As filed with the Securities and Exchange Commission on July 18, 2016

Registration No. 333-212092

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

Amendment No. 1
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	**2834**	**30-0793665**
(State or jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(IRS Employer Identification No.)**

324 S. Hyde Park Avenue, Ste. 350
Tampa, Florida 33606
(813) 864-2559
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mr. Nicholas J. Virca
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324 S. Hyde Park Avenue, Ste. 350
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

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

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

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

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

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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☒

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 (7)
Shares of common stock (2)	30,600,000	$—	$—	$(2)
Shares of common stock (3) (7)	55,000,000	$0.265(5)	$14,575,000.00	$1,467.71
Shares of common stock underlying warrants (3) (7)	55,000,000	$0.12(6)	$6,600,000.00	$664.62
Shares of common stock underlying warrants (3)	466,000	$0.12(6)	$55,920.00	$5.63
Shares of common stock underlying warrants (4) (7)	479,236	$0.12(6)	$57,508.32	$5.79
Total (7)	**141,545,236**	**—**	**$21,288,428.32**	**$2,143.75**

(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 (ii) 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) 55,000,000 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) 55,000,000 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.

(4) Represents 479,236 shares of common stock underlying warrants purchased pursuant to a right of first refusal held by an investor which constituted such investors' pro rata share, on a fully-diluted basis, of all warrants issued to FINRA-member agents that assisted in securing investors for the 2016 Private Placement.

(5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low sales price of the common stock on the OTCQB Market on June 13, 2016.

(6) Proposed maximum offering price per share is based on the exercise price of the warrants in accordance with Rule 457(g).

(7) Previously paid, except that the registrant will not be registering 56,249,236 shares of common stock consisting of (i) 27,885,000 shares of common stock and (ii) 28,364,236 shares of common stock underlying warrants. The registrant expects to utilize the excess registration fee ($1,071.96) paid to the Securities and Exchange Commission at the initial filing of this Registration Statement on a future filing with the Securities and Exchange Commission in accordance with Rule 457(p).

Pursuant to Rule 429 under the Securities Act, the prospectus contained in this 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 is a new registration statement and also constitutes Post-Effective Amendment No. 1 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 is a new registration statement, also constitutes Post-Effective Amendment No. 1 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.

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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 July 18, 2016
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 significant 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 which is controlled by Black Robe Capital LLC, of which Frank E. O'Donnell, Jr., M.D. (our Executive Chairman) is the manager, 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.

Our common stock is listed for quotation on the OTCQB Market operated by OTC Markets Group, Inc., or the OTCQB, under the ticker symbol "HPPI." On July 13, 2016, closing price of our common stock was $0.23.

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, 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 7 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 , 2016.

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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.

PROSPEC TUS 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 clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. Our preliminary focus is on the development of therapies for skin, lung and prostate cancers in the United States of America market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome).

Our proposed therapy for treatment of cancers is based upon SUBA™-Itraconazole, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole to which we hold an exclusive U.S. license. We believe that the dosing of oral capsules of this formulation 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 basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration (or FDA) for, and has been extensively used to treat, fungal infections and has an extensive history of safe and effective use in humans.

"SUBA™" (which stands for "super bioavailability") technology is designed to improve the bioavailability of orally administered drugs that are poorly soluble. In studies conducted by Mayne Pharma Ventures Pty Ltd. and its affiliates (which we refer to herein as 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 has been demonstrated to deliver itraconazole of up to 90% bioavailability;
- Itraconazole absorption is not dependent on an acidic stomach; itraconazole is released in the lower pH conditions found in the intestine, improving drug delivery and bioavailability;
- SUBA-Itraconazole levels have been demonstrated to be more consistent within subjects and between subjects compared to generic or branded itraconazole;
- it 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 lead us to believe that SUBA-Itraconazole could be well-suited for chronic use in treating cancer due to its more predictable therapeutic levels and lower toxicity.

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

- Poor drug delivery resulting in average bioavailability of only 55%,
- Inconsistent blood plasma levels in individual subjects and between subjects,
- 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, and
- Many patients require proton-pump inhibitor drugs to control acid reflux, which provides gastric conditions that are not favorable for absorption of itraconazole from non-SUBA formulations of itraconazole.

Following a meeting between our management and representatives of the FDA in August 2014, we submitted an Investigational New Drug (or IND) application in November 2014 for the use of our product candidate to treat basal cell carcinoma in patients with Gorlin Syndrome, which, among other conditions, causes the chronic formation of basal cell tumors. Our IND application was cleared by the FDA in December 2014, and we commenced patient recruiting during the third quarter of 2015 for our Phase II(b) clinical trial. We then began studying the safety and efficacy of the SUBA-Itraconazole formulation during the fourth quarter 2015 to determine how well it reduces basal cell carcinoma tumor burden in patients with Gorlin Syndrome. In May 2016, we received notice of Orphan Drug Designation for treatment of patients with Gorlin Syndrome with our oral formulation of SUBA-Itraconazole Capsules. We expect to publicly report preliminary results in the next 12 months in patients who continue treatment under our open-label protocol. Also, during the second half of 2016 and thereafter, we intend to file an additional clinical trial protocol to expand the study of SUBA-Itraconazole for an additional target cancer indication.

Our regulatory strategy 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 (in our case, 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, which may create the potential for significantly reducing the risk and time to achieve FDA approval of our cancer therapy compared to new chemical entities.

We have developed, licensed and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole. We have exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole Capsules for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner and significant shareholder Mayne Pharma under a Supply and License Agreement, originally dated September 3, 2013, amended and restated on June 24, 2014 and most recently amended and restated on May 15, 2015. We refer to this agreement herein as the Supply and License Agreement. 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 supply partner, under the Supply and License Agreement and related agreements, Mayne Pharma holds a significant minority equity stake in our company and holds important rights with respect to our company, such as the right to appoint a member to our board of directors.

In addition, on August 31, 2015, we entered into a sublicense agreement with Mayne Pharma, pursuant to which Mayne Pharma 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. Mayne Pharma 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. We paid a license fee of $75,000 to Mayne Pharma upon entering into the sublicense agreement.

Based on the results of previous physician-sponsored studies conducted by others (including *in vitro*, animal and human studies), we believe that itraconazole affects the Hedgehog signaling pathway in cells, which could in turn impact 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, it appears that itraconazole may 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 on-going research. These studies formed the basis of our interest in the clinical development of itraconazole for treatment of human cancers.

We believe we have the opportunity to clinically progress and, if regulatory approvals are secured, commercialize SUBA-Itraconazole oral capsules as an anti-cancer therapy in the United States based on the following:

- We have been cleared by FDA and have moved directly into a Phase II(b) trial based upon the track record of long-term, safe and effective use of itraconazole for treatment of human fungal infections;
- The safety of human data regarding the use of the SUBA-Itraconazole formulation for anti-fungal studies;
- Existing Phase II human data for skin, lung and prostate cancers have already demonstrated initial efficacy of itraconazole as an anti-cancer therapy;
- There are large and growing total available markets for our proposed anti-cancer indications;
- We may qualify for one or more expedited review and approval programs by the FDA;
- We have received an orphan designation from FDA for use of SUBA-Itraconazole to treat basal cell carcinoma in patients with BCCNS (Gorlin Syndrome);
- If approved, our therapies could be offered at reduced cost compared to current treatments;

- We have exclusive rights to develop and commercialize SUBA-Itraconazole for the treatment of human cancer via oral administration in the U.S. through Mayne Pharma for a patented, more bioavailable formulation of itraconazole which we believe will allow us to treat cancer patients with less toxicity and greater consistency than the conventional formulations;
- We have secured a cGMP (clinical good manufacturing practice) supply of product for clinical trials and eventual commercialization in the U.S. under exclusivity through Mayne Pharma; and
- Our management, contract research and consulting teams bring extensive, prior experience in the clinical development of oncology therapeutics.

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 U.S. Market Opportunity

Cancer	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market
Skin[1]	Patients with BCC (basal cell carcinoma) lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring surgery Follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures	Less toxic therapy than vismodegib for Gorlin Patients to delay surgeries; low toxicity therapy to delay or minimize surgical intervention for facial 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 and $600M for patients with BCC facial lesions requiring surgery based upon HedgePath estimates of ~ $4K-$5K monthly cost of therapy for target populations
Lung[2]	Patients with advanced non-squamous cell, non-small cell lung cancer (NSCLC) who will be placed on Cisplatin/Pemetrexed IV Therapy	Improve the current median 8-10 month survival achieved with best supportive care	56,000 men and women with late-stage disease on chemotherapy treatment	$1.7 B based on HedgePath estimates of ~ $4K-$5K monthly cost of therapy
Prostate[3]	Patients with non metastatic castrate resistant prostate cancer (NMCRPC) and rising PSA levels on "off-label" androgen deprivation therapy (ADT)	Delay the progression to metastatic disease while preventing or reducing the use of ADT and its associated side-effects	45,000 high-risk men with prostate cancer which may lead to metastases of the bone	$1.5B based on HedgePath estimates of ~ $4K-$5K monthly cost of therapy

References:

(1) J Am Academy Dermatology, 2006; Skin Cancer Foundation, 2009; International Medicine News, 2011; Seeking Alpha, 2012; BCCNS Life Support Network 2014, Genetics Home Reference 2015

(2) STATS MGU, 2009; Global Industry Analysts, 2010; BMC Health Services, 2011; World Health Organization, 2011; Cost of Treating Lung Cancer, 2012; National Center for Biotechnology Information, 2012

(3) J. Urology, 2003; Oncology, 2004; J. Clinical Oncology, 2011; Medscape, 2012; Landes Bioscience, 2012

Our Strategy

Our goal is to be a leader in the development and commercialization of SUBA-Itraconazole-based therapeutics for the treatment of cancer patients. 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 I human trials to establish safety, and therefore were able to move directly into a Phase II(b) human trial. We filed an IND to test SUBA-Itraconazole for the treatment of basal cell carcinoma in patients with Gorlin Syndrome, and the IND was cleared by FDA for human testing as of late December 2014. As a result, we began recruiting patients for a Phase II(b) trial during the third quarter of 2015 and dosing patients during the fourth quarter of 2015. We intend to file individualized clinical protocols during the second half of 2016 and beyond to expand the study of SUBA-Itraconazole for additional target cancer indications.
- *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 or more of these designations, which could help expedite the regulatory review process. In May 2016, we received notice of Orphan Drug Designation for treatment of patients with Gorlin Syndrome with our oral formulation of SUBA-Itraconazole oral capsules.
- *Commercialize and Market with Exclusivity.* We have opened clinical trial sites for the clinical testing of SUBA-Itraconazole for treatment of basal cell carcinoma in an initial Phase II(b) trial for patients with Gorlin Syndrome, in order to later seek FDA approval based upon its efficacy for this new indication. In addition, should we gain FDA approval for treatment of BCC in patients with Gorlin Syndrome, for which we currently have an orphan designation, we would be entitled to 7 years of market exclusivity following FDA approval. We are also developing other specific clinical trial designs to address different forms of cancer in order to pursue New Drug Application (or NDA) approvals for multiple indications. Further, we believe SUBA-Itraconazole can be commercialized in a way that maximizes benefits for cancer patients, based on our specific therapy regimens, while eliminating generic substitution and providing us with market exclusivity protections through our intellectual property rights.

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

- public and private financings and, potentially, from strategic transactions;
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product to augment their product profile in the treatment of cancers; and
- 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 "start-up" company with no history of revenue generating operations, and it will take several years to have any proposed products approved, assuming such approval can be obtained at all. We therefore do not expect to generate revenue for at least the next several years.

- Notwithstanding the successful completion of a financing in May 2016 in which we received approximately $5.4 million in net proceeds, as a result of the pre-revenue nature of our business and our then current lack of financial liquidity, our auditors' report for our 2015 financial statements, which is included as part of this prospectus, contains a statement concerning our ability to continue as a "going concern."
- 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 Mayne Pharma. The loss of our license with Mayne Pharma or Mayne Pharma's inability to supply clinical trial materials or commercial quantities of SUBA-Itraconazole could lead to the failure of our business.
- Mayne Pharma holds a significant equity stake in our company and has important rights with respect to our company, such as the right to nominate a member of our board of directors, the right to invest in future offerings of our securities and the right to remove certain officers of our company if key milestones are not met.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We are subject to extensive regulation, and 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.
- 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 began our current business in August 2013 as a Delaware corporation following the emergence of CBI from its voluntary bankruptcy proceedings.

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 324 South Hyde Park Avenue, Suite 350, Tampa, Florida 33606 and our telephone number is (813) 864-2559 and 700 West Harbor Drive, Suite 1104, San Diego, California 92101 where our telephone number is (858) 722-3043.

The Offering

Common Stock Outstanding:	300,353,270 shares as of the date of this prospectus.
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 $3.4 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.
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 Registration Statement No. 333-198800 which was declared effective on August 10, 2015 (which we refer to as the Prior Registration Statement). See "Selling Stockholders."

RIS K 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 Related to Our Business

We are a pre-revenue biopharmaceutical company and are thus subject to the risks associated with new businesses in that industry.

We emerged from bankruptcy in August 2013, and the business opportunity we acquired in connection with our reorganization (the development of itraconazole anti-cancer therapies) is a new business opportunity. As such, we are a clinical stage biopharmaceutical company with no history of revenue-generating operations, and our only assets consist of the intellectual property and related assets contributed to us by our stockholder Hedgepath, LLC on August 13, 2013, in connection with our emergence from bankruptcy. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties inherent in a new business, in particular new businesses engaged in the development of pharmaceuticals. We still must establish and implement many important functions necessary to operate a business, including the clinical development of our product candidate, acquiring additional intellectual property rights related to itraconazole beyond our exclusive Supply and License Agreement with Mayne Pharma for SUBA-Itraconazole, establishing our managerial and administrative structure and implementing financial systems and controls.

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 create a business plan that is sound;
- maintain our anticipated management team;
- 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, as a pre-revenue biopharmaceutical company, we expect to 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.

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 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.

Moreover, Hedgepath, LLC, from whom we acquired the itraconazole business opportunity as part of our plan of bankruptcy reorganization, was only formed in late 2011 and thus itself has a limited operating history. Our operations are presently limited to planning for clinical trials, conducting our current Phase II(b) clinical trial testing the efficacy and safety of SUBA-Itraconazole for treatment of basal cell carcinoma in patients with Gorlin Syndrome, and arranging for the raising of capital, developing our technology and identifying potential commercial partners. We have not yet demonstrated our ability to complete any clinical trials, 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 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 exclusive rights to commercialize SUBA-Itraconazole for the treatment of patients with cancer via oral administration 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. As such, this agreement and our collaboration with Mayne Pharma are critical to our business. In the event that the Mayne Pharma Supply and License Agreement is terminated or Mayne Pharma is unable to supply the product, we may lose the ability to commercialize SUBA-Itraconazole, and our business prospects would be materially damaged.

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

Pursuant to 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 (as described in further detail in the section entitled "Certain Relationships and Related Party Transactions"), 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, 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.

The right of Mayne Pharma to introduce accredited investors to us to participate in a private offering of our securities could impair our ability to raise capital.

Under our Equity Holders Agreement, Mayne Pharma has been granted the right until May 15, 2017 to introduce accredited investors to us to participate in up to 50% of any private offering of our securities (subject to certain exceptions as described in the Equity Holders Agreement). The existence of such right, or the exercise of such rights, may deter potential private investors from providing us needed financing, or may deter investment banks or other placement agents from working with us, which would have a material adverse effect on our ability to finance our company.

Mayne Pharma may exert significant influence over our business and affairs and the corporate governance rights afforded to Mayne Pharma under the Equity Holders Agreement may adversely affect the management of our company.

Mayne Pharma currently beneficially owns approximately 59.4% of our outstanding common stock. Under the terms of our Equity Holders Agreement, Mayne Pharma has the right to purchase any shares of common stock being transferred or sold by the individual account of our current President and Chief Executive Officer and Executive Chairman. In addition to Mayne Pharma's current common stock ownership, Mayne Pharma also 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 our board of directors or replace or remove our President and Chief Executive Officer and Executive Chairman (such veto right being the result of each of the foregoing Board of Director actions requiring the unanimous consent of the board of directors). Mayne Pharma's significant ownership of our common stock plus the existence of these additional rights will for the foreseeable future enable Mayne Pharma to exert influence over our company and matters requiring stockholder approval including the election of directors, financing activities or a merger or sale of our assets. 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).

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

Our operations are dependent upon a relatively small group of individuals and, in particular, our current officers and directors, including most notably Nicholas J. Virca and Dr. Frank E. O'Donnell, Jr. We believe that our ability to implement our business plans depends on the continued service of these individuals and/or other officers and directors. In particular, Dr. O'Donnell is presently required to commit only 25% of his time to our affairs and, accordingly, he may have conflicts of interest in allocating management time among various business activities, and these conflicts of interest may not be resolved in our favor. We do presently have an executive chairman agreement and an employment agreement with Dr. O'Donnell and Mr. Virca, respectively. However, the agreements are terminable upon 60 days' notice to us with or without good reason. 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.

Prior to Hedgepath, LLC's contribution of certain assets to us in August 2013, the business opportunity and assets we acquired had been operated privately. In addition, although our predecessor, CBI, was a company that filed public reports with the SEC, the business of CBI effectively ceased concurrently with its entry into federal bankruptcy proceedings in 2011. As a consequence, our current business has no historical nexus to that of CBI's.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities (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

Despite the implementation of security measures, 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. 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 sufficient to run our planned operations through the fourth quarter of 2017. However, given the clinical stage, pre-revenue nature of our business, 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 anti-cancer therapies. Accordingly, we will need to obtain 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 as an anti-cancer therapy;
- the costs, timing and outcome of clinical trials of our product candidate for one or more types of cancer;
- the costs, timing and outcome of regulatory review of our product candidate for one or more types of cancer;
- 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 candidate as a treatment for one or more types of cancer;
- 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 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 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 several years, 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 or otherwise, and we therefore have a limited source of cash to meet our future capital requirements. We do not expect to generate revenues 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 very early stage of our company, the rights of certain of our stockholders 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 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, 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 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.

As a result of our current lack of financial liquidity, our auditors have expressed substantial doubt regarding our ability to continue as a "going concern."

As a result of our historical losses and our current lack of financial liquidity, our auditors' report for our 2015 financial statements, which are included as part of this prospectus, contains a statement concerning our ability to continue as a going concern. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

Our continuation as a going concern is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow include engaging in offerings of securities, negotiating up-front and milestone payments on pipeline products under development and royalties from sales of our products which secure regulatory approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. However, we may be unable to achieve these goals and therefore may be unable to continue as a going concern.

Risks Related to the Clinical Development of Our Product Candidate

We are very early in our development efforts and have only one product candidate. If we are unable to clinically develop and ultimately commercialize itraconazole as an anti-cancer therapy or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have only one product candidate, namely SUBA-Itraconazole for the treatment of cancer. While itraconazole has previously been approved by the FDA for use as an anti-fungal agent, the use of itraconazole to treat cancer has not been approved and has been subject to limited clinical testing by others. Moreover, we are only recently engaged in such testing ourselves, and our operations as of our emergence from bankruptcy in August 2013 have been limited to developing our own intellectual property and know how, while acquiring the technology and rights of others in order to pursue the clinical development of the itraconazole formulation, SUBA-Itraconazole, as an anti-cancer therapy and the launch of a single Phase II (b) trial for which patient dosing began in the fourth quarter of 2015.

Therefore, our ability to generate product 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 healthcare coverage and adequate reimbursement; 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 cancer therapy, 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 basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome, also known as Gorlin Syndrome. We are thus faced with the risk that SUBA-Itraconazole could be ineffective in addressing this particular initial cancer indication, and if our efforts to demonstrate the efficacy of SUBA-Itraconazole in treating basal cell carcinoma in this target patient population 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 an anti-cancer therapy, 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 an anti-cancer therapy 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 adversely affect market acceptance of SUBA-Itraconazole as a cancer therapy. 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 cancer therapy 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, will prove effective and safe in humans or will receive regulatory approval for any form of cancer or any other indication. Before obtaining marketing approval from regulatory authorities for the sale of SUBA-Itraconazole as a cancer therapy, we must conduct extensive 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.

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 other than our current Phase II(b) trial, 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 exclusive 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 clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidate 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 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 our 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.

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 SUBA-Itraconazole for the treatment of cancer 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. If we are unable to develop SUBA-Itraconazole for the treatment of cancer due to reported adverse effects or characteristics, our business would be severely harmed.

For the foreseeable future, we expect to expend our limited resources 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 only on the clinical development of SUBA-Itraconazole for the treatment of cancer as a therapy for basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome, also known as Gorlin Syndrome. 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;
- 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 would be materially or perhaps significantly 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.

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 SUBA-Itraconazole for the treatment of cancer receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.

Even if SUBA-Itraconazole for the treatment of cancer receives marketing approval, it 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 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, 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.

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 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 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;
- 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 an anti-cancer therapy. We seek to protect our proprietary position through our exclusive license for SUBA-Itraconazole with Mayne Pharma and other licenses, and by filing patent applications in the United States related to our novel technologies, including the issuance of a patent relating to our own intellectual property regarding our product candidate. We also expect to license additional applicable patents from third parties.

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 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.

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 third party preissuance 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.

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 would be harmed, possibly materially. Even though we have obtained exclusive rights to additional patents from Mayne Pharma during the second half of 2015 and have had a patent issued for our own inventions in the United States in November 2015, if we were not able to maintain or obtain our current or additional licenses, or were not able to maintain or obtain such licenses on commercially reasonable terms, our business would be harmed, possibly substantially if we are not able to maintain or obtain such licenses, or are not able to maintain or obtain such licenses on commercially reasonable terms, our business would 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 candidate (SUBA-Itraconazole as an anti-cancer therapy) and the activities associated with its 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 candidate will prevent us from commercializing the product candidate. We have not received approval to market SUBA-Itraconazole as an anti-cancer therapy or any other product from regulatory authorities in any jurisdiction and it will likely be years before we are even eligible to receive such approval.

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 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.

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 Health Insurance Portability and Accountability Act of 1996 (or HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs 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 as an anti-cancer therapy 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 an anti-cancer therapy 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 a New Drug Application (or 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 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 may 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 as an anti-cancer therapy 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.

A breakthrough therapy designation by the FDA for our product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidate will receive marketing approval.

We may seek a "breakthrough therapy" designation for our product candidate. 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 as an anti-cancer therapy 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. Even if such designation is granted, of which no assurances may be given, the receipt of a breakthrough therapy designation for our 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 as an anti-cancer therapy 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.

Even if we obtain marketing approval for our product candidate, 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 SUBA-Itraconazole as an anti-cancer therapy, 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 cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If our product candidate receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our product. 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;
- 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 Our an Investment in Our Common Stock

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

As we only emerged from bankruptcy in August 2013 and are in the early stages of our business plan, 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 MKT (formerly known as the NYSE AMEX market). 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 listed on the so called "Pink Sheets", 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.

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 in the "pink sheets" 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 approval from the 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;
- 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 (HPLLC and Mayne Pharma) own or exercise voting and investment control of approximately 85% of our outstanding common stock. 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 HPLLC 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 board of directors has the authority to declare a reverse split of our common stock which could adversely affect our capitalization and stock price.

On July 18, 2014, our board of directors acted unanimously to adopt an amendment to Article FOURTH of our Certificate of Incorporation, as amended (referred to as our Certificate of Incorporation), to effect a reverse split of our issued and outstanding common stock (and, at the sole discretion of the board of directors, our authorized common stock) at a ratio of between one-for-five and one-for-twenty, with such ratio to be determined at the sole discretion of the board of directors and with such reverse split to be effected at such time and date, if at all, as determined by our board in its sole discretion. On September 30, 2014, our majority stockholders, acting by written consent, approved such amendment and the reverse split.

The principal purpose of the reverse split would be to help increase the per share market price of our common stock by up to a factor of twenty, which could help us with our fundraising efforts. We cannot assure you, however, that the reverse split, if implemented, will accomplish either of these objectives for any meaningful period of time or at all. While we expect that the reduction in the number of outstanding shares of common stock will increase the market price of our common stock, we cannot assure you that the reverse split will increase the market price of our common stock by an equivalent multiple, or result in any permanent increase in the market price of our common stock. The price of our common stock is dependent upon many factors, including our business and financial performance, general market conditions and prospects for future success. If the per share market price does not increase

proportionately as a result of the reverse split, then the value of our company as measured by our stock capitalization will be reduced, perhaps significantly. Moreover, while it is believed that a higher stock price could assist in our ability to raise capital, there is a risk that these benefits will not be realized.

In addition, the number of shares held by each individual stockholder would be reduced if the reverse split is implemented. This will increase the number of stockholders who hold less than a "round lot," or 100 shares. This would have the disadvantage that the transaction costs to stockholders selling "odd lots" are typically higher on a per share basis. Consequently, the reverse split could increase the transaction costs to existing stockholders in the event they wish to sell all or a portion of their position.

Also, although it is believed that the decrease in the number of shares of our common stock outstanding as a consequence of the reverse split and the anticipated increase in the market price of our common stock could encourage interest in our common stock and possibly promote greater liquidity for our stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse split.

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

Our common stock may be considered to be a "penny stock" if it does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Securities Exchange Act of 1934, as amended (or the Exchange Act). Our common stock may be a "penny stock" if 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. As we are a start-up company, we are at the very early stages of establishing, and we may be unable to effectively establish such systems. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. 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 our 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.

In addition, our Certificate of Incorporation and amended and restated 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 amended and restated 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 capital 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.

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:

- our lack of operating history;
- our potential lack of the capital resources needed to progress our business plan;
- acceptance of our business model (namely the repurposing of the drug itraconazole (currently approved as an anti-fungal agent) for the treatment of cancer) by investors and potential commercial collaborators;
- our current and 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;
- 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 $3.4 million. As of the date of this prospectus, we have not received proceeds from such exercises.

Any net proceeds we receive 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. As of the date of this prospectus, we cannot specify with certainty the particular uses for the net proceeds we may receive. 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 capital 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.

DETERMINATIO N 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

Holders of Common Stock

As of the date of this prospectus, we have approximately 52 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 quoted on the OTCQB markets under the symbol “HPPI.” The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock as reported by the OTC Market Group:

Period Ended	High	Low
June 30, 2016	$0.40	$0.11
March 31, 2016	$0.20	$0.08
March 31, 2015	$0.24	$0.11
June 30, 2015	$0.24	$0.11
September 30, 2015	$0.19	$0.07
December 31, 2015	$0.20	$0.11
March 31, 2014	$0.30	$0.08
June 30, 2014	$0.23	$0.05
September 30, 2014	$0.19	$0.05
December 31, 2014	$0.17	$0.08

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 July 13, 2016, the last reported sales price of a share of our common stock on the OTCQB was $0.23. 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.

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, subject to approval by our majority stockholders:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance (c)
Equity compensation plans approved by security holders	27,191,738(1)	n/a	5,391,737
Equity compensation plans not approved by security holders	—	n/a	—

(1) Consists of restricted stock units of which 20,041,738 vest on March 15, 2017; 3,500,000 vest on September 3, 2017; 1,600,000 vest on the earlier to occur of September 5, 2017 or approval of an NDA for SUBA-Itraconazole by the relevant regulatory authority; 750,000 vest over three years beginning on August 14, 2015; and 650,000 vest over three years beginning July 1, 2016. Additionally, 650,000 stock options vest over three years beginning July 1, 2016.

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

We are a clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. Our preliminary focus is on the development of therapies for skin, lung and prostate cancers in the U.S. market, with the first indication targeting basal cell carcinoma in patients with Gorlin Syndrome for which we have begun dosing in our Phase II(b) clinical trial. Our proposed therapy is based upon the use of a patented formulation of the currently marketed anti-fungal drug itraconazole. We believe that the dosing of oral capsules of this formulation 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 basal cell carcinoma. 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.

We have developed, licensed and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole. We have exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole capsules for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner and significant shareholder Mayne Pharma under the Supply and License Agreement. In addition to being our licensor and supply partner, under the Supply and License Agreement and related agreements, Mayne Pharma holds a significant minority equity stake in our company and holds important rights with respect to our company, such as the right to appoint a member to our board of directors.

Following a meeting between our management and representatives of the FDA in August 2014, we submitted an IND application in November 2014 for the use of our product candidate to treat basal cell carcinoma in patients with Gorlin Syndrome, which, among other conditions, causes the chronic formation of basal cell tumors. Our IND application was cleared by the FDA in December 2014, and we commenced patient recruiting during the third quarter of 2015 for our Phase II(b) clinical trial. We then began studying the safety and efficacy of the SUBA-Itraconazole formulation during the fourth quarter 2015 to determine how well it reduces basal cell carcinoma tumor burden in patients with Gorlin Syndrome. In May 2016, we received notice of Orphan Drug Designation for treatment of patients with Gorlin Syndrome with our oral formulation of SUBA-Itraconazole Capsules. We expect to publicly report preliminary results during the second half of 2016 in patients who continue treatment under our open-label protocol. Also, during the second half of 2016 and thereafter, we intend to file an additional clinical trial protocol to expand the study of SUBA-Itraconazole for an additional target cancer indication.

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 began our current business 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 condensed 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. Miscellaneous income is recognized when earned by us.

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 $250,000 for substantially all depository accounts.

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 us and 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, or FASB, Accounting Standards Codification, or 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 equity securities issued are determined by us based predominantly on the trading price of the common stock. 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.

Recent accounting pronouncements:

In May 2014, the 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. The new standard, as updated in 2015, will be effective for us in the first quarter of 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. We will evaluate the impact of adoption of the new standard on its financial statements upon commencement of revenue generating activities.

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”, we refer to this as ASU 2014-15. ASU 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosure. This ASU provides guidance to an organization’s management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We are evaluating the impact the guidance will have on its financial statements.

Results of Operations

For the three months ended March 31, 2016 compared to the three months ended March 31, 2015

Research and Development Expenses. We recognized approximately $0.6 million in research and development expenses during the three months ended March 31, 2016 compared to approximately $0.3 million for the three months ended March 31, 2015. Research and development expenses for the current period primarily include expenses related to our clinical trial for Basal Cell Carcinoma Nevus Syndrome, regulatory activities, legal expenses relating to patents, and stock-based compensation. Research and development expenses for the prior period consists primarily of salaries and stock-based compensation related to clinical trial design and regulatory activities.

General and Administrative Expenses. We recognized approximately $0.6 million in general and administrative expenses during both the three months ended March 31, 2016 and 2015. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes.

For the Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

Research and Development Expenses. We recognized approximately $1.7 million and $2.4 million in research and development expenses during the years ended December 31, 2015 and 2014, respectively. For the year ended December 31, 2015, research and development expenses consisted of approximately $0.9 million in direct clinical trial expense and $0.8 million in salaries, non-cash stock-based compensation, and consulting expense related to clinical trial design and regulatory activities. For the year ended December 31, 2014, research and development expenses consist of approximately $1.9 million of in-process research and development associated with the issuance of common stock shares and warrants to Mayne Pharma upon entering into our Amended and Restated Supply and License Agreement in June 2014. The balance of the research and development expenses consists primarily of salaries and consulting fees related to clinical trial design and regulatory activities as well as stock compensation expense related to research and development activities.

General and Administrative Expenses. We recognized approximately $2.3 million and $1.5 million in general and administrative expenses during the years ended December 31, 2015 and 2014, respectively. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, and consulting. The increase of approximately $0.8 million is primarily a result of the increase in non-cash stock-based compensation expense of $0.6 million during 2015. The increase in non-cash stock-based compensation was a result of the issuance, during 2015, of additional restricted stock units to certain employees and Directors under the 2014 Equity Incentive Plan.

Interest Expense. We recognized no interest expense during the year ended December 31, 2015 and approximately $0.04 million in interest expense during the year ended December 31, 2014. Former employee notes which accrued interest were paid in full in December 2014.

Liquidity and Capital Resources

We had approximately $0.1 million cash on hand at March 31, 2016. Subsequent to March 31, 2016, we closed the 2016 Private Placement offering with net proceeds received through the final closing date of May 25, 2016 of approximately $5.4 million.

We intend to seek additional financing for our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- proceeds from public and private financings and, potentially, other strategic transactions;
- proceeds from the exercise of warrants issued in public and private financings;
- partnering with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront 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 material risk that none of these plans will be implemented and that we will be unable to obtain additional financing on commercially reasonable terms, if at all. If adequate funds are not available, 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 our company, our viability, our financial condition and our results of operations in 2016 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

As a result of the foregoing circumstances, there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has included a paragraph emphasizing “going concern” uncertainty in their audit report on the 2015 financial statements dated February 1, 2016. The financial statements do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

Contractual Obligations and Commercial Commitments

Our non-cancellable contractual obligations as of December 31, 2015 are as follows:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Employment contracts	$624,600	$328,200	$296,400	$ —	$ —
Total contractual cash obligations	$624,600	$328,200	$296,400	$ —	$ —

Off Balance Sheet Arrangements

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

B USINESS

Overview

We are a clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. Our preliminary focus is on the development of therapies for skin, lung and prostate cancers in the United States of America market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome).

Our proposed therapy for treatment of cancers is based upon SUBA-Itraconazole, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole to which we hold an exclusive U.S. license. We believe that the dosing of oral capsules of this formulation 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 basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration (or FDA) for, and has been extensively used to treat, fungal infections and has an extensive history of safe and effective use in humans.

"SUBA" (which stands for "super bioavailability") technology is designed to improve the bioavailability of orally administered drugs that are poorly soluble. In studies conducted by Mayne Pharma Ventures Pty Ltd. and its affiliates (which we refer to herein as 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 has been demonstrated to deliver itraconazole of up to 90% bioavailability;
- Itraconazole absorption is not dependent on an acidic stomach; itraconazole is released in the lower pH conditions found in the intestine, improving drug delivery and bioavailability;
- SUBA-Itraconazole levels have been demonstrated to be more consistent within subjects and between subjects compared to generic or branded itraconazole;
- it 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 lead us to believe that SUBA-Itraconazole could be well-suited for chronic use in treating cancer due to its more predictable therapeutic levels and probable lower toxicity.

In contrast, we believe that the use of the non-SUBA formulation of itraconazole to treat cancer 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 subjects and between subjects,
- 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, and
- Many patients require proton-pump inhibitor drugs to control acid reflux, which provides gastric conditions that are not favorable for absorption of itraconazole from non-SUBA formulations of itraconazole.

Following a meeting between our management and representatives of the FDA in August 2014, we submitted an Investigational New Drug (or IND) application in November 2014 for the use of our product candidate to treat basal cell carcinoma in patients with Gorlin Syndrome, which, among other conditions, causes the chronic formation of basal cell tumors. Our IND application was cleared by the FDA in December 2014, and we commenced patient recruiting during the third quarter of 2015 for our Phase II(b) clinical trial. We then began studying the safety and efficacy of the SUBA-Itraconazole formulation during the fourth quarter 2015 to determine how well it reduces basal cell carcinoma tumor burden in patients with Gorlin Syndrome. In May 2016, we received notice of Orphan Drug Designation for treatment of patients with Gorlin Syndrome with our oral formulation of SUBA-Itraconazole Capsules. We expect to publicly report preliminary results during the second half of 2016 in patients who continue treatment under our open-label protocol. Also, during the second half of 2016 and thereafter, we intend to file an individual clinical trial protocol to expand the study of SUBA-Itraconazole for an additional target cancer indication.

Our regulatory strategy 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 (in our case, 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, which may create the potential for significantly reducing the risk and time to achieve FDA approval of our cancer therapy.

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 candidate, its methods of use, related technology and other inventions that are important to our business.

We have developed, licensed and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole. We have exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole Capsules for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner and significant shareholder Mayne Pharma under the Supply and License Agreement. 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 supply partner, under the Supply and License Agreement and related agreements, Mayne Pharma holds a significant minority equity stake in our company and holds important rights with respect to our company, such as the right to appoint a member to our board of directors.

In addition, on August 31, 2015, we entered into a sublicense agreement with Mayne Pharma, pursuant to which Mayne Pharma 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. Mayne Pharma 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. We paid a license fee of $75,000 to Mayne Pharma upon entering into the sublicense agreement.

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 Mayne Pharma/HedgePath 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 have been sublicensed to us by Mayne Pharma:

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

Johns Hopkins University US Patent 8,980,930
Angiogenesis Inhibitors
Issued: 03-17-2015

Mayne Pharma Intellectual Property Licensed to HedgePath. Three 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 II(b) human trials which have been underway since August 2015. 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

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

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

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

HedgePath Intellectual Property. We recently received notice that over 30 claims have been allowed by the US Patent and Trademark Office to cover our own inventions, and a patent was issued on November 24, 2015 (US Patent 9,129,609, *Treatment and Prognostic Monitoring of Proliferation Disorders Using Hedgehog Pathway Inhibitors*). Initial target applications include itraconazole therapies for skin, lung and prostate cancers.

We plan to continue to expand our intellectual property estate by 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 previous physician-sponsored studies conducted by others (including*in vitro*, animal and human studies), we believe that itraconazole affects the Hedgehog signaling pathway in cells, which could in turn impact 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, it appears that itraconazole may 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 on-going research. These studies formed the basis of our 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, we believe that inhibiting the Hedgehog pathway could 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. 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 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, GDC-0449 (vismodegib, developed by Genentech, Inc., a subsidiary of Roche), is the first Hedgehog inhibitor based-therapy and sonidegib (developed by Novartis) is the second orally available compound, that has been approved for treatment of advanced stages of basal cell carcinoma by the FDA.

Repurposing Itraconazole for Treating Cancer

We are implementing clinical and regulatory plans to enable the repurposing of itraconazole, via the use of the new formulation 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. Initial target applications include therapies for skin, lung and prostate cancers, among others.

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, all of which are the basis of our interest in the clinical development of SUBA-Itraconazole for treatment of human cancers.

We believe that our development of SUBA-Itraconazole as an anti-cancer therapy may lead to its use as an inhibitor of the Hedgehog pathway, thereby retarding the progression of cancer.

In animal models, itraconazole has 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.

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

Basal Cell Carcinoma

SUBA-Itraconazole may offer a significant alternative therapy to Genentech's drug, vismodegib, for treatment of basal cell carcinoma (known as BCC). Vismodegib is the first FDA-approved Hedgehog inhibitor based-therapy, yet has many reported toxicities and is associated with serious side effects that result in suspension of chronic dosing. As a result, basal cell tumors reoccur and patients are faced with the choice of returning to vismodegib therapy or, if possible, surgical alternatives. The SUBA-Itraconazole formulation of itraconazole may prove to be a more acceptable therapy for a larger number of patients or considered as a therapy which could easily be alternated with vismodegib, especially for patients who cannot endure vismodegib side-effects for extended periods or treatment. Additionally, recent reports indicate that vismodegib has led to resistance in some BCC patients, so use of SUBA-Itraconazole as an alternative therapy in this sub-population of patients could prove to be very useful for long term oral drug therapy.

Gorlin Syndrome is our first indication being studied in a Phase II(b) trial which was launched in August of 2015 and where we began recruiting and dosing patients during the fourth quarter of 2015. Patients being enrolled in this trial must have been diagnosed with Gorlin Syndrome and have numerous BCC tumors as well as meet a well-defined list of inclusion criteria in order to qualify for enrollment.

Gorlin Syndrome is caused by a mutation in a gene called PTCH1. This mutation causes PTCH1 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 ongoing Phase II(b) trial is 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.

Lung Cancer

Patients with advanced non-squamous non-small cell lung cancer (most often caused by cigarette smoking) have few options when considering therapies to extend survival. With a median survival of only 8-10 months while on approved chemotherapy regimens, we believe that new therapies are needed. We believe that the pre-clinical data and recently reported human data 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. If these data prove to be applicable to human treatment by improving survival, while dosing SUBA-Itraconazole in combination with first-line chemotherapy therapy (the combination of chemotherapy drugs Pemetrexed and Cisplatin), the treatment may qualify for one or more FDA accelerated programs, such as a breakthrough therapy or fast track status.

Prostate Cancer

Itraconazole has already been tested as a treatment for men with metastatic castrate resistant prostate cancer in a multi-institutional Phase II 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 non-metastatic prostate cancer (who are castrate resistant, either based upon drug therapy or surgery) to study the effect of itraconazole therapy in delaying metastases. There is no currently approved drug therapy for these patients and yet they are treated with drugs designed for metastatic disease on an "off-label" basis. We believe this is a significant opportunity for us since we are offering a non-toxic, non-androgen dependent small molecule therapy to a very large population of patients. Therapy with SUBA-Itraconazole may offer great promise for delaying the use of, and associated side-effects due to, those Androgen Deprivation Therapy (ADT) Drugs which are formulated to lower testosterone levels but are intended for metastatic disease treatment.

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 U.S. Market Opportunity

Cancer	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market
Skin(1)	Patients with BCC (basal cell carcinoma) lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring surgery Follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures	Less toxic therapy than vismodegib for Gorlin Patients to delay surgeries; low toxicity therapy to delay or minimize surgical intervention for facial 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 and $600M for patients with BCC facial lesions requiring surgery based upon HedgePath estimates of ~ $4K-$5K monthly cost of therapy for target populations
Lung(2)	Patients with advanced non-squamous cell, non-small cell lung cancer (NSCLC) who will be placed on Cisplatin/Pemetrexed IV Therapy	Improve the current median 8-10 month survival achieved with best supportive care	56,000 men and women with late-stage disease on chemotherapy treatment	$1.7 B based on HedgePath estimates of ~ $4K-$5K monthly cost of therapy
Prostate(3)	Patients with non metastatic castrate resistant prostate cancer (NMCRPC) and rising PSA levels on "off-label" androgen deprivation therapy (ADT)	Delay the progression to metastatic disease while preventing or reducing the use of ADT and its associated side-effects	45,000 high-risk men with prostate cancer which may lead to metastases of the bone	$1.5B based on HedgePath estimates of ~ $4K-$5K monthly cost of therapy

References:

(1) J Am Academy Dermatology, 2006; Skin Cancer Foundation, 2009; International Medicine News, 2011; Seeking Alpha, 2012; BCCNS Life Support Network 2014, Genetics Home Reference 2015

(2) STATS MGU, 2009; Global Industry Analysts, 2010; BMC Health Services, 2011; World Health Organization, 2011; Cost of Treating Lung Cancer, 2012; National Center for Biotechnology Information, 2012

(3) J. Urology, 2003; Oncology, 2004; J. Clinical Oncology, 2011; Medscape, 2012; Landes Bioscience, 2012

Our Strategy

Our goal is to be a leader in the development and commercialization of SUBA-Itraconazole-based therapeutics for the treatment of cancer patients. 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 I human trials to establish safety, and therefore were able to move directly into a Phase II(b) human trial. We filed an IND to test SUBA-Itraconazole for the treatment of basal cell carcinoma in patients with Gorlin Syndrome, and the IND was cleared by FDA for human testing as of late December 2014. As a result, we began recruiting patients for a Phase II(b) trial during the third quarter of 2015 and dosing patients during the fourth quarter of 2015. We intend to file individualized clinical protocols during the second half of 2016 and thereafter to expand the study of SUBA-Itraconazole for additional target cancer indications.
- *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 or more of these designations, which could help expedite the regulatory review process. In May 2016, we received notice of Orphan Drug Designation for treatment of patients with Gorlin Syndrome with our oral formulation of SUBA-Itraconazole oral capsules.
- *Commercialize and Market with Exclusivity.* We have opened clinical trial sites for the clinical testing of SUBA-Itraconazole for treatment of basal cell carcinoma in an initial Phase II(b) trial for patients with Gorlin Syndrome, in order to later seek FDA approval based upon its efficacy for this new indication. In addition, we are developing other specific clinical trial designs to address different forms of cancer in order to pursue New Drug Application (or NDA) approvals for multiple indications. Further, we believe SUBA-Itraconazole can be commercialized in a way that maximizes benefits for cancer patients, based on our specific therapy regimens, while eliminating generic substitution and providing us with market exclusivity protections through our intellectual property rights.

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

- public and private financings and, potentially, from strategic transactions;
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product to augment their product profile in the treatment of cancers; and
- 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 2013 there were approximately 1.6 million new cases of cancer and approximately 580,000 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.

The Itraconazole Approach to Treating Cancer

We are focusing our developments on Hedgehog pathway inhibitor therapeutics for patients with certain cancers, including skin, lung and prostate cancers. Our initial product candidate is a new formulation of itraconazole, which is based upon new 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, we believe have compelling evidence of being potential Hedgehog inhibitors for treatment of cancer in humans. We have obtained exclusive U.S. rights to use and develop SUBA-Itraconazole, a patented, more bioavailable formulation of the currently marketed drug itraconazole, which we have licensed from Mayne Pharma through an exclusive Supply and License Agreement.

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, 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 and sonidegib was approved for the same indication in mid-2015. 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 are in the early stages of development and thus we do not have any production facilities or manufacturing personnel. We currently have a Supply and License Agreement in place with Mayne Pharma for the patented formulation of itraconazole, SUBA-Itraconazole. The agreement provides for the supply to HPPI of specially formulated capsules of SUBA-Itraconazole, manufactured by Mayne Pharma under cGMP (current good manufacturing practice) standards, for use by HPPI in its anticipated clinical trials, including the trial for basal cell carcinoma in patients with Gorlin Syndrome which was cleared by the FDA in December 2014 and for which we began dosing patients during 2015, and for the future exclusive commercial supply following FDA approvals, if obtained.

Pursuant to the Supply and License Agreement, Mayne Pharma is obligated to: (i) supply us with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being skin, lung and prostate cancer) in the United States, (ii) provide us with an exclusive license to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer via oral administration in the United States and (iii) participate in a joint development committee (or JDC) with us to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States. Mayne Pharma will also provide certain services to us (in accordance with the development plan and budget for our product) including to direct clinical programming (subject to the oversight and approval by the JDC and, in certain circumstances, our board of directors), and to direct the regulatory approval process and intellectual property strategy related to the product. Any services provided to us by Mayne Pharma in this regard will be provided at Mayne Pharma's expense (other than third party costs agreed to by us and Mayne Pharma), and such services will be subject to our prior approval. The Supply and License Agreement may be terminated by Mayne Pharma if we fail to achieve regulatory approval to commercialize SUBA-Itraconazole in the U.S. by June 30, 2017, if we breach any provision of our Equity Holders Agreement, if we materially breach the Supply and License Agreement and do not cure such breach within a specified time period, or if either party files for bankruptcy or insolvency proceedings.

Also, pursuant to the Supply and License Agreement, we will develop and exploit SUBA-Itraconazole through a development plan which will be authorized by the JDC and updated as necessary. We cannot make changes to the development plan without Mayne Pharma's consent. The license granted to us under the Supply and License Agreement may only be assigned or sub-licensed with the prior approval of Mayne Pharma. In addition, in support of the exclusive nature of the Supply and License Agreement, during the term, Mayne Pharma is prohibited from directly or indirectly importing, promoting, marketing, distributing or selling SUBA-Itraconazole for the treatment of cancer in the United States. If any other form of the SUBA-Itraconazole manufactured by Mayne Pharma is sold as a result of any non-promoted use, we shall be entitled to a royalty on such non-promoted sales. Further, during the term of and for a period following the term of the Supply and License Agreement, we may not develop products that are competitive with SUBA-Itraconazole for the treatment of cancer. Under the Supply and License Agreement, we are responsible for obtaining all of our requirements for SUBA-Itraconazole from Mayne Pharma, including for use in clinical trials, importation, promotion, marketing, sale and distribution in the United States. We and Mayne Pharma have established certain minimum floor prices that we must pay per unit of SUBA-Itraconazole and minimum order quantities for SUBA-Itraconazole. In addition, the agreement provides for certain annual minimum order quantities for SUBA-Itraconazole, and, if such quantities are not met, we must pay the shortfall or Mayne Pharma may terminate the agreement.

On June 24, 2014, we and Mayne Pharma, along with Nicholas J. Virca, our President and Chief Executive Officer, Frank E. O'Donnell, Jr., M.D., our Executive Chairman, and Hedgepath, LLC, a Florida limited liability company and the then majority stockholder of our company which is controlled by Black Robe Capital LLC, of which Dr. O'Donnell is the manager, consummated a series of related transactions to fulfill certain conditions of the Supply and License Agreement. In connection therewith, we and Mayne Pharma entered into an Amended and Restated Supply and License Agreement. In addition, on the June 24, 2014, in fulfillment of one of the conditions under the Supply and License Agreement, we entered into a Securities Purchase Agreement with Mayne Pharma (which we refer to as the Mayne Purchase Agreement). Pursuant to the terms of the Mayne Purchase Agreement, we issued to Mayne Pharma (i) 258,363.280 shares of our Series A Preferred Stock, and (ii) a warrant to purchase 10,250,569 shares of our common stock. The shares of Series A Preferred Stock converted into 87,843,897 shares of common stock on August 14, 2014. Such warrant has an exercise price of $0.0878 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on June 24, 2019.

On May 15, 2015, we and Mayne Pharma, along with Mr. Virca and Dr. O'Donnell consummated a series of related transactions to fulfill certain conditions of the Supply and License Agreement. In connection therewith, we and Mayne Pharma entered into a Second Amended and Restated Supply and License Agreement. In addition, on May 15, 2015, we entered into a Securities Purchase Agreement with Mayne Pharma (which we refer to as the 2015 Mayne Purchase Agreement). Pursuant to the terms of the 2015 Mayne Purchase Agreement, 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. As a result of the 2015 Mayne Purchase Agreement, Mayne Pharma owned approximately 51.1% of our equity securities on a fully diluted basis immediately following consummation of the offering. See "Certain Relationships and Related Party Transactions" for further information.

Sales and Marketing

We are in the early stages of development and thus have not yet established a sales, marketing or product distribution infrastructure because our product candidate is still in clinical 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 candidate, 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. 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 seeking to develop 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 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:

Names	Company	Description	Status
Taxotere® docetaxel	Sanofi-Aventis	Anti-tumor agent for MCRPC and late-stage NSCLC	Approved 2004; and new generics
Jevtana® cabazitaxel	Sanofi-Aventis	MCRPC following docetaxel failure	Approved 2010
Provenge® sipuleucel-T	Dendreon	Immunotherapy for asymptomatic MCRPC	Approved 2010
Zytiga® aberaterone	Janssen Biotech	Androgen synthesis inhibitor for MCRPC	Approved 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	Novartis	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
Gemzar® gemcitabine	Lilly	Cytotoxic chemotherapy agent for NSCLC in combination with platinum drugs	Approved for multiple cancers since 1996
Trexall® methotrexate	Teva	Antimetabolite therapy to slow cancer cell growth	Approved before 1984
Tarceva® erlotinib		Epidermal growth factor inhibitor treatment for NSCLC—maintenance therapy after chemo or metastatic disease after chemo	Approved in 2013
Xalkori® crizotinib	Pfizer	Selective inhibitor for late-state NSCLC patients who express the ALK gene	Approved in 2011
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
Opdivo® nivolumab	BMS	Metastatic squamous NSCLC	Approved 2015
Portrassa® necitumumab	Lilly	Metastatic squamous NSCLC	Approved 2015
Tagrisso® osimertinib	AstraZenica	EGFR mutation positive NSCLC	Approved 2015

Abbreviations: MCRPC (metastatic castrate resistant prostate cancer), NSCLC (non-small cell lung cancer), BCC (basal cell carcinoma), EGFR (epidermal growth factor receptor).

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 new drug

applications, or 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;
- 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 (or 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 have successfully avoided pre-clinical studies or any Phase I 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 based upon 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, at the Phase II level and the December 2014 clearance of our IND for human testing in a Phase II(b) clinical trial for which we began dosing patients during fourth quarter of 2015.

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 (institutional review board) 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 I, 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 II, 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 III, 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 I, Phase II and Phase III 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. As mentioned previously, we are moving directly into Phase II trials with SUBA-Itraconazole for our targeted anti-cancer indications 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 and the IND clearance by FDA which occurred in December 2014.

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 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 IV 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 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.

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 (or collectively 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. 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 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.

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 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 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 may be available for our proposed application of itraconazole as an anti-cancer therapy.

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.

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. In May 2016, we were granted orphan drug designation and exclusivity for our product candidate to include treatment of basal cell carcinoma in patients with Gorlin syndrome. We may, in the future, apply for orphan drug indication for stage IV non-squamous, non-small cell lung cancer.

Foreign Regulation

Although it is not presently our intention to seek approval of our product candidate 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. This would be the responsibility of one or more of our potential marketing partners. 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 (or CTA) 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 the date of this prospectus, we have 3 full-time employees and 1 part-time employee. One is involved in our clinical development program and operations and three handle our administration and accounting. None 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 and a contract research organization to spearhead our efforts on clinical development. We consider relations with all of our employees to be good. Each of our employees has entered into confidentiality, intellectual property assignment and non-competition agreements with us.

Facilities

Hedgepath, LLC has allocated space for our use in its offices in Tampa, Florida and San Diego, California, for which we currently pay a pro-rated portion of the rent of approximately $2,000 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 in the Bankruptcy Court for the Eastern District of Virginia seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code (or the Bankruptcy Code). The Chapter 11 case was captioned In re Commonwealth Biotechnologies, Inc., Case No. 11-30381-KRH. On January 4, 2013, CBI filed an Amended Plan of Reorganization (or the Plan) with the Bankruptcy Court. The Plan was approved by a vote of creditors and CBI stockholders on March 21, 2013. Hedgepath, LLC, a Florida limited liability company and a significant stockholder of our company of which our current Executive Chairman acts as manager, was the winning bidder for CBI (which is sometimes referred to herein as HPPI in its capacity as the reorganized company, after giving effect to the consummation of the transactions contemplated by the reincorporation merger and acquisition described below). CBI received an auction fee of $30,000 from Hedgepath, LLC in addition to an agreement to contribute certain assets related to our current business of commercializing innovative therapeutics for patients with cancer using the approved pharmaceutical itraconazole (or the Itra Business Opportunity).

On March 29, 2013, the Bankruptcy Court entered an order confirming the Plan pursuant to Chapter 11 of the Bankruptcy Code, and on April 17, 2013, CBI issued a press release announcing the effectiveness of such confirmation order.

Under the terms of the Plan, and pursuant to a Contribution Agreement, dated August 13, 2013, Hedgepath, LLC contributed and assigned to HPPI certain assets relating to the Itra Business Opportunity, as the reorganized debtor, in exchange for 90% of fully diluted voting equity in HPPI (in the form of newly issued Series A Preferred Stock, which was subsequently converted to common stock) on the date of issuance, with the prior stockholders of CBI retaining approximately 10% voting equity in HPPI, represented by 100% of HPPI's issued and outstanding shares of common stock. As the elements of the Plan have been implemented (including the payment in full of all company creditors), HPPI formally closed CBI's bankruptcy case on September 20, 2013.

On August 12, 2013, CBI consummated a short-form reincorporation merger with and into HPPI, its wholly-owned Delaware subsidiary, pursuant to which CBI changed its name to "HedgePath Pharmaceuticals, Inc." and became reincorporated as a Delaware corporation.

On August 13, 2013, HPPI and Hedgepath LLC consummated the transactions contemplated by the Contribution Agreement, including the acquisition of Itra Business Opportunity assets, as contemplated by the Plan.

Prior to such transactions, CBI was a shell company, as defined in Rule 12b-2 under the Exchange Act, having been subject to bankruptcy proceedings and with no operations. CBI formally emerged from Chapter 11 bankruptcy following the consummation of such transactions, which satisfied the final condition to effectiveness of the Plan.

MAN AGEMENT

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
Frank E. O'Donnell, Jr., M.D.	66	Executive Chairman and Director
Nicholas J. Virca	69	President and Chief Executive Officer
Garrison J. Hasara, CPA	46	Chief Financial Officer and Treasurer
Samuel P. Sears, Jr.	72	Director
W. Mark Watson, CPA	65	Director
Stefan J. Cross	43	Director
Dr. R. Dana Ono	63	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.

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

Frank E. O'Donnell, Jr., M.D. is our Executive Chairman of the Board of Directors and a Director of our company. He has been the Chairman of the Board of BioDelivery Sciences International (NASDAQ:BDSI) since 2002, and currently serves as Executive Chairman of such company. For more than twenty years, Dr. O'Donnell has been involved with various private limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare, including Hedgepath, LLC. Dr. O'Donnell is qualified to serve on our board of directors due to his medical training and extensive experience with investing in and operating biotechnology companies. Dr. O'Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital. Dr. O'Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. He is a trustee of St. Louis University.

Nicholas J. Virca 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 currently serves on the board of Panoptix Events and on the Life Sciences Advisory Board of Entegris, Inc. 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 therapy using itraconazole for treatment of cancer, and is a member of numerous biotechnology organizations for which he has been a speaker and organizer over the last two decades.

Garrison J. Hasara, CPA has been our Chief Financial Officer and Treasurer since September 2013. From January 2011 to September 2013, he was the Acting Chief Financial Officer, Principal Financial Officer and Principal Accounting Officer of Accentia Biopharmaceuticals, Inc., or Accentia, 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.

Samuel P. Sears, Jr. is a director of our company and Chairman of the Compensation Committee. He has been a member of the Board of Directors of BioDelivery Sciences International since October 2011 (NASDAQ: BDSI). Mr. Sears has extensive experience in the biopharmaceutical, nutraceutical and biotechnology industries. Since 2006, Mr. Sears has been a partner at the law firm of Cetrulo LLP, where he currently serves as managing partner, and from 2000 to 2006, he provided private consulting and legal advisory services to start-up and early stage development companies. From 2000 to 2013, Mr. Sears served as Director, Chairman of the Audit Committee, Chairman of the Executive Committee, and Member of the Compensation Committee of Commonwealth Biotechnologies, Inc., a research and development support services company. From 1998 to 2000, Mr. Sears served as Vice Chairman and Treasurer of American Prescription Providers, Inc., a specialty pharmacy network offering prescriptions and nutraceuticals to patients with chronic diseases. From 1994 through May 1998, Mr. Sears was Chief Executive Officer and Chairman of Star Scientific, Inc. From 1968 to 1993, Mr. Sears was in private law practice. Mr. Sears is qualified to serve on our board of directors because of his extensive legal and business experience, including in the pharmaceutical industry. Mr. Sears is a graduate of Harvard College and Boston College Law School.

W. Mark Watson, CPA is a director of our company and Chairman of the Audit Committee. 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 health and life sciences sector, having played a significant role in the development of Deloitte's audit approach for health and life sciences companies and leading its national healthcare regulatory and compliance practice. He has served as lead audit partner and advisory partner on the accounts of many public companies ranging from middle market firms to Fortune 500 enterprises. 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 pharmaceutical companies. He received his undergraduate degree in Accounting from Marquette University.

Stefan J. Cross is a director of our company and the appointee of Mayne Pharma to our board of directors. Since November 2013, Mr. Cross has served as the President of the U.S. subsidiaries of Mayne Pharma Group Limited (ASX: MYX). Mr. Cross has more than 20 years of experience in the pharmaceutical industry. Prior to his current appointment as President, 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 is a director of our company and Chairman of the Nominating and Governance Committee. Dr. Ono is a co-founder of, and since 2000 has been associated with, 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 30 years of experience in managing public and private life science companies, including, from 1995 to 2000, serving as President and Chief Executive Officer of IntraImmune Therapies, Inc., which was sold to Abgenix, Inc. in 2000. 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. 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.

Involvement in Certain Legal Proceedings

From September 2003 through December 2011, Dr. O'Donnell served as chief executive officer of Accentia. From February 2009 through December 2011, Dr. O'Donnell also served as chief executive officer of Biovest International, Inc., a majority-owned subsidiary of Accentia, or Biovest. In November 2008, Accentia and its subsidiaries, including Biovest, filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. In November 2010, both companies emerged from Chapter 11. In May 2013, Biovest again filed a voluntary petition to reorganize under Chapter 11 of the United States Bankruptcy Code. In July 2013, Biovest emerged from Chapter 11. We have not and do not have any projects with Accentia or Biovest.

On July 24, 2013 and August 5, 2013, purported class actions were filed in the United States District Court for the Middle District of Florida (Tampa Division) against Accentia, and several current and former directors and officers of Accentia and its former subsidiary, Biovest (we refer to such actions as the Class Action), including Frank E. O'Donnell, Jr. M.D., our Executive Chairman. The complaints allege that the defendants violated federal securities laws by making or causing Accentia and/or Biovest to make false statements, and by failing to disclose or causing Accentia and/or Biovest to fail to disclose material information, concerning the results of the clinical trial of Biovest's cancer vaccine, BiovaxID, and status of its approval by the FDA. Plaintiffs seek damages in an unspecified amount on behalf of shareholders who purchased common stock of Accentia or Biovest during a defined time period. All defendants, including Dr. O'Donnell, believe this litigation to be without merit, deny any wrongdoing or liability and have vigorously defended the alleged claims. A settlement of this matter, in which defendants make no admissions of wrongdoing or liability, was agreed upon by all parties and approved by the Court in 2014.

Board Committees and Director Independence

Director Independence

Of our current directors, we have determined that Samuel P. Sears, Jr., Dr. R. Dana Ono, and W. Mark Watson are "independent" as defined by applicable rules and regulations. 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, Stefan J. Cross and Samuel P. Sears, Jr. Mr. Watson and Mr. Sears are independent directors as defined in accordance with section Rule 10A-3 of the Exchange Act and the rules of the NASDAQ Stock Market. Mr. Watson serves as chairman of the committee. Our 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;
- 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;
- oversees all aspects of our systems of internal accounting and financial reporting control and corporate governance functions on behalf of the board; and
- 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 Dr. R. Dana Ono, Stefan Cross 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. Dr. Ono and Mr. Watson 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.

Compensation Committee

Our board of directors also has a Compensation Committee, which reviews or recommends the compensation arrangements for our management and employees and also 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 will be reviewed annually) and is composed of three members: Samuel P. Sears, Jr., Stefan Cross and Dr. R. Dana Ono. Mr. Sears serves as chairman of this committee. Mr. Sears and Dr. Ono are independent in accordance with rules of the NASDAQ Stock Market.

Code of Business Conduct and Ethics and Insider Trading Policy

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/ . A copy of our code of ethics is also available in print, without charge, upon written request to our company at 324 S Hyde Park Ave #350, Tampa, FL 33606 Attn: Garrison J. Hasara, CPA.

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, 2015 and 2014. 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, 2015.

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	2015	$150,000	—	—	—	—	—	$ 10,009(2)	$ 160,009
President and Chief Executive Officer (1)	2014	$136,250	—	$2,557,095	—	—	—	$ 1,886(2)	$2,695,231
Garrison J. Hasara, CPA	2015	$135,000	—	—	—	—	—	$ 13,234(4)	$ 148,234
Chief Financial Officer and Treasurer (3)	2014	$135,000	—	$ 980,000	—	—	—	$ 10,964(4)	$1,125,964

(1) Nicholas J. Virca was hired as Chief Executive Officer on August 1, 2013.
(2) Includes: $10,009 and $1,886 of health insurance premiums paid in 2015 and 2014, respectively.
(3) Garrison J. Hasara was hired as Chief Financial Officer on August 1, 2013.
(4) Includes: $13,234 and $10,964 of health insurance premiums paid in 2015 and 2014, 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 -On June 24, 2014, Nicholas J. Virca entered into an employment agreement with us. Pursuant to his employment agreement, Mr. Virca will act as our President and Chief Executive Officer for a term of three (3) years from the effective date of the agreement. At the end of the three year term, the agreement will automatically renew for successive one year terms unless prior written notice is received from either party within 60 days prior to the end of the particular term. Mr. Virca will earn a base salary of $150,000 per year for services rendered. Such base salary will automatically increase to $250,000 per year upon achievement of certain funding goals as described in the employment agreement. Mr. Virca is also eligible for a bonus in cash or in kind of up to 50% of his base salary based upon his achievement of certain goals as established by our board of directors or a committee of the board of directors. In addition, in July 2014, Mr. Virca was awarded 15,041,738 restricted stock units from the 2014 Equity Incentive Plan, or the EIP, subsequently approved by our majority stockholders. Such restricted stock units vest on March 15, 2017.

Mr. Virca's employment agreement may be terminated with or without cause by us or for or without good reason by Mr. Virca. In the event that the employment agreement is terminated for cause by us or without good reason by Mr. Virca, Mr. Virca is entitled to receive all accrued but unpaid salary and bonus amounts. In the event that the employment agreement is terminated without cause by

us or for good reason by Mr. Virca, Mr. Virca is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to six months of Mr. Virca's base salary, provided that such payment will equal twelve months of Mr. Virca's base salary if we have reached certain milestones. In the event that the employment agreement is terminated for good reason by Mr. Virca following a change of control, Mr. Virca is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to twelve months of Mr. Virca's base salary, provided that such payment will equal eighteen months of Mr. Virca's base salary if we have reached certain performance milestones. The employment agreement is also terminable upon death and disability and upon the terms as described in the Equity Holders Agreement between Hedgepath, LLC and Mayne Pharma described under "Certain Relationships and Related Party Transactions. Mr. Virca may not compete against us or solicit employees or customers from us for a period of one (1) year after termination of his employment for any reason as described in his employment agreement.

On May 15, 2015, as a condition of closing of the 2015 Mayne Purchase Agreement, Mr. Virca entered into the first amendment to employment agreement amends the terms of his employment agreement principally to redefine Mr. Virca's responsibilities in his present role with our company, including that Mr. Virca will report both to the board of directors and the JDC, remove a provision from the employment agreement requiring an automatic increase of Mr. Virca's base salary to $250,000 per year upon achievement of certain funding goals and otherwise update the employment agreement in consideration of the Equity Holders Agreement. All other terms of the employment agreement remain in full force and effect. On June 28, 2016, the Board approved a salary increase to $225,000 per year effective July 1, 2016 for Mr. Virca.

Garrison J. Hasara, Chief Financial Officer and Treasurer - On September 4, 2014, we and Garrison Hasara, our Chief Financial Officer and Treasurer, entered into an employment agreement to memorialize the terms under which Mr. Hasara will continue to serve in such capacity. The employment agreement has a term through December 31, 2017. For services rendered, Mr. Hasara is entitled to cash compensation of $135,000 per year, increasing to $180,000 per year upon closing on a follow-on public offering. Mr. Hasara is further entitled to an annual bonus in cash or in securities of our company of up to 50% of Mr. Hasara's annual fee beginning with fiscal year 2015. However, no bonuses were awarded for 2015. On June 28, 2016, the Board approved a salary increase to $200,000 per year. In addition, Mr. Hasara was awarded 7,000,000 restricted stock units from the EIP, subsequently approved by our majority stockholders. 3,500,000 of such restricted stock units vest on March 15, 2017. The balance will vest on September 3, 2017.

Mr. Hasara's employment agreement may be terminated with or without cause by us or for or without good reason by Mr. Hasara. In the event that the employment agreement is terminated for cause by us or without good reason by Mr. Hasara, Mr. Hasara is entitled to receive all accrued but unpaid salary and bonus amounts. In the event that the employment agreement is terminated without cause by us or for good reason by Mr. Hasara, Mr. Hasara is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to six months of Mr. Hasara's base salary, provided that such payment will equal twelve months of Mr. Hasara's base salary if we have reached certain milestones. In the event that the employment agreement is terminated for good reason by Mr. Hasara following a change of control, Mr. Hasara is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to twelve months of Mr. Hasara's base salary. The employment agreement is also terminable upon death and disability. Mr. Hasara may not compete against us or solicit employees or customers from us for a period of one (1) year after termination of his employment for any reason as described in his employment agreement.

Outstanding equity awards

The following table summarizes outstanding unexercised options, unvested stocks and equity incentive plan awards held by each of our named executive officers, as of December 31, 2015:

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	OPTION AWARDS					STOCK AWARDS			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	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 Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not vested ($)
Nicholas J. Virca	—	—	—	—	—	—	—	15,041,738(1)	$ 1,955,426
Garrison J. Hasara, CPA	—	—	—	—	—	—	—	7,000,000(2)	$ 910,000

(1) Includes unvested stock awards consist of Restricted Stock Units which are rights to acquire shares of our common stock. Mr. Virca's 15,041,738 Restricted Stock Units vest on March 15, 2017.

(2) Includes unvested stock awards consist of Restricted Stock Units which are rights to acquire shares of our common stock. Mr. Hasara's 7,000,000 Restricted Stock Units will as follows: 3,500,000 of such restricted stock units vest on March 15, 2017. The balance will vest on September 3, 2017.

2014 Equity Incentive Plan

In July 2014, our board of directors adopted our 2014 Equity Incentive Plan. 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 will be 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 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 Securities Exchange Act of 1934, as amended.

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, 2015 or 2014.

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 summarizes the compensation of our directors for the fiscal year ended December 31, 2015.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) (1)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Frank E. O'Donnell, Jr., MD	$ 43,200(2)	$ —	—	—	—	$ —	$43,200
Stefan J. Cross	$ —	$33,000	—	—	—	$ —	$33,000
Dr. R. Dana Ono	$ —	$33,000	—	—	—	$ —	$33,000
Samuel P. Sears, Jr.	$ —	$33,000	—	—	—	$ —	$33,000
W. Mark Watson, CPA	$ —	$44,000	—	—	—	$ —	$44,000

(1) Each Director that is not the Executive Chairman received 300,000 Restricted Stock Units issued under the 2014 Equity Incentive Plan which will vest on the earlier to occur of September 5, 2017 or the receipt of written notice of approval of an NDA by us for SUBA-Itraconazole by the relevant regulatory authority. Mr. Watson received an additional 100,000 Restricted Stock Units with the same vesting terms under the 2014 Equity Incentive Plan for his role as Chairman of the Audit Committee.

(2) Compensation for serving as Executive Chairman.

CERTAIN RELATIONSHI PS AND RELATED PARTY TRANSACTIONS

Hedgepath, LLC

August 2013 Contribution Agreement

As part of our bankruptcy reorganization plan, on August 13, 2013, we entered into the Contribution Agreement with Hedgepath, LLC, one of our principal stockholders, pursuant to which we acquired certain assets related to our current business, and Hedgepath, LLC was issued the Series A Preferred Stock representing a 90% equity voting interest in our company. Hedgepath, LLC is a private company. BlackRobe Capital LLC, an entity managed by our executive chairman, Dr. O'Donnell, is also the manager of Hedgepath, LLC. Effectively, Dr. O'Donnell controls Hedgepath, LLC.

June 2014 Purchase Agreement

On the June 24, 2014 as a condition to the Mayne Purchase Agreement (as defined and described below), 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.

Debt Forgiveness Agreement

On June 24, 2014, as a condition of closing of the Mayne Purchase Agreement, we entered into a Debt Forgiveness Agreement with Hedgepath, LLC pursuant to which Hedgepath, LLC waived, canceled and forgave payment from us of an aggregate of $639,767 of indebtedness previously advanced by Hedgepath, LLC to us in exchange for 2,530,237 shares of common stock, 71,635.981 shares of Series A Preferred Stock and a warrant to purchase 10,250,569 shares of common stock. The shares of Series A Preferred Stock converted into 82,156,842 shares of common stock on August 14, 2014. The warrant may be exercised by Hedgepath, LLC at an exercise price of $0.0878 per share at any time, from time to time, by Hedgepath, LLC prior to expiration on June 24, 2019.

Equity Holders Agreement

On June 24, 2014, in fulfillment of one of the conditions of the Mayne Purchase Agreement, we, Mayne Pharma, Hedgepath, LLC, Dr. O'Donnell and Mr. Virca (who for these purposes we refer to together as the Equity Holder Parties) entered into an Equity Holders Agreement. On May 15, 2015, as a condition of the 2015 Mayne Purchase Agreement, the Equity Holder Parties entered into the Amended and Restated Equity Holders Agreement. On December 17, 2015, the Equity Holder Parties entered into Amendment No. 1 to 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 agreed that while the Equity Holders Agreement remains in effect, Mayne Pharma will not act in concert as part of a "group" (as defined in Section 13(d) of the Securities Exchange Act of 1934, as amended) with any other person or persons to own or control more than fifty percent (50%) of the outstanding common stock;
- 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;
- Mr. Virca agreed to lock-up his equity securities of our company until the earlier of: (i) September 3, 2016, (ii) the receipt of written notice of acceptance for the filing of an NDA for the product licensed to us by Mayne Pharma, or, (iii) to the extent provided in an applicable award agreement, upon his death or disability;
- For as long as either Hedgepath, LLC or Mayne Pharma own more than forty percent (40%) of our common stock on a fully-diluted basis, without the approval of either or both of Hedgepath, LLC and Mayne Pharma, as applicable, we shall not increase the number of shares authorized under the EIP, amend the EIP, adopt a new stock grant plan or issue, grant or award more than 5,000,000 shares of common stock under the EIP in the aggregate (in addition to previous EIP grants);
- The Equity Holder Parties agreed that all awards included in the initial issuance of securities from the EIP are subject to restriction on exercise until the earlier of: (i) September 3, 2016 or (ii) the receipt of written notice of acceptance for the filing of an NDA by us an NDA for the product licensed to us by Mayne Pharma, provided that any awards granted after June 24, 2014 are not subject to this restriction;

- 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 that, for as long as Mayne Pharma has the right to designate a director to our board of directors, all of the Equity Holder Parties will vote their shares in favor of appointing the Mayne Pharma candidate to the board;
- The Equity Holder Parties agree not to increase or decrease the size of our board of directors except with the unanimous consent of the board until the Voting Rights Termination Date;
- Until the Voting Rights Termination Date, the Equity Holder Parties agree that any replacement or removal of Mr. Virca requires the unanimous approval of the board of directors and any replacement or removal of Dr. O'Donnell requires the approval of all of the members of the board of directors except for Dr. O'Donnell. Notwithstanding the foregoing, Mr. Virca and Dr. O'Donnell may be removed without unanimous approval of the board of directors upon the occurrence of the Majority Holder Condition (described below), or Material Breach Condition (described below);
- 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 our board of directors (we collectively refer to this breach as the Material Breach Condition);
- The Equity Holder Parties agree to vote for our board of directors in its current composition (unless mutually agreed upon by Mayne Pharma and Hedgepath, LLC) until such time as (i) either Mayne Pharma or Hedgepath, LLC, alone, and not in concert as part of a "group," own a majority of our outstanding shares of common stock (we refer to this condition as the Majority Holder Condition), and (ii) upon the occurrence of a Material Breach Condition. Upon the occurrence of the Majority Holder Condition, the majority holder or Mayne Pharma, respectively, may remove any current director and appoint a new director as long as our board of directors continues to consist of a majority of Independent Directors. Upon the occurrence of the Material Breach Condition, the requirement that the board of directors consist of a majority of Independent Directors will cease and Mayne Pharma will have the right to remove any current director and appoint a new director. Mayne Pharma may remove current directors and appoint new directors by written consent or by calling a meeting in accordance with our Bylaws, as amended; and
- 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.

In addition to the foregoing, pursuant to the Equity Holders Agreement, the Equity Holder Parties agreed that we would seek to (i) close on one or more registered or unregistered equity, debt or equity-linked financings in which we receive aggregate net proceeds of at least $5,000,000 or (ii) enter into a license, development, commercialization or similar agreement relating to our product, provided that we receive a net upfront payment of at least $5,000,000 in connection with such agreement and that such agreement will be subject to the approval of Mayne Pharma (collectively, we refer to this goal as the Performance Goal) on or before May 31, 2016 (we refer to this date as the Performance Goal Date). Under the Equity Holders Agreement, all previously required performance goals as set forth in the original Equity Holders Agreement have been removed and replaced solely with the Performance Goal. On May 25, 2016, with the closing of the 2016 Private Placement, we met the Performance Goal.

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 Amended and Restated 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.

In connection with their entry into the Equity Holders Agreement, the Equity Holder Parties agreed to waive, among other things, certain specified prior breaches by us of our obligations under the Amended and Restated Equity Holders Agreement entered into in June 2014.

Mayne Pharma

Second Amended and Restated License and Supply Agreement

Pursuant to our Supply and License Agreement with Mayne Pharma, which was originally entered into on September 3, 2013, amended and restated on June 24, 2014 and most recently amended and restated on May 15, 2015, Mayne Pharma is obligated to: (i) supply us with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being prostate, lung and skin cancer) in the United States, (ii) provide us with an exclusive license to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer via oral administration in the United States and (iii) participate in a joint development committee (or JDC) with us to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States. Mayne Pharma will also provide certain services to us (in accordance with the development plan and budget for our product) including to direct clinical programming (subject to the oversight and approval by the JDC and, in certain circumstances, the board of directors), and to direct the regulatory approval process and intellectual property strategy related to the product. Any services provided to us by Mayne Pharma in this regard will be provided at Mayne Pharma's expense (other than third party costs agreed to by us and Mayne Pharma), and such services will be subject to our prior approval. The Supply and License Agreement may be terminated by Mayne Pharma if we fail to achieve regulatory approval to commercialize SUBA-Itraconazole in the U.S. by June 30, 2017, if we breach any provision of our Equity Holders Agreement or purchase agreements with Mayne Pharma, if we materially breach the Supply and License Agreement and do not cure such breach within a specified time period, or if either party files for bankruptcy or insolvency proceedings.

On June 24, 2014 and again on May 15, 2015, we and Mayne Pharma, along with Nicholas J. Virca, our President and Chief Executive Officer, Frank E. O'Donnell, Jr., M.D., our Executive Chairman, and Hedgepath, LLC consummated a series of related transactions to fulfill certain conditions of the original Supply and License Agreement and Amended and Restated Supply and License Agreements, respectively. In connection therewith, we and Mayne Pharma entered into the Second Amended and Restated Supply and License Agreement.

Securities Purchase Agreements with Mayne Pharma

On June 24, 2014, in fulfillment of one of the conditions under the original Supply and License Agreement, we entered into the Mayne Purchase Agreement. Pursuant to the terms of the Mayne Purchase Agreement, we issued to Mayne Pharma (i) 258,363.280 shares of our Series A Preferred Stock, and (ii) a warrant to purchase 10,250,569 shares of our common stock. The shares of Series A Preferred Stock converted into 87,843,897 shares of common stock on August 14, 2014. Such warrant has an exercise price of $0.0878 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on June 24, 2019.

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.

On May 25, 2016, in connection with the 2016 Private Placement, we entered into a purchase agreement with Mayne Pharma. For more information regarding this offering, see "Selling Stockholders."

Executive Chairman

On June 24, 2014, Frank E. O'Donnell, Jr., M.D. entered into an Executive Chairman Agreement with us to memorialize the terms under which Dr. O'Donnell will continue to serve in such capacity and as a director of our company. The First Amendment to the Executive Chairman Agreement was entered into on May 15, 2015. The Executive Chairman Agreement will continue until the date that Dr. O'Donnell is no longer serving as a member of our board of directors. For services rendered as Executive Chairman, Dr. O'Donnell is entitled to cash compensation of $43,200 per year, increasing to $72,000 per year upon achievement of the certain funding goals. Dr. O'Donnell is further entitled to an annual bonus in cash or in securities of our company of up to 50% of Dr. O'Donnell's annual fee. On June 28, 2016, the Board approved an increase to Dr. O'Donnell's annual cash compensation to $112,500 effective July 1, 2016. Dr. O'Donnell may not compete against us or solicit employees or customers from us for a period of one year after termination of the Executive Chairman Agreement as described in further detail in the same. The Executive Chairman Agreement may be terminated by either us or Dr. O'Donnell with 60 days' written notice and upon the terms as described above in the Equity Holders Agreement. Upon termination, we will be required to pay Dr. O'Donnell all compensation and expenses that are owed to him as of the date of termination.

PRINCIPAL STOCKHOLDERS

The following table sets forth 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)	221,010,368	59.4%
Hedgepath, LLC(3)(5)	92,377,638	29.7%
Black Robe Capital LLC(4)(5)	92,377,638	29.7%
Hopkins Capital Group II, LLC(6)	16,560,000	5.5%
Frank E. O'Donnell, Jr., M.D.(4) (5) (6)	108,937,638	35.1%
Nicholas J. Virca(7)	—	—
Garrison J. Hasara, CPA(8)	—	—
Samuel P. Sears(9)	1,106,096	*
Stefan J. Cross(10)	—	—
Dr. R. Dana Ono(11)	—	—
W. Mark Watson, CPA(12)	1,010,000	*
All directors and executive officers as a group (7 persons)	111,053,734	35.8%

* Less than 1%

(1) Applicable percentages are based on 300,353,270 shares outstanding as of the date of this prospectus. This table is based upon information supplied by officers, directors, and principal stockholders 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 149,062,230 shares of our common stock and a warrant to purchase an additional 71,948,138 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 82,127,069 shares of our common stock and a warrant to purchase an additional 10,250,569 shares of our common stock. The address for Hedgepath, LLC is 324 S Hyde Park Avenue, Suite 350, Tampa, Florida 33606.

(4) Includes 82,127,069 shares of our common stock and a warrant to purchase an additional 10,250,569 shares of our common stock. The address for Black Robe Capital LLC is 324 S Hyde Park Avenue, Suite 350, Tampa, Florida 33606.

(5) Black Robe is the sole manager of Hedgepath, LLC, and has sole voting and dispositive power over the securities held by Hedgepath, LLC. Frank E. O'Donnell, Jr., MD, our Executive Chairman, is the co-manager of Black Robe LLC, with sole voting and dispositive power over Black Robe LLC, and The Francis E. O'Donnell Jr. Irrevocable Trust No. 7 is the sole member of Black Robe LLC. Pursuant to his manager role at Black Robe, LLC, Dr. O'Donnell may be considered for SEC reporting purposes the beneficial owner of any shares held by Hedgepath, LLC. He disclaims ownership of any shares in HedgePath LLC in which he does not have a pecuniary interest.

(6) The address for Hopkins Capital Group II, LLC is 324 S Hyde Park Suite 350, Tampa, Florida 33606. As a co-manager of Hopkins Capital Group II, LLC, Dr. O'Donnell may be considered for SEC reporting purposes the beneficial owner of any shares held by Hopkins Capital Group II, LLC. He disclaims ownership of any shares in Hopkins Capital Group II, LLC in which he does not have a pecuniary interest.

(7) Mr. Virca is our Chief Executive Officer and President. Excludes 15,041,738 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Virca's address is 700 West Harbor Drive #1104, San Diego, CA 92101.

(8) Mr. Hasara is our Chief Financial Officer and Treasurer. Excludes 7,000,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Hasara's address is 16904 Melissa Ann Drive, Lutz, FL 33558.

(9) Mr. Sears is a director of our company. Excludes 600,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Sears' address is 1 Fieldstone Drive, Winchester, MA. 01890.

(10) Mr. Cross is a director of our company. Excludes 600,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Cross' address is 1240 Sugg Parkway, Greenville, NC 27834.

(11) Dr. Ono is a director of our company. Excludes 300,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Dr. Ono's address is 18 Spring Road, Concord, MA, 01742.

(12) Mr. Watson is a director of our company. Excludes 700,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Watson's address is c/o our company, 324 South Hyde Park Avenue, Suite 350, Tampa, FL 33606.

DESCRIPTIO N OF SECURITIES

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 300,353,270 shares of common stock issued and outstanding, and no shares of 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.

Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 10,000,000 shares of blank check preferred stock with such designation, rights and preferences as may be determined from time to time by our board of directors. No shares of preferred stock are currently issued or outstanding as all were converted into shares of common stock as of August 14, 2014. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. We may issue some or all of the preferred stock to effect a business transaction. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us.

Warrants

As of the date of this prospectus, warrants to purchase 109,779,707 shares of common stock were issued and outstanding. Warrants, issued in the amount of 10,250,569 to each of HPLLC and Mayne Pharma on June 24, 2014, have a term of 5 years and an exercise price of $0.878. Additional warrants to purchase 33,333,333 shares of common stock issued to Mayne Pharma on May 15, 2015 have a term of 5 years and an exercise price of $0.075. Further, upon closing of the 2016 Private Placement, 55,945,236 warrants are outstanding 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.

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
- 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 amended and restated 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 Amended and Restated Bylaws

On May 15, 2015, our board of directors approved and adopted our second amended and restated bylaws. Provisions of our second amended and restated 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 amended and restated 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 ST OCKHOLDERS

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

For information regarding the June 24, 2014 private placement with Hedgepath, LLC, see "Certain Relationships and Related Party Transactions."

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 (3)(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 Feinburg (3)	500,000	500,000	—	—
Rivka Lara Feinburg (3)	700,000	700,000	—	—
W. Mark Watson (3)(6)	1,010,000	1,000,000	10,000	*
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. (3)(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 (3)	85,000	85,000	—	—
Tom Masterson (3)	85,000	85,000	—	—
Newbridge Securities (3)(14)	30,000	30,000	—	—
Hedgepath, LLC (15)	92,337,638	7,440,000	84,937,638	27.3%
MOAB Investments, LP (16)(17)	6,000,000	6,000,000	—	—
Hopkins Capital Group II, LLC (16)(18)	16,560,000	16,560,000	—	—
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 300,353,270 shares of common stock outstanding as of June 13, 2016.

(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 Frank E. O'Donnell, Jr., M.D. (our Executive Chairman) and James A. McNulty are the managers.
(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) Frank E. O'Donnell, Jr., M.D. (our Executive Chairman) is a co-manager of Hopkins Capital Group II, LLC. James A. McNulty and Frank E. O'Donnell, Jr. have voting and investment power over the securities held by Hopkins Capital Group II, LLC.

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;
- 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 reallowed 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.

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 $75,000 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.

LEGA L 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.

EXP ERTS

The financial statements of our company appearing in this prospectus have been included herein in reliance upon the report (which report includes an explanatory paragraph relating to our ability to continue as a going concern) 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 FI ND 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. You may read and copy any reports, statements, or other information we file at the SEC's public reference room at 100 F. Street, N.E., Washington D.C. 20549. You can request copies of these documents, upon payment of a duplicating fee by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. 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 F INANCIAL STATEMENTS

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
AS OF MARCH 31, 2016 AND DECEMBER 31, 2015
(Unaudited)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 118,623	$ 601,445
Other current assets	52,017	34,414
Total current assets	170,640	635,859
Other long term assets	250,000	250,000
Total assets	$ 420,640	$ 885,859
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 647,114	$ 383,356
Other liabilities	96,316	78,524
Total current liabilities	743,430	461,880
Total liabilities	743,430	461,880
Commitments and contingencies (note 6)	—	—
Stockholders' (deficit) equity:		
Common stock, $0.0001 par value; 340,000,000 shares authorized; 245,353,270 shares issued and outstanding	24,535	24,535
Additional paid-in capital	37,019,678	36,571,982
Accumulated deficit	(37,367,003)	(36,172,538)
Total stockholders' (deficit) equity	(322,790)	423,979
Total liabilities and stockholders' (deficit) equity	$ 420,640	$ 885,859

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2016 AND 2015
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
Total Revenues:	$ —	$ —
Expenses:		
Research and development expenses	582,513	313,017
General and administrative	611,952	609,657
Total Expenses:	1,194,465	922,674
Net loss	$ (1,194,465)	$ (922,674)
Basic and diluted net loss per share	$ 0.00	$ 0.00
Weighted average common stock shares outstanding	245,353,270	211,419,937

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' (DEFICIT) EQUITY
FOR THE THREE MONTHS ENDED MARCH 31, 2016
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount			
Balances, January 1, 2016	245,353,270	$24,535	$36,571,982	$(36,172,538)	$ 423,979
Stock based compensation	—	—	447,696	—	447,696
Net loss	—	—	—	(1,194,465)	(1,194,465)
Balances, March 31, 2016	245,353,270	$24,535	$37,019,678	$(37,367,003)	$ (322,790)

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED MARCH 31, 2016 AND 2015
(Unaudited)

	Three months Ended March 31,	
	2016	2015
Operating activities:		
Net loss	$ (1,194,465)	$ (922,674)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Stock based compensation	447,696	419,703
Changes in assets and liabilities:		
Prepaid expense and other current assets	(17,603)	54,094
Accounts payable and other current liabilities	281,550	167,667
Net cash used in operating activities	(482,822)	(281,210)
Net change in cash and cash equivalents	(482,822)	(281,210)
Cash and cash equivalents at beginning of period	601,445	365,161
Cash and cash equivalents at end of period	$ 118,623	$ 83,951

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2016 AND 2015
(Unaudited)

1. Corporate overview:

Overview

The accompanying unaudited condensed financial statements of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company", "HPPI", "we", "us" or similar terminology), have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows as of March 31, 2016, and for all periods presented, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to the Securities and Exchange Commission ("SEC") rules and regulations. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2015, which are included in the Company's 2015 Annual Report on Form 10-K, filed with the SEC on February 1, 2016 (the "2015 Annual Report"). The accompanying condensed balance sheet as of December 31, 2015 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements.

As used herein, the term "Common Stock" means the Company's common stock, $0.0001 par value per share.

The results of operations for the three month period ended March 31, 2016 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this Quarterly Report are strongly encouraged to review the risk factors relating to the Company which are set forth in the 2015 Annual Report and our other filings with the SEC.

The accompanying financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities of the Company in the normal course of business. If the Company is unable to raise required funding to continue to pursue its business plan, it may have to cease operations. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Nature of the Business and Background

The Company is a clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. The Company's proposed therapy is based upon the use of SUBA™ Itraconazole, which is a patented, oral formulation of the currently marketed anti-fungal drug itraconazole. The Company believes that the dosing of oral capsules of this formulation 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 basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration (the "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.

The Company's preliminary focus is on the development of therapies for skin, lung and prostate cancers in the United States of America ("U.S.") market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome) for which the Company is presently conducting a Phase II(b) clinical trial.

Relationship with Mayne Pharma Ventures Pty Ltd.

The Company has exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole capsules for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by the Company's manufacturing partner and significant shareholder Mayne Pharma Ventures Pty Ltd. and its affiliates ("Mayne Pharma") under a supply and license agreement, originally dated September 3, 2013 and most recently amended and restated on May 15, 2015 (the "SLA"). 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 the Company's licensor and supply partner, under the SLA and related agreements, Mayne Pharma holds a significant minority equity stake in the Company and holds important rights with respect to the Company, such as the right to appoint a member to the Company's Board of Directors.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2016 AND 2015
(Unaudited)

2. Liquidity and management's plans:

The Company presently has very limited cash resources and requires significant additional financing for its research and development, commercialization and distribution efforts and its working capital and intends to finance these activities primarily through:

- proceeds from public and private financings and, potentially, from strategic transactions;
- proceeds from the exercise of warrants issued in public and private financings;
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of its products for which the Company would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where the Company would receive funding based on out-licensing its product; and
- seeking government or private foundation grants which would be awarded to the Company to further develop its current and future anti-cancer therapies.

However, there is a material 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, its viability, its financial condition and its results of operations beyond 2016. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders. The Company had cash and cash equivalents of approximately $118,623 as of March 31, 2016 (see note 7 for information regarding an equity offering by the Company subsequent to March 31, 2016).

3. Summary of Significant Accounting Policies:

Estimates

The preparation of condensed 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 is recognized when earned by the Company.

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 which is $250,000 for substantially all depository accounts. As of March 31, 2016, the Company had did not have any depository accounts containing a cash balance in excess of these insured limits.

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 and purchased in-process research and development.

HEDGEPATH PHARMACEUTICALS, INC.
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(Unaudited)

3. Summary of Significant Accounting Policies (continued):

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 equity securities issued are determined by the Company based predominantly on the trading price of the common stock. 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.

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 of 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 August 2014, the Financial Accounting Standards Board issued ASU No. 2014-15, "Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosure. This ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company is evaluating the impact the guidance will have on its financial statements.

4. Other liabilities

At March 31, 2016 and December 31, 2015, other liabilities include $52,500 payable to a third party service provider which is required to be settled in stock upon the completion of at least a $5 million stock offering. Additional other liabilities include approximately $30,000 in accrued legal expenses and $14,000 in accrued payroll at March 31, 2016, and approximately $20,000 in accrued legal expenses and $6,000 in accrued payroll expenses at December 31, 2015.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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5. Stockholders' Equity:

Employee Stock Plans

Total stock-based compensation for the three months ended March 31, 2016 was approximately $0.45 million and is related to certain restricted stock units ("RSUs") issued in 2014 and 2015 in connection with the Company's Equity Incentive Plan. The expense is classified as research and development expense and general and administrative expense in the accompanying condensed statements of operations. There was approximately $1.1 million in unamortized stock-based compensation relating the RSUs at March 31, 2016, which is expected to be recognized over the next 29 months. The grant date fair value of RSUs was determined using the quoted market price of the Common Stock on the date of issuance and the number of shares expected to vest. As of March 31, 2016, there were 25,891,738 RSUs granted to various members of the Board of Directors, management and other employees.

6. 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.

7. Subsequent Events:

In April 2016, the Company initiated a private placement offering (the "Offering") of up to $5.5 million solely to "accredited investors" pursuant to Rule 506(c) of regulation D promulgated by the SEC. The Offering is being undertaken on a "no minimum" basis, meaning that the Company is free to raise less than the maximum $5.5 million amount of the Offering. In the Offering, the Company is offering up to 55,000,000 units, with each unit comprised of one (1) share of Common Stock and one (1) 5-year warrant to purchase one (1) share of Common Stock. Each unit is being offered at a price of $0.10, and the exercise price of each warrant is $0.12 per share. No actual units will be issued, and each investor will only receive shares of Common Stock and warrants to purchase Common Stock. Both the shares and the shares underlying the warrants will be subject to customary registration rights. As of May 9, 2016, approximately $2.3 million has been raised under the Offering resulting in the issuance of approximately 23.0 million shares of Common Stock and warrants to purchase 23.0 million shares of Common Stock. Under agreements previously entered into with the Company, Mayne has the right to purchase the Company's securities in new equity offerings of the Company in an amount necessary to maintain its percentage ownership in the fully-diluted capitalization of the Company. Mayne has provided the Company with written notice of its exercise of such right in connection with the Offering, and it is expected that Mayne will purchase all of its pro rata share, on a fully-diluted basis, of the securities issued by the Company in connection with the Offering.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of HedgePath Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of HedgePath Pharmaceuticals, Inc. (the "Company") as of December 31, 2015 and 2014 and the related statements of operations, stockholders' equity and cash flows for the years then ended. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis of designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing 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.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of HedgePath Pharmaceuticals, Inc. as of December 31, 2015 and 2014 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company incurred cumulative net losses since inception of approximately $36 million at December 31, 2015, of which approximately $9.4 million was incurred subsequent to the emergence from bankruptcy, as discussed in Note 1. Furthermore, the Company expects to continue to incur net losses through the foreseeable future. These factors, among others as discussed in Note 2 to the financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Cherry Bekaert LLP

Tampa, Florida
February 1, 2016

HEDGEPATH PHARMACEUTICALS, INC.
BALANCE SHEETS
DECEMBER 31, 2015 AND 2014

	December 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 601,445	$ 365,161
Prepaid expenses	34,414	97,817
Total current assets	635,859	462,978
Other long term assets	250,000	—
Total assets	$ 885,859	$ 462,978
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 383,356	$ 324,966
Other liabilities	78,524	75,933
Total current liabilities	461,880	400,899
Total liabilities	461,880	400,899
Commitments and contingencies	—	—
Stockholders' equity:		
Series A Preferred Stock, $0.0001 par value; 500,000 shares authorized; no shares issued and outstanding.	—	—
Undesignated Preferred Stock, $0.0001 par value; 9,500,000 shares authorized; no shares issued or outstanding.	—	—
Common Stock, $0.0001 par value; 340,000,000 shares authorized; 245,353,270 and 211,419,937 shares issued and outstanding in 2015 and 2014, respectively	24,535	21,142
Additional paid-in capital	36,571,982	32,263,890
Accumulated deficit	(36,172,538)	(32,222,953)
Total stockholders' equity	423,979	62,079
Total liabilities and stockholders' equity	$ 885,859	$ 462,978

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2015 AND 2014

	Year Ended December 31,	
	2015	2014
Revenues:	$ —	$ —
Total revenues	—	—
Expenses:		
Research and development	1,680,250	2,430,735
General and administrative	2,269,335	1,507,082
Total expenses	3,949,585	3,937,817
Loss from operations	(3,949,585)	(3,937,817)
Interest expense	—	(37,481)
Net loss	$ (3,949,585)	$ (3,975,298)
Basic and diluted loss per share	$ (0.02)	$ (0.04)
Weighted average common shares outstanding	232,616,649	95,884,524

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2015 AND 2014

	Preferred Stock Series A		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Common Stock Subscription Receivable – Related Party	Accumulated Deficit	Total Stockholders' Equity
Balances, December 31, 2013	170,001	$ 17	18,888,971	$ 1,889	$27,479,913	$ —	$(28,247,655)	$ (765,836)
Issuance of preferred and common stock in debt forgiveness transaction	71,636	7	2,530,227	253	189,508	—	—	189,768
Sale of common stock to related party	—	—	20,000,000	2,000	1,498,000	(1,250,000)	—	250,000
Issuance of warrants for debt forgiveness	—	—	—	—	450,000	—	—	450,000
Issuance of common stock warrants in acquisition of research and development and development license agreement	—	—	—	—	619,134	—	—	619,134
Issuance of preferred stock in acquisition of research and development license agreement	258,363	26	—	—	1,290,700	—	—	1,290,726
Collection of stock subscription receivable	—	—	—	—	—	1,250,000	—	1,250,000
Conversion of preferred stock to common stock	(500,000)	(50)	170,000,739	17,000	(16,950)	—	—	—
Stock compensation expense	—	—	—	—	753,585	—	—	753,585
Net Loss							(3,975,298)	(3,975,298)
Balances, December 31, 2014	—	—	211,419,937	21,142	32,263,890	—	(32,222,953)	62,079
Sale of common stock and common stock warrants to related party	—	—	33,333,333	3,333	2,496,667	—	—	2,500,000
Common shares issued for payment of trade payables	—	—	600,000	60	89,940	—	—	90,000
Stock-based compensation	—	—	—	—	1,721,485	—	—	1,721,485
Net loss	—	—	—	—	—	—	(3,949,585)	(3,949,585)
Balances, December 31, 2015	—	$ —	245,353,270	$24,535	$36,571,982	$ —	$(36,172,538)	$ 423,979

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2015 AND 2014

	Year Ended December 31,	
	2015	**2014**
Operating activities:		
Net loss	$ (3,949,585)	$ (3,975,298)
Adjustments to reconcile net loss to net cash flows from operating activities:		
In-process research and development purchased with the issuance of preferred stock and common stock warrants	—	1,909,860
Non-cash interest expense	—	34,819
Stock-based compensation	1,721,485	753,585
Changes in assets and liabilities:		
Prepaid expenses	63,403	(87,817)
Other assets	(250,000)	—
Accounts payable and other current liabilities	150,981	61,327
Net cash flows from operating activities	(2,263,716)	(1,303,524)
Financing activities:		
Proceeds from related party advances	—	273,638
Payments on notes payable	—	(105,170)
Proceeds from sale of common stock and collection of stock subscription receivable, related party	2,500,000	1,500,000
Net cash flows from financing activities	2,500,000	1,668,468
Net change in cash and cash equivalents	236,284	364,944
Cash and cash equivalents at beginning of year	365,161	217
Cash and cash equivalents at end of year	$ 601,445	$ 365,161
Cash paid for interest	$ —	$ 2,005
Supplemental disclosure of non-cash financing activities:		
Issuance of common stock in payment of trade payables	$ 90,000	$ —
Issuance of preferred and common stock in debt forgiveness transaction	$ —	$ 189,768
Issuance of warrants in debt forgiveness transaction	$ —	$ 450,000

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2015 AND 2014

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 clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. The Company's preliminary focus is on the development of therapies for skin, lung and prostate cancers in the U.S. market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome) for which the Company has begun dosing its Phase II(b) clinical trial. The Company's proposed therapy is based upon the use of SUBA-Itraconazole, which is a patented, oral formulation of the currently marketed anti-fungal drug itraconazole. The Company believes that the dosing of oral capsules of this formulation 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 basal cell carcinoma. Itraconazole is approved by the U.S. Food and Drug Administration (the "FDA") for, and 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.

Second Amended and Restated Supply and License Agreement

Pursuant to the Company's Supply and License Agreement with Mayne Pharma Ventures Pty Ltd. and its affiliates ("Mayne Pharma") which was originally entered into on September 3, 2013, amended and restated on June 24, 2014 and most recently amended and restated on May 15, 2015, Mayne Pharma is obligated to: (i) supply the Company with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being prostate, lung and skin cancer) in the United States, (ii) provide the Company with an exclusive license to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer via oral administration in the United States and (iii) participate in a joint development committee (the "JDC") with the Company to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States. Mayne Pharma will also provide certain services (in accordance with the development plan and budget for the Company's product) including to direct clinical programming (subject to the oversight and approval by the JDC and, in certain circumstances, the Board of Directors), and to direct the regulatory approval process and intellectual property strategy related to the product. Any services provided to the Company by Mayne Pharma in this regard will be provided at Mayne Pharma's expense (other than third party costs agreed to by the Company and Mayne Pharma), and such services will be subject to the Company's prior approval. The Supply and License Agreement may be terminated by Mayne Pharma if the Company fails to achieve regulatory approval to commercialize SUBA-Itraconazole in the U.S. by June 30, 2017, if the Company breaches any provision of the Equity Holders Agreement or purchase agreements with Mayne Pharma (each as described below), if the Company materially breaches the Supply and License Agreement and do not cure such breach within a specified time period, or if either party files for bankruptcy or insolvency proceedings.

Mayne Pharma Sublicense Agreement

On September 2, 2015, the Company entered into a sublicense agreement with Mayne Pharma. Pursuant to the Agreement, Mayne Pharma sublicensed to the Company the exclusive U.S. rights to two additional 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. Mayne Pharma 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 Company paid a license fee of $75,000 to Mayne Pharma upon entering into the sublicense agreement, which is included in research and development expenses in the accompanying 2015 condensed statement of operations.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2015 AND 2014

1. Corporate overview (continued):

Mayne Pharma Securities Purchase Agreements

On June 24, 2014, the Company and Mayne Pharma entered into a Securities Purchase Agreement (the "Mayne Purchase Agreement"). Pursuant to the Mayne Purchase Agreement, the Company (i) issued 258,363 shares of Series A Preferred Stock (the "Mayne Series A Shares") and (ii) issued, upon closing of a separate Securities Purchase Agreement, dated June 24, 2014 (as described further below, the "HPLLC Purchase Agreement") by and between the Company and Hedgepath, LLC, a warrant to purchase 10,250,569 shares of Common Stock (the "Mayne Make-Up Warrant"). The Mayne Series A Shares converted into 87,843,897 shares of Common Stock on August 14, 2014 pursuant to the terms of the Equity Holders Agreement (discussed below) and in accordance with the terms of the Series A Preferred Stock. The Mayne Make-Up Warrant has an exercise price of $0.0878 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on June 24, 2019. In conjunction with the execution of the Mayne Purchase Agreement, the Company has expensed, as in-process research and development costs, approximately $1.9 million for the fair value of the preferred stock and warrant issued. The value of the issued stock was calculated by taking approximately 42% of the market capitalization on the date the agreement was entered into to reflect the 42% ownership exchanged for entering into the agreement. The value of the warrant was calculated by using the Black-Scholes valuation model that uses assumptions for expected volatility (104.9%), expected dividends (none), expected term (5 years), and risk-free interest rate (1.7%). Expected volatilities are based on historical volatilities of peer companies. The risk-free rate is based upon the U.S. Treasury yield curve in effect at the time of the grant for the period of the expected term.

On May 15, 2015, the Company and Mayne Pharma entered into a Securities Purchase Agreement (the "2015 Mayne Purchase Agreement") pursuant to which, in consideration of Mayne Pharma's investment of $2.5 million in the Company, the Company issued (i) 33,333,333 shares of Common Stock and (ii) a warrant to purchase 33,333,333 shares of Common Stock (the "Warrant") for an aggregate purchase price of $2,500,000, or $0.075 per share. The transaction contemplated by the 2015 Mayne Purchase Agreement formally closed on May 18, 2015. The Warrant is immediately exercisable, subject to certain restrictions, at an exercise price of $0.075 per share and expires on May 15, 2020.

Hedgepath, LLC Purchase Agreement

On June 24, 2014, the Company and Hedgepath, LLC entered into the Hedgepath, LLC Purchase Agreement, pursuant to which the Company sold Hedgepath, LLC 20,000,000 shares of Common Stock at a purchase price of $0.075 per share for an aggregate purchase price of $1,500,000, which monies were funded in monthly installments through December 2014 pursuant to the promissory note (the "HPLLC Note") issued by Hedgepath, LLC to the Company on June 24, 2014. Funds received under this transaction are being used by the Company for research and development as well as for general and administrative expenses.

Equity Holders Agreement

On June 24, 2014, in fulfillment of one of the conditions of the Mayne Purchase Agreement, the Company, Mayne Pharma, Hedgepath, LLC, Dr. Frank O'Donnell and Mr. Nicholas J. Virca (who for these purposes are referred to together as the "Equity Holder Parties") entered into an Amended and Restated Equity Holders Agreement (the "Equity Holders Agreement"). On May 15, 2015, as a condition of the 2015 Mayne Purchase Agreement, the Equity Holder Parties entered into the Second Amended and Restated Equity Holders Agreement. The Equity Holders Agreement governs the rights and obligations of each of the parties as they pertain to the Company's securities and to the present and future governance of the Company. Pursuant to the Equity Holders Agreement:

- Mayne Pharma and Hedgepath, LLC each agreed not to offer, pledge, sell, contract to sell, swap or enter into any other transfer arrangement any of their company securities until June 24, 2015 (which is referred to as the Lock-Up Period) without prior written consent of the other Equity Holder Parties, except for in limited circumstances as described in the Equity Holders Agreement;
- Mayne Pharma, Hedgepath, LLC, Mr. Virca and Dr. O'Donnell each agreed that during the Lock-Up Period none of them will own greater than 49.5% of the Company's common stock on a fully-diluted basis (such ownership to include individual and affiliate ownership) except that Mayne Pharma is permitted to own greater than 49.5% of the Company's common stock on a fully-diluted basis, but only as a result of its ownership of the shares and the warrant issued pursuant to the 2015 Mayne Purchase Agreement, it being understood that Mayne Pharma will not exercise the Warrant until after the Lock-up Period;
- Mayne Pharma agreed that while the Equity Holders Agreement remains in effect, Mayne Pharma will not act in concert as part of a "group" (as defined in Section 13(d) of the Securities Exchange Act of 1934, as amended) with any other person or persons to own or control more than fifty percent (50%) of the outstanding common stock;

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2015 AND 2014

1. Corporate overview (continued):

- 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 been granted the right until June 24, 2016 to introduce accredited investors to participate in a private offering of the Company's securities (with some exceptions as described in the Equity Holders Agreement). In the event that the Company contemplates a private offering of its securities, such accredited investors introduced by Mayne Pharma to have the right to participate in up to 50% of the private offering;
- Mr. Virca agreed to lock-up his equity securities of our company until the earlier of: (i) September 3, 2016, (ii) the receipt of written notice of acceptance for the filing of an NDA for the product licensed to us by Mayne Pharma, or, (iii) to the extent provided in an applicable award agreement, upon his death or disability;
- Dr. O'Donnell and the Company agreed that Dr. O'Donnell is not entitled to receive any equity securities under our EIP until the Performance Goal Date (as described below);
- The Company agreed not to amend the Company's 2014 Equity Incentive Plan (the "EIP") in any way during the Lock-Up Period without written consent of Mayne Pharma;
- For as long as either Hedgepath, LLC or Mayne Pharma own more than forty percent (40%) of the Company's common stock on a fully-diluted basis, without the approval of either or both of Hedgepath, LLC and Mayne Pharma, as applicable, the Company shall not increase the number of shares authorized under the EIP, amend the EIP, adopt a new stock grant plan or issue, grant or award more than 5,000,000 shares of common stock under the EIP in the aggregate (in addition to previous EIP grants);
- The Equity Holder Parties agreed that all awards included in the initial issuance of securities from the EIP are subject to restriction on exercise until the earlier of: (i) September 3, 2016 or (ii) the receipt of written notice of acceptance for the filing of an NDA by us an NDA for the product licensed to the Company by Mayne Pharma, provided that any awards granted after June 24, 2014 are not subject to this restriction;
- 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 that, for as long as Mayne Pharma has the right to designate a director to our Board of Directors, all of the Equity Holder Parties will vote their shares in favor of appointing the Mayne Pharma candidate to the board;
- The Equity Holder Parties agree not to increase or decrease the size of our Board of Directors except with the unanimous consent of the board until the Voting Rights Termination Date;
- Until the Voting Rights Termination Date, the Equity Holder Parties agree that any replacement or removal of Mr. Virca requires the unanimous approval of the Board of Directors and any replacement or removal of Dr. O'Donnell requires the approval of all of the members of the Board of Directors except for Dr. O'Donnell. Notwithstanding the foregoing, Mr. Virca and Dr. O'Donnell may be removed without unanimous approval of the Board of Directors upon the occurrence of the Majority Holder Condition (described below), Failure Condition (described below) or Material Breach Condition (described below);
- 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 the 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 the Company's 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, excluding the occurrence of a the Failure Condition, and Mayne Pharma has not otherwise nominated, designated, elected or appointed a majority of the directors on the Board of Directors (collectively referred to as the Material Breach Condition);

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1. Corporate overview (continued):

- The Equity Holder Parties agree to vote for the Board of Directors in its current composition (unless mutually agreed upon by Mayne Pharma and Hedgepath, LLC) until such time as (i) either Mayne Pharma or Hedgepath, LLC, alone, and not in concert as part of a "group," own a majority of the Company's outstanding shares of common stock (the Company refers to this condition as the Majority Holder Condition), (ii) one hundred and fifty days after the Performance Goal (as described below) is not satisfied (the Company refers to this condition as the Failure Condition) and (iii) upon the occurrence of a Material Breach Condition. Upon the occurrence of the Majority Holder Condition or Failure Condition, the majority holder or Mayne Pharma, respectively, may remove any current director and appoint a new director as long as the Board of Directors continues to consist of a majority of Independent Directors. Upon the occurrence of the Material Breach Condition, the requirement that the Board of Directors consist of a majority of Independent Directors will cease and Mayne Pharma will have the right to remove any current director and appoint a new director. Mayne Pharma may remove current directors and appoint new directors by written consent or by calling a meeting in accordance with the Bylaws, as amended; and
- Mayne Pharma was granted a right of first refusal to purchase any shares of the Company's 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;

In addition to the foregoing, pursuant to the Equity Holders Agreement, the Equity Holder Parties agreed that the Company would seek to (i) close on one or more registered or unregistered equity, debt or equity-linked financings in which the Company receive aggregate net proceeds of at least $5,000,000 or (ii) enter into a license, development, commercialization or similar agreement relating to the Company's product, provided that the Company receive a net upfront payment of at least $5,000,000 in connection with such agreement and that such agreement will be subject to the approval of Mayne Pharma (collectively, the Company refers to this goal as the Performance Goal) on or before May 31, 2016 (the Company refers to this date as the Performance Goal Date). Under the Equity Holders Agreement, all previously required performance goals as set forth in the original Equity Holders Agreement have been removed and replaced solely with the Performance Goal.

If the Company does not meet the Performance Goal, in addition to the remedies described above, Dr. O'Donnell may be required by Mayne Pharma to resign from his position as Executive Chairman (in connection with his removal as a director), Dr. O'Donnell will forfeit all then unvested options, warrants, restricted stock units, or other right to acquire common stock (or securities convertible into common stock) and Hedgepath, LLC may be required to forfeit certain shares of common stock it owns. Furthermore, Mayne Pharma will continue to have the right to purchase (i) by written notice to Dr. O'Donnell all company securities owned by Dr. O'Donnell individually, including vested options, vested warrants, vested restricted stock units and the like, or otherwise transferred by him, as the case may be, at the fair market value (as such term is described in the Equity Holders Agreement) as of the date of such resignation or termination and (ii) any shares required to be forfeited by Hedgepath, LLC at the price described in the Equity Holders Agreement.

The Equity Holders Agreement terminates (i) if the Company receives an adjudication of bankruptcy, the Company executes an assignment for the benefit of creditors, a receiver is appointed for the Company or the Company is voluntarily or involuntarily dissolved or (ii) if the Company, Hedgepath, LLC and Mayne Pharma expressly agree in writing. Additionally, certain limited provisions of the Amended and Restated 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.

In connection with their entry into the Equity Holders Agreement, the Equity Holder Parties agreed to waive, among other things, certain specified prior breaches by us of our obligations under the Amended and Restated Equity Holders Agreement entered into in June 2014.

Related Party Debt Forgiveness Agreement

Following the Company's emergence from bankruptcy in August 2013, certain expenses had been incurred for officer salary, travel, legal and patent expenses. These expenses, totaling $639,768, were paid by Hedgepath, LLC on behalf of the Company. This debt was forgiven pursuant to a Debt Forgiveness Agreement, dated June 24, 2014 (the "Debt Forgiveness Agreement"), which was entered into by the Company and Hedgepath, LLC as a condition of closing of the Mayne Purchase Agreement and was accounted for as a capital transaction due to the related party nature of the agreement. Pursuant to the Debt Forgiveness Agreement, Hedgepath, LLC waived, canceled and forgave payment from the Company of the aforementioned $639,768 of

HEDGEPATH PHARMACEUTICALS, INC.
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1. Corporate overview (continued):

indebtedness previously advanced by Hedgepath, LLC to the Company in exchange for 2,530,227 shares of Common Stock, 71,636 shares of Series A Preferred Stock (the "Debt Forgiveness Series A Shares") and a warrant (the "Debt Forgiveness Warrant") to purchase 10,250,569 shares of Common Stock. The Debt Forgiveness Series A Shares together with Series A Preferred Shares previously issued to Hedgepath, LLC converted into 82,156,842 shares of Common Stock on August 14, 2014 pursuant to the terms of the Equity Holders Agreement and in accordance the with the terms of the Series A Preferred Stock. The Debt Forgiveness Warrant may be exercised by Hedgepath, LLC at an exercise price of $0.0878 per share at any time, from time to time, prior to the expiration of the Debt Forgiveness Warrant on June 24, 2019.

2. Liquidity and management's plans:

The Company presently has very limited cash resources and requires significant additional financing for its research and development, commercialization and distribution efforts and its working capital and intends to finance these activities primarily through:

- proceeds from public and private equity and debt financings and, potentially, from strategic transactions;
- proceeds from the exercise of warrants issued in public and private financings;
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of its products for which the Company would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where the Company would receive funding based on out-licensing its product; and
- seeking government or private foundation grants which would be awarded to the Company to further develop its current and future anti-cancer therapies.

However, there can be no assurance that any of these plans will be implemented on commercially reasonable terms, if at all.

The Company had cash and cash equivalents of $601,445 as of December 31, 2015.

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 August 2014, the Financial Accounting Standards Board issued ASU No. 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern"

("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosure. This ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company is evaluating the impact the revised guidance will have on its financial statements.

HEDGEPATH PHARMACEUTICALS, INC.
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YEARS ENDED DECEMBER 31, 2015 AND 2014

3. Summary of Significant Accounting Policies (continued):

Management has considered all other recent accounting pronouncements issued, but not effective, and they do not believe that they will have a significant impact on the Company's financial statements.

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 is recognized when earned by the Company.

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, 2015, the Company had approximately $213,000 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 equity securities issued are determined by the Company based predominantly on the trading price of the common stock. 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 7 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, 2015 or 2014.

4. Prepaid Expenses:

At December 31, 2015, prepaid expenses of $34,414 consisted primarily of approximately $27,000 in prepaid Directors and Officers and clinical trial insurance premiums and $7,500 in OTCQB exchange fees relating to 2016. Prepaid expenses as of December 31, 2014 related primarily to prepaid Directors and Officers insurance premiums of approximately $40,000 and prepaid financing expenses of $50,000.

HEDGEPATH PHARMACEUTICALS, INC.
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5. Other Long-term Assets:

Other long-term assets at December 31, 2015 consists of a $250,000 deposit with our independent contract research organization. The deposit is fully refundable at the conclusion of our clinical trial which targets basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome. There were no long-term assets at December 31, 2014.

6. Other Liabilities:

At December 31, 2015, other liabilities of $78,524 includes approximately $73,000 of accrued legal expenses (of which $52,500 are related to the 2013 reorganization and are required to be settled in stock upon completion of at least a $5 million stock offering) and $6,000 of accrued payroll expenses. At December 31, 2014, other liabilities of $75,933 includes the $52,500 relating to the reorganization as mentioned above, $20,678 for unbilled legal and research & development expenses, and $2,755 in accrued payroll.

7. Income Taxes:

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

	December 31,	
	2015	2014
Income taxes benefit computed at statutory rate	$(1,342,859)	$(1,351,601)
State income tax benefit, net	(136,332)	(137,219)
Other	20,950	80,899
Change in valuation allowance	1,458,241	1,407,921
Total	$ —	$ —

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

	December 31,	
Deferred tax assets (liabilities)	**2015**	**2014**
In-process research and development	$ 996,154	$ 996,154
Net operating loss carry forward	1,681,549	878,706
R&D credit	60,213	15,779
Share-based compensation	841,524	256,219
Accrued expenses	17,850	17,850
	3,597,290	2,164,708
Less: valuation allowance	(3,597,290)	(2,164,708)
Total	$ —	$ —

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, 2015 and 2014, the Company recorded a 100% valuation allowance against its deferred tax assets as it has determined such amounts will not be realizable.

The Company has a federal net operating loss (“NOLs”) of approximately $4.5 million as of December 31, 2015. 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 $4.3 million as of December 31, 2015. The loss carryforwards begin to expire in 2018.

HEDGEPATH PHARMACEUTICALS, INC.
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8. 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 authorizes the issuance of up to 32,583,475 shares of the Company's common stock. In July 2014, 15,041,738 restricted stock units ("RSUs") were granted to the Company's Chief Executive Officer, Nicholas J. Virca, and shall vest upon the earlier to occur of (i) September 3, 2016 or (ii) the acceptance by the FDA of a New Drug Application ("NDA") by the Company for any Company product candidate with a cancer indication utilizing the Company's licensed SUBA-itraconazole technology, provided that Mr. Virca is actively employed by the Company on the earlier of such date. An additional 1.5 million RSUs were issued to various Board members and officers with the same vesting schedule. In August 2014, 7,000,000 RSUs were issued to the Company's Chief Financial Officer, Garrison J. Hasara. Of those RSUs, 50% shall vest upon the earlier to occur of (i) September 3, 2016 or (ii) the acceptance by the FDA of a NDA by the Company for any Company product candidate with a cancer indication utilizing the Company's licensed SUBA-itraconazole technology, provided that Mr. Hasara is actively employed by the Company on the earlier of such date. Mr. Hasara's balance of RSUs will vest September 3, 2017.

In August 2015, the Company issued 2,350,000 RSUs to various members the Board of Directors and management of the Company. The 750,000 RSUs issued to management will vest over three years. The balance of 1,600,000 will vest the earlier of September 5, 2017 and FDA approval of an NDA for any product candidate with a cancer indication utilizing the Company's licensed SUBA-itraconazole technology.

Going forward, 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 $1,721,485 and $753,585 in stock-based compensation expense related to Restricted Stock Units for the years ended December 31, 2015 and 2014, respectively. As of December 31, 2015 there was approximately $1.6 million in unamortized stock-based compensation cost related to non-vested stock awards.

Issuance of Preferred and Common Stock

Upon entering into the Amended and Restated Supply and License Agreement with Mayne Pharma, the Company issued 258,363 shares of Series A Preferred Stock to Mayne Pharma. The fair value of such issued shares of Series A Preferred Stock has been accounted for as in-process research and development totaling approximately $1.3 million and is included in research and development expense for the year ended December 31, 2014. All outstanding Preferred Stock converted to Common Stock on August 14, 2014. Each share of Preferred Stock converted into approximately 340 shares of Common Stock on August 14, 2014.

See Note 1 for discussion of Series A Preferred Stock issued for related party debt forgiveness.

See Note 1 for discussion of Common Stock issued.

Warrants

Pursuant to the Mayne Purchase Agreement (Note 1), a warrant to purchase 10,250,569 shares of the Company's common stock at $0.0878 were granted to Mayne Pharma. The warrant will expire on June 24, 2019. The fair value of warrants has been accounted for as in-process research and development totaling approximately $0.6 million and is included in research and development expense for the year ended December 31, 2014.

Pursuant to the Debt Forgiveness Agreement (Note 1) with Hedgepath, LLC, a warrant to purchase 10,250,569 shares of the Company's common stock at $0.0878 was granted to Hedgepath, LLC. The warrant will expire on June 24, 2019. The amount of debt forgiven of $450,000 was recorded as additional paid-in capital for the year ended December 31, 2014.

See Note 1 for discussion of warrants issued in conjunction with the Mayne Pharma Purchase Agreement.

HEDGEPATH PHARMACEUTICALS, INC.
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9. Related party transactions:

As part of the short-form reincorporation merger with HPPI, certain expenses had been incurred for officer salary, travel, legal and patent expense. These expenses, totaling $639,768, were paid by Hedgepath, LLC on behalf of HPPI. The balance due was exchanged for preferred stock, common stock and common stock warrants as discussed further in Note 1 (*Related Party Debt Forgiveness Agreement).*

The Company also has significant contractual agreements with Mayne Pharma as discussed in Note 1.

10. Legal Proceedings:

The Company is not currently 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.

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

, 2016

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.

Description	*Amount to be Paid*
Filing Fee - Securities and Exchange Commission	$ 2,143.75
Attorney's fees and expenses	60,000*
Accountant's fees and expenses	5,000*
Transfer agent's and registrar fees and expenses	5,000*
Printing and engraving expenses	15,000*
Miscellaneous expenses	5,000*
Total	$ 92,143.75*

* 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 amended and restated 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 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 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 amended and restated 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 amended and restated 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 amended and restated bylaws.

Our obligation to provide indemnification under our amended and restated 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 amended and restated 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 amended and restated bylaws, be interpreted as follows: an "other enterprise" shall be deemed to include such an employee benefit plan, including without 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 amended and restated 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 amended and restated 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 August 13, 2013, we issued to Hedgepath, LLC, as consideration for the contribution of certain assets as described in that certain contribution agreement, dated August 13, 2013 by and between us and Hedgepath, LLC, an aggregate of 170,000.739 shares of Series A Preferred Stock which have since been converted into 82,156,842 shares of common stock. 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 June 24, 2014 as a condition to the Mayne Purchase Agreement, we entered into a Securities 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. Such purchase price is payable as follows: (i) an advance payment of $125,000 made by Hedgepath, LLC on June 4, 2014 was deemed partial funding of the purchase price; (ii) a payment of $125,000 was made by Hedgepath, LLC on June 24, 2014; and (iii) the remaining $1,250,000 will be funded in monthly installments through December 31, 2014 pursuant to a promissory note issued by Hedgepath, LLC to us. Pursuant to the note, commencing on June 30, 2014 and ending on December 31, 2014, Hedgepath, LLC must make monthly payments to us in accordance with the terms and conditions of the note. We have the right, in our sole discretion, to request an advance payment of part or all of the principal of the note. The note bears no interest except upon an event of default in which case interest accrues at 18% per annum. In the event that Hedgepath, LLC defaults on part or all of the note, we have the right to declare by written notice that Hedgepath, LLC forfeit some or all of the 20,000,000 shares of common stock purchased as well as 17,646.98 shares of Series A Preferred Stock (or the common stock equivalent upon conversion thereof) held by Hedgepath, LLC. 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 June 24, 2014, as a condition of closing of the Mayne Purchase Agreement, we entered into a Debt Forgiveness Agreement with Hedgepath, LLC pursuant to which Hedgepath, LLC waived, canceled and forgave payment from us of an aggregate of $639,767 of indebtedness previously advanced by Hedgepath, LLC to us in exchange for 2,530,227 shares of common stock, 71,635.981 shares of Series A Preferred Stock and a warrant to purchase 10,250,569 shares of common stock. The shares of Series A Preferred Stock converted into 82,156,842 shares of common stock on August 14, 2014. The warrant may be exercised by Hedgepath, LLC at an exercise price of $0.0878 per share at any time, from time to time, by Hedgepath, LLC prior to expiration on June 24, 2019. The issuances contemplated by the Debt Forgiveness Agreement are exempt from registration pursuant to Section 4(a)(2) and/or 3(a)(9) of the Securities Act.

On June 24, 2014, in fulfillment of one of the conditions under the Supply and License Agreement, we entered into the Mayne Purchase Agreement. Pursuant to the terms of the Mayne Purchase Agreement, we issued to Mayne Pharma (i) 258,363.280 shares of our Series A Preferred Stock, and (ii) a warrant to purchase 10,250,569 shares of our common stock. The shares of Series A Preferred Stock converted into 87,843,897 shares of common stock on August 14, 2014. The warrant has an exercise price of $0.0878 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on June 24, 2019. As a result of the Mayne Purchase Agreement, Mayne Pharma owns approximately 40% of our equity securities on a fully diluted basis. 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 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 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.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of August 9, 2013, between Commonwealth Biotechnologies, Inc., and the Company (1)
3.1	Certificate of Incorporation of the Company (1)
3.2	Amended and Restated Certificate of Designation for Series A Preferred Stock (5)
3.3	Certificate of Amendment to the Company's Certificate of Incorporation (8)
3.4	Second Amended and Restated Bylaws of the Company (2)
3.5	Certificate of Amendment to the Company's Certificate of Incorporation (11)
4.1	Warrant, dated June 24, 2014 issued to Mayne Pharma Ventures Pty Ltd. (3)
4.2	Warrant, dated June 24, 2014 issued to Hedgepath, LLC (3)
4.3	Warrant, dated May 15, 2015 issued to Mayne Pharma Ventures Pty Ltd. (9)
4.4	Form of Warrant issued in the 2016 Private Placement (12)
5.1	Opinion of Ellenoff Grossman & Schole LLP covering 30,600,00 shares of common stock (8)
5.2	Opinion of Ellenoff Grossman & Schole LLP(**)
10.1	Contribution Agreement, dated August 13, 2013, by and between Hedgepath, LLC, and the Company (1)
10.2	Securities Purchase Agreement, dated June 24, 2014, by and between the Company and Mayne Pharma Ventures Pty Ltd. (3)
10.3	Stock Purchase Agreement, dated June 24, 2014, by and between HedgePath Pharmaceuticals, Inc. and Hedgepath, LLC (3)
10.4	Promissory Note, dated June 24, 2014, issued to the Company by Hedgepath, LLC (3)
10.5	Equity Holders Agreement, dated June 24, 2014, by and between the Company, Mayne Pharma Ventures Pty Ltd., Hedgepath, LLC, Nicholas J. Virca and Frank O'Donnell, Jr. M.D. (3)+
10.6	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. (9)+
10.7	Debt Forgiveness Agreement, dated June 24, 2014, by and between the Company and Hedgepath, LLC (3)
10.8	Employment Agreement, dated June 24, 2014, between the Company and Nicholas J. Virca (3)+
10.9	First Amendment to Employment Agreement, dated May 15, 2015, between the Company and Nicholas J. Virca (9)
10.10	Executive Chairman Agreement, dated June 24, 2014, between the Company and Frank O'Donnell, Jr. M.D. (3)
10.11	First Amendment to Executive Chairman Agreement, dated May 15, 2015, between the Company and Frank O'Donnell, Jr. M.D. (9)
10.12	Supply and License Agreement, dated September 3, 2013, by and among the Company and Mayne Pharma. (5)+
10.13	Amendment No. 1 to Supply and License Agreement, dated December 17, 2013, between the Company and Mayne Pharma. (6)
10.14	Amendment No. 2 to Supply and License Agreement, dated March 4, 2014, between the Company and Mayne Pharma. (7)
10.15	Amended and Restated Supply and License Agreement, dated June 24, 2014, by and among the Company and Mayne Pharma. (3)+
10.16	Second Amended and Restated Supply and License Agreement, dated May 15, 2015, by and among the Company and Mayne Pharma. (9)+

10.17	Employment Agreement, dated September 4, 2014, between the Company and Garrison J. Hasara (4)
10.18	Securities Purchase Agreement, dated May 15, 2015, by and between the Company and Mayne Pharma Ventures Pty Ltd. (9)
10.19	Master Clinical Services Agreement, dated June 15, 2015, by and between the Company and SciQuus, Inc. (9)+
10.20	Sublicense Agreement, entered into effective as of September 2, 2015, by and between Mayne Pharma International Pty Ltd and the Company. (10)+
10.21	Form of Securities Purchase Agreement issued in the 2016 Private Placement (12)
23.1	Consent of Cherry Bekaert LLP(*)
23.2	Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.1)
24.1	Power of Attorney(**)
101.ins	XBRL Instance Document(**)
101.xsd	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	XBRL Taxonomy Presentation Linkbase Document(**)

* Filed herewith.
** Previously filed.
\+ 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.
(1) Previously filed with Form 8-K, dated August 16, 2013.
(2) Previously filed with Form 8-K, dated May 21, 2015.
(3) Previously filed with Form 8-K, dated June 30, 2014.
(4) Previously filed with Form 8-K, dated September 9, 2014.
(5) Previously filed with Form 8-K, dated September 10, 2013.
(6) Previously filed with Form 8K, December 23, 2013.
(7) Previously filed with Form 8-K, March 11, 2014.
(8) Previously filed with Form S-1/A on July 22, 2015.
(9) Previously filed with Form 10-Q on August 14, 2015.
(10) Previously filed with Form 8-K, dated September 9, 2015.
(11) Previously filed with Form 8-K, dated May 26, 2016.
(12) Previously filed with Form 8-K, dated April 15, 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.

(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.

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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 July 18, 2016.

HEDGEPATH PHARMACEUTICALS, INC.

/s/ Nicholas J. Virca
Name: Nicholas J. Virca
Title: President and Chief Executive Officer
(Principal Executive Officer)

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

Signature	Title	Date
/s/ Nicholas J. Virca Nicholas J. Virca	President and Chief Executive Officer (Principal Executive Officer)	July 18, 2016
/s/ Garrison J. Hasara Garrison J. Hasara	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	July 18, 2016
/s/ *. Frank E. O'Donnell, Jr., M.D.	Executive Chairman and Director	July 18, 2016
/s/ * Samuel P. Sears, Jr.	Director	July 18, 2016
/s/ * W. Mark Watson	Director	July 18, 2016
/s/ * Stefan J. Cross	Director	July 18, 2016
/s/ * Dr. R. Dana Ono	Director	July 18, 2016

* By: /s/ Nicholas J. Virca
Nicholas J. Virca, Attorney-in-Fact

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference of our firm under the caption "Experts" in this Registration Statement on Form S-1/A and related prospectuses of Hedgepath Pharmaceuticals, Inc. dated July 18, 2016 and to the inclusion therein of our report, dated February 1, 2016, with respect to the financial statements of HedgePath Pharmaceuticals, Inc. included in its Form 10-K filed February 1, 2016 with the Securities and Exchange Commission.

/s/ CHERRY BEKAERT LLP

Tampa, Florida
July 18, 2016