before interim and annual reporting periods beginning after December 15, 2016. Entities have the choice to apply the ASUs either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. The Company will evaluate the impact of adoption of the new standard on its financial statements upon commencement of revenue generating activities.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification ("ASC") Topic 718, Compensation – Stock Compensation. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. The Company evaluated the impact of the revised guidance on its financial statements and determined it had no significant impact.

Management has considered all other recent accounting pronouncements that are issued, but not effective, and it does not believe that they will have a significant impact on the Company's results of operations or financial position.

Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Revenue Recognition

The Company currently has no ongoing source of revenues. Miscellaneous income, including interest, is recognized when earned by the Company. Deferred revenue represents cash received for royalties in advance of being earned. Such payments are reflected as deferred revenue until recognized under the Company's revenue recognition policy. Deferred revenue would be classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date. Deferred revenue will be recognized when the product is sold and the royalty is earned. Since all

3. Summary of Significant Accounting Policies (continued):

deferred revenue is related to the BCCNS product which is yet to be approved by FDA, the Company has determined that 100% of the advances of the royalty received by Mayne Pharma should be classified as non-current. At December 31, 2018, Deferred Revenue consisted of \$0.5 million of royalties advanced by Mayne Pharma under the Third Amended SLA. There was no Deferred Revenue at December 31, 2017.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts of \$250,000 for substantially all accounts. As of December 31, 2018, the Company had approximately \$0.8 million in excess of the amount covered by Federal Deposit Insurance Corporation with one financial institution.

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties who conduct research and development activities on behalf of the Company as well as purchased in-process research and development.

Stock-Based Compensation

The Company accounts for stock-based awards to employees and non-employees using Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 718 – Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of restricted stock units issued are determined by the Company based predominantly on the trading price of the common stock on the date of grant. Fair value of each common stock option is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of a peer group’s common stock and other factors estimated over the expected term of the options. The expected term of the options granted is derived using the “simplified method” which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

In applying the Black-Scholes option pricing model for options issued in March 2018 that vested on the grant date, the assumptions were as follows: expected price volatility of 113.67%; risk-free interest rate of 2.64%; weighted average expected life in years of 5; and no dividend yield. In applying the Black-Scholes option pricing model for options issued in March 2018 that will vest on the anniversary of the grant date, the assumptions were as follows: expected price volatility of 116.59%; risk-free interest rate of 2.64%; weighted average expected life in years of 6; and no dividend yield. In applying the Black-Scholes option pricing model for options issued in June 2018 that will vest on the anniversary of the grant date, the assumptions were as follows: expected price volatility of 112.6%; risk-free interest rate of 2.81%; weighted average expected life in years of 6; and no dividend yield. The value of these awards is based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

Income taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. See Note 4 for details. Management has evaluated the guidance relating to accounting for uncertainty in income taxes and has determined that the Company had no uncertain income tax positions that could have a significant effect on the financial statements for the years ended December 31, 2018 or 2017.

Table of Contents

4. Income Taxes:

The difference between expected income tax benefits and income tax benefit recorded in the financial statements is explained below:

	December 31,	
	2018	2017
Income taxes benefit computed at statutory rate	\$ (955,548)	\$(1,734,396)
State income tax benefit, net	(188,002)	(176,082)
Change in effective tax rate	—	2,701,758
Other	(24,357)	(369,400)
Change in valuation allowance	1,167,907	(421,880)
Total	<u>\$ —</u>	<u>\$ —</u>

The significant components of deferred income tax assets and liabilities consist of the following:

Deferred tax assets (liabilities)	December 31,	
	2018	2017
In-process research and development	\$ 736,325	\$ 736,325
Net operating loss carry forward	5,807,112	4,759,727
R&D credit	310,682	211,461
Share-based compensation	33,943	9,424
Other	2,607	5,825
	<u>6,890,669</u>	<u>5,722,762</u>
Less: valuation allowance	<u>(6,890,669)</u>	<u>(5,722,762)</u>
Total	<u>\$ —</u>	<u>\$ —</u>

In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. At December 31, 2018 and 2017, the Company recorded a 100% valuation allowance against its deferred tax assets as it has determined such amounts will not be currently realizable.

The Company has a federal net operating loss (“NOLs”) of approximately \$23.1 million as of December 31, 2018. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a “loss corporation”, as defined, there are annual limitations on the amount of the NOLs and other deductions which are available to the Company. The portion of the NOLs incurred prior to August 12, 2013 is subject to this limitation. As such, the use of these NOLs to offset taxable income is limited to approximately \$35,000 per year and the Company has written off the deferred tax assets associated with the NOLs limited due to the ownership change that occurred on August 12, 2013. The Company’s State NOLs are approximately \$23.1 million as of December 31, 2018. The loss carryforwards began to expire in 2018.

5. Stockholders’ Equity:

Employee Stock Plans

A 2009 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. There are no options outstanding under this plan.

On July 18, 2014, the EIP was adopted by the Company’s Board of Directors. On September 30, 2014, the EIP was approved by the majority of stockholders. The 2014 EIP initially authorized the issuance of up to 32,583,475 shares of the Company’s common stock. An additional 11 million shares were added to the 2014 EIP for a total of 43,583,475 shares pursuant to the Agreement entered into by the Company and Mayne Pharma in December 2018.

5. **Stockholders' Equity (continued):**

All previously outstanding RSUs vested upon the change in control as a result of Mayne Pharma's November 2016 warrant exercise, in connection with which Mayne Pharma became the Company's majority stockholder. On March 8, 2017, 26,541,738 previously vested but unpaid RSUs were settled by issuing shares of common stock. Upon settlement of the RSUs, the Company issued 15,739,594 shares of common stock to employees (including executive officers), current and former Board members, and contractors. Additionally, 10,802,144 shares of common stock, valued at approximately \$3.7 million, were withheld from issuance representing estimated income taxes due from the RSU recipients as the fair value of the shares is considered taxable income upon issuance. The Company subsequently remitted to the appropriate taxing authorities in cash both the Company's tax withholdings and the RSU recipient portions of the tax withholdings in the amount of approximately \$3.7 million.

Stock option activity for the years ended December 31, 2017 and 2018 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2017	650,000	\$ 0.24	\$ 97,500
No activity in 2017	—	—	
Outstanding at December 31, 2017	650,000	\$ 0.24	\$ 6,500
Granted to Directors and Officers in 2018	2,774,000	\$ 0.29	
Exercised	—	—	
Forfeited	—	—	
Outstanding at December 31, 2018	<u>3,424,000</u>	<u>\$ 0.28</u>	<u>\$ 0</u>

Options outstanding at December 31, 2018 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 0.20 - \$ 0.25	650,000	7.50	\$ 0.24	\$ 0
\$ 0.26 - \$ 0.30	1,862,000	9.21	\$ 0.27	\$ 0
\$ 0.30 - \$ 0.33	912,000	9.46	\$ 0.33	\$ 0
	<u>3,424,000</u>			<u>\$ 0</u>

Options exercisable at December 31, 2018 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 0.20 - \$ 0.25	650,000	7.50	\$ 0.24	\$ 0
\$ 0.26 - \$ 0.30	758,000	9.21	\$ 0.27	\$ 0
	<u>1,408,000</u>			<u>\$ 0</u>

The weighted average grant date fair value of options granted during the year ended December 31, 2018 was \$0.24. There were no options granted during the year ended December 31, 2017.

5. Stockholders' Equity (continued):

Non-vested stock option activity for the year ended December 31, 2018 is as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price Per Share</u>	<u>Aggregate Intrinsic Value</u>
Non-vested at December 31, 2017	—		
Granted	2,774,000		
Vested	(758,000)		
Forfeited	—		
Non-vested at December 31, 2018	<u>2,016,000</u>	<u>\$ 0.25</u>	<u>\$ 0</u>

Incentive awards may be in the form of stock options, restricted stock, restricted stock units and performance and other awards. In the case of incentive stock options, the exercise price will not be less than 100% of the fair market value of shares covered at the time of the grant, or 110% for incentive stock options granted to persons who own more than 10% of the Company's voting stock. Options granted will generally vest over a three-year period from the date of grant and will be exercisable for ten years, except that the term may not exceed five years for incentive stock options granted to persons who own more than 10% of the Company's outstanding common stock.

Stock-based compensation expense is determined based on the fair value of the stock-based awards and recognized over the vesting period. The Company recognized \$543,089 and \$1,865,993 in stock-based compensation expense related to stock options for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, there was unamortized stock-based compensation of approximately \$0.1 million.

Preferred Stock Issuances

See Note 1 for discussion of preferred stock issued to Mayne Pharma in 2018.

Warrants

See Note 1 for discussion of warrants issued in conjunction with the Mayne Pharma Purchase Agreement. See Note 1 for discussion of the warrants issued in connection with the Series B Preferred Stock Purchase Agreement.

Details of the 2017 and 2018 warrant exercises can be found in the chart below:

<u>Year</u>	<u>Warrant Holder</u>	<u># of Warrants Exercised</u>	<u>Exercise Price</u>	<u>Total Proceeds</u>
2017	May 2016 Financing Investors	412,500	\$ 0.12	\$49,500
2018	May 2016 Financing Investors	100,000	\$ 0.12	\$12,000

There were 64,868,959 outstanding common stock warrants at December 31, 2018 with a weighted average exercise price of \$0.13 and a weighted average remaining life of 2.1 years.

6. Related party transactions:

The Company has significant contractual agreements with majority stockholder Mayne Pharma as discussed in Note 1 and Note 3. There were no amounts due to or from Mayne Pharma at December 31, 2018.

7. Legal Proceedings:

The Company is currently not subject to any material legal proceedings. However, the Company may from time to time become a party to various legal proceedings arising in the ordinary course of business.

8. Subsequent Events:

In January 2019, the Company entered into a 6-month lease for office space in Tampa, Florida related to the relocation of their corporate office beginning February 1, 2019. The monthly rent payment beginning February 1, 2019 is \$3,511.

On January 15, 2019, the Company issued 362,121 shares of common stock to Mayne Pharma in payment of the Series B Preferred Stock dividend for the period of July 1, 2018 through December 31, 2018.

You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.



**85,296,000 SHARES OF
COMMON STOCK**

PROSPECTUS

, 2019

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

The following table sets forth the expenses in connection with this registration statement. All of such expenses are estimates, other than the filing fees payable to the Securities and Exchange Commission and to FINRA.

<i>Description</i>	<i>Amount to be Paid</i>
Filing Fee—Securities and Exchange Commission	\$ —
Attorney’s fees and expenses	7,500 *
Accountant’s fees and expenses	2,000 *
Miscellaneous expenses	5,000 *
Total	\$ 14,500 *

* Estimated

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending or completed actions, suits or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee or agent of the corporation. Section 145 of the Delaware General Corporation Law also provides that expenses (including attorneys’ fees) incurred by a director or officer in defending an action may be paid by a corporation in advance of the final disposition of an action if the director or officer undertakes to repay the advanced amounts if it is determined such person is not entitled to be indemnified by the corporation. The Delaware General Corporation Law provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise. Our second amended and restated bylaws (which we refer to as the bylaws) provide that, to the fullest extent permitted by law, we shall indemnify and hold harmless any person who was or is made or is threatened to be made a party or is otherwise involved in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative by reason of the fact that such person, or the person for whom he is the legally representative, is or was a director or officer of ours, against all liabilities, losses, expenses (including attorney’s fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such proceeding.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director’s duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions, or (iv) for any transaction from which the director derived an improper personal benefit.

Our certificate of incorporation, as amended (which we refer to as our certificate of incorporation) provides that we shall, to the maximum extent permitted from time to time under the law of the State of Delaware, indemnify and upon request shall advance expenses to any person who is or was a party or is threatened to be made a party to any threatened, pending or completed action, suit, proceeding or claim, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was or has agreed to be a director or officer of ours or while a director or officer is or was serving at our request as a director, officer, partner, trustee, employee or agent of any corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys’ fees and expenses), judgments, fines, penalties and amounts paid in settlement incurred in connection with the investigation, preparation to defend or defense of such action, suit, proceeding or claim; provided, however, that the foregoing shall not require us to indemnify or advance expenses to any person in connection with any action, suit, proceeding or claim initiated by or on behalf of such person or any counterclaim against us initiated by or on behalf of such person. Such indemnification shall not be exclusive of other

Table of Contents

indemnification rights arising under any by-law, agreement, vote of directors or stockholders or otherwise and shall inure to the benefit of the heirs and legal representatives of such person. Any person seeking indemnification shall be deemed to have met the standard of conduct required for such indemnification unless the contrary shall be established. Any repeal or modification of our certificate of incorporation shall not adversely affect any right or protection of a director or officer of ours with respect to any acts or omissions of such director or officer occurring prior to such repeal or modification.

Our bylaws provide we shall, to the fullest extent permitted under the laws of the State of Delaware, as amended and supplemented from time to time, indemnify each 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, by reason of the fact that such party is or was, or has agreed to become, a director or officer of ours, or is or was serving, or has agreed to serve, at our request, as a director, officer or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, including any employee benefit plan, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such party or on such party's behalf in connection with such action, suit or proceeding and any appeal therefrom.

Expenses incurred by such a person in defending a civil or criminal action, suit or proceeding by reason of the fact that such person is or was, or has agreed to become, a director or officer of ours, or is or was serving, or has agreed to serve, at our request, as a director, officer or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, including any employee benefit plan, or by reason of any action alleged to have been taken or omitted in such capacity shall be paid by us in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such person to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by us as authorized by relevant sections of the Delaware General Corporation Law. Notwithstanding the foregoing, we shall not be required to advance such expenses to a person who is a party to an action, suit or proceeding brought by us and approved by a majority of our Board of Directors that alleges willful misappropriation of corporate assets by such person, disclosure of confidential information in violation of such person's fiduciary or contractual obligations to us or any other willful and deliberate breach in bad faith of such person's duty to us or our stockholders.

We shall not indemnify any such person seeking indemnification in connection with a proceeding (or part thereof) initiated by such person unless the initiation thereof was approved by our Board of Directors.

The indemnification rights provided in our bylaws shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any by-law, agreement or vote of stockholders or disinterested directors or otherwise, both as to action in their official capacities and as to action in another capacity while holding such office, continue as to such person who has ceased to be a director or officer, and inure to the benefit of the heirs, executors and administrators of such a person.

If the Delaware General Corporation Law is amended to expand further the indemnification permitted to indemnitees, then we shall indemnify such persons to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

We may, to the extent authorized from time to time by our Board of Directors, grant indemnification rights to other employees or agents of ours or other persons serving us and such rights may be equivalent to, or greater or less than, those set forth in our bylaws.

Our obligation to provide indemnification under our bylaws shall be offset to the extent of any other source of indemnification or any otherwise applicable insurance coverage under a policy maintained by us or any other person.

To assure indemnification under our bylaws of all directors, officers, employees or agents who are determined by us or otherwise to be or to have been "fiduciaries" of any employee benefit plan of ours that may exist from time to time, Section 145 of the Delaware General Corporation Law shall, for the purposes of our bylaws, be interpreted as follows: an "other enterprise" shall be deemed to include such an employee benefit plan, including without

Table of Contents

limitation, any plan of ours that is governed by the Act of Congress entitled “Employee Retirement Income Security Act of 1974,” as amended from time to time; we shall be deemed to have requested a person to serve an employee benefit plan where the performance by such person of his duties to us also imposes duties on, or otherwise involves services by, such person to the plan or participants or beneficiaries of the plan; and excise taxes assessed on a person with respect to an employee benefit plan pursuant to such Act of Congress shall be deemed “fines.”

Our bylaws shall be deemed to be a contract between us and each 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, by reason of the fact that person is or was, or has agreed to become, a director or officer of ours, or is or was serving, or has agreed to serve, at our request, as a director, officer or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, including any employee benefit plan, or by reason of any action alleged to have been taken or omitted in such capacity, at any time while this by-law is in effect, and any repeal or modification thereof shall not affect any rights or obligations then existing with respect to any state of facts then or theretofore existing or any action, suit or proceeding theretofore or thereafter brought based in whole or in part upon any such state of facts.

The indemnification provision of our bylaws does not affect directors’ responsibilities under any other laws, such as the federal securities laws or state or federal environmental laws.

We may purchase and maintain insurance on behalf of any person who is or was a director, officer or employee of ours, or is or was serving at our request as a director, officer, employee or agent of another company, partnership, joint venture, trust or other enterprise against liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not we would have the power to indemnify him against liability under the provisions of this section. We currently maintain such insurance.

The right of any person to be indemnified is subject to our right, in lieu of such indemnity, to settle any such claim, action, suit or proceeding at our expense of by the payment of the amount of such settlement and the costs and expenses incurred in connection therewith.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission, 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 the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered herewith, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

On May 15, 2015, we entered into the 2015 Mayne Purchase Agreement pursuant to which we issued to Mayne Pharma (i) 33,333,333 shares of our common stock and (ii) a warrant to purchase 33,333,333 shares of our common stock. Such warrant has an exercise price of \$0.075 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on May 15, 2020. Such securities were issued in a transaction exempt from the registration requirements under Section 4(a)(2) and/or Regulation D of the Securities Act inasmuch as they were issued to less than ten sophisticated persons who represented to us that they are accredited investors as defined in Rule 501 of Regulation D promulgated under the Securities Act and acquiring the securities for investment, for their own account, and not for resale or with a view to distribution thereof in violation of the Securities Act, and the rules and regulations promulgated thereunder.

On May 25, 2016, we closed our “best efforts/no minimum” private placement offering to accredited investors of units (each a Unit) at a price of \$0.10 per Unit, with each Unit consisting of: (i) one (1) share of common stock and (ii) a five-year warrant to purchase one (1) share of common stock at an exercise price of \$0.12 per share. No

Table of Contents

actual Units were issued, and each investor received shares of common stock and warrants only. During the course of the 2016 Private Placement, which began on March 30, 2016, we sold all 55,000,000 Units reserved for the 2016 Private Placement for aggregate gross proceeds of \$5,500,000. We conducted the first closing of the 2016 Private Placement on April 11, 2016. The sales were made pursuant to the exemptions from registration provided by Rule 506(c) of Regulation D promulgated under the Securities Act because, among other things, the investors were “accredited investors”, they purchased the securities for investment purposes only and not for resale and we took appropriate measures to restrict the transfer of the securities sold and verify the accredited investor status of the investors. In connection with the offering, we engaged certain FINRA-member agents to help it secure investors for the offering. Such agents’ secured investors for an aggregate of \$582,500 for the offering and received commissions equal to an aggregate of \$46,600 in cash and warrants (in substantially the form of the warrants issued in the offering) to purchase 466,000 shares of common stock. Pursuant to a right of first refusal held by Mayne Pharma, we issued and sold to Mayne Pharma a warrant to purchase 479,236 shares of common stock for a purchase price of \$47,924, which constituted Mayne Pharma’s pro rata share, on a fully-diluted basis, of all warrants issued in connection with the finder’s arrangements.

On January 8, 2018, we entered into a definitive securities purchase agreement with Mayne Pharma pursuant to which Mayne Pharma agreed to purchase (over three closings as described further below, each a Closing): (i) up to 7,246,377 shares of the Company’s newly designated Series B Convertible Preferred Stock (or the Series B Preferred Stock) at \$0.69 per share of Series B Preferred Stock (with each share of Series B Preferred Stock being convertible into three (3) shares of the Company’s common stock, for an effective price per share of common stock of \$0.23), for potential gross proceeds of \$5,000,000; (ii) Series A warrants (or the Series A Warrants) to purchase up to an aggregate 5,434,783 shares of common stock, with a two year term from the date of issuance and an exercise price per share of \$0.23; and (iii) Series B warrants (or the Series B Warrants) to purchase up to an aggregate of 5,434,783 shares of common stock, with a five year term from the date of issuance and an exercise price per share of \$0.275 (the Series B Warrants together with the Series A Warrants, referred to as the Warrants). The transactions contemplated by the Purchase Agreement are referred to herein as the Financing. The Financing contemplates three closings (each, a “Closing”), as follows: (A) \$2.4 million was funded at an initial closing of the Financing that occurred on January 10, 2018 (or the Initial Closing); (B) \$1.6 million shall be funded on or before July 1, 2018 (or the Second Closing); and (C) \$1.0 million may be funded on or before December 31, 2018 (or the Third Closing). There are no operational milestones of the Company associated with Mayne Pharma’s obligation to purchase the shares of Series B Preferred Stock and Warrants at the Second Closing, which shall only be subject to customary closing conditions, and there are certain operational milestone associated with the Third Closing. Such securities were issued in a transaction exempt from the registration requirements under Section 4(a)(2) and/or Regulation D of the Securities Act inasmuch as they were issued to less than ten sophisticated persons who represented to us that they are accredited investors as defined in Rule 501 of Regulation D promulgated under the Securities Act and acquiring the securities for investment, for their own account, and not for resale or with a view to distribution thereof in violation of the Securities Act, and the rules and regulations promulgated thereunder.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit No.	Description
3.1	Certificate of Incorporation of the Company (1)
3.2	Amended and Restated Certificate of Designation for Series A Preferred Stock (2)
3.3	Certificate of Amendment to the Company’s Certificate of Incorporation (3)
3.4	Second Amended and Restated Bylaws of the Company (4)
3.5	Certificate of Amendment to the Company’s Certificate of Incorporation (5)
3.6	Amended and Restated Certificate of Designation of Series B Preferred Stock of the Company, dated February 1, 2019 (6)
4.1	Warrant, dated June 24, 2014 issued to Hedgepath, LLC (7)

Table of Contents

Exhibit No.	Description
4.2	Form of Warrant issued in the 2016 Private Placement (8)
4.3	Form of Warrant issued in the January 2018 Series B Preferred Stock Financing (9)
5.1	Opinion of Ellenoff Grossman & Schole LLP covering 30,600,00 shares of common stock (3)
5.2	Opinion of Ellenoff Grossman & Schole LLP (15)
10.1	Amended and Restated Equity Holders Agreement, dated May 15, 2015, by and between the Company, Mayne Pharma Ventures Pty Ltd., Hedgepath, LLC, Nicholas J. Virca and Frank O'Donnell, Jr. M.D. (10)+
10.2	Amendment No. 1 to Amended and Restated Equity Holders Agreement, dated December 17, 2015, Company, Mayne Pharma Ventures Pty Ltd., Hedgepath, LLC., Nicholas J. Virca and Frank O'Donnell (11)
10.3	Employment Letter Agreement, dated December 31, 2018, between the Company and Nicholas J. Virca (12)
10.4	Employment Letter Agreement, dated December 31, 2018, between the Company and Garrison J. Hasara (12)
10.5	Third Amended and Restated Supply and License Agreement, dated December 17, 2018, by and among Mayne Pharma, Mayne Pharma International and the Company (14)+
10.6	Amended and Restated Sublicense Agreement, dated December 17, 2018, by and among Mayne Pharma, Mayne Pharma International and the Company (14)+
10.7	Agreement, dated December 17, 2018, by and among Mayne Pharma, Mayne Pharma International and the Company (14)+
10.8	Master Clinical Services Agreement, dated June 15, 2015, by and between the Company and SciQuus, Inc. (10)+
10.9	Securities Purchase Agreement, dated January 8, 2018, between the Company and Mayne Pharma (9)
14	Code of Ethical Conduct (13)
23.1	Consent of Cherry Bekaert LLP *
23.2	Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.1)
23.3	Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.2)
24.1	Power of Attorney (See signature page)
101.ins	XBRL Instance Document*
101.sch	XBRL Taxonomy Extension Schema Document*
101.cal	XBRL Taxonomy Calculation Linkbase Document*
101.def	XBRL Taxonomy Definition Linkbase Document*
101.lab	XBRL Taxonomy Label Linkbase Document*
101.pre	XRL Taxonomy Presentation Linkbase Document*

* Filed herewith

+ Confidential treatment has been granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.

Table of Contents

- (1) Previously filed with Form 8-K, dated August 16, 2013.
- (2) Previously filed with Form 8-K, dated September 10, 2013.
- (3) Previously filed with Form S-1/A on July 22, 2015.
- (4) Previously filed with Form 8-K, dated May 21, 2015.
- (5) Previously filed with Form 8-K, dated May 26, 2016.
- (6) Previously filed with Definitive Information Statement, filed on January 8, 2019.
- (7) Previously filed with Form 8-K, dated June 30, 2014.
- (8) Previously filed with Form 8-K, dated April 15, 2016.
- (9) Previously filed with Form 8-K, dated January 11, 2018.
- (10) Previously filed with Form 10-Q on August 14, 2015.
- (11) Previously filed with Form 8-K, dated December 22, 2016.
- (12) Previously filed with Form 8-K, dated December 31, 2018.
- (13) Previously filed with Form 10-K on February 13, 2015.
- (14) Previously filed with Form 10-K on March 7, 2019.
- (15) Previously filed with Form S-1/A on July 21, 2016.

ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes:

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

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

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

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

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

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

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Table of Contents

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

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

[Table of Contents](#)

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused its registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Tampa, State of Florida, on April 26, 2019.

HEDGEPATH PHARMACEUTICALS, INC.

/s/ Nicholas J. Virca

Name: Nicholas J. Virca

Title: President and Chief Executive Officer
(Principal Executive Officer)

NOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Nicholas J. Virca and Garrison J. Hasara his true and lawful attorney-in-fact, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments including post-effective amendments to this registration statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, hereby ratifying and confirming all that said attorney-in-fact or his 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Nicholas J. Virca</u> Nicholas J. Virca	President and Chief Executive Officer (Principal Executive Officer)	April 26, 2019
<u>/s/ Garrison J. Hasara</u> Garrison J. Hasara	Chief Financial Officer, Chief Compliance Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	April 26, 2019
<u>/s/ W. Mark Watson</u> W. Mark Watson	Chairman of the Board and Director	April 26, 2019
<u>/s/ Robert Martin</u> Robert Martin	Director	April 26, 2019
<u>/s/ E. Brendan Magrab</u> E. Brendan Magrab	Director	April 26, 2019
<u>/s/ Stefan J. Cross</u> Stefan J. Cross	Director	April 26, 2019
<u>/s/ Dr. R. Dana Ono</u> Dr. R. Dana Ono	Director	April 26, 2019

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference of our firm under the caption “Experts” in this Post-Effective Amendment No. 3 to the Registration Statement on FormS-1 and related prospectus of Hedgepath Pharmaceuticals, Inc. dated April x, 2019 and to the inclusion therein of our report, dated March 7, 2019, with respect to the financial statements of HedgePath Pharmaceuticals, Inc. included in its Form 10-K filed March 7, 2019 with the Securities and Exchange Commission.

/s/ CHERRY BEKAERT LLP

Tampa, Florida
April 26, 2019