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

FORM S-8
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

HedgePath Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

30-0793665
(I.R.S. Employer
Identification No.)

324 S. Hyde Park Avenue Ste. 350
Tampa, FL 33606
(Address of Principal Executive Offices) (Zip Code)

2014 Equity Incentive Plan
(Full Title of the Plan)

Mr. Nicholas J. Virca
President and Chief Executive Officer
324 S. Hyde Park Avenue, Ste. 350
Tampa, Florida 33606
(Name and Address of Agent for Service)

(813) 864-2559
(Telephone Number, including area code, of agent for service)

Copies to:

Barry I. Grossman, Esq.
Lawrence Rosenbloom, Esq.
Ellenoff Grossman & Schole LLP
1345 Avenue of Americas, 11th Floor
New York, New York 10105
(212) 370-1300
Fax: (212) 370-7889

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 definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer☐

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

Accelerated filer☐

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 unit (2)	Proposed maximum aggregate offering price	Amount of registration fee
Shares of common stock issuable pursuant to the 2014 Equity Incentive Plan	32,583,475	\$0.45	\$14,662,563.75	\$1,699.39

- (1) This Registration Statement shall also cover any additional shares of the Registrant’s common stock that become issuable in respect of the securities identified in the above table by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the Registrant’s receipt of consideration which results in an increase in the number of the outstanding shares of the Registrant’s common stock.
- (2) Calculated solely for the purposes of this offering under Rule 457(c), the average of the high and low prices reported in the consolidated reporting system within 5 business days prior to the date of filing the Registration Statement.

Explanatory Note

This Registration Statement on Form S-8 of HedgePath Pharmaceuticals, Inc. (“we,” “us,” “our” or the “Company”) has been prepared in accordance with the requirements of Form S-8 under the Securities Act of 1933, as amended (the “Securities Act”) to register 32,583,475 shares of our common stock, par value \$0.0001 per share, to be issued under our 2014 Equity Incentive Plan (the “Plan”) to our, or our affiliates (as such term is defined in the Plan), employees, directors, consultants and advisors.

This Registration Statement also includes reoffer prospectus prepared in accordance with the requirements of Part I of Form S-3 (in accordance with the General Instruction C to Form S-8). The reoffer prospectus covers reoffers and resales of shares of our common stock that have been or will be acquired by certain of our officers and directors (collectively, the “selling stockholders”) which may be deemed to be “control securities” and/or “restricted securities” (as such terms are defined in General Instruction C to Form S-8) of the Company. The reoffer prospectus relates to the resale of up to 25,541,738 shares of common stock that have been or may be issued under the Plan to the various selling stockholders. The amount of securities to be offered or resold by means of the reoffer prospectus by the designated selling stockholders may not exceed, during any three month period, the amount specified in Rule 144(e).

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Item 1. Plan Information.*

Item 2. Registrant Information and Employee Plan Annual Information.*

* Pursuant to the Note to Part I on Form S-8, the documents containing the information specified in Part I of this Registration Statement will be sent or given to plan participants as specified by Rule 428(b)(1) of the Securities Act of 1934, as amended, or the Securities Act. Such documents are not required to be filed, and are not filed, with the United States Securities and Exchange Commission, or the SEC, either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 of the Securities Act. These documents and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Form S-8, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

Reoffer Prospectus



**25,541,738 Shares
Common Stock**

This reoffer prospectus is being used in connection with the offering from time to time by certain selling stockholders of HedgePath Pharmaceuticals, Inc., which we refer to herein as “we,” “us,” “our” or the “Company,” or their successors in interest of shares of our common stock, par value \$0.0001 per share, which we refer to as the common stock, issued or to be issued, or which may be acquired upon the exercise of stock options issued or to be issued, pursuant to our 2014 Equity Incentive Plan, which we refer to herein as the Plan. The amount of securities to be offered or resold by means of the reoffer prospectus by the designated selling stockholders may not exceed, during any three month period, the amount specified in Rule 144(e).

The common stock may be sold from time to time by the selling stockholders or by their pledgees, donees, transferees or other successors in interest. Such sales may be made in the over-the-counter market or otherwise at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. The common stock may be sold by one or more of the following: (a) block trades in which the broker or dealer so engaged will attempt to sell the shares as agent but may position and resell portions of the block as principal to facilitate the transaction; (b) purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus; (c) an exchange distribution in accordance with the rules of such exchange; and (d) ordinary brokerage transactions and transactions in which the broker solicits purchases. In effecting sales, brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers will receive commissions or discounts from selling stockholders in amounts to be negotiated immediately prior to the sale. Such brokers or dealers and any other participating brokers or dealers may be deemed to be “underwriters” within the meaning of the Securities Act, in connection with such sales. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus. We will not receive any of the proceeds from the sale of these shares, although we have paid the expenses of preparing this prospectus and the related Registration Statement.

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 October 20, 2016, closing price of our common stock was \$0.50.

Our principal executive offices are located at 324 South Hyde Park Avenue, Suite 350, Tampa, Florida 33606 and our telephone number is (813) 864-2559.

Investing in our common stock involves a high degree of risk. See the section entitled “[Risk Factors](#)” beginning on page 8 and in the documents incorporated by reference herein before you decide to buy 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 October 24, 2016

TABLE OF CONTENTS

	Page No.
Cautionary Note on Forward Looking Statements	ii
Prospectus Summary	1
Our Company	
Risk Factors	8
Use of Proceeds	33
Selling Stockholders	34
Plan of Distribution	35
Legal Matters	37
Experts	37
Incorporation of Certain Documents By Reference	37
Where You Can Find More Information	37
Disclosure of Commission Position on Indemnification for Securities Law Violations	38

You should rely only upon the information contained in this prospectus and the Registration Statement of which this reoffer prospectus is a part. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume the information appearing in this reoffer prospectus is accurate only as of the date on the front cover of this reoffer prospectus. Our business, financial condition, results of operations and prospects may have changed since that date. This reoffer prospectus is based on information provided by us and other sources that we believe are reliable. We have summarized certain documents and other information in a manner we believe to be accurate, but we refer you to the actual documents for a more complete understanding of what we discuss in this reoffer prospectus. In making an investment decision, you must rely on your own examination of our business and the terms of the offering, including the merits and risks involved.

We obtained statistical data, market data and other industry data and forecasts used throughout, or incorporated by reference in, this reoffer prospectus from market research, publicly available information and industry publications. Industry publications generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy and completeness of the information. Similarly, while we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information. We have not sought the consent of the sources to refer to their reports appearing or incorporated by reference in this reoffer prospectus.

This reoffer prospectus contains, or incorporates by reference, trademarks, tradenames, service marks and service names of HedgePath Pharmaceuticals, Inc. and other companies.

CAUTIONARY NOTE ON FORWARD LOOKING STATEMENTS

This reoffer prospectus contains a number of “forward-looking statements.” Specifically, all statements other than statements of historical facts included in this reoffer 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 reoffer 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 Securities Exchange Act of 1934, as amended, or 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 reoffer prospectus and the documents incorporated by reference herein might not occur.

PROSPECTUS SUMMARY

The following summary highlights selected information contained or incorporated by reference in this reoffer prospectus. This summary does not contain all of the information you should consider before investing in the securities. Before making an investment decision, you should read the entire reoffer prospectus and any supplement hereto carefully, including the risk factors section as well as the financial statements and the notes to the financial statements incorporated herein by reference.

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). We are presently conducting an open label, Phase II(b) clinical trial of proposed therapy for Gorlin Syndrome, and in August 2016, we announced positive interim data from this trial.

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;

Table of Contents

- 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 open label 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 August 2016, we announced positive interim data from our Phase II(b) trial. The data reported was derived from our interim analysis of results in 13 subjects who completed 16 weeks of SUBA-Itraconazole dosing. Based on these encouraging interim results, we intend to continue collecting data on subjects being enrolled and treated at 5 centers in the U.S. while we interact with FDA regarding ongoing results demonstrating efficacy and tolerability for SUBA-Itraconazole the treatment for 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 an open label Phase II(b) trial based upon the track record of long-term, safe and effective use of itraconazole for treatment of human fungal infections, and we have already report positive interim results from this trial;
- 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

Table of Contents

Cancer	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market
Lung⁽²⁾	Patients with advanced non-squamous cell, non-small cell lung cancer (NSCLC) who will be placed on 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) <i>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</i>				
(2) <i>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</i>				
(3) <i>J. Urology, 2003; Oncology, 2004; J. Clinical Oncology, 2011; Medscape, 2012; Landes Bioscience, 2012</i>				
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:				
<ul style="list-style-type: none"> • <i>Rapidly Advance the Clinical Development of Our Therapies.</i> 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 an open label 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 announced positive interim data from this trial in August 2016. 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. • <i>Seek FDA Programs to Expedite Drug Approvals.</i> 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. • <i>Commercialize and Market with Exclusivity.</i> 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 reoffer 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 reoffer prospectus, including the financial statements and the related notes included elsewhere in this reoffer prospectus, before deciding whether to invest in our common stock. If any of the risks discussed in this reoffer 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 incorporated by reference as part of this reoffer 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.

[Table of Contents](#)

	The Offering
Outstanding Common Stock	As of October 21, 2016, there were 300,438,270 shares of common stock issued and outstanding.
Common Stock Offered	Up to 25,541,738 shares of common stock for sale by the selling stockholders for their own account, which shares were received pursuant to a grant of restricted stock units or options to purchase shares under the Plan.
Selling Stockholders	The selling stockholders are set forth in the Section entitled “Selling Stockholders” of this reoffer prospectus on page 34. The amount of securities to be offered or resold by means of the reoffer prospectus by the designated selling stockholders may not exceed, during any three month period, the amount specified in Rule 144(e).
Proceeds	We will not receive any proceeds from the sale of our common stock by the selling stockholders. We would, however, receive proceeds upon the exercise of the stock options by those who receive options under the Plan and exercise such options for cash. Any cash proceeds will be used by us for general corporate purposes.
Risk Factors	The securities offered hereby involve a high degree of risk. See “Risk Factors.”
OTCQB Symbol	HPPI

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors, together with all of the other information included in this reoffer prospectus. Our business, financial condition or results of operations could be affected materially and adversely by any of the risks discussed below.

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. 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 and maintaining 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.

Table of Contents

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 (which we refer to the Equity Holders Agreement), Mayne Pharma and its affiliates have been granted a right of first refusal to purchase a pro rata share of any new securities issued by us, 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

Table of Contents

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.

Table of Contents

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 reoffer 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.

Not included in the foregoing estimate of the timing for the availability of existing cash reserves is the potential that we might be required to use cash to pay payroll taxes upon the vesting of certain restricted stock units in 2017 in the event we are unable to secure funding to cover the payroll tax liability or otherwise employ strategies aimed at satisfying such liability. Such payment could significantly reduce the our cash resources and possibly require us to raise new funding earlier than expected in order to fund planned operations as projected.

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

Table of Contents

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 incorporated by reference as part of this reoffer prospectus, contains a

Table of Contents

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.

Table of Contents

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 or if 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;

Table of Contents

- 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.

Table of Contents

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 primarily pursue a particular product candidate, leaving us unable to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of clinical and commercial development.

Because we have limited financial and managerial resources, we will focus for the foreseeable future primarily on the clinical development of SUBA-Itraconazole for the treatment of 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

Table of Contents

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.

Table of Contents

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

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

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

Risks Related to the Commercialization of Our Product Candidate

Even if 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.

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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-

Table of Contents

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;

Table of Contents

- 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.

Table of Contents

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, but not limited to, 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.

Table of Contents

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 83% 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.

Table of Contents

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 15c-2 through 15c-9 promulgated under the Exchange Act. For example, Rule 15c-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 15c-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.

Table of Contents

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 reoffer 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. We may be unable to effectively establish and maintain 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 or provide research coverage of us. This stigma could impair our fundraising opportunities and our reputation generally.

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

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

Table of Contents

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 reoffer 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.

USE OF PROCEEDS

The shares which may be sold under this reoffer prospectus will be sold for the respective accounts of each of the selling stockholders listed herein (who are our executive officers and directors). Accordingly, we will not realize any proceeds from the sale of the shares of our common stock. We will receive proceeds from the exercise of the options; however, no assurance can be given as to when or if any or all of the options will be exercised. If any options are exercised, the proceeds derived therefrom will be used for working capital and general corporate purposes. All expenses of the registration of the shares will be paid by us. See “Selling Stockholders” and “Plan of Distribution.”

SELLING STOCKHOLDERS

This reoffer prospectus relates to the shares of our common stock that are being registered for reoffers and resale by selling stockholders who have acquired or may acquire shares pursuant to the Plan. Offers and sales by selling stockholders who are our employees, consultants and “affiliates” (as such term is defined in Rule 405 under the Securities Act) are also covered by this reoffer prospectus. The amount of securities to be offered or resold by means of the reoffer prospectus by the designated selling stockholders may not exceed, during any three month period, the amount specified in Rule 144(e).

The selling stockholders are our current directors, officers and affiliates who have acquired or may acquire in the future shares of our common stock under the Plan. The selling stockholders may, from time to time, resell all, a portion or none of the shares of our common stock covered by this reoffer prospectus. The following table sets forth information as of October 15, 2016 with respect to ownership of our common stock by each selling stockholder whose identity is known as of the date of this reoffer prospectus. There is no assurance that any of the selling stockholders will sell any or all of the shares offered by them under this Registration Statement. The address for each selling stockholders listed below is c/o HedgePath Pharmaceuticals, Inc., 324 South Hyde Park Avenue, Suite 350, Tampa, Florida 33606.

Any changed information will be set forth in an amendment to the Registration Statement or supplement to this reoffer prospectus, to the extent required by law.

<u>Name</u>	<u>Position, Office, or Other Material Relationship</u>	<u>Number of Shares Owned (1)</u>	<u>Number of Shares to be Offered for the Account of the Selling Stockholder (2)(3)</u>	<u>Number of Shares to be Owned After Offering</u>	<u>% Owned After Offering</u>
Nicholas J. Virca	(4)	—	15,041,738 ⁽⁵⁾	—	—
Garrison J. Hasara, CPA	(6)	—	7,000,000 ⁽⁷⁾	—	—
Samuel P. Sears	(8)	1,106,096	900,000 ⁽⁹⁾	1,106,096	*
Stefan J. Cross	(10)	—	600,000 ⁽¹¹⁾	—	—
Dr. R. Dana Ono	(12)	—	900,000 ⁽¹³⁾	—	—
W. Mark Watson, CPA	(14)	510,000	1,100,000 ⁽¹⁵⁾	510,000	*

* Less than 1%

(1) Represents common stock owned.

(2) Represents vested and unvested options.

(3) These shares constitute “control securities” as such term is defined in General Instruction C to Form S-8.

(4) Nicholas J. Virca is our President and Chief Executive Officer.

(5) Includes 15,041,738 unvested restricted stock units. All restricted stock units have been granted under the Plan.

(6) Garrison J. Hasara is our Treasurer and Chief Financial Officer.

(7) Includes 7,000,000 unvested restricted stock units. All restricted stock units have been granted under the Plan.

(8) Samuel P. Sears is a member of our Board of Directors.

(9) Includes options to purchase 150,000 shares of our common stock, none of which are currently exercisable, and 750,000 unvested restricted stock units. All options and restricted stock units have been granted under the Plan.

(10) Stefan J. Cross is a member of our Board of Directors.

(11) Includes 600,000 unvested restricted stock units. All restricted stock units have been granted under the Plan.

(12) Dr. R. Dana Ono is a member of our Board of Directors.

(13) Includes options to purchase 150,000 shares of our common stock, none of which are currently exercisable, and 750,000 unvested restricted stock units. All options and restricted stock units have been granted under the Plan.

(14) W. Mark Watson is a member of our Board of Directors.

(15) Includes options to purchase 200,000 shares of our common stock, none of which are currently exercisable, and 900,000 unvested restricted stock units. All options and restricted stock units have been granted under the Plan.

PLAN OF DISTRIBUTION

In this section of the reoffer prospectus, the term “selling stockholder” means and includes:

- the persons identified in the table above as the selling stockholders;
- those persons whose identities are not known as of the date hereof but may in the future be eligible to receive options under the Plan; and
- any of the purchasers, assignees, donees, pledgees, distributees, transferees or other successors in interest of those persons referenced above who may: (a) receive any of the shares of our common stock offered hereby after the date of this reoffer prospectus and (b) offer or sell those shares hereunder.

The shares of our common stock offered by this reoffer prospectus may be sold from time to time directly by the selling stockholders. Alternatively, the selling stockholders may from time to time offer such shares through underwriters, brokers, dealers, agents or other intermediaries. The selling stockholders as of the date of this reoffer prospectus have advised us that there were no underwriting or distribution arrangements entered into with respect to the common stock offered hereby. The distribution of the common stock by the selling stockholders may be effected: in one or more transactions that may take place on the OTCQB or any other stock exchange (including one or more block transaction) through customary brokerage channels, either through brokers acting as agents for the selling stockholders, or through market makers, dealers or underwriters acting as principals who may resell these shares on the OTCQB or any other stock exchange; in privately-negotiated sales; by a combination of such methods; or by other means. These transactions may be effected at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at other negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling stockholders in connection with sales of our common stock.

The selling stockholders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares of our common stock in the course of hedging the positions they assume with the selling stockholders. The selling stockholders also may sell shares short and redeliver the shares to close out such short positions. The selling stockholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of shares of our common stock. The broker-dealer may then resell or otherwise transfer such shares of common stock pursuant to this reoffer prospectus.

The selling stockholders also may lend or pledge shares of our common stock to a broker-dealer. The broker-dealer may sell the shares of common stock so lent, or upon a default the broker-dealer may sell the pledged shares of common stock pursuant to this reoffer prospectus. Any securities covered by this reoffer prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this reoffer prospectus.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares of common stock the selling stockholders.

Although the shares of common stock covered by this reoffer prospectus are not currently being underwritten, the selling stockholders or their underwriters, brokers, dealers or other agents or other intermediaries, if any, that may participate with the selling security holders in any offering or distribution of common stock may be deemed “underwriters” within the meaning of the Securities Act and any profits realized or commissions received by them may be deemed underwriting compensation there under.

Under applicable rules and regulations under the Exchange Act, any person engaged in a distribution of shares of the common stock offered hereby may not simultaneously engage in market making activities with respect to the common stock for a period of up to five days preceding such distribution. The selling stockholders will be subject to the applicable provisions of the Exchange Act and the rules and regulations promulgated there under, including without limitation Regulation M, which provisions may limit the timing of purchases and sales by the selling stockholders.

[Table of Contents](#)

In order to comply with certain state securities or blue sky laws and regulations, if applicable, the common stock offered hereby will be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the common stock may not be sold unless they are registered or qualified for sale in such state, or unless an exemption from registration or qualification is available and is obtained.

We will bear all costs, expenses and fees in connection with the registration of the common stock offered hereby. However, the selling stockholders will bear any brokerage or underwriting commissions and similar selling expenses, if any, attributable to the sale of the shares of common stock offered pursuant to this reoffer prospectus. We have agreed to indemnify certain of the selling security holders against certain liabilities, including liabilities under the Securities Act, or to contribute to payments to which any of those security holders may be required to make in respect thereof.

There can be no assurance that the selling stockholders will sell any or all of the securities offered by them hereby.

LEGAL MATTERS

The validity of the securities being offered herein has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The financial statements of our company incorporated by reference in this reoffer 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.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The following documents are incorporated by reference into this reoffer prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2015 as filed with the SEC on February 1, 2016;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016 and June 30, 2016 as filed with the SEC on May 13, 2016 and August 12, 2016, respectively;
- our Current Reports on Form 8-K as filed with the SEC on April 15, 2016, May 3, 2016, May 26, 2016 and June 1, 2016; and
- the description of our common stock contained in our Form 8-A filed with the SEC on October 7, 1997, and as it may be further amended from time to time, under the caption “Description of Registrant’s Securities to be Registered.”

All reports and definitive proxy or information statements filed pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the filing of this Registration Statement and prior to the filing of a post-effective amendment which indicates that all securities offered hereby have been sold or which de-registers all securities then remaining unsold shall be deemed to be incorporated by reference into this Registration Statement and to be a part hereof from the date of filing such documents, except as to specific sections of such statements as set forth therein. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained in any subsequently filed document which also is deemed to be incorporated by reference herein modifies or supersedes such statement.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a Registration Statement with the Securities and Exchange Commission under the Securities Act with respect to the shares of our common stock offered by this reoffer prospectus. This reoffer prospectus is part of that Registration Statement and does not contain all the information included in the Registration Statement. For further information with respect to our common stock and us, you should refer to the Registration Statement, its exhibits and the materials incorporated by reference therein. Portions of the exhibits have been omitted as permitted by the rules and regulations of the Securities and Exchange Commission. Statements made in this reoffer prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts or other documents filed as exhibits to the Registration Statement, and these statements are hereby qualified in their entirety by reference to the contract or document. The Registration Statement may be inspected and copied at the public reference facilities maintained by the Securities and Exchange Commission at Room 1024, Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549 and the Regional Offices at the Commission located in the Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and at 233 Broadway, New York, New York 10279. Copies of those filings can be obtained from the Commission’s Public Reference Section, Judiciary Plaza, 100 F Fifth Street, N.E., Washington, D.C. 20549 at prescribed rates and

Table of Contents

may also be obtained from the web site that the Securities and Exchange Commission maintains at <http://www.sec.gov>. You may also call the Commission at 1-800-SEC-0330 for more information. We file annual, quarterly and current reports and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information on file at the Commission's public reference room in Washington, D.C. You can request copies of those documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

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

Table of Contents

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,

Table of Contents

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.

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 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.



**32,583,475 Shares
Common Stock**

PROSPECTUS

October 24, 2016

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 3. Incorporation of Documents by Reference.

The Company hereby incorporates by reference into this Registration Statement the following documents previously filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2015 as filed with the SEC on February 1, 2016;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016 and June 30, 2016 as filed with the SEC on May 13, 2016 and August 12, 2016, respectively;
- our Current Reports on Form 8-K as filed with the SEC on April 15, 2016, May 3, 2016, May 26, 2016 and June 1, 2016; and
- the description of our common stock contained in our Form 8-A filed with the SEC on October 7, 1997, and as it may be further amended from time to time, under the caption “Description of Registrant’s Securities to be Registered.”

All reports and definitive proxy or information statements filed pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the filing of this Registration Statement and prior to the filing of a post-effective amendment which indicates that all securities offered hereby have been sold or which de-registers all securities then remaining unsold shall be deemed to be incorporated by reference into this Registration Statement and to be a part hereof from the date of filing such documents, except as to specific sections of such statements as set forth therein. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained in any subsequently filed document which also is deemed to be incorporated by reference herein modifies or supersedes such statement.

Item 4. Description of Securities.

Not applicable.

Item 5. Interests of Named Experts and Counsel.

The validity of the shares of common stock offered hereby will be passed upon by Ellenoff Grossman & Schole LLP, counsel to the Registrant.

Item 6. Indemnification of Officers and Directors.

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 7. Exemption from Registration Claimed.

All shares of common stock registered hereunder for reoffer or resale have been or will be issued to our employees and consultants pursuant to the Plan and a restrictive legend is placed on the certificates for the shares of common stock purchased and transfer stops are placed against such certificates. Such shares may only be reoffered and sold pursuant to registration under the Securities Act or pursuant to an applicable exemption under the Securities Act. As a result, such offers and sales are exempt from the registration requirements of the Securities Act pursuant to the provisions of Section 4(a)(2) of the Securities Act.

Item 8. Exhibits.

Number	Description
5.1	Opinion of Ellenoff Grossman & Schole LLP (*)
23.1	Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.1) (*)
23.2	Consent of Cherry Bekaert LLP (*)
24.1	Power of Attorney (included in the signature page to this Registration Statement)
99.1	HedgePath Pharmaceuticals, Inc. 2014 Equity Incentive Plan (*)

* Filed herewith

Item 9. Undertakings.

(a) The 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;

(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 SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement;

(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;

Provided, however, that paragraphs (a)(1)(a) and (a)(1)(b) do not apply if the Registration Statement is on Form S-8 and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the SEC by the Registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the Registration Statement.

Table of Contents

(2) That, for the purpose of determining any liability under the Securities Act, 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.

(b) The Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the Registration Statement 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.

(c) Insofar as indemnification for liabilities arising under the Securities Act 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 SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than 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 and will be governed by the final adjudication of such issue.

[Table of Contents](#)

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Tampa, State of Florida, on October 24, 2016.

HEDGEPATH PHARMACEUTICALS, INC.

/s/ Nicholas J. Virca

Name: Nicholas J. Virca

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below does hereby constitute and appoint Nicholas J. Virca and Frank E. O'Donnell, Jr., M.D., and each of them, with full power of substitution, such person's true and lawful attorneys-in-fact and agents for such person, with full power and authority to do any and all acts and things and to execute any and all instruments which said attorneys and agents, and any one of them, determine may be necessary or advisable or required to enable said corporation to comply with the Securities Act of 1933, as amended, and any rules or regulations or requirements of the Securities and Exchange Commission in connection with this Registration Statement. Without limiting the generality of the foregoing power and authority, the powers granted include the power and authority to sign the names of the undersigned officers and directors in the capacities indicated below to this Registration Statement, to any and all amendments, both pre-effective and post-effective, and supplements to this Registration Statement, and to any and all instruments or documents filed as part of or in conjunction with this Registration Statement or amendments or supplements thereof, and each of the undersigned hereby ratifies and confirms that all said attorneys and agents, or any one of them, shall do or cause to be done by virtue hereof. This Power of Attorney may be signed in several counterparts.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Nicholas J. Virca</u> Nicholas J. Virca	President and Chief Executive Officer (Principal Executive Officer)	October 24, 2016
<u>/s/ Garrison J. Hasara</u> Garrison J. Hasara	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	October 24, 2016
<u>/s/ Frank E. O'Donnell, Jr., M.D.</u> Frank E. O'Donnell, Jr., M.D.	Executive Chairman and Director	October 24, 2016
<u>/s/ Samuel P. Sears, Jr.</u> Samuel P. Sears, Jr.	Director	October 24, 2016
<u>/s/ W. Mark Watson</u> W. Mark Watson	Director	October 24, 2016
<u>/s/ Stefan J. Cross</u> Stefan J. Cross	Director	October 24, 2016
<u>/s/ Dr. R. Dana Ono</u> Dr. R. Dana Ono	Director	October 24, 2016

ELLENOFF GROSSMAN & SCHOLE LLP
ATTORNEYS AT LAW
1345 Avenue of Americas, 11th FLOOR
NEW YORK, NEW YORK 10105
TELEPHONE: (212) 370-1300 FACSIMILE: (212) 370-7889
www.egsllp.com

October 24, 2016

HedgePath Pharmaceuticals, Inc.
324 S. Hyde Park Avenue Ste. 350
Tampa, Florida 33606

Re: Registration Statement on S-8

Ladies and Gentlemen:

We have acted as counsel to HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company"), in connection with the preparation of the Company's Registration Statement on Form S-8 (the "Registration Statement") being filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended. The Registration Statement relates to the registration of (i) 33,583,475 shares (the "Plan Shares") of common stock, par value \$0.0001 per share (the "Common Stock"), issuable pursuant to the Company's 2014 Equity Incentive Plan (the "Plan") and (ii) the resale of 25,541,738 shares of Common Stock issued or issuable upon vesting or exercise of restricted stock units or options under the Plan (collectively, the "Resale Shares"), such Resale Shares or related awards under the Plan being held by the executive officers and directors of the Company.

In arriving at the opinion expressed below, we have examined and relied on the following documents:

- (1) the Certificate of Incorporation and Second Amended and Restated Bylaws of the Company, each as amended as of the date hereof;
- (2) the Plan; and
- (3) records of meetings and consents of the Board of Directors of the Company provided to us by the Company.

In addition, we have examined and relied on the originals or copies certified or otherwise identified to our satisfaction of all such corporate records of the Company and such other instruments and other certificates of public officials, officers and representatives of the Company and such other persons, and we have made such investigations of law, as we have deemed appropriate as a basis for the opinion expressed below. In such examination, we have assumed, without independent verification, the genuineness of all signatures (whether original or photostatic), the accuracy and completeness of each document submitted to us, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as facsimile, electronic, certified, conformed or photostatic copies thereof. We have further assumed the legal capacity of natural persons, that persons identified to us as officers of the Company are actually serving in such capacity, that the representations of officers and employees of the Company are correct as to questions of fact and that each party to the

documents we have examined or relied on (other than the Company) has the power, corporate or other, to enter into and perform all obligations thereunder and also have assumed the due authorization by all requisite action, corporate or other, of the execution and delivery by such parties of such documents, and the validity and binding effect thereon on such parties. We have also assumed that the Company will not in the future issue or otherwise make unavailable so many shares of its Common Stock that there are insufficient authorized and unissued shares of Common Stock for issuance of the shares issuable upon exercise of the options being registered in the Registration Statement. We have not independently verified any of these assumptions.

The opinions expressed in this opinion letter are limited to the General Corporation Law of the State of Delaware. We are not opining on, and we assume no responsibility for, the applicability or effect on any of the matters covered herein of: (a) any other laws; (b) the laws of any other jurisdiction; or (c) the laws of any country, municipality or other political subdivision or local government agency or authority. The opinions set forth below are rendered as of the date of this opinion letter. We assume no obligation to update or supplement such opinions to reflect any change of law or fact that may occur.

Based upon and subject to the foregoing, it is our opinion that the Plan Shares and Resale Shares have been duly authorized and, upon issuance and payment therefore in accordance with the terms of the Plan (and the awards, agreements or certificates issued thereunder) and any awards or agreements relating to the Resale Shares, respectively, will be validly issued, fully paid and nonassessable.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement. In giving such consent, we do not thereby admit that we are experts with respect to any part of the Registration Statement within the meaning of the term "expert" as used in Section 11 of the Securities Act or the rules and regulations promulgated thereunder by the Securities and Exchange Commission, nor do we admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Securities and Exchange Commission promulgated thereunder.

Very truly yours,

/s/ Ellenoff Grossman & Schole LLP

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-8 and to the incorporation by reference therein of our report, dated February 1, 2016, with respect to the financial statements of Hedgepath Pharmaceuticals, Inc. (the “Company”) included in the Annual Report on Form 10-K of the Company for the year ended December 31, 2015 as on filed February 1, 2016 with the Securities and Exchange Commission.

/s/ CHERRY BEKAERT LLP

Tampa, Florida
October 24, 2016

**HEDGEPATH PHARMACEUTICALS, INC.
2014 EQUITY INCENTIVE PLAN**

1. *Purpose.* The purpose of the HedgePath Pharmaceuticals, Inc. 2014 Equity Incentive Plan is to provide a means through which the Company and its Affiliates may attract and retain key personnel and to provide a means whereby directors, officers, managers, employees, consultants and advisors (and prospective directors, officers, managers, employees, consultants and advisors) of the Company and its Affiliates can acquire and maintain an equity interest in the Company, or be paid incentive compensation, which may (but need not) be measured by reference to the value of Common Shares, thereby strengthening their commitment to the welfare of the Company and its Affiliates and aligning their interests with those of the Company's stockholders.

2. *Definitions.* The following definitions shall be applicable throughout this Plan:

(a) "Affiliate" means (i) any person or entity that directly or indirectly controls, is controlled by or is under common control with the Company and/or (ii) to the extent provided by the Committee, any person or entity in which the Company has a significant interest as determined by the Committee in its discretion. The term "control" (including, with correlative meaning, the terms "controlled by" and "under common control with"), as applied to any person or entity, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such person or entity, whether through the ownership of voting or other securities, by contract or otherwise.

(b) "Award" means, individually or collectively, any Incentive Stock Option, Nonqualified Stock Option, Stock Appreciation Right, Restricted Stock, Restricted Stock Unit, Stock Bonus Award and Performance Compensation Award granted under this Plan.

(c) "Board" means the Board of Directors of the Company.

(d) "Business Combination" has the meaning given such term in the definition of "Change in Control."

(e) "Business Day" means any day other than a Saturday, a Sunday or a day on which banking institutions in New York City are authorized or obligated by federal law or executive order to be closed.

(f) "Cause" means, in the case of a particular Award, unless the applicable Award agreement states otherwise, (i) the Company or an Affiliate having "cause" to terminate a Participant's employment or service, as defined in any employment or consulting agreement or similar document or policy between the Participant and the Company or an Affiliate in effect at the time of such termination or (ii) in the absence of any such employment or consulting agreement, document or policy (or the absence of any definition of "Cause" contained therein): (A) the repeated and demonstrated failure of the Participant to carry out the reasonable instructions of the Board or the Participant's direct report in all material respects, provided such instructions reasonably relate to and are not inconsistent with the Participant's position and standing, which such conduct is not cured within fifteen (15) days after receipt of written notice thereof by the Participant from the Company; (B) the breach by the Participant of any of the terms or provisions any agreement between the Participant, on the one hand, and the Company, on the other hand, on the part of the Participant to be observed or performed, which failure or breach is not cured within fifteen (15) days after receipt of written notice thereof by the Executive from the Company; (C) the Participant's knowing and willful neglect or refusal for any reason to attend to the Participant's material

duties and responsibilities with the Company, which such conduct is not cured within fifteen (15) days after receipt of written notice thereof by the Participant from the Company; (D) any criminal liability of the Company which was substantially caused by the conduct of the Participant; or (E) the Participant's conviction by, or entry of a plea of guilty or nolo contendere in, a court of competent jurisdiction of an act of fraud, embezzlement or willful breach of fiduciary duty to the Company, or any crime constituting a felony. Any determination of whether Cause exists shall be made by the Committee in its sole discretion.

(g) "Change in Control" shall, in the case of a particular Award, unless the applicable Award agreement states otherwise or contains a different definition of "Change in Control," be deemed to occur upon:

(i) An acquisition (whether directly from the Company or otherwise) of any voting securities of the Company (the "Voting Securities") by any "Person" (as the term person is used for purposes of Section 13(d) or 14(d) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act")), immediately after which such Person has "Beneficial Ownership" (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than fifty percent (50%) of the combined voting power of the Company's then outstanding Voting Securities.

(ii) The individuals who constitute the members of the Board cease, by reason of a financing, merger, combination, acquisition, takeover or other non-ordinary course transaction affecting the Company, to constitute at least fifty-one percent (51%) of the members of the Board; or

(iii) The consummation of any of the following events:

(A) A merger, consolidation or reorganization involving the Company, where either or both of the events described in clauses (i) or (ii) above would be the result;

(B) A liquidation or dissolution of or appointment of a receiver, rehabilitator, conservator or similar person for, or the filing by a third party of an involuntary bankruptcy against, the Company; provided, however, that to the extent necessary to comply with Section 409A of the Code, the occurrence of an event described in this subsection (B) shall not permit the settlement of Restricted Stock Units granted under this Plan; or

(C) An agreement for the sale or other disposition of all or substantially all of the assets of the Company to any Person (other than a transfer to a subsidiary of the Company).

(h) "Closing Price" means (A) during such time as the Common Shares are registered under Section 12 of the Exchange Act, the closing price of the Common Shares as reported by an established stock exchange or automated quotation system on the day for which such value is to be determined, or, if no sale of the Common Shares shall have been made on any such stock exchange or automated quotation system that day, on the next preceding day on which there was a sale of such Common Shares, or (B) during any such time as the Common Shares are not listed upon an established stock exchange or automated quotation system, the mean between dealer "bid" and "ask" prices of the Common Shares in the over-the-counter market on the day for which such value is to be determined, as reported by the Financial Industry Regulatory Authority, Inc., or (C) during any such time as the Common Shares cannot be valued pursuant to (A) or (B) above, the fair market value shall be as determined by the Committee considering all relevant information including, by example and not by limitation, the services of an independent appraiser.

(i) “Code” means the Internal Revenue Code of 1986, as amended, and any successor thereto. References in this Plan to any section of the Code shall be deemed to include any regulations or other interpretative guidance under such section, and any amendments or successor provisions to such section, regulations or guidance.

(j) “Committee” means a committee of at least two people as the Board may appoint to administer this Plan or, if no such committee has been appointed by the Board, the Board. Unless altered by an action of the Board, the Committee shall be the Compensation Committee of the Board.

(k) “Common Shares” means the common stock, par value \$0.0001 per share, of the Company (and any stock or other securities into which such common shares may be converted or into which they may be exchanged).

(l) “Company” means HedgePath Pharmaceuticals, Inc., a Delaware corporation, together with its successors and assigns.

(m) “Date of Grant” means the date on which the granting of an Award is authorized, or such other date as may be specified in such authorization.

(n) “Disability” means a “permanent and total” disability incurred by a Participant while in the employ of the Company or an Affiliate. For this purpose, a permanent and total disability shall mean that the Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months.

(o) “Effective Date” means the date as of which this Plan is adopted by the Board, subject to Section 3 of this Plan.

(p) “EHA” means that certain Equity Holders Agreement, dated June 24, 2014, by and among Mayne Pharma Ventures Pty Ltd, Hedgepath LLC, the Company, Frank E. O'Donnell, Jr., M.D., and Nicholas J. Virca.

(q) “Eligible Director” means a person who is (i) a “non-employee director” within the meaning of Rule 16b-3 under the Exchange Act, and (ii) an “outside director” within the meaning of Section 162(m) of the Code.

(r) “Eligible Person” means any (i) individual employed by the Company or an Affiliate; *provided, however*, that no such employee covered by a collective bargaining agreement shall be an Eligible Person unless and to the extent that such eligibility is set forth in such collective bargaining agreement or in an agreement or instrument relating thereto; (ii) director of the Company or an Affiliate; (iii) consultant or advisor to the Company or an Affiliate, provided that if the Securities Act applies such persons must be eligible to be offered securities registrable on Form S-8 under the Securities Act; or (iv) prospective employees, directors, officers, consultants or advisors who have accepted offers of employment or consultancy from the Company or its Affiliates (and would satisfy the provisions of clauses (i) through (iii) above once he or she begins employment with or begins providing services to the Company or its Affiliates).

(s) “Exchange Act” has the meaning given such term in the definition of “Change in Control,” and any reference in this Plan to any section of (or rule promulgated under) the Exchange Act shall be deemed to include any rules, regulations or other interpretative guidance under such section or rule, and any amendments or successor provisions to such section, rules, regulations or guidance.

(t) “Exercise Price” has the meaning given such term in Section 7(b) of this Plan.

(u) “Fair Market Value”, unless otherwise provided by the Committee in accordance with all applicable laws, rules regulations and standards, means, on a given date, (i) if the Common Shares (A) are listed on a national securities exchange or (B) are not listed on a national securities exchange, but is quoted by the OTC Markets Group, Inc. (www.otcm Markets.com) or any successor or alternative recognized over-the-counter market or another inter-dealer quotation system, on a last sale basis, the average selling price of the Common Shares reported on such national securities exchange or other inter-dealer quotation system, determined as the arithmetic mean of such selling prices over the thirty (30)-Business Day period preceding the Date of Grant, weighted based on the volume of trading of such Common Shares on each trading day during such period; or (ii) if the Common Shares are not listed on a national securities exchange or quoted in an inter-dealer quotation system on a last sale basis, the amount determined by the Committee in good faith to be the fair market value of the Common Shares.

(v) “Immediate Family Members” shall have the meaning set forth in Section 15(b) of this Plan.

(w) “Incentive Stock Option” means an Option that is designated by the Committee as an incentive stock option as described in Section 422 of the Code and otherwise meets the requirements set forth in this Plan.

(x) “Indemnifiable Person” shall have the meaning set forth in Section 4(e) of this Plan.

(y) “Intellectual Property Products” shall have the meaning set forth in Section 15(c) of this Plan.

(z) “Mature Shares” means Common Shares owned by a Participant that are not subject to any pledge or security interest and that have been either previously acquired by the Participant on the open market or meet such other requirements, if any, as the Committee may determine are necessary in order to avoid an accounting earnings charge on account of the use of such shares to pay the Exercise Price or satisfy a withholding obligation of the Participant.

(aa) “Negative Discretion” shall mean the discretion authorized by this Plan to be applied by the Committee to eliminate or reduce the size of a Performance Compensation Award consistent with Section 162(m) of the Code.

(bb) “Nonqualified Stock Option” means an Option that is not designated by the Committee as an Incentive Stock Option.

(cc) “Option” means an Award granted under Section 7 of this Plan.

(dd) “Option Period” has the meaning given such term in Section 7(c) of this Plan.

(ee) “Outstanding Company Common Shares” has the meaning given such term in the definition of “Change in Control.”

(ff) “Outstanding Company Voting Securities” has the meaning given such term in the definition of “Change in Control.”

(gg) “Participant” means an Eligible Person who has been selected by the Committee to participate in this Plan and to receive an Award pursuant to Section 6 of this Plan.

(hh) “Performance Compensation Award” shall mean any Award designated by the Committee as a Performance Compensation Award pursuant to Section 11 of this Plan.

(ii) “Performance Criteria” shall mean the criterion or criteria that the Committee shall select for purposes of establishing the Performance Goal(s) for a Performance Period with respect to any Performance Compensation Award under this Plan.

(jj) “Performance Formula” shall mean, for a Performance Period, the one or more objective formulae applied against the relevant Performance Goal to determine, with regard to the Performance Compensation Award of a particular Participant, whether all, some portion but less than all, or none of the Performance Compensation Award has been earned for the Performance Period.

(kk) “Performance Goals” shall mean, for a Performance Period, the one or more goals established by the Committee for the Performance Period based upon the Performance Criteria.

(ll) “Performance Period” shall mean the one or more periods of time, as the Committee may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to, and the payment of, a Performance Compensation Award.

(mm) “Permitted Transferee” shall have the meaning set forth in Section 15(b) of this Plan.

(nn) “Person” has the meaning given such term in the definition of “Change in Control.”

(oo) “Plan” means this HedgePath Pharmaceuticals, Inc. 2014 Equity Incentive Plan, as amended from time to time.

(pp) “Retirement” means the fulfillment of each of the following conditions: (i) the Participant is good standing with the Company as determined by the Committee; (ii) the voluntary termination by a Participant of such Participant’s employment or service to the Company and (B) that at the time of such voluntary termination, the sum of: (1) the Participant’s age (calculated to the nearest month, with any resulting fraction of a year being calculated as the number of months in the year divided by 12) and (2) the Participant’s years of employment or service with the Company (calculated to the nearest month, with any resulting fraction of a year being calculated as the number of months in the year divided by 12) equals at least 62 (provided that, in any case, the foregoing shall only be applicable if, at the time of Retirement, the Participant shall be at least 55 years of age and shall have been employed by or served with the Company for no less than 5 years).

(qq) “Restricted Period” means the period of time determined by the Committee during which an Award is subject to restrictions or, as applicable, the period of time within which performance is measured for purposes of determining whether an Award has been earned.

(rr) “Restricted Stock Unit” means an unfunded and unsecured promise to deliver Common Shares, cash, other securities or other property, subject to certain restrictions (including, without limitation, a requirement that the Participant remain continuously employed or provide continuous services for a specified period of time), granted under Section 9 of this Plan.

(ss) “Restricted Stock” means Common Shares, subject to certain specified restrictions (including, without limitation, a requirement that the Participant remain continuously employed or provide continuous services for a specified period of time), granted under Section 9 of this Plan.

(tt) “SAR Period” has the meaning given such term in Section 8(c) of this Plan.

(uu) “Securities Act” means the Securities Act of 1933, as amended, and any successor thereto. Reference in this Plan to any section of the Securities Act shall be deemed to include any rules, regulations or other official interpretative guidance under such section, and any amendments or successor provisions to such section, rules, regulations or guidance.

(vv) “Stock Appreciation Right” or “SAR” means an Award granted under Section 8 of this Plan which meets all of the requirements of Section 1.409A-1(b)(5)(i) (B) of the Treasury Regulations.

(ww) “Stock Bonus Award” means an Award granted under Section 10 of this Plan.

(xx) “Strike Price” means, except as otherwise provided by the Committee in the case of Substitute Awards, (i) in the case of a SAR granted in tandem with an Option, the Exercise Price of the related Option, or (ii) in the case of a SAR granted independent of an Option, the Fair Market Value on the Date of Grant.

(yy) “Subsidiary” means, with respect to any specified Person:

(i) any corporation, association or other business entity of which more than 50% of the total voting power of shares of Outstanding Company Voting Securities (without regard to the occurrence of any contingency and after giving effect to any voting agreement or stockholders’ agreement that effectively transfers voting power) is at the time owned or controlled, directly or indirectly, by that Person or one or more of the other Subsidiaries of that Person (or a combination thereof); and

(ii) any partnership or limited liability company (or any comparable foreign entity) (a) the sole general partner or managing member (or functional equivalent thereof) or the managing general partner of which is such Person or Subsidiary of such Person or (b) the only general partners or managing members (or functional equivalents thereof) of which are that Person or one or more Subsidiaries of that Person (or any combination thereof).

(zz) “Substitute Award” has the meaning given such term in Section 5(e).

(aaa) “Treasury Regulations” means any regulations, whether proposed, temporary or final, promulgated by the U.S. Department of Treasury under the Code, and any successor provisions.

3. *Effective Date; Duration.* The Plan shall be effective as of the Effective Date, but no Award shall be exercised or paid (or, in the case of a stock Award, shall be granted unless contingent on stockholder approval) unless and until this Plan has been approved by the stockholders of the Company,

which approval shall be within twelve (12) months after the date this Plan is adopted by the Board. The expiration date of this Plan, on and after which date no Awards may be granted hereunder, shall be the tenth anniversary of the Effective Date; *provided, however*, that such expiration shall not affect Awards then outstanding, and the terms and conditions of this Plan shall continue to apply to such Awards.

4. Administration.

(a) The Committee shall administer this Plan. To the extent required to comply with the provisions of Rule 16b-3 promulgated under the Exchange Act (if the Board is not acting as the Committee under this Plan) or necessary to obtain the exception for performance-based compensation under Section 162(m) of the Code, as applicable, it is intended that each member of the Committee shall, at the time he takes any action with respect to an Award under this Plan, be an Eligible Director. However, the fact that a Committee member shall fail to qualify as an Eligible Director shall not invalidate any Award granted by the Committee that is otherwise validly granted under this Plan. The acts of a majority of the members present at any meeting at which a quorum is present or acts approved in writing by a majority of the Committee shall be deemed the acts of the Committee. Whether a quorum is present shall be determined based on the Committee's charter as approved by the Board.

(b) Subject to the provisions of this Plan and applicable law, the Committee shall have the sole and plenary authority, in addition to other express powers and authorizations conferred on the Committee by this Plan and its charter, to: (i) designate Participants; (ii) determine the type or types of Awards to be granted to a Participant; (iii) determine the number of Common Shares to be covered by, or with respect to which payments, rights, or other matters are to be calculated in connection with, Awards; (iv) determine the terms and conditions of any Award; (v) determine whether, to what extent, and under what circumstances Awards may be settled or exercised in cash, Common Shares, 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; (vi) determine whether, to what extent, and under what circumstances the delivery of cash, Common Shares, other securities, other Awards or other property and other amounts payable with respect to an Award; (vii) interpret, administer, reconcile any inconsistency in, settle any controversy regarding, correct any defect in and/or complete any omission in this Plan and any instrument or agreement relating to, or Award granted under, this Plan; (viii) establish, amend, suspend, or waive any rules and regulations and appoint such agents as the Committee shall deem appropriate for the proper administration of this Plan; (ix) accelerate the vesting or exercisability of, payment for or lapse of restrictions on, Awards; and (x) make any other determination and take any other action that the Committee deems necessary or desirable for the administration of this Plan.

(c) The Committee may delegate to one or more officers of the Company or any Affiliate the authority to act on behalf of the Committee with respect to any matter, right, obligation, or election that is the responsibility of or that is allocated to the Committee herein, and that may be so delegated as a matter of law, except for grants of Awards to persons (i) subject to Section 16 of the Exchange Act or (ii) who are, or who are reasonably expected to be, "covered employees" for purposes of Section 162(m) of the Code.

(d) Unless otherwise expressly provided in this Plan, all designations, determinations, interpretations, and other decisions under or with respect to this Plan or any Award or any documents evidencing Awards granted pursuant to this Plan shall be within the sole discretion of the Committee, may be made at any time and shall be final, conclusive and binding upon all persons or entities, including, without limitation, the Company, any Affiliate, any Participant, any holder or beneficiary of any Award, and any stockholder of the Company.

(e) No member of the Board, the Committee, delegate of the Committee or any employee, advisor or agent of the Company or the Board or the Committee (each such person, an “*Indemnifiable Person*”) shall be liable for any action taken or omitted to be taken or any determination made in good faith with respect to this Plan or any Award hereunder. Each Indemnifiable Person shall be indemnified and held harmless by the Company against and from (and the Company shall pay or reimburse on demand for) any loss, cost, liability, or expense (including attorneys’ fees) that may be imposed upon or incurred by such Indemnifiable Person in connection with or resulting from any action, suit or proceeding to which such Indemnifiable Person may be a party or in which such Indemnifiable Person may be involved by reason of any action taken or omitted to be taken under this Plan or any Award agreement and against and from any and all amounts paid by such Indemnifiable Person with the Company’s approval, in settlement thereof, or paid by such Indemnifiable Person in satisfaction of any judgment in any such action, suit or proceeding against such Indemnifiable Person, provided, that the Company shall have the right, at its own expense, to assume and defend any such action, suit or proceeding and once the Company gives notice of its intent to assume the defense, the Company shall have sole control over such defense with counsel of the Company’s choice. The foregoing right of indemnification shall not be available to an Indemnifiable Person to the extent that a final judgment or other final adjudication (in either case not subject to further appeal) binding upon such Indemnifiable Person determines that the acts or omissions of such Indemnifiable Person giving rise to the indemnification claim resulted from such Indemnifiable Person’s bad faith, fraud or willful criminal act or omission or that such right of indemnification is otherwise prohibited by law or by the Company’s Certificate of Incorporation or Bylaws. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such Indemnifiable Persons may be entitled under the Company’s Certificate of Incorporation or Bylaws, as a matter of law, or otherwise, or any other power that the Company may have to indemnify such Indemnifiable Persons or hold them harmless.

(f) Notwithstanding anything to the contrary contained in this Plan, the Board may, in its sole discretion, at any time and from time to time, grant Awards and administer this Plan with respect to such Awards. In any such case, the Board shall have all the authority granted to the Committee under this Plan.

5. Grant of Awards; Shares Subject to this Plan; Limitations

(a) The Committee may, from time to time, grant Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Stock Bonus Awards and/or Performance Compensation Awards to one or more Eligible Persons.

(b) Subject to Sections 3, 11 and 12 of this Plan, the Committee is authorized to deliver under this Plan an aggregate of **THIRTY-TWO MILLION FIVE HUNDRED EIGHTY THREE THOUSAND FOUR HUNDRED SEVENTY-FIVE (32,583,475)** Common Shares. Each Common Share subject to an Option or a Stock Appreciation Right will reduce the number of Common Shares available for issuance by one share, and each Common Share underlying an Award of Restricted Stock, Restricted Stock Units, Stock Bonus Awards and Performance Compensation Awards will reduce the number of Common Shares available for issuance by 1.15 shares.

(c) Common Shares underlying Awards under this Plan that are forfeited, cancelled, expire unexercised, or are settled in cash shall be available again for Awards under this Plan at the same ratio at which they were previously granted. Notwithstanding the foregoing, the following Common Shares shall not be available again for Awards under the Plan: (i) shares tendered or held back upon the exercise of an Option or settlement of an Award to cover the Exercise Price of an Award; (ii) shares that are used or withheld to satisfy tax obligations of the Participant; and (iii) shares subject to a Stock Appreciation Right that are not issued in connection with the stock settlement of the SAR upon exercise thereof.

(d) Common Shares delivered by the Company in settlement of Awards may be authorized and unissued shares, shares held in the treasury of the Company, shares purchased on the open market or by private purchase, or a combination of the foregoing.

(e) Subject to compliance with Section 1.409A-3(f) of the Treasury Regulations, Awards may, in the sole discretion of the Committee, be granted under this Plan in assumption of, or in substitution for, outstanding awards previously granted by an entity acquired by the Company or with which the Company combines ("Substitute Awards"). The number of Common Shares underlying any Substitute Awards shall be counted against the aggregate number of Common Shares available for Awards under this Plan.

6. *Eligibility.* Participation shall be limited to Eligible Persons who have entered into an Award agreement or who have received written notification from the Committee, or from a person designated by the Committee, that they have been selected to participate in this Plan.

7. *Options.*

(a) Generally. Each Option granted under this Plan shall be evidenced by an Award agreement (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)). Each Option so granted shall be subject to the conditions set forth in this Section 7, and to such other conditions not inconsistent with this Plan as may be reflected in the applicable Award agreement. All Options granted under this Plan shall be Nonqualified Stock Options unless the applicable Award agreement expressly states that the Option is intended to be an Incentive Stock Option. Notwithstanding any designation of an Option, to the extent that the aggregate Fair Market Value of Common Shares with respect to which Options designated as Incentive Stock Options are exercisable for the first time by any Participant during any calendar year (under all plans of the Company or any Subsidiary) exceeds \$100,000, such excess Options shall be treated as Nonqualified Stock Options. Incentive Stock Options shall be granted only to Eligible Persons who are employees of the Company and its Affiliates, and no Incentive Stock Option shall be granted to any Eligible Person who is ineligible to receive an Incentive Stock Option under the Code. No Option shall be treated as an Incentive Stock Option unless this Plan has been approved by the stockholders of the Company in a manner intended to comply with the stockholder approval requirements of Section 422(b)(1) of the Code, provided that any Option intended to be an Incentive Stock Option shall not fail to be effective solely on account of a failure to obtain such approval, but rather such Option shall be treated as a Nonqualified Stock Option unless and until such approval is obtained. In the case of an Incentive Stock Option, the terms and conditions of such grant shall be subject to and comply with such rules as may be prescribed by Section 422 of the Code. If for any reason an Option intended to be an Incentive Stock Option (or any portion thereof) shall not qualify as an Incentive Stock Option, then, to the extent of such nonqualification, such Option or portion thereof shall be regarded as a Nonqualified Stock Option appropriately granted under this Plan.

(b) Exercise Price. The exercise price ("Exercise Price") per Common Share for each Option shall not be less than 100% of the Fair Market Value of such share determined as of the Date of Grant; *provided, however*, that in the case of an Incentive Stock Option granted to an employee who, at the time of the grant of such Option, owns shares representing more than 10% of the voting power of all classes of shares of the Company or any Affiliate, the Exercise Price per share shall not be less than 110% of the Fair Market Value per share on the Date of Grant; *and, provided further*, that notwithstanding any provision herein to the contrary, the Exercise Price shall not be less than the par value per Common Share.

(c) Vesting and Expiration. Options shall vest and become exercisable in such manner and on such date or dates determined by the Committee and as set forth in the applicable Award agreement, and shall expire after such period, not to exceed ten (10) years from the Date of Grant, as may be determined by the Committee (the "Option Period"); *provided, however*, that the Option Period shall not exceed five (5) years from the Date of Grant in the case of an Incentive Stock Option granted to a Participant who on the Date of Grant owns shares representing more than 10% of the voting power of all classes of shares of the Company or any Affiliate; *and, provided, further*, that notwithstanding any vesting dates set by the Committee, the Committee may, in its sole discretion, accelerate the exercisability of any Option, which acceleration shall not affect the terms and conditions of such Option other than with respect to exercisability. Unless otherwise provided by the Committee in an Award agreement:

(i) an Option shall vest and become exercisable with respect to 100% of the Common Shares subject to such Option on the third (~~3d~~) anniversary of the Date of Grant;

(ii) the unvested portion of an Option shall expire upon termination of employment or service of the Participant granted the Option, and the vested portion of such Option shall remain exercisable for:

(A) one year following termination of employment or service by reason of such Participant's death or Disability (with the determination of Disability to be made by the Committee on a case by case basis), but not later than the expiration of the Option Period;

(B) for directors, officers and employees of the Company only, for the remainder of the Option Period following termination of employment or service by reason of such Participant's Retirement (it being understood that any Incentive Stock Option held by the Participant shall be treated as a Nonqualified Stock Option if exercise is not undertaken within 90 days of the date of Retirement);

(C) 90 calendar days following termination of employment or service for any reason other than such Participant's death, Disability or Retirement, and other than such Participant's termination of employment or service for Cause, but not later than the expiration of the Option Period; and

(iii) both the unvested and the vested portion of an Option shall immediately expire upon the termination of the Participant's employment or service by the Company for Cause.

(d) Method of Exercise and Form of Payment. No Common Shares shall be delivered pursuant to any exercise of an Option until payment in full of the Exercise Price therefor is received by the Company and the Participant has paid to the Company an amount equal to any federal, state, local and non-U.S. income and employment taxes required to be withheld. Options that have become exercisable may be exercised by delivery of written or electronic notice of exercise to the Company in accordance with the terms of the Award agreement accompanied by payment of the Exercise Price. The Exercise Price shall be payable (i) in cash, check (subject to collection), cash equivalent and/or vested Common Shares valued at the Closing Price at the time the Option is exercised (including, pursuant to procedures approved by the Committee, by means of attestation of ownership of a sufficient number of Common Shares in lieu of actual delivery of such shares to the Company); *provided, however*, that such Common Shares are not subject to any pledge or other security interest and are Mature Shares and; (ii) by such other method as the Committee may permit in accordance with applicable law, in its sole

discretion, including without limitation: (A) in other property having a fair market value (as determined by the Committee in its discretion) on the date of exercise equal to the Exercise Price or (B) if there is a public market for the Common Shares at such time, by means of a broker-assisted "cashless exercise" pursuant to which the Company is delivered a copy of irrevocable instructions to a stockbroker to sell the Common Shares otherwise deliverable upon the exercise of the Option and to deliver promptly to the Company an amount equal to the Exercise Price or (C) by a "net exercise" method whereby the Company withholds from the delivery of the Common Shares for which the Option was exercised that number of Common Shares having a Closing Price equal to the aggregate Exercise Price for the Common Shares for which the Option was exercised. Any fractional Common Shares shall be settled in cash.

(e) Notification upon Disqualifying Disposition of an Incentive Stock Option. Each Participant awarded an Incentive Stock Option under this Plan shall notify the Company in writing immediately after the date he makes a disqualifying disposition of any Common Shares acquired pursuant to the exercise of such Incentive Stock Option. A disqualifying disposition is any disposition (including, without limitation, any sale) of such Common Shares before the later of (A) two years after the Date of Grant of the Incentive Stock Option or (B) one year after the date of exercise of the Incentive Stock Option. The Company may, if determined by the Committee and in accordance with procedures established by the Committee, retain possession of any Common Shares acquired pursuant to the exercise of an Incentive Stock Option as agent for the applicable Participant until the end of the period described in the preceding sentence.

(f) Compliance With Laws, etc. Notwithstanding the foregoing, in no event shall a Participant be permitted to exercise an Option in a manner that the Committee determines would violate the Sarbanes-Oxley Act of 2002, if applicable, or any other applicable law or the applicable rules and regulations of the Securities and Exchange Commission or the applicable rules and regulations of any securities exchange or inter-dealer quotation system on which the securities of the Company are listed or traded.

8. *Stock Appreciation Rights.*

(a) Generally. Each SAR granted under this Plan shall be evidenced by an Award agreement (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)). Each SAR so granted shall be subject to the conditions set forth in this Section 8, and to such other conditions not inconsistent with this Plan as may be reflected in the applicable Award agreement. Any Option granted under this Plan may include tandem SARs. The Committee also may award SARs to Eligible Persons independent of any Option.

(b) Exercise Price. The Exercise Price per Common Share for each Option shall not be less than 100% of the Fair Market Value of such share determined as of the Date of Grant.

(c) Vesting and Expiration. A SAR granted in connection with an Option shall become exercisable and shall expire according to the same vesting schedule and expiration provisions as the corresponding Option. A SAR granted independent of an Option shall vest and become exercisable and shall expire in such manner and on such date or dates determined by the Committee and shall expire after such period, not to exceed ten years, as may be determined by the Committee (the "SAR Period"); *provided, however*, that notwithstanding any vesting dates set by the Committee, the Committee may, in its sole discretion, accelerate the exercisability of any SAR, which acceleration shall not affect the terms and conditions of such SAR other than with respect to exercisability. Unless otherwise provided by the Committee in an Award agreement:

(i) a SAR shall vest and become exercisable with respect to 100% of the Common Shares subject to such SAR on the third anniversary of the Date of Grant;

(ii) the unvested portion of a SAR shall expire upon termination of employment or service of the Participant granted the SAR, and the vested portion of such SAR shall remain exercisable for:

(A) one year following termination of employment or service by reason of such Participant's death or Disability (with the determination of Disability to be made by the Committee on a case by case basis), but not later than the expiration of the SAR Period;

(B) for directors, officers and employees of the Company only, for the remainder of the SAR Period following termination of employment or service by reason of such Participant's Retirement;

(C) 90 calendar days following termination of employment or service for any reason other than such Participant's death, Disability or Retirement, and other than such Participant's termination of employment or service for Cause, but not later than the expiration of the SAR Period; and

(iii) both the unvested and the vested portion of a SAR shall expire immediately upon the termination of the Participant's employment or service by the Company for Cause.

(d) Method of Exercise. SARs that have become exercisable may be exercised by delivery of written or electronic notice of exercise to the Company in accordance with the terms of the Award, specifying the number of SARs to be exercised and the date on which such SARs were awarded. Notwithstanding the foregoing, if on the last day of the Option Period (or in the case of a SAR independent of an option, the SAR Period), the Closing Price exceeds the Strike Price, the Participant has not exercised the SAR or the corresponding Option (if applicable), and neither the SAR nor the corresponding Option (if applicable) has expired, such SAR shall be deemed to have been exercised by the Participant on such last day and the Company shall make the appropriate payment therefor.

(e) Payment. Upon the exercise of a SAR, the Company shall pay to the Participant an amount equal to the number of shares subject to the SAR that are being exercised multiplied by the excess, if any, of the Closing Price of one Common Share on the exercise date over the Strike Price, less an amount equal to any federal, state, local and non-U.S. income and employment taxes required to be withheld. The Company shall pay such amount in cash, in Common Shares valued at fair market value, or any combination thereof, as determined by the Committee. Any fractional Common Share shall be settled in cash.

9. Restricted Stock and Restricted Stock Units.

(a) Generally. Each grant of Restricted Stock and Restricted Stock Units shall be evidenced by an Award agreement (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)). Each such grant shall be subject to the conditions set forth in this Section 9, and to such other conditions not inconsistent with this Plan as may be reflected in the applicable Award agreement.

(b) Restricted Accounts; Escrow or Similar Arrangement. Upon the grant of Restricted Stock, a book entry in a restricted account shall be established in the Participant's name at the

Company's transfer agent and, if the Committee determines that the Restricted Stock shall be held by the Company or in escrow rather than held in such restricted account pending the release of the applicable restrictions, the Committee may require the Participant to additionally execute and deliver to the Company (i) an escrow agreement satisfactory to the Committee, if applicable, and (ii) the appropriate share power (endorsed in blank) with respect to the Restricted Stock covered by such agreement. If a Participant shall fail to execute an agreement evidencing an Award of Restricted Stock and, if applicable, an escrow agreement and blank share power within the amount of time specified by the Committee, the Award shall be null and void *ab initio*. Subject to the restrictions set forth in this Section 9 and the applicable Award agreement, the Participant generally shall have the rights and privileges of a stockholder as to such Restricted Stock, including without limitation the right to vote such Restricted Stock and the right to receive dividends, if applicable. To the extent shares of Restricted Stock are forfeited, any share certificates issued to the Participant evidencing such shares shall be returned to the Company, and all rights of the Participant to such shares and as a stockholder with respect thereto shall terminate without further obligation on the part of the Company.

(c) *Vesting; Acceleration of Lapse of Restrictions* Unless otherwise provided by the Committee in an Award agreement: (i) the Restricted Period shall lapse with respect to 100% of the Restricted Stock and Restricted Stock Units on the third (3rd) anniversary of the Date of Grant; and (ii) the unvested portion of Restricted Stock and Restricted Stock Units shall terminate and be forfeited upon termination of employment or service of the Participant granted the applicable Award.

(d) *Delivery of Restricted Stock and Settlement of Restricted Stock Units* (i) Upon the expiration of the Restricted Period with respect to any shares of Restricted Stock, the restrictions set forth in the applicable shall be of no further force or effect with respect to such shares, except as set forth in the applicable Award agreement. If an escrow arrangement is used, upon such expiration, the Company shall deliver to the Participant, or his beneficiary, without charge, the share certificate evidencing the shares of Restricted Stock that have not then been forfeited and with respect to which the Restricted Period has expired (rounded down to the nearest full share). Dividends, if any, that may have been withheld by the Committee and attributable to any particular share of Restricted Stock shall be distributed to the Participant in cash or, at the sole discretion of the Committee, in Common Shares having a Closing Price equal to the amount of such dividends, upon the release of restrictions on such share and, if such share is forfeited, the Participant shall have no right to such dividends (except as otherwise set forth by the Committee in the applicable Award agreement).

(ii) Unless otherwise provided by the Committee in an Award agreement, upon the expiration of the Restricted Period with respect to any outstanding Restricted Stock Units, the Company shall deliver to the Participant, or his beneficiary, without charge, one Common Share for each such outstanding Restricted Stock Unit; *provided, however*, that the Committee may, in its sole discretion and subject to the requirements of Section 409A of the Code, elect to (i) pay cash or part cash and part Common Share in lieu of delivering only Common Shares in respect of such Restricted Stock Units or (ii) defer the delivery of Common Shares (or cash or part Common Shares and part cash, as the case may be) beyond the expiration of the Restricted Period if such delivery would result in a violation of applicable law until such time as is no longer the case. If a cash payment is made in lieu of delivering Common Shares, the amount of such payment shall be equal to the Closing Price of the Common Shares as of the date on which the Restricted Period lapsed with respect to such Restricted Stock Units, less an amount equal to any federal, state, local and non-U.S. income and employment taxes required to be withheld.

10. *Stock Bonus Awards*. The Committee may issue unrestricted Common Shares, or other Awards denominated in Common Shares, under this Plan to Eligible Persons, either alone or in tandem with other awards, in such amounts as the Committee shall from time to time in its sole discretion

determine. Each Stock Bonus Award granted under this Plan shall be evidenced by an Award agreement (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)). Each Stock Bonus Award so granted shall be subject to such conditions not inconsistent with this Plan as may be reflected in the applicable Award agreement.

11. *Performance Compensation Awards.*

(a) Generally. The Committee shall have the authority, at the time of grant of any Award described in Sections 7 through 10 of this Plan, to designate such Award as a Performance Compensation Award intended to qualify as “performance-based compensation” under Section 162(m) of the Code. The Committee shall have the authority to make an award of a cash bonus to any Participant and designate such Award as a Performance Compensation Award intended to qualify as “performance-based compensation” under Section 162(m) of the Code.

(b) Discretion of Committee with Respect to Performance Compensation Awards. With regard to a particular Performance Period, the Committee shall have sole discretion to select the length of such Performance Period, the type(s) of Performance Compensation Awards to be issued, the Performance Criteria that will be used to establish the Performance Goal(s), the kind(s) and/or level(s) of the Performance Goals(s) that is (are) to apply and the Performance Formula. Within the first 90 calendar days of a Performance Period (or, if longer or shorter, within the maximum period allowed under Section 162(m) of the Code, if applicable), the Committee shall, with regard to the Performance Compensation Awards to be issued for such Performance Period, exercise its discretion with respect to each of the matters enumerated in the immediately preceding sentence and record the same in writing.

(c) Performance Criteria. The Performance Criteria that will be used to establish the Performance Goal(s) shall be based on the attainment of specific levels of performance of the Company and/or one or more Affiliates, divisions or operational units, or any combination of the foregoing, as determined by the Committee. Any one or more of the Performance Criteria adopted by the Committee may be used on an absolute or relative basis to measure the performance of the Company and/or one or more Affiliates as a whole or any business unit(s) of the Company and/or one or more Affiliates or any combination thereof, as the Committee may deem appropriate, or any of the above Performance Criteria may be compared to the performance of a selected group of comparison companies, or a published or special index that the Committee, in its sole discretion, deems appropriate, or as compared to various stock market indices. The Committee also has the authority to provide for accelerated vesting of any Award based on the achievement of Performance Goals pursuant to the Performance Criteria specified in this paragraph. To the extent required under Section 162(m) of the Code, the Committee shall, within the first 90 calendar days of a Performance Period (or, if longer or shorter, within the maximum period allowed under Section 162(m) of the Code), define in an objective fashion the manner of calculating the Performance Criteria it selects to use for such Performance Period and thereafter promptly communicate such Performance Criteria to the Participant.

(d) Modification of Performance Goal(s). In the event that applicable tax and/or securities laws change to permit Committee discretion to alter the governing Performance Criteria without obtaining stockholder approval of such alterations, the Committee shall have sole discretion to make such alterations without obtaining stockholder approval. The Committee is authorized at any time during the first 90 calendar days of a Performance Period (or, if longer or shorter, within the maximum period allowed under Section 162(m) of the Code, if applicable), or at any time thereafter to the extent the exercise of such authority at such time would not cause the Performance Compensation Awards granted to any Participant for such Performance Period to fail to qualify as “performance-based compensation” under Section 162(m) of the Code, in its sole discretion, to adjust or modify the calculation of a

Performance Goal for such Performance Period, based on and in order to appropriately reflect the following events: (i) asset write-downs; (ii) litigation or claim judgments or settlements; (iii) the effect of changes in tax laws, accounting principles, or other laws or regulatory rules affecting reported results; (iv) any reorganization and restructuring programs; (v) extraordinary nonrecurring items as described in Accounting Principles Board Opinion No. 30 (or any successor pronouncement thereto) and/or in management's discussion and analysis of financial condition and results of operations appearing in the Company's annual report to stockholders for the applicable year; (vi) acquisitions or divestitures; (vii) any other specific unusual or nonrecurring events, or objectively determinable category thereof; (viii) foreign exchange gains and losses; and (ix) a change in the Company's fiscal year.

(c) *Payment of Performance Compensation Awards.*

(i) *Condition to Receipt of Payment.* Unless otherwise provided in the applicable Award agreement, a Participant must be employed by the Company on the last day of a Performance Period to be eligible for payment in respect of a Performance Compensation Award for such Performance Period.

(ii) *Limitation.* A Participant shall be eligible to receive payment in respect of a Performance Compensation Award only to the extent that: (A) the Performance Goals for such period are achieved; and (B) all or some of the portion of such Participant's Performance Compensation Award has been earned for the Performance Period based on the application of the Performance Formula to such achieved Performance Goals.

(iii) *Certification.* Following the completion of a Performance Period, the Committee shall review and certify in writing whether, and to what extent, the Performance Goals for the Performance Period have been achieved and, if so, calculate and certify in writing that amount of the Performance Compensation Awards earned for the period based upon the Performance Formula. The Committee shall then determine the amount of each Participant's Performance Compensation Award actually payable for the Performance Period and, in so doing, may apply Negative Discretion.

(iv) *Use of Negative Discretion.* In determining the actual amount of an individual Participant's Performance Compensation Award for a Performance Period, the Committee may reduce or eliminate the amount of the Performance Compensation Award earned under the Performance Formula in the Performance Period through the use of Negative Discretion if, in its sole judgment, such reduction or elimination is appropriate. The Committee shall not have the discretion, except as is otherwise provided in this Plan, to (A) grant or provide payment in respect of Performance Compensation Awards for a Performance Period if the Performance Goals for such Performance Period have not been attained; or (B) increase a Performance Compensation Award above the applicable limitations set forth in Section 5 of this Plan.

(f) *Timing of Award Payments.* Performance Compensation Awards granted for a Performance Period shall be paid to Participants as soon as administratively practicable following completion of the certifications required by this Section 11, but in no event later than two-and-one-half months following the end of the fiscal year during which the Performance Period is completed in order to comply with the short-term deferral rules under Section 1.409A-1(b)(4) of the Treasury Regulations. Notwithstanding the foregoing, payment of a Performance Compensation Award may be delayed, as permitted by Section 1.409A-2(b)(7)(i) of the Treasury Regulations, to the extent that the Company reasonably anticipates that if such payment were made as scheduled, the Company's tax deduction with respect to such payment would not be permitted due to the application of Section 162(m) of the Code.

12. *Changes in Capital Structure and Similar Events.* In the event of (a) any dividend or other distribution (whether in the form of cash, Common Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, amalgamation, consolidation, split-up, split-off, combination, repurchase or exchange of Common Shares or other securities of the Company, issuance of warrants or other rights to acquire Common Shares or other securities of the Company, or other similar corporate transaction or event (including, without limitation, a Change in Control) that affects the Common Shares, or (b) unusual or nonrecurring events (including, without limitation, a Change in Control) affecting the Company, any Affiliate, or the financial statements of the Company or any Affiliate, or changes in applicable rules, rulings, regulations or other requirements of any governmental body or securities exchange or inter-dealer quotation system, accounting principles or law, such that in either case an adjustment is determined by the Committee in its sole discretion to be necessary or appropriate, then the Committee shall make any such adjustments that are equitable, including without limitation any or all of the following:

(i) adjusting any or all of (A) the number of Common Shares or other securities of the Company (or number and kind of other securities or other property) that may be delivered in respect of Awards or with respect to which Awards may be granted under this Plan (including, without limitation, adjusting any or all of the limitations under Section 5 of this Plan) and (B) the terms of any outstanding Award, including, without limitation, (1) the number of Common Shares or other securities of the Company (or number and kind of other securities or other property) subject to outstanding Awards or to which outstanding Awards relate, (2) the Exercise Price or Strike Price with respect to any Award or (3) any applicable performance measures (including, without limitation, Performance Criteria and Performance Goals);

(ii) providing for a substitution or assumption of Awards, accelerating the exercisability of, lapse of restrictions on, or termination of, Awards or providing for a period of time for exercise prior to the occurrence of such event; and

(iii) subject to the requirements of Section 409A of the Code, canceling any one or more outstanding Awards and causing to be paid to the holders thereof, in cash, Common Shares, other securities or other property, or any combination thereof, the value of such Awards, if any, as determined by the Committee (which if applicable may be based upon the price per Common Share received or to be received by other stockholders of the Company in such event), including without limitation, in the case of an outstanding Option or SAR, a cash payment in an amount equal to the excess, if any, of the fair market value (as of a date specified by the Committee) of the Common Shares subject to such Option or SAR over the aggregate Exercise Price or Strike Price of such Option or SAR, respectively (it being understood that, in such event, any Option or SAR having a per share Exercise Price or Strike Price equal to, or in excess of, the fair market value of a Common Share subject thereto may be canceled and terminated without any payment or consideration therefor);

provided, however, that in the case of any “equity restructuring” (within the meaning of the Financial Accounting Standards Board Statement of Financial Accounting Standards No. 123 (revised 2004) or ASC Topic 718, or any successor thereto), the Committee shall make an equitable or proportionate adjustment to outstanding Awards to reflect such equity restructuring. Any adjustment in Incentive Stock Options under this Section 12 (other than any cancellation of Incentive Stock Options) shall be made only to the extent not constituting a “modification” within the meaning of Section 424(h)(3) of the Code, and any adjustments under this Section 12 shall be made in a manner that does not adversely affect the exemption provided pursuant to Rule 16b-3 under the Exchange Act. The Company shall give each Participant notice of an adjustment hereunder and, upon notice, such adjustment shall be conclusive and binding for all purposes.

13. *Effect of Change in Control* Except to the extent otherwise provided in an Award agreement, in the event of a Change in Control, notwithstanding any provision of this Plan to the contrary, with respect to all or any portion of a particular outstanding Award or Awards:

- (a) all of the then outstanding Options and SARs shall immediately vest and become immediately exercisable as of a time prior to the Change in Control;
- (b) the Restricted Period shall expire as of a time prior to the Change in Control (including without limitation a waiver of any applicable Performance Goals);

(c) Performance Periods in effect on the date the Change in Control occurs shall end on such date, and the Committee shall (i) 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 (ii) cause the Participant to receive partial or full payment of Awards for each such Performance Period based upon the 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 Committee.

To the extent practicable, any actions taken by the Committee under the immediately preceding clauses (a) through (c) shall occur in a manner and at a time which allows affected Participants the ability to participate in the Change in Control transactions with respect to the Common Shares subject to their Awards.

14. *Amendments and Termination.*

(a) *Amendment and Termination of this Plan.* Subject to the terms of the EHA, the Board may amend, alter, suspend, discontinue, or terminate this Plan or any portion thereof at any time; provided, that (i) no amendment to the definition of Eligible Employee in Section 2, Section 5(i), Section 11(c) or Section 14(b) (to the extent required by the proviso in such Section 14(b)) shall be made without stockholder approval and (ii) no such amendment, alteration, suspension, discontinuance or termination shall be made without stockholder approval if such approval is necessary to comply with any tax or regulatory requirement applicable to this Plan (including, without limitation, as necessary to comply with any rules or requirements of any securities exchange or inter-dealer quotation system on which the Common Shares may be listed or quoted or to prevent the Company from being denied a tax deduction under Section 162(m) of the Code); and, provided, further, that any such amendment, alteration, suspension, discontinuance or termination that would materially and adversely affect the rights of any Participant or any holder or beneficiary of any Award theretofore granted shall not to that extent be effective without the prior written consent of the affected Participant, holder or beneficiary.

(b) *Amendment of Award Agreements.* Subject to the terms of the EHA, the Committee may, to the extent consistent with the terms of any applicable Award agreement, waive any conditions or rights under, amend any terms of, or alter, suspend, discontinue, cancel or terminate, any Award theretofore granted or the associated Award agreement, prospectively or retroactively; provided, however that any such waiver, amendment, alteration, suspension, discontinuance, cancellation or termination that would materially and adversely affect the rights of any Participant with respect to any Award theretofore granted shall not to that extent be effective without the consent of the affected Participant; and, provided, further, that without stockholder approval, except as otherwise permitted under Section 12 of this Plan, (i) no amendment or modification may reduce the Exercise Price of any Option or the Strike Price of any SAR, (ii) the Committee may not cancel any outstanding Option or SAR and replace it with a new Option or SAR, another Award or cash or take any action that would have the effect of treating such Award as a new Award for tax or accounting purposes and (iii) the Committee may not take any other action that is considered a "repricing" for purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on which the Common Shares are listed or quoted.

15. *General.*

(a) Award Agreements. Each Award under this Plan shall be evidenced by an Award agreement, which shall be delivered to the Participant (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)) and shall specify the terms and conditions of the Award and any rules applicable thereto, including without limitation, the effect on such Award of the death, Disability or termination of employment or service of a Participant, or of such other events as may be determined by the Committee. The Company's failure to specify any term of any Award in any particular Award agreement shall not invalidate such term, provided such terms was duly adopted by the Board or the Committee.

(b) Nontransferability; Trading Restrictions.

(i) Each Award shall be exercisable only by a Participant during the Participant's lifetime, or, if permissible under applicable law, by the Participant's legal guardian or representative. No Award may be assigned, alienated, pledged, attached, sold or otherwise transferred or encumbered by a Participant other than by will or by the laws of descent and distribution and any such purported assignment, alienation, pledge, attachment, sale, transfer or encumbrance shall be void and unenforceable against the Company or an Affiliate; provided that the designation of a beneficiary shall not constitute an assignment, alienation, pledge, attachment, sale, transfer or encumbrance.

(ii) Notwithstanding the foregoing, the Committee may, in its sole discretion, permit Awards (other than Incentive Stock Options) to be transferred by a Participant, with or without consideration, subject to such rules as the Committee may adopt consistent with any applicable Award agreement to preserve the purposes of this Plan, to: (A) any person who is a "family member" of the Participant, as such term is used in the instructions to Form S-8 under the Securities Act (collectively, the "Immediate Family Members"); (B) a trust solely for the benefit of the Participant and his or her Immediate Family Members; or (C) a partnership or limited liability company whose only partners or stockholders are the Participant and his or her Immediate Family Members; or (D) any other transferee as may be approved either (I) by the Board or the Committee in its sole discretion, or (II) as provided in the applicable Award agreement (each transferee described in clauses (A), (B) (C) and (D) above is hereinafter referred to as a "Permitted Transferee"); provided, that the Participant gives the Committee advance written notice describing the terms and conditions of the proposed transfer and the Committee notifies the Participant in writing that such a transfer would comply with the requirements of this Plan.

(iii) The terms of any Award transferred in accordance with the immediately preceding sentence shall apply to the Permitted Transferee and any reference in this Plan, or in any applicable Award agreement, to a Participant shall be deemed to refer to the Permitted Transferee, except that (A) Permitted Transferees shall not be entitled to transfer any Award, other than by will or the laws of descent and distribution; (B) Permitted Transferees shall not be entitled to exercise any transferred Option unless there shall be in effect a registration statement on an appropriate form covering the Common Shares to be acquired pursuant to the exercise of such Option if the Committee determines, consistent with any applicable Award agreement, that such a registration statement is necessary or appropriate; (C) the Committee or the Company shall not be required to provide any notice to a Permitted Transferee, whether or not such notice is or would otherwise have been required to be given to the Participant under this Plan or otherwise; and (D) the consequences of the termination of the Participant's employment by, or services to, the Company or an Affiliate under the terms of this Plan and the

applicable Award agreement shall continue to be applied with respect to the Participant, including, without limitation, that an Option shall be exercisable by the Permitted Transferee only to the extent, and for the periods, specified in this Plan and the applicable Award agreement.

(iv) The Committee shall have the right, either on an Award-by-Award basis or as a matter of policy for all Awards or one or more classes of Awards, to condition the delivery of vested Common Shares received in connection with such Award on the Participant's agreement to such restrictions as the Committee may determine.

(c) Tax Withholding.

(i) A Participant shall be required to pay to the Company or any Affiliate, or the Company or any Affiliate shall have the right and is hereby authorized to withhold, from any cash, Common Shares, other securities or other property deliverable under any Award or from any compensation or other amounts owing to a Participant, the amount (in cash, Common Shares, other securities or other property) of any required withholding taxes in respect of an Award, its exercise, or any payment or transfer under an Award or under this Plan and to take such other action as may be necessary in the opinion of the Committee or the Company to satisfy all obligations for the payment of such withholding and taxes.

(ii) Without limiting the generality of clause (i) above, the Committee may, in its sole discretion, permit a Participant to satisfy, in whole or in part, the foregoing withholding liability by (A) the delivery of Common Shares (which are not subject to any pledge or other security interest and are Mature Shares) owned by the Participant having a fair market value equal to such withholding liability or (B) having the Company withhold from the number of Common Shares otherwise issuable or deliverable pursuant to the exercise or settlement of the Award a number of shares with a fair market value equal to such withholding liability (but no more than the minimum required statutory withholding liability).

(d) No Claim to Awards; No Rights to Continued Employment; Waiver. No employee of the Company or an Affiliate, or other person, shall have any claim or right to be granted an Award under this Plan or, having been selected for the grant of an Award, to be selected for a grant of any other Award. There is no obligation for uniformity of treatment of Participants or holders or beneficiaries of Awards. The terms and conditions of Awards and the Committee's determinations and interpretations with respect thereto need not be the same with respect to each Participant and may be made selectively among Participants, whether or not such Participants are similarly situated. Neither this Plan nor any action taken hereunder shall be construed as giving any Participant any right to be retained in the employ or service of the Company or an Affiliate, nor shall it be construed as giving any Participant any rights to continued service on the Board. The Company or any of its Affiliates may at any time dismiss a Participant from employment or discontinue any consulting relationship, free from any liability or any claim under this Plan, unless otherwise expressly provided in this Plan or any Award agreement. By accepting an Award under this Plan, a Participant shall thereby be deemed to have waived any claim to continued exercise or vesting of an Award or to damages or severance entitlement related to non-continuation of the Award beyond the period provided under this Plan or any Award agreement, notwithstanding any provision to the contrary in any written employment contract or other agreement between the Company and its Affiliates and the Participant, whether any such agreement is executed before, on or after the Date of Grant.

(e) International Participants. With respect to Participants who reside or work outside of the United States of America and who are not (and who are not expected to be) "covered employees" within the meaning of Section 162(m) of the Code, the Committee may in its sole discretion

amend the terms of this Plan or outstanding Awards (or establish a sub-plan) with respect to such Participants in order to conform such terms with the requirements of local law or to obtain more favorable tax or other treatment for a Participant, the Company or its Affiliates.

(f) Designation and Change of Beneficiary. Each Participant may file with the Committee a written designation of one or more persons as the beneficiary(ies) who shall be entitled to receive the amounts payable with respect to an Award, if any, due under this Plan upon his or her death. A Participant may, from time to time, revoke or change his or her beneficiary designation without the consent of any prior beneficiary by filing a new designation with the Committee. The last such designation filed with the Committee shall be controlling; *provided, however*, that no designation, or change or revocation thereof, shall be effective unless received by the Committee prior to the Participant's death, and in no event shall it be effective as of a date prior to such receipt. If no beneficiary designation is filed by a Participant, the beneficiary shall be deemed to be his or her spouse or, if the Participant is unmarried at the time of death, his or her estate. Upon the occurrence of a Participant's divorce (as evidenced by a final order or decree of divorce), any spousal designation previously given by such Participant shall automatically terminate.

(g) Termination of Employment/Service. Unless determined otherwise by the Committee at any point following such event: (i) neither a temporary absence from employment or service due to illness, vacation or leave of absence nor a transfer from employment or service with the Company to employment or service with an Affiliate (or vice-versa) shall be considered a termination of employment or service with the Company or an Affiliate; and (ii) if a Participant's employment with the Company and its Affiliates terminates, but such Participant continues to provide services to the Company and its Affiliates in a non-employee capacity (or vice-versa), such change in status shall not be considered a termination of employment with the Company or an Affiliate.

(h) No Rights as a Stockholder. Except as otherwise specifically provided in this Plan or any Award agreement, no person shall be entitled to the privileges of ownership in respect of Common Shares that are subject to Awards hereunder until such shares have been issued or delivered to that person.

(i) Government and Other Regulations.

(i) The obligation of the Company to settle Awards in Common Shares or other consideration shall be subject to all applicable laws, rules, and regulations, and to such approvals by governmental agencies as may be required. Notwithstanding any terms or conditions of any Award to the contrary, the Company shall be under no obligation to offer to sell or to sell, and shall be prohibited from offering to sell or selling, any Common Shares pursuant to an Award unless such shares have been properly registered for sale pursuant to the Securities Act with the Securities and Exchange Commission or unless the Company has received an opinion of counsel, satisfactory to the Company, that such shares may be offered or sold without such registration pursuant to an available exemption therefrom and the terms and conditions of such exemption have been fully complied with. The Company shall be under no obligation to register for sale under the Securities Act any of the Common Shares to be offered or sold under this Plan. The Committee shall have the authority to provide that all certificates for Common Shares or other securities of the Company or any Affiliate delivered under this Plan shall be subject to such stop transfer orders and other restrictions as the Committee may deem advisable under this Plan, the applicable Award agreement, the federal securities laws, or the rules, regulations and other requirements of the Securities and Exchange Commission, any securities exchange or inter-dealer quotation system upon which such shares or other securities are then listed or quoted and any other applicable federal, state, local or non-U.S. laws, and, without limiting the generality of Section 9 of this Plan, the Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such

restrictions. Notwithstanding any provision in this Plan to the contrary, the Committee reserves the right to add any additional terms or provisions to any Award granted under this Plan that it in its sole discretion deems necessary or advisable in order that such Award complies with the legal requirements of any governmental entity to whose jurisdiction the Award is subject.

(ii) The Committee may cancel an Award or any portion thereof if it determines, in its sole discretion, that legal or contractual restrictions and/or blockage and/or other market considerations would make the Company's acquisition of Common Shares from the public markets, the Company's issuance of Common Shares to the Participant, the Participant's acquisition of Common Shares from the Company and/or the Participant's sale of Common Shares to the public markets, illegal, impracticable or inadvisable. If the Committee determines to cancel all or any portion of an Award in accordance with the foregoing, unless doing so would violate Section 409A of the Code, the Company shall pay to the Participant an amount equal to the excess of (A) the aggregate fair market value of the Common Shares subject to such Award or portion thereof canceled (determined as of the applicable exercise date, or the date that the shares would have been vested or delivered, as applicable), over (B) the aggregate Exercise Price or Strike Price (in the case of an Option or SAR, respectively) or any amount payable as a condition of delivery of Common Shares (in the case of any other Award). Such amount shall be delivered to the Participant as soon as practicable following the cancellation of such Award or portion thereof. The Committee shall have the discretion to consider and take action to mitigate the tax consequence to the Participant in cancelling an Award in accordance with this clause.

(j) Payments to Persons Other Than Participants. If the Committee shall find that any person to whom any amount is payable under this Plan is unable to care for his affairs because of illness or accident, or is a minor, or has died, then any payment due to such person or his estate (unless a prior claim therefor has been made by a duly appointed legal representative) may, if the Committee so directs the Company, be paid to his spouse, child, relative, an institution maintaining or having custody of such person, or any other person deemed by the Committee to be a proper recipient on behalf of such person otherwise entitled to payment. Any such payment shall be a complete discharge of the liability of the Committee and the Company therefor.

(k) Nonexclusivity of this Plan. Neither the adoption of this Plan by the Board nor the submission of this Plan to the stockholders of the Company for approval shall be construed as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of stock options or other equity-based awards otherwise than under this Plan, and such arrangements may be either applicable generally or only in specific cases.

(l) No Trust or Fund Created. Neither this Plan nor any Award shall create or be construed to create a trust or separate fund of any kind or a fiduciary relationship between the Company or any Affiliate, on the one hand, and a Participant or other person or entity, on the other hand. No provision of this Plan or any Award shall require the Company, for the purpose of satisfying any obligations under this Plan, to purchase assets or place any assets in a trust or other entity to which contributions are made or otherwise to segregate any assets, nor shall the Company maintain separate bank accounts, books, records or other evidence of the existence of a segregated or separately maintained or administered fund for such purposes. Participants shall have no rights under this Plan other than as general unsecured creditors of the Company, except that insofar as they may have become entitled to payment of additional compensation by performance of services, they shall have the same rights as other employees under general law.

(m) Reliance on Reports. Each member of the Committee and each member of the Board shall be fully justified in acting or failing to act, as the case may be, and shall not be liable for

having so acted or failed to act in good faith, in reliance upon any report made by the independent public accountant of the Company and its Affiliates and/or any other information furnished in connection with this Plan by any agent of the Company or the Committee or the Board, other than himself.

(n) Relationship to Other Benefits. No payment under this Plan shall be taken into account in determining any benefits under any pension, retirement, profit sharing, group insurance or other benefit plan of the Company except as otherwise specifically provided in such other plan.

(o) Governing Law. The Plan shall be governed by and construed in accordance with the internal laws of the State of Delaware, without giving effect to the conflict of laws provisions.

(p) Severability. If any provision of this Plan or any Award or Award agreement is or becomes or is deemed to be invalid, illegal, or unenforceable in any jurisdiction or as to any person or entity or Award, or would disqualify this Plan or any Award under any law deemed applicable by the Committee, such provision shall be construed or deemed amended to conform to the applicable laws in the manner that most closely reflects the original intent of the Award or the Plan, or if it cannot be construed or deemed amended without, in the determination of the Committee, materially altering the intent of this Plan or the Award, such provision shall be construed or deemed stricken as to such jurisdiction, person or entity or Award and the remainder of this Plan and any such Award shall remain in full force and effect.

(q) Obligations Binding on Successors. The obligations of the Company under this Plan shall be binding upon any successor corporation or organization resulting from the merger, amalgamation, consolidation or other reorganization of the Company, or upon any successor corporation or organization succeeding to substantially all of the assets and business of the Company.

(r) Code Section 162(m) Approval. If so determined by the Committee, the provisions of this Plan regarding Performance Compensation Awards shall be disclosed and reapproved by stockholders no later than the first stockholder meeting that occurs in the fifth year following the year in which stockholders previously approved such provisions, in each case in order for certain Awards granted after such time to be exempt from the deduction limitations of Section 162(m) of the Code. Nothing in this clause, however, shall affect the validity of Awards granted after such time if such stockholder approval has not been obtained.

(s) Expenses; Gender; Titles and Headings. The expenses of administering this Plan shall be borne by the Company and its Affiliates. Masculine pronouns and other words of masculine gender shall refer to both men and women. The titles and headings of the sections in this Plan are for convenience of reference only, and in the event of any conflict, the text of this Plan, rather than such titles or headings shall control.

(t) Other Agreements. Notwithstanding the above, the Committee may require, as a condition to the grant of and/or the receipt of Common Shares under an Award, that the Participant execute lock-up, stockholder or other agreements, as it may determine in its sole and absolute discretion.

(u) Section 409A. The Plan and all Awards granted hereunder are intended to comply with, or otherwise be exempt from, the requirements of Section 409A of the Code. The Plan and all Awards granted under this Plan shall be administered, interpreted, and construed in a manner consistent with Section 409A of the Code to the extent necessary to avoid the imposition of additional taxes under Section 409A(a)(1)(B) of the Code. Notwithstanding anything in this Plan to the contrary, in no event shall the Committee exercise its discretion to accelerate the payment or settlement of an Award where such payment or settlement constitutes deferred compensation within the meaning of Section 409A of the

Code unless, and solely to the extent that, such accelerated payment or settlement is permissible under Section 1.409A-3(j)(4) of the Treasury Regulations. If a Participant is a "specified employee" (within the meaning of Section 1.409A-1(i) of the Treasury Regulations) at any time during the twelve (12)-month period ending on the date of his termination of employment, and any Award hereunder subject to the requirements of Section 409A of the Code is to be satisfied on account of the Participant's termination of employment, satisfaction of such Award shall be suspended until the date that is six (6) months after the date of such termination of employment.

(v) Payments. Participants shall be required to pay, to the extent required by applicable law, any amounts required to receive Common Shares under any Award made under this Plan.

* * *

As adopted by the Board of Directors of HedgePath Pharmaceuticals, Inc. on July 18, 2014.