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

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2013

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to _____

Commission file number 001-13467

HedgePath Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**30-0793665**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
324 S. Hyde Park Avenue Ste. 350 Tampa, FL	**33606**
(Address of principal executive offices)	**(Zip Code)**

Issuer's telephone number: 813-864-2559

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of exchange on which registered**
None	**n/a**

Securities registered pursuant to Section 12(g) of the Act: Common stock, par value $.0001

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) Yes ☐ No ☒

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 28, 2013 was approximately $152,743 based on the closing sale price of the company's common stock on such date of $0.03 per share, as reported by the OTC Markets Group, Inc.

As of April 11, 2014, there were 18,888,971 shares of company common stock issued and outstanding.

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HedgePath Pharmaceuticals, Inc.

Annual Report on Form 10-K

For the fiscal year ended December 31, 2013

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Unless we have indicated otherwise, or the context otherwise requires, references in this Report to "HPPI," ,"CBI", the "Company," "we," "us" and "our" or similar terms refer to HedgePath Pharmaceuticals, Inc., a Delaware corporation.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report and the documents we have filed with the SEC that are incorporated by reference herein contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, that involve significant risks and uncertainties. Any statements contained, or incorporated by reference, in this Report that are not statements of historical fact may be forward-looking statements. When we use the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" and other similar terms and phrases, including references to assumptions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by those 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 current 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.

The foregoing does not represent an exhaustive list of risks that may impact upon the forward-looking statements used herein or in the documents incorporated by reference herein. Please see "Risk Factors" for additional risks which could adversely impact our business and financial performance and related forward-looking statements.

Moreover, new risks regularly emerge and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Report are based on information available to us on the date hereof. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Report and the documents we have filed with the SEC.

PART I

Item 1. Description of Business.

Overview

Pre-Bankruptcy and Emergence from Bankruptcy

Our predecessor, Commonwealth Biotechnologies, Inc. (which we refer to as CBI) was founded as a Virginia corporation in 1992, and completed an initial public offering in October 1997. Its business model was providing, on a contract basis, specialized life sciences services to the pharmaceutical and biotechnology sector.

On January 20, 2011, CBI filed a voluntary petition in the Bankruptcy Court for the Eastern District of Virginia seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code (or the Bankruptcy Code). The Chapter 11 case was captioned *In re Commonwealth Biotechnologies, Inc.*, Case No. 11-30381-KRH. On January 4, 2013, CBI filed an Amended Plan of Reorganization (or the Plan) with the Bankruptcy Court. The Plan was approved by a vote of creditors and CBI stockholders on March 21, 2013. Hedgepath, LLC, a Florida limited liability company and a significant stockholder of our company of which our current Executive Chairman acts as manager, was the winning bidder for CBI (which is sometimes referred to herein as HPPI in its capacity as the reorganized company, after giving effect to the consummation of the transactions contemplated by the reincorporation merger and acquisition). CBI received an auction fee of $30,000 from Hedgepath, LLC in addition to an agreement to contribute certain assets related to our current business of commercializing innovative therapeutics for patients with cancer using the approved pharmaceutical itraconazole (or the Itra Business Opportunity), as further described below.

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

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

The assets contributed to our company by Hedgepath, LLC related to the Itra Business Opportunity consisted of the following:

(i) U.S. Provisional Patent Application 61-813,122, "Prostate-Specific Antigen as Biomarker for Hedgehog Pathway Inhibitor Treatment and Prognostic Monitoring of Prostate Cancer" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

(ii) U.S. Provisional Patent Application 61-813,823, "Treatment and Prognostic Monitoring of Cancer Using Hedgehog Pathway Inhibitors" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

(iii) Assignment of Patents, dated November 1, 2012, by Dr. Frank E. O'Donnell, Jr. in favor of Hedgepath, LLC;

(iv) Assignment of Patents, dated November 1, 2012, by Nicholas J. Virca in favor of Hedgepath, LLC;

(v) Consulting Agreement, dated and effective as of September 1, 2012, by and between HPPI (as successor to Hedgepath, LLC) and Emmanuel Antonarakis, MD ("Antonarakis").

(vi) Confidentiality and Intellectual Property Assignment Agreement, dated and effective September 1, 2012, between Antonarakis and HPPI (as successor to Hedgepath, LLC), which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Antonarakis under such agreement.

(vii) Consulting Agreement, effective as of April 11, 2013, by and between Hedgepath, LLC and Arianne Consulting, Inc. ("Arianne"); and

(viii) Confidentiality and Intellectual Property Assignment Agreement, dated and effective April 11, 2013, between Arianne and Hedgepath, LLC , which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Arianne under such agreement.

The Contribution Agreement was entered into to carry out the purposes and intent of the Plan filed by CBI and confirmed by the Bankruptcy Court in connection with the Chapter 11 case.

As part of the Contribution Agreement, Hedgepath, LLC, which owned a certain claim against CBI in the amount of $52,500, payable to a third party service provider, contributed such claim to our company. HPPI has agreed to issue to such service provider a number of restricted shares of its Common Stock to be determined based on the valuation of the shares to be issued to purchasers in

connection with HPPI's planned $5 million offering of securities as described in the Plan. Such shares of Common Stock are to be issued to such service provider within five (5) business days of the final determination of such valuation (as memorialized in the final transaction documentation for such offering).

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

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

Prior to such transactions, CBI was a shell company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, having been subject to bankruptcy proceedings and with no operations. CBI formally emerged from Chapter 11 bankruptcy following the consummation of such transactions, which satisfied the final condition to effectiveness of the Plan.

Current Business of HPPI

We are currently a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer. We are currently focused on the development of therapies for a variety of cancers, with initial emphasis on skin, prostate and lung cancers in the U.S. market, based upon the use of SUBA™-Itraconazole, a patented, more bioavailable formulation of the currently marketed drug itraconazole, which we have licensed from Mayne Pharma International Pty Ltd. ("Mayne Pharma"). Mayne Pharma will also act as our supplier of SUBA-Itraconazole (see "Manufacturing and Product Supply and Relationship with Mayne Pharma" below for more information).

We believe that SUBA-Itraconazole could affect the Hedgehog signaling pathway in cells, a major regulator of many fundamental cellular processes, which could in turn impact the development and growth of certain cancers. Itraconazole is approved for and extensively used to treat anti-fungal infections and has a significant history of safe and effective use in humans. We have developed, and have optioned and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole and have applied for patents to cover our inventions.

The Hedgehog Pathway

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

We believe that the targeted inhibition of Hedgehog signaling may be effective in the treatment and prevention of many types of human cancers. We also believe that the discovery and synthesis of specific Hedgehog pathway inhibitors may have significant clinical implications regarding the development of novel cancer therapies. Several synthetic Hedgehog antagonists are now being studied, some of which are undergoing clinical evaluation. The orally available compound, GDC-0449 (vismodegib, developed by Genentech, Inc., a subsidiary of Roche), is the first Hedgehog inhibitor based-therapy that has been approved for treatment of advanced stages of basal cell carcinoma by the U.S. Food and Drug Administration ("FDA").

Repurposing Itraconazole for Treating Cancer

We are implementing clinical and regulatory plans to enable the repurposing of itraconazole for the treatment of a variety of cancers. This strategy is intended to significantly reduce the risk and time to potential FDA approvals for marketing in the United States. Initial target applications include therapies for prostate, lung and skin cancers, among others.

Itraconazole appears to have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of ongoing research. These anti-cancer effects have been demonstrated in various animal models and, subsequently in human studies over the last few years, all of which are the basis of our interest in the clinical development of itraconazole for treatment of human cancers.

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

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

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

Basal Cell Carcinoma

SUBA-Itraconazole may offer a significant alternative therapy to Genentech's drug, vismodegib, for treatment of advanced basal cell carcinoma (known as BCC). Vismodegib is the first FDA-approved Hedgehog inhibitor based-therapy, yet has many reported toxicities and is associated with serious side effects that result in suspension of chronic dosing. As a result, basal cell tumors reoccur and patients are faced with the choice of returning to vismodegib therapy or, if possible, surgical alternatives. The SUBA-Itraconazole formulation of itraconazole may prove to be a more acceptable therapy for a larger number of patients or considered as a therapy which could easily be alternated with vismodegib, especially for patients with advanced disease. Additionally, recent reports indicate that vismodegib has led to resistance in some BCC patients, so use of itraconazole as an alternative therapy in this sub-population of patients could prove to be very useful for long term oral drug therapy. SUBA-Itraconazole treatment of advanced BCC patients and patients with Gorlin Syndrome (a genetic disease which causes chronic BCC tumors) may qualify for orphan drug status, an FDA designation that expedites review of drugs for the treatment of diseases that have relatively small patient populations.

Lung Cancer

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

Prostate Cancer

Itraconazole has already been tested as a treatment for men with metastatic castrate resistant prostate cancer in a multi-institutional Phase II trial led by Johns Hopkins University and completed in 2011 and published in 2013, which showed that, at a specified dose, there was a significant correlation to slowing the progression of cancer and extending survival. Based on those encouraging results in metastatic disease, we are planning to test SUBA- Itraconazole in high-risk men with non-metastatic prostate cancer (who are castrate resistant, either based upon drug therapy or surgery) to study the effect of itraconazole therapy in delaying metastases. There is no currently approved drug therapy for these patients and yet they are treated with drugs designed for metastatic disease on an "off-label" basis. We believe this is a significant opportunity for us since we are offering a non-toxic, non-androgen dependent small molecule therapy to a very large population of patients. Therapy with SUBA-Itraconazole may offer great promise for delaying the use of, and associated side-effects due to those Androgen Deprivation Therapy (ADT) Drugs which are formulated to lower testosterone levels but are intended for metastatic disease treatment.

Our Strategy

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

- *Rapidly Advance the Clinical Development of Our Therapies.* With the history of safe use of itraconazole in humans for anti-fungal indications, we believe we can bypass each of the required pre-clinical animal studies for toxicity and Phase I human trials to establish safety, and therefore move directly into Phase II human trials. We intend to apply for Investigational New Drug (or IND) approval for SUBA-Itraconazole for the treatment of cancer as a disease category, and thereafter file individualized clinical trial protocols for each of our target cancer indications in order to have the ability to initiate our clinical trials in parallel.
- *Seek FDA Programs to Expedite Drug Approvals.* The FDA has various programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. These expedited programs help ensure that therapies for serious conditions are available as soon as it can be concluded that the therapies' benefits justify their risks, taking into account the seriousness of the condition and the availability of alternative treatments. These programs include breakthrough therapy designation, fast track designation, accelerated approval, and priority review. We believe that SUBA-Itraconazole for the treatment of cancer may qualify for one of these designations, which could help expedite the regulatory review process.

- *Commercialize and Market with Exclusivity.* We are currently preparing for the clinical testing of SUBA-Itraconazole for treatment of cancer in order to later seek FDA approvals based upon its efficacy for this new indication. We have developed 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:

- partnering with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- 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;
- receiving government or private foundation grants which would be awarded to us to further develop our current and future anti-cancer therapies; and
- securing proceeds from public and private financings and other strategic transactions.

Background on Cancer

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

Cancer is the second leading cause of death in the United States, exceeded only by heart disease. The American Cancer Society estimates that in 2013 there will be approximately 1.6 million new cases of cancer and approximately 580,000 deaths from cancer in the United States.

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

Cytotoxic Chemotherapies. The earliest approach to pharmacological cancer treatment was to develop drugs, referred to as cytotoxic drugs, which kill rapidly proliferating cancer cells through non-specific mechanisms, such as disrupting cell metabolism or causing damage to cellular components required for survival and rapid growth. While these kinds of drugs have been effective in the treatment of some cancers, many unmet medical needs for the treatment of cancer remain. Also, cytotoxic drug therapies act in an indiscriminate manner, acting upon the metabolism of healthy as well as cancerous cells. Due to their mechanism of action, many cytotoxic drugs have a narrow dose range above which the toxicity causes unacceptable or even fatal levels of damage and below which the drugs are not effective in eradicating cancer cells.

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

Oncogenic Therapies. A more recent approach to pharmacological cancer treatment is to develop drugs that affect the drivers that cause uncontrolled growth of cancer cells because of a specific genetic alteration. In some cases, these agents were identified as therapeutics without knowledge of the underlying genetic change causing the disease. To date, the shortcoming of this research

approach has been that it often follows a conventional trial and error approach to drug discovery. In this approach, clinical development involves the treatment of large populations from which a defined subpopulation that responds to treatment is identified. As a result, this approach can be time-consuming and costly, with success often uncertain. Another major concern of these newly discovered drugs, some of which have been recently approved, is that resistance to them occurs as the cancer finds new ways to circumvent the genetic pathway.

The Itraconazole Approach to Treating Cancer

We are focusing our developments on Hedgehog pathway inhibitor therapeutics for patients with certain cancers, including skin, lung and prostate cancers. Our initial product candidate is itraconazole, which has exhibited anti-cancer properties in human trials and therefore, based on pre-clinical research regarding specific indicators of Hedgehog pathway inhibition, we believe has compelling evidence of being a potential Hedgehog inhibitor for treatment of cancer in humans. We have obtained an exclusive rights to use and develop SUBA-Itraconazole, a patented, more bioavailable formulation of the currently marketed drug itraconazole, which we have licensed from Mayne Pharma through an exclusive Supply and License Agreement,

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

Cancer and Hedgehog Inhibitors. The Hedgehog (also known as Hh) proteins comprise a group of secreted proteins that regulate cell growth, differentiation and survival. They are involved in organogenesis (the formation of organs), and have been shown to promote adult stem cell proliferation. Inappropriate activation of the Hh signaling pathway has been implicated in the development of several types of cancers including prostate, lung, pancreas, breast, brain and skin. Hedgehog pathway inhibitors are a relatively new class of therapeutic agents that act by targeting the proteins involved in the regulation of the Hh pathway. Many of these newly discovered inhibitors are currently undergoing preclinical testing and some have entered clinical studies as anti-cancer agents for a variety of cancers.

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

Intellectual Property

We strive to protect the intellectual property that we believe will be important to our business, including seeking our own patent protection (or seeking licenses to patents) intended to cover the composition of matter of our product candidate, its methods of use, related technology and other inventions that are important to our business. As part of the acquisition, we have acquired from Hedgepath, LLC the following two provisional patents related to Hedgehog pathway inhibitors via an assignment of patents underlying these provisional patents from each Dr. Frank E. O'Donnell, Jr. our executive chairman and director, and Nicholas J. Virca, our president, chief executive officer and director:

- U.S. Provisional Patent Application 61-813,122, "Prostate-Specific Antigen as Biomarker for Hedgehog Pathway Inhibitor Treatment and Prognostic Monitoring of Prostate Cancer" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors).
- U.S. Provisional Patent Application 61-813,823, "Treatment and Prognostic Monitoring of Cancer Using Hedgehog Pathway Inhibitors" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors).Under United States patent law, a provisional application is a legal document filed in the United States Patent and Trademark Office (or USPTO), that establishes an early filing date, but which does not mature into an issued patent unless the applicant files a regular non-provisional patent application within one year, which we are currently working on. A provisional application includes a specification, i.e. a description, and drawing(s) of an invention but does not require formal patent claims, inventors' oaths or declarations or any information disclosure statement. A provisional application can establish an early effective filing date in one or more continuing patent applications later claiming the priority date of an invention disclosed in earlier provisional applications by one or more of the same inventors.

Additionally, the following Patent Application, filed by Hedgepath, LLC and dated February 5, 2014 was received by the USPTO on March 10, 2014 and also assigned to HPPI:

- US Patent Application Serial # 14/173,588, “Treatment and Prognostic Monitoring of Proliferation Disorders Using Hedgehog Pathway Inhibitors” (assigned to HedgePath Pharmaceuticals, Inc., Dr. Frank E. O’Donnell, Jr and Nicholas J. Virca, as inventors).

We will also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We also intend to obtain an option for exclusive rights from a leading US research institution (with rights to sublicense) related to the selection and monitoring of patients for cancer therapy while being treated with itraconazole.

Our viability as a company (including our ability to test, develop and ultimately commercialize itraconazole for the treatment of cancer) will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, methods, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also will rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of anti-cancer therapy.

A third party may hold intellectual property, including patent rights, which are important or necessary to the development of our products or therapies. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products or therapies, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. For example, some of the possible formulations of itraconazole include components covered by patents held by third parties. Although we believe that licenses to these patents are available from these third parties on commercially reasonable terms, if we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

We also plan to continue to expand our intellectual property estate by filing patent applications directed to dosage forms, methods of treatment, therapies for other cancers and additional Hedgehog inhibitor compounds and their derivatives.

Manufacturing and Product Supply and Relationship with Mayne Pharma

We are in the early stages of development and thus we do not have any production facilities or manufacturing personnel. We currently have a supply and license agreement in place with Mayne Pharma for the patented formulation of itraconazole, SUBA-Itraconazole. The agreement provides for the supply to HPPI of specially formulated capsules of SUBA-Itraconazole, manufactured by Mayne Pharma under cGMP (current good manufacturing practice) standards, for use by HPPI in its anticipated clinical trials, and for the future exclusive commercial supply following FDA approvals, if obtained.

On September 3, 2013, we entered into an exclusive Supply and License Agreement with Mayne Pharma (which was subsequently amended) pursuant to which Mayne Pharma has agreed to: (i) supply us with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being prostate, lung and skin cancer) in the United States, (ii) provide us with an exclusive license to use and develop the intellectual property related to SUBA-Itraconazole for the treatment of cancer in the United States and (iii) participate in a joint development committee with us (or JDC) to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States.

Pursuant to the Supply and License Agreement, we will develop and exploit SUBA-Itraconazole through a development plan which will be authorized by the JDC and updated as necessary. The license granted to us under the Supply and License Agreement may only be assigned or sub-licensed with the prior approval of Mayne Pharma. In addition, in support of the exclusive nature of the Supply and License Agreement, during the term, Mayne Pharma is prohibited from directly or indirectly importing, promoting, marketing, distributing or selling SUBA-Itraconazole for the treatment of cancer in the United States. If any other form of the SUBA-Itraconazole manufactured by Mayne Pharma is sold as a result of any off label use, we shall be entitled to a royalty on such off-label sales. Further, we may not develop products that are competitive with SUBA-Itraconazole for the treatment of cancer, which period extends for a certain period following the end of the term.

Under the Supply and License Agreement, we are responsible for obtaining all of our requirements for SUBA-Itraconazole from Mayne Pharma, including for use in clinical trials, importation, promotion, marketing, sale and distribution in the United States. We and Mayne Pharma have established certain minimum floor prices that we must pay per unit of SUBA-Itraconazole and minimum order quantities for SUBA-Itraconazole.

Any intellectual property created by us, either on its own or jointly with Mayne Pharma, relating to SUBA-Itraconazole for the treatment of cancer will be owned by us, except that we have granted Mayne Pharma an exclusive, perpetual, irrevocable, royalty free license to copy and exploit such developed intellectual property outside of the United States.

Although the Supply and License Agreement was effectively immediately, it remains subject to early termination by Mayne Pharma if certain conditions (the Conditions) are not met by April 25, 2014 (originally December 16, 2013 but subsequently extended). Such Conditions include: (i) we shall have raised $5 million in an equity financing (or such lesser amount as may be agreed to by Mayne Pharma) (which we refer to as the Equity Financing); (ii) a representative of Mayne Pharma shall have been appointed to our board of directors, and we shall have entered into an agreement granting Mayne Pharma certain board appointment rights; (iii) Mayne Pharma shall, pursuant to customary definitive documentation to be negotiated by the parties, acquire from us, as part of the consideration under the Supply and License Agreement, certain shares of our Series A Preferred Stock, par value $0.0001 per share (the Series A Preferred Stock), representing, on an as fully converted, fully diluted basis, 45% of the issued and outstanding shares of capital stock of our company (prior to the Equity Financing and the anticipated adoption by the Company of an equity incentive plan); (iv) Hedgepath, LLC, Nicholas J. Virca (our President and Chief Executive Officer) ("Virca") and Mayne Pharma shall have entered into an agreement providing for certain restrictions on transfers and ownership of equity in our company; (v) we and Mayne Pharma shall have entered into an agreement granting Mayne Pharma and accredited investors introduced to us by Mayne Pharma certain participation rights in future Company equity financings; and (vi) Virca and Frank E. O'Donnell, Jr., our Executive Chairman, shall have entered into customary agreements regarding their positions with the Company.

On March 5, 2014, we and Mayne Pharma amended the Supply and License Agreement to add the following additional Conditions: (i) we and Mayne Pharma acknowledged and agreed that if warrants are issued in connection with an Equity Financing, Mayne Pharma will receive a warrant on the same terms as the warrants issued in the Equity Financing for such a number of shares that will ensure that Mayne Pharma will hold at least 30% of the issued and outstanding shares of capital stock of our company on a fully diluted, fully converted basis following the Equity Financing; (ii) we and Mayne Pharma shall have entered into an agreement that if we do not (A) submit a complete IND application to the FDA for SUBA-Itraconazole for at least one cancer indication and commence dosing patients in at least two phase II or phase II/III clinical trials across at least two indications in cancer by March 31, 2015 or (B) submit an application for an NDA to the FDA for at least one cancer indication by March 31, 2016, then Mayne Pharma may, by notice to Frank E. O'Donnell, Jr. M.D. and Virca, require each of them to resign from their positions with the company, in which case each of Hedgepath LLC, Mr. Virca and Dr. O'Donnell will forfeit all of their respective unvested options in our company, and Mayne Pharma will have the right to purchase all issued and outstanding shares of our company's capital stock held by Mr. Virca and Dr. O'Donnell at market price, and neither Mr. Virca nor Dr. O'Donnell will be entitled to receive any severance or similar payments from our company; (iii) we and Mayne Pharma shall have entered into an agreement that in the event that Dr. O'Donnell or Mr. Virca are removed or resign from our board of directors, any replacement appointees will need to obtain unanimous approval from the remaining board members.

Subject to earlier termination if the Conditions are not met as described above, the term of the Supply and License Agreement shall last until the later of: (i) 10 years from the date of the first commercial sale of the Product for the treatment of human patients with cancer via oral administration or (ii) the date on which all issued patents of Mayne Pharma or any of its affiliates referred to in the Supply and License Agreement have lapsed or expired.

The Supply and License Agreement is further subject to termination in certain circumstances, including: (i) by either party in the event of (a) a material default that is not cured within a specified number of days after notice is received or is not capable of remedy, (b) if marketing authorizations for SUBA-Itraconazole are not obtained prior to the agreed upon target launch date for SUBA-Itraconazole or (c) a force majure event precluding performance by the other party for a specified period of time, (ii) the voluntary or involuntary bankruptcy of either party, (iii) by Mayne Pharma if either Hedgepath LLC or Virca breach their respective agreements with Mayne Pharma to restrict the sale and or transfer of their shares our company equity and such breach is not cured within a specified number of days after notice is received or such breach is not capable of remedy, (iv) by Mayne Pharma if we breach certain of its obligations relating to the Conditions (once they are satisfied) and such breach is not cured within a specified number of days after notice is received or such breach is not capable of remedy, (v) by Mayne Pharma if, under certain circumstances, we fail to purchase the minimum agreed upon amounts of SUBA-Itraconazole in any given year or (vi) by Mayne Pharma, under certain circumstances, upon a change of control of our company.

Sales and Marketing

We are in the early stages of development and thus have not yet established a sales, marketing or product distribution infrastructure because our product candidate is still in clinical development. We may either license commercialization rights to our product candidate to larger third party partners, who will be responsible for sales, distribution and marketing efforts, or we may (assuming adequate resources are available) retain commercial rights for our product candidate, in which case we would seek to access the oncology market through a focused, specialized sales force of our own or in conjunction with a marketing partner under a co-promotion agreement.

Competition

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

Below are some examples of companies seeking to develop potentially competitive anti-cancer therapies or related products, though the examples are not all-inclusive. Many of these entities have significantly greater research and development capabilities than do we, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' research, financial, marketing, manufacturing and other resources. Such potential competitive anti-cancer therapies may ultimately prove to be safer, more effective or less costly than any product candidates that we are currently developing or may be able to develop. Additionally, our competitive position may be materially affected by our ability to develop or commercialize our drugs and technologies before any such competitor. Other external factors may also impact the ability of our products to meet expectations or effectively compete, including pricing pressures, healthcare reform and other government interventions.

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

Names	Company	Description	Status
Taxotere® docetaxel	Sanofi-Aventis	Anti-tumor agent for MCRPC and late-stage NSCLC	Approved 2004; and new generics
Jevtana® cabazitaxel	Sanofi-Aventis	MCRPC following docetaxel failure	Approved 2010
Provenge® sipuleucel-T	Dendreon	Immunotherapy for asymptomatic MCRPC	Approved 2010
Zytiga® aberaterone	Janssen Biotech	Androgen synthesis inhibitor for MCRPC	Approved 2011
Xtandi® enzalutamide	Astellas	Androgen receptor inhibitor for MCRPC previously on docetaxel	Approved 2012
Erivedge® vismodegib	Roche Genentech	Hedgehog inhibitor for advanced BCC and Gorlin Syndrome	Approved 2012
LDE225 - erismodegib	Novartis	Hedgehog inhibitor for advanced BCC and Gorlin Syndrome	mid to late stage clinical trials
Avastin® bevacizumab	Genentech	angiogenesis inhibitor for NSCLC except squamous cell lung cancer	Approved for multiple cancers since 2004
Gemzar® gemcitabine	Lilly	Cytotoxic chemotherapy agent for NSCLC in combination with platinum drugs	Approved for multiple cancers since 1996
Trexall® methotrexate	Teva	Antimetabolite therapy to slow cancer cell growth	Approved before 1984
Tarceva® erlotinib		Epidermal growth factor inhibitor treatment for NSCLC - maintenance therapy after chemo or metastatic disease after chemo	Approved in 2013
Xalkori® crizotinib	Pfizer	Selective inhibitor for late-state NSCLC patients who express the ALK gene	Approved in 2011

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

Government Regulation and Product Approval

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

United States Government Regulation

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (or IRB) at each clinical site before each trial may be initiated;
- performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices (or cGMP) and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance; and
- FDA review and approval of the NDA.

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

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

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

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase I, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase II, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase III, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. As mentioned previously, we intend to move directly into Phase II trials with SUBA-Itraconazole for our targeted anti-cancer indications based upon the previous, well-established safety profile of itraconazole use in humans for treatment of anti-fungal indications and based upon the previous human data regarding the use of itraconazole for anti-cancer indications such as basal cell carcinoma, lung cancer and prostate cancer.

Marketing Approval. Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (or PDUFA) guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application.

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

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA typically refers a question regarding a novel drug to an external advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including

Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS (Risk Evaluation Mitigation Strategy) which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

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

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

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

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

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

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

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations

from cGMP and impose reporting and documentation requirements upon the sponsor and any third party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

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

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

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

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

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

Exclusivity and Approval of Competing Products

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

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

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

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

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed drug. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA.

The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

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

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

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals annually in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. We intend to seek orphan drug designation and exclusivity for our product candidate which may include advanced basal cell carcinoma, Gorlin syndrome and stage IV non-squamous, non-small cell lung cancer.

Foreign Regulation

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

Employees

As of April 11, 2014, we have 2 full-time employees and 2 part-time employees. One is involved in our clinical development program and operations and three handle our administration and accounting. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our clinical development and administrative functions. We consider relations with all of our employees to be good. Each of our employees has entered into confidentiality, intellectual property assignment and non-competition agreements with us.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (which we refer to herein as the Exchange Act), are filed with the SEC. Such reports and other information that we file with the SEC are available free of charge on our website at http://www.hedgepathpharma.com/#!investor-relations/ctts when such reports are available on the SEC website. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. The contents of these websites are not incorporated into this filing. Further, the foregoing references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before purchasing our common stock, you should carefully consider the following risk factors as well as all other information contained in this Report, including our consolidated financial statements and the related notes. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Relating to Our Business

We are a clinical stage biopharmaceutical company and are thus subject to the risks associated with new businesses.

We only recently emerged from bankruptcy, and the business opportunity we acquired in connection with our reorganization (the development of itraconazole anti-cancer therapies) is a new business opportunity. As such, we are a clinical stage biopharmaceutical company with no history of revenue-generating operations, and our only assets consist of the intellectual property and related assets contributed to us by Hedgepath, LLC on August 13, 2013. 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 many important functions necessary to operate a business, including acquiring additional intellectual property rights related to itraconazole beyond our exclusive Supply and License Agreement with Mayne Pharma for SUBA-Itraconazole, establishing our managerial and administrative structure, continuing product and technology development 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 that our business plan 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 potentially 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 clinical stage 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 transaction 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 only recently acquired the assets related to this business opportunity on August 13, 2013 as part of our emergence from bankruptcy. Our pre-bankruptcy historic business operations ceased contemporaneously with our becoming subject to bankruptcy proceedings in 2011, and all assets supporting our earlier lines of business have been disposed of. Accordingly, we only recommenced active operations on August 13, 2013, the date we emerged from bankruptcy.

Moreover, Hedgepath, LLC, from whom we acquired the itraconazole business opportunity as part of our plan of bankruptcy reorganization, was only formed in late 2011 and thus itself has a limited operating history. Our operations are presently limited to organizing and staffing our company, business planning, arranging for the raising of capital, developing our technology, identifying potential commercial partners and planning for clinical trials. 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.

Under our Supply and License Agreement with Mayne Pharma, we have secured license rights to the SUBA-Itraconazole technology for the indication of cancer in the United States, and under such agreement, expect to obtain all required supply of SUBA-Itraconazole for our clinical trials. As such, this agreement and our collaboration with Mayne Pharma are critical to our business. Among other rights, Mayne Pharma has the right to terminate the Supply and License Agreement if the Conditions are not met by April 25, 2014 or such date as agreed to by the parties. We are seeking to fulfill such Conditions, but we may be unable to do so. If our agreement with Mayne Pharma were terminated, our business plan and prospects would be materially impaired and our business might fail.

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 Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca. We believe that our ability to effect our business plans depends on the continued service of our officers and directors. Our officers and directors are not presently required to commit any specified amount of time to our affairs and, accordingly, 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 not presently have an employment agreement with or key-man insurance on the life of, any of our directors or officers. 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, the Itra 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 (and the Itra Business Opportunity we will operate will be) subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (which we refer to herein as the Exchange Act), the Sarbanes-Oxley Act, the Dodd-Frank Act and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities (including activities previously undertaken in a private company context) more difficult, time-consuming or costly and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our ability to implement our business plans. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

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

Our officers, directors, security holders and their respective affiliates may have competitive pecuniary interests that conflict with our interests.

We have not adopted a policy that expressly prohibits our directors, officers, security holders or affiliates from having a direct or indirect pecuniary interest in any investment to be acquired or disposed of by us or in any transaction to which we are a party or have an interest. Furthermore, we do not have a policy that expressly prohibits any such persons from engaging for their own account in business activities of the types conducted by us. Accordingly, such persons or entities may have a conflict between their interests and ours, and those conflicts may not be resolved in our favor.

Risks Related to Our Financial Position and Need For Additional Capital

We will require substantial additional funding. 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.

We currently have no cash resources, and have relied on loans from our insiders and affiliates to fund our operations. We therefore must raise funds as soon as possible in order to operate our business. In addition, we are required to raise at least $5 million under our agreement with Mayne Pharma, and our failure to do so could lead to a termination of that key collaboration.

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

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

- the progress and results of our development efforts for itraconazole as a cancer therapy;
- the costs, timing and outcome of clinical trials of our product candidate for one or more types of cancer;
- the costs, timing and outcome of regulatory review of our product candidate for one or more types of cancer;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- competing technological and market developments;
- market acceptance of our product candidate as a treatment for one or more types of cancer;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidate for which we receive marketing approval;
- the revenue, if any, received from commercial sales of any product candidate for which we may receive marketing approval;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

Developing pharmaceutical products, conducting preclinical testing and clinical trials and seeking regulatory approval of such products is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidate, if approved (of which no assurances may be given), may not achieve any level 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 many 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.

Our company does not generate any revenue from product sales or otherwise, and we therefore have no current source of cash to meet our future capital requirements. We may not be able to raise funds, 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 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 sufficient 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.

We do not currently have any financing arrangements in place as a source of funds, and 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 candidate products, 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 current lack of financial liquidity, our auditors' report for our 2013 financial statements, which are included as part of this Report, contains a statement concerning our ability to continue as a "going concern." Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

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

Risks Related to the Clinical Development of Our Product Candidate

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

We are very early in our development efforts and have only one product candidate, namely SUBA-Itraconazole for the treatment of cancer. While itraconazole has previously been approved 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 have not engaged in any such testing ourselves, since our operations to date (as undertaken by HPPI) has 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 a cancer therapy.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the development and eventual commercialization of 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 regulatory exclusivity for our product candidate and protecting our rights in our intellectual property portfolio;
- maintaining our arrangement 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;
- 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.

If we are unable to convince physicians as to the benefits of SUBA-Itraconazole as a cancer therapy, we may incur delays or additional expense in our attempt to establish market acceptance.

Use of SUBA-Itraconazole as a cancer therapy will require physicians to be informed regarding the intended benefits of the product for a new indication. The time and cost of such an educational process may be substantial. Inability to carry out this physician education process may adversely affect market acceptance of SUBA-Itraconazole as a cancer therapy. We may be unable to timely educate physicians in sufficient numbers regarding our intended application of SUBA-Itraconazole to achieve our marketing plans or to achieve product acceptance. Any delay in physician education or acceptance may materially delay or reduce demand for our product candidate. In addition, we may expend significant funds toward physician education before any acceptance or demand for SUBA-Itraconazole as a cancer therapy is created, if at all.

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

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

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- clinical trials of our product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, which would be time consuming and costly;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of materials necessary to conduct clinical trials of our product candidate may be insufficient or inadequate; and
- 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.

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 whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidate or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate and may harm our business and results of operations.

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

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

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;

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

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

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

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

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

Because we have limited financial and managerial resources, we will focus for the foreseeable future only on the clinical development of SUBA-Itraconazole for the treatment of cancer. As a 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 will 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.

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

- collaborators may not perform their obligations as expected;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of our product candidate, might lead to additional responsibilities for us with respect to such product candidate, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators could independently develop or be associated with products that compete directly or indirectly with our product candidate;
- collaborators could have significant discretion in determining the efforts and resources that they will apply to our arrangements with them;
- should our product candidate achieve regulatory approval, a collaborator with marketing and distribution rights to our product candidate may not commit sufficient resources to the marketing and distribution of such product;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- 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 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. 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.

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 need to do so. Even though we have established an agreement with Mayne Pharma or if we are able to establish agreements with other third party manufacturers, reliance on third party manufacturers entails additional risks, including:

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

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

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

Also, any performance failure on the part of Mayne Pharma could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If Mayne Pharma cannot perform as agreed, we may be required to replace such manufacturers, which would lead to added costs and delays in identifying and qualifying any such replacement.

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 like 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 itraconazole for the treatment of cancer, if approved for commercial sale, will depend on a number of factors, including:

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

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

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

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

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

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

If we are unable to 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 by filing patent applications in the United States related to our novel technologies and product candidate and 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.

Recent 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 recently developed new 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, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

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

Competitors may infringe our issued 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. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

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

We have and/or expect to enter into licenses with third parties that hold intellectual property, including patent rights, that are important or necessary to the development of itraconazole, and SUBA-Itraconazole in particular, as an anti-cancer therapy, and it may be necessary for us to use the patented or proprietary technology of third parties, such as Mayne Pharma, to commercialize

itraconazole as an anti-cancer therapy, in which case we have or would be required to obtain a license from these third parties on commercially reasonable terms, or else our business could be harmed, possibly materially. If we were not able to maintain or obtain such licenses, or were not able to maintain or obtain such licenses on commercially reasonable terms, our business could be harmed, possibly substantially.

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

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

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

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

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

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

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

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

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

Our product candidate (SUBA-Itraconazole as an anti-cancer therapy) and the activities associated with its clinical development and commercialization, including matters relating to design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA (including under the Federal Food, Drug and Cosmetic Act) and other regulatory agencies in the United States and by the European Medicines Agency (known as the EMA) and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product

candidate will prevent us from commercializing the product candidate. We have not received approval to market SUBA-Itraconazole as an anti-cancer therapy or any other product from regulatory authorities in any jurisdiction and it will likely be years before we are even eligible to receive such approval.

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

The process of obtaining marketing approvals in the United States is very expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

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

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

It is our intention to seek to avail ourselves of the FDA's 505(b)(2) approval procedure where it is appropriate to do so, particularly for SUBA-Itraconazole as an anti-cancer therapy since itraconazole has previously been approved for another indication. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act permits an applicant to file a NDA 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. 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 itraconazole as an anti-cancer therapy may be eligible for this designation, we cannot assure you that the FDA would decide to grant it should we apply for this designation. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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

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

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that 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.

We may seek but be unable to obtain orphan drug exclusivity for our product candidate. If our competitors are able to obtain orphan drug exclusivity for their products that are the same drug as our product candidate, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities may designate drugs for relatively small patient populations as orphan drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which, subject to certain exceptions, precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable market exclusivity period is seven years in the United States.

Obtaining orphan drug exclusivity for SUBA-Itraconazole as an anti-cancer therapy may be important to our commercial strategy. If a competitor obtains orphan drug exclusivity for and approval of a product with the same indication as our itraconazole product before we do, and if the competitor's product is the same drug or a similar medicinal product as ours, we could be excluded from the market. Even if we obtain orphan drug exclusivity for itraconazole as an anti-cancer therapy, we may not be able to maintain it. For example, if a competitive product that is the same drug or a similar medicinal product as our product candidate is shown to be

clinically superior to our product candidate, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. In addition, orphan drug exclusivity will not prevent the approval of a product that is the same drug as our product candidate if the FDA finds that we cannot assure the availability of sufficient quantities of the drug to meet the needs of the persons with the disease or condition for which the drug was designated. If one or more of these events occur, it could have a material adverse effect on our company.

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

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

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

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

- restrictions on such product, our manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of the product;
- restrictions of product distribution use;
- requirements to conduct post-marketing studies or clinical trials;
- the need to utilize warning letters;
- suspension or withdrawal of marketing approvals;
- withdrawal of the product from the market or product recalls;
- refusal by regulatory authorities to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenues;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

Risks Related to Our Securities

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

As we only recently emerged from bankruptcy 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 Over-the-counter bulletin board (or OTCBB) and 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 OTCBB and OTCQB markets are relatively unorganized, inter-dealer, over-the-counter markets that provide significantly less liquidity than NASDAQ or the NYSE MKT (formerly known as the NYSE AMEX). In this event, there would be a highly illiquid market for our common stock and you may be unable 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 OTCBB and 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 OTC Bulletin Board or OTCQB inclusion, and therefore you may be unable to sell your shares.

Our common stock is eligible for quotation on the OTCBB and 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 OTCBB or 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 OTCBB and OTCQB, any quotation in our common stock could be conducted in the “pink sheets” market. As a result, a purchaser of our common stock may find it more difficult to dispose of, or to obtain accurate quotations as to the price of their shares. This would materially and adversely affect the liquidity of our securities.

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

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

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

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

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

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

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

Our 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 (the "Exchange Act"). Our common stock may be a "penny stock" if it meets one or more of the following conditions: (i) the stock trades at a price less than $5 per share; (ii) it is not traded on a "recognized" national exchange; or (iii) is issued by a company (such as ours) that has been in business less than three years with net tangible assets less than $5 million.

The principal result or effect of being designated a "penny stock" is that securities broker-dealers participating in sales of our common stock will be subject to the "penny stock" regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act. For example, Rule 15g-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor's account. Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to: (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in

penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

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

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

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

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

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

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

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. As we are a start-up company, we are at the very early stages of establishing, and we may be unable to effectively establish such systems. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially and adversely impact us.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We may be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for our fiscal year ended December 31, 2013. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC.

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 bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our certificate of incorporation and bylaws:

- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to thwart a takeover attempt;
- provide that vacancies on our board of directors, including newly created directorships, may be filled only by a majority vote of directors then in office;
- provide that special meetings of stockholders may only be called by our Chairman and/or President, our board of directors or a super-majority (66 2/3%) of our stockholders;
- place restrictive requirements (including advance notification of stockholder nominations and proposals) on how special meetings of stockholders may be called by our stockholders;
- do not provide stockholders with the ability to cumulate their votes; and
- provide that only a super-majority of our stockholders (66 2/3%) may amend our bylaws.

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 Report 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Description of Property.

Hedgepath, LLC has allocated space for our use in its offices in Tampa, Florida and San Diego, California, for which we currently do not pay rent.

Item 3. Legal Proceedings.

Fornova

On February 10, 2012, CBI filed a law suit against Fornova Pharmaworld, Inc. ("Fornova") in Bankruptcy Court, disputing the validity of the Fornova's claim and disputing that it was owed $500,000 plus accrued interest relating to a convertible note that was originated in 2007. CBI sought to have the claim disallowed in its entirety or, in the alternative, reclassified as an equity investment. In October 2012, the Bankruptcy Court disallowed Fornova's claim in its entirety. An appeal was taken by Fornova to the Federal District Court for the Eastern District of Virginia and that appeal was dismissed.

Chien

In April 2013, Mr. Andrew Chien ("Chien"), allegedly acting on behalf of Fornova, filed an adversary proceeding in the Bankruptcy Court seeking to recover monetary and injunctive relief against the CBI and against CBI's president, Richard J. Freer. On July 1, 2013 the Bankruptcy Court dismissed Mr. Chien's complaint. Mr. Chien appealed the Bankruptcy Court's ruling to the United States District Court for the Eastern District of Virginia, and this appeal was dismissed.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is listed for quotation on the OTCBB and OTCQB markets under the symbol "HPPI" (and we traded under "CBI" until September 12, 2013). The range of reported high and reported low sales prices per share for our common stock for each fiscal quarter during 2013 and 2012, as reported by the OTC Markets Group, is set forth below.

Quarterly Common Stock Price Ranges

Fiscal Year 2013, Quarter Ended:	High	Low
March 31, 2013	$0.10	$0.01
June 30, 2013	$0.12	$0.03
September 30, 2013	$0.20	$0.03
December 31, 2013	$0.18	$0.08

Fiscal Year 2012, Quarter Ended:	High	Low
March 31, 2012	$0.05	$0.01
June 30, 2012	$0.03	$0.02
September 30, 2012	$0.02	$0.02
December 31, 2012	$0.02	$0.01

As of April 11, 2014, we had approximately 49 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain earnings for further business development and do not expect to pay cash dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

There were no shares of common stock authorized for issuance under equity incentive plans as of December 31, 2013. All equity incentive plans have been cancelled pursuant to the emergence of bankruptcy in April 2013.

Item 6. Selected Financial Data.

We are a "smaller reporting company" as defined by Regulation S-K and as such, are not required to provide the information contained in this item pursuant to Regulation S-K.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those which are not within our control.

Background of Our Company

We are a clinical stage biopharmaceutical company that endeavors to discover, develop and commercialize innovative therapeutics for patients with certain cancers. We are currently focused on the development of therapies for certain cancers, with initial emphasis on skin, lung and prostate cancers in the U.S. market, based upon the use of the currently marketed anti-fungal drug itraconazole. We believe that, based on recent pre-clinical and clinical research, our licensed formulation of itraconazole, SUBA-Itraconazole, could affect the Hedgehog signaling pathway in cells, a major regulator of many fundamental cellular processes, which could, in turn, impact the development and growth of certain cancers.

Until August 2013, we were known as Commonwealth Biotechnologies, Inc. CBI was a specialized life sciences outsourcing business that offered certain peptide-based discovery chemistry and biology products and services. In 2011, CBI filed a voluntary petition seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code. On January 4, 2013, CBI filed an Amended Plan of Reorganization with the Bankruptcy Court, which was subsequently approved by a vote of creditors and CBI stockholders on March 21, 2013. As part of CBI's reorganization under the Plan, Hedgepath, LLC contributed and assigned certain assets related to the Itra Business Opportunity in exchange for the right to receive 90% of fully diluted voting equity in HPPI (in the form of the Series A Preferred Stock) on the date of issuance, with the prior stockholders of CBI retaining approximately 10% voting equity in HPPI, represented by 100% of the issued and outstanding shares of Common Stock. Concurrently, we redomiciled our company from a Virginia corporation to a Delaware corporation.

Critical Accounting Policies and Estimates

Estimates

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

Revenue Recognition

We currently have no ongoing source of revenues. Any miscellaneous income is recognized when earned by us.

Cash and Cash Equivalents

We consider all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, we may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts.

Accounting for Enterprises in Reorganization

Financial Accounting Standards Board (" FASB") Accounting Standards Codification ("ASC") Topic 852—*Reorganizations* ("ASC Topic 852"), which is applicable to companies in Chapter 11, generally does not change the manner in which financial statements are prepared. However, it does require that the financial statements for periods subsequent to the filing of the Chapter 11 petition distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Revenues, expenses, realized gains and losses, and provisions for losses that can be directly associated with the reorganization and restructuring of the business must be reported separately as reorganization items in the statements of operations beginning in the quarter ending March 31, 2011. The balance sheet must distinguish prepetition liabilities subject to compromise from both those prepetition liabilities that are not subject to compromise and from post-petition liabilities. Liabilities that may be affected by a plan of reorganization must be reported at the amounts expected to be allowed by the Bankruptcy Court, even if they may be settled for lesser amounts. In addition, cash flows from reorganization items must be disclosed separately in the statement of cash flows. The Company became subject to ASC Topic 852 effective on January 20, 2011, and has segregated those items as outlined above for all reporting periods after such date. The Company officially emerged from bankruptcy on April 17, 2013, followed by the reincorporation merger, which satisfied the final condition to effectiveness of the Plan.

Results of Operations

For the Year Ended December 31, 2013 Compared to the Year Ended December 31, 2012

Chapter 11 Expenses. We recognized $117,324 in Chapter 11 expenses during the year ended December 31, 2013. Chapter 11 expenses consist solely of U.S. Trustee fees and legal fees relating to the Company's bankruptcy filing. There was no such expense during the corresponding period in 2012.

Research and Development Expenses. We recognized $1,065,169 in research and development expenses during the year ended December 31, 2013. There was no such expense during the corresponding period in 2012. Research and development expenses consist of the in-process research and development purchased with the issuance of the preferred shares to Hedgepath, LLC, and salaries related to clinical trial design and regulatory activities.

General and Administrative Expenses. We recognized $817,316 and $560,670 in general and administrative expenses during the years ended December 31, 2013 and 2012, respectively. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes. This increase is primarily a result of officer and employee compensation, accounting and legal fees.

Interest Expense. We recognized $1,923 in interest expense during the year ended December 31, 2013. There was no such expense during the corresponding period in 2012.

Gain on Reorganization. We recognized an aggregate of $166,676 and $747,036 in gain on reorganization during the years ended December 31, 2013 and 2012, respectively. Gain on reorganization is associated with the final payments under the Chapter 11 reorganization plan.

Liquidity and Capital Resources

During 2013, our business underwent substantial changes in relation to size, scale and scope of activities. Having emerged from bankruptcy in April 2013, and with the bankruptcy case being formally terminated as of September 2013, we are presently developing our clinical and regulatory business plans and seeking financing to fund such plans. We currently have no cash on hand and have not generated revenue since emerging from bankruptcy and do not anticipate generating revenue for the foreseeable future. A continued lack of cash resources resulting from our inability to generate cash flow from operations or to raise capital from external sources would force us in the near future to substantially curtail or cease operations and would, therefore, have a material adverse effect on our business and overall viability. In addition, such lack of funding, if not agreed otherwise by the parties, could force a termination of our key supply and license agreement with Mayne Pharma, which would cause substantial harm to our business prospects.

There can be no assurance that any funds required during the next twelve months or thereafter can be generated from our operations. Nor can there be any assurance that funds will be available from external sources, such as debt or equity financing or other potential sources on commercially acceptable terms, or at all (including, without limitation, a proposed $5 million equity financing).

Given our current lack of cash and cash equivalents, we have relied on loans from our insiders and affiliates to fund our operations until we are able to raise additional capital. Subsequent to December 31, 3013, working capital advances as of the date of this report from Hedgepath, LLC approximate $100,000, and have been used for officer and employee salaries, legal and professional fees.

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

- securing proceeds from public and private financings and other strategic transactions;
- partnering with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing its product to augment their product profile in the treatment of cancers; and
- seeking government or private foundation grants which would be awarded to us to further develop our current and future anti-cancer therapies.

Contractual Obligations and Commercial Commitments

Our non-cancellable contractual obligations as of December 31, 2013 are as follows:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Notes	$68,428	$ 68,428	$ —	$ —	$ —
Total contractual cash obligations	$68,428	$ 68,428	$ —	$ —	$ —

Off Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a “smaller reporting company” as defined by Regulation S-K and as such, are not required to provide the information contained in this item pursuant to Regulation S-K.

Item 8. Financial Statements and Supplementary Data.

Our Financial Statements and Notes thereto and the report of Cherry Bekaert LLP , our independent registered public accounting firm, and report of PB Mares, LLP, our prior independent registered public accounting firm, are set forth on pages F-1 through F-17 of this Report.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.

Pursuant to the filing of a Form 8-K on August 28, 2013, the Company changed their auditing firm to Cherry Bekaert LLP.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, at December 31, 2013, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Changes in Certifying Officers

During our third fiscal quarter of 2013 and in conjunction with the short-form merger between the Company and HPPI, the Company's management and Certifying Officers were replaced, and new officers were appointed. The Company does not believe that the change in Certifying Officers will materially affect, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

As required by the SEC rules and regulations for the implementation of Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at December 31, 2013. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at December 31, 2013.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of April 11, 2014 are as follows:

Name	Age	Position(s) Held
Frank E. O'Donnell, Jr., M.D.	64	Executive Chairman and Director
Nicholas J. Virca	67	President, Chief Executive Officer and Director
Garrison J. Hasara	44	Chief Financial Officer and Treasurer
Samuel P. Sears, Jr.	70	Director
James A. McNulty	63	Secretary and Compliance Officer

There are no arrangements between our directors and any other person pursuant to which our directors were nominated or elected for their positions. There are no family relationships between any of our directors or executive officers.

Frank E. O'Donnell, Jr., M.D., age 64, is our Executive Chairman of the Board and a Director of our company. He has been the Chairman of the Board of BioDelivery Sciences International (NASDAQ:BDSI) since 2002, and currently serves as Executive Chairman of BDSI. For more than six years, Dr. O'Donnell has been involved with various private limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare, including HedgePath, LLC. Dr. O'Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital. Dr. O'Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. He is a trustee of St. Louis University.

Nicholas J. Virca, age 67, is our President, Chief Executive Officer and Director. Since April 2012, Mr. Virca has been responsible for business planning, technology acquisition and development, interactions with Key Opinion Leaders and consultants and in-licensing activities and pending commercial partnerships. Since 2008, Mr. Virca served as the Chief Operating Officer for LamdaGen Corporation, a privately held company focused on monitoring assays for biopharmaceutical development and manufacturing applications, as well as high-sensitivity detection for human diagnostic biomarkers, such as oncoproteins related to cervical cancer. From 2005 to 2008, Mr. Virca was Vice President for Global Biotechnology at Pall Life Sciences where he was responsible for growth strategies and programs in the biotechnology arena, including new technology and product initiatives, joint ventures, licensing and acquisitions. He also founded the first Scientific Advisory Board for Pall's Biopharmaceuticals Division. From 1997 to 2004, Mr. Virca was COO, and later CEO and President of Adventrx Pharmaceuticals focusing on anti-cancer drug development in human clinical trials. He was instrumental in transitioning the company from a private corporation to a listing on the American Stock Exchange. Mr. Virca held various marketing and general management positions at Damon Biotech, Promega Corporation, Nicolet Imaging Systems, Ortho Diagnostic Systems, Fisher Scientific, Waters, Ross Laboratories and Pfizer Diagnostics. Mr. Virca currently serves on the boards of HedgePath, LLC and Panoptix Events and on the Life Sciences Advisory Board of Entegris, Inc. He previously served on the boards of Adventrx Pharmaceuticals between 2001 and 2004, and Diametrix Detectors between 1991 and 1997. He earned a bachelor's degree in Biology from Youngstown State University, is the co-inventor of packaging technology for enzyme research reagents, and is a member of numerous biotechnology organizations for which he has been a speaker and organizer over the last two decades.

Samuel P. Sears, Jr., age 70, is a Director of our company. He has been a member of the Board of Directors of BioDelivery Sciences International since October, 2011 (NASDAQ: BDSI). Mr. Sears has extensive experience in the biopharmaceutical, nutraceutical and biotechnology industries. Since 2006, Mr. Sears has been a partner at the law firm of Cetrulo LLP, where he currently serves as managing partner, and from 2000 to 2006, he provided private consulting and legal advisory services to start-up and early stage development companies. From 2000 to 2013, Mr. Sears served as Director, Chairman of the Audit Committee, Chairman of the Executive Committee, and Member of the Compensation Committee of Commonwealth Biotechnologies, Inc., a research and development support services company. From 1998 to 2000, Mr. Sears served as Vice Chairman and Treasurer of American Prescription Providers, Inc., a specialty pharmacy network offering prescriptions and nutraceuticals to patients with chronic diseases. From 1994 through May 1998, Mr. Sears was Chief Executive Officer and Chairman of Star Scientific, Inc. From 1968 to 1993, Mr. Sears was in private law practice. Mr. Sears is qualified to serve on our Board of Directors because of his extensive legal and business experience, including in the pharmaceutical industry. Mr. Sears is a graduate of Harvard College and Boston College Law School.

Garrison J. Hasara, CPA age 44, is our Chief Financial Officer and Treasurer. From January 2011 to September 2013, he was the Acting Chief Financial Officer, Principal Financial Officer and Principal Accounting Officer of Accentia Biopharmaceuticals, Inc.,

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

James A. McNulty, CPA, age 63, is our Secretary and Compliance Officer. From 2000 through October 2013, Mr. McNulty served as Chief Financial Officer of BioDelivery Sciences International, Inc., and currently serves as Senior Vice President - Finance and Treasurer (NASDAQ:BDSI). Mr. McNulty also serves as Chief Financial Officer for Hopkins Capital Group, an affiliation of limited liability companies which engage in venture investing activities. He was the CFO of Star Scientific, Inc. from 1998 - 2000 and from 2000 - 2002 he was the CFO/COO of American Prescription Providers, Inc. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded Pender McNulty & Newkirk, which became one of Florida's largest regional CPA firms, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He is a Director of Quantum Technology Sciences, Inc., a private company. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty is qualified to serve on our management team because of his extensive experience in public and private accounting. Mr. McNulty is a graduate of University of South Florida, a licensed Certified Public Accountant, a member of the American and Florida Institutes of CPA's and is a board member of the Tampa Bay chapter of Financial Executives International.

Meetings of the Board of Directors

Our board of directors met telephonically 3 times during 2013. Each member of our board of directors was present at sixty-seven (67%) percent or more of the board of directors meetings held.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our directors and executive officers and persons who beneficially own more than 10% of our common stock (referred to herein as the "reporting persons") file with the SEC various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2013, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons.

Item 11. Executive Compensation.

The following table sets forth all compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2013 and 2012. Individuals we refer to as our "named executive officers" include our Chief Executive Officer and our most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2013.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compen-sation ($)	Nonqualified Deferred Compen-sation Earnings ($)	All Other Compen-sation ($)	Total ($)
Nicholas J. Virca	2013	$120,000	—	—	—	—	—	—	$120,000
President, Chief Executive Officer and Director(1)	2012	—	—	—	—	—	—	—	—
Garrison J. Hasara	2013	$ 72,692	—	—	—	—	—	$ 3,890(3)	$ 76,582
Chief Financial Officer and Treasurer(2)	2012	—	—	—	—	—	—	—	—
Richard J. Freer,	2013	$186,296(5)	—	—	—	—	—	$ 29,912(6)	$216,208
Ph.D. former Chief Executive Officer(4)	2012	$ 18,984	—	—	—	—	—	$ 44,325(7)	$ 63,309

(1) Nicholas J. Virca was hired as Chief Executive Officer on August 1, 2013
(2) Garrison J. Hasara was hired as Chief Financial Officer on August 1, 2013
(3) Includes: $3,890 of health insurance premiums paid in 2013.
(4) Richard J. Freer served as Chief Executive Officer until August 1, 2013
(5) The compensation disclosed in this item is composed of accrued 2012 and 2011 compensation, as paid in 2013.
(6) Includes: $28,100 in consulting services and $1,812 of health insurance premiums paid in 2013.
(7) Includes: $44,325 in consulting services paid in 2012.

Outstanding equity awards

There were no outstanding unexercised options, unvested stocks and equity incentive plan awards held by each of our named executive officers, as of December 31, 2013. All equity incentive plans were canceled on July 16, 2013, which was 90 days subsequent to the effective date of the emergence from bankruptcy.

Equity Incentive Plan

We intend to adopt an equity incentive plan ("EIP"). The EIP will be implemented by HPPI with the plan being approved by our board of directors. We anticipate that the EIP will initially be comprised of approximately 32,600,000 (subject to adjustments for stock splits approved by our board of directors, the "Initial EIP Pool") shares of our common stock (ranking pari passu with our issued and outstanding common stock) to be available in the form of incentive stock options, non-qualified stock options, restricted stock, restricted stock units, performance awards and other customary equity incentives.

Option Exercises and Stock Vested

There were no options exercised by the executive officers during the year ended December 31, 2013:

Compensation of Directors

There was no compensation to directors during the year ended December 31, 2013:

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth, as of April 11, 2014, by: (i) each of our directors, (ii) all persons who, to our knowledge, are the beneficial owners of more than 5% of the outstanding shares of common stock, (iii) each of the executive officers, and (iv) all of our directors and executive officers, as a group. Each person named in this table has sole investment power and sole voting power with respect to the shares of common stock set forth opposite such person's name, except as otherwise indicated. Unless otherwise indicated, the address for each person listed below is in care of HedgePath Pharmaceuticals, Inc.324 S Hyde Park Avenue #350, Tampa, FL 33606

Name and address of beneficial owners	Amount and nature of beneficial ownership of Common Stock	Approximate percentage of outstanding Common Stock (1)	Amount and nature of beneficial ownership of Series A Preferred Stock	Approximate percentage of outstanding Series A Preferred Stock
Richard J. Freer, Ph.D.(2)	7,485,141	39.63%	—	
VenturePharm Laboratories, Ltd.(3)	2,613,426	13.84%	—	
Bill Guo(4)	2,613,426	13.84%	—	
Hedgepath, LLC(5)	—		170,000.74	100%
Black Robe Capital LLC(6)	—		170,000.74	100%
Frank E. O'Donnell, Jr., M.D.(6)	—		170,000.74	100%
Nicholas J. Virca	—		—	
Garrison J. Hasara	—		—	
Samuel P. Sears(7)	1,106,096	5.86%	—	
James A. McNulty	—		—	
All directors and executive officers as a group (5 persons)	1,106,096	5.86%	170,000.74	100%

* Less than 1%

(1) Applicable percentages are based on 18,888,971 shares outstanding on March 28, 2014. This table is based upon information supplied by officers, directors, and principal stockholders and Schedule 13G(s) filed with the SEC. Unless indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.
(2) Dr. Freer's address is 718 Grove Road, Richmond, Virginia 23114.
(3) As of August 19, 2008, VPL acquired the outstanding stock from PharmAust Chemistry LTD, an Australian Limited company. Total shares transferred were 2,150,000. On July, 7, 2008, CBI completed a sale of stock subject to a $1 million put right with VPL. Under the terms of the put agreement, CBI sold 463,426 shares of common stock to VPL at a price of $2.15 per share. In consideration of the sale of shares, CBI received $500,000 in cash and 2,229,664 of VPL's ordinary shares.
(4) Mr. Guo's address is 718 Grove Road, Richmond, Virginia 23114. The number of shares deemed to be beneficially owned by Mr. Guo includes 2,613,426 shares held by VPL over which Mr. Guo exercises voting power.
(5) The address for Hedgepath, LLC is 324 S Hyde Park, Suite 350, Tampa, Florida 33606.
(6) The address for Black Robe Capital, LLC ("Black Robe") is 324 S Hyde Park, Suite 350, Tampa, Florida 33606. Black Robe is the sole manager of Hedgepath, LLC, and has sole voting and dispositive power over HedgePath LLC. Frank E. O'Donnell, Jr., MD, our Executive Chairman, is the sole manager of Black Robe LLC, with sole voting and dispositive power over Black Robe LLC, and The Francis E. O'Donnell Jr. Irrevocable Trust No. 7 is the sole member of Black Robe LLC. Pursuant to his manager role at Black Robe, LLC, Dr. O'Donnell may be considered for SEC reporting purposes the beneficial owner of any shares held by Hedgepath, LLC. He disclaims ownership of any shares in HedgePath LLC in which he does not have a pecuniary interest.
(7) Mr. Sears' address is 1 Fieldstone Drive, Winchester, MA. 01890.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The following is a listing of our related party transactions:

Hedgepath, LLC

Pursuant to the Plan, on August 13, 2013, we entered into the Contribution Agreement with Hedgepath, LLC, pursuant to which we acquired the Assets related to the Itra Business Opportunity, and Hedgepath, LLC was issued the Series A Preferred Stock representing a 90% equity voting interest in us. Hedgepath, LLC is a private company. Frank E. O'Donnell, Jr., our executive chairman and director, is the executive chairman of HPPI. Blackrobe Capital LLC, an entity managed by Dr. O'Donnell, is also the manager of Hedgepath, LLC. Effectively, Dr. O'Donnell controls Hedgepath, LLC.

As part of the short-form reincorporation merger with HPPI, certain expenses have been incurred for officer salary, travel, legal and patent expense. These expenses, totaling $366,130, were paid by Hedgepath, LLC on behalf of the newly formed HPPI as of December 31, 2013. This non-interest bearing loan is anticipated to be paid on upon the Company's first capital raise. Subsequent to December 31, 2013, working capital advances as of the date of this Report from Hedgepath, LLC amounted to approximately $100,000.

Other

As a matter of corporate governance policy, we have not and will not make loans to officers or loan guarantees available to "promoters" as that term is commonly understood by the SEC and state securities authorities.

We believe that the terms of the above transaction with an affiliate were as favorable to us or our affiliate as those generally available from unaffiliated third parties. At the time of certain of the above referenced transactions, we did not have sufficient disinterested directors to ratify or approve the transactions; however, the present board of directors includes one independent director. We believe that Samuel P. Sears, Jr. qualifies as an independent director for NASDAQ Stock Market purposes.

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

To the best of our knowledge, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds $120,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

Item 14. Principal Accountant Fees and Services.

Audit Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the year ended December 31, 2013 totaled $70,000. The aggregate fees billed by PBMares, LLP (formerly Witt Mares, PLC) for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the year ended December 31, 2012 totaled $75,320.

Audit-Related Fees. None

Tax Fees. The aggregate fees billed by PBMares, LLP (formely Witt Mares, PLC) for professional services rendered for tax compliance, for the year ended December 31, 2012 was $7,228. There were no fees billed or rendered for tax compliance, for the year ended December 31, 2013.

All Other Fees. None

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of August 9, 2013, between Commonwealth Biotechnologies, Inc., and HedgePath Pharmaceuticals, Inc. (1)
3.1	Articles of Incorporation of the Registrant (1)
3.2	Bylaws of the Registrant (1)
3.3	Certificate of Designation for Series A Preferred Stock (1)
3.4	Certificate of Ownership and Merger (1)
3.5	Amended and Restated Certificate of Designation of Series A Convertible Preferred Stock. (2)
10.1	Contribution Agreement, dated August 13, 2013, by and between Hedgepath, LLC, and HedgePath Pharmaceuticals, Inc. (1)
10.2	Supply and License Agreement, dated September 3, 2013, by and among the Company and Mayne Pharma. (2)+
10.3	Amendment No. 1 to Supply and License Agreement, dated December 17, 2013, between the Company and Mayne Pharma. (3)
10.4	Amendment No. 2 to Supply and License Agreement, dated March 4, 2014, between the Company and Mayne Pharma. (4)
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *#
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *#
101.ins	XBRL Instance Document
101.xsd	XBRL Taxonomy Extension Schema Document
101.cal	XBRL Taxonomy Calculation Linkbase Document
101.def	XBRL Taxonomy Definition Linkbase Document
101.lab	XBRL Taxonomy Label Linkbase Document
101.pre	XBRL Taxonomy Presentation Linkbase Document

* Filed herewith

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

\# A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

(1) Previously filed with Form 8K, August 16, 2013.

(2) Previously filed with Form 8K, September 10, 2013.
(3) Previously filed with Form 8K, December 23, 2013.
(4) Previously filed with Form 8K, March 11, 2014.

HEDGEPATH PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of HedgePath Pharmaceuticals, Inc.

We have audited the accompanying balance sheet of HedgePath Pharmaceuticals, Inc. (the "Company") as of December 31, 2013 and the related statements of operations, stockholders' (deficit) equity and cash flows for the year then ended. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis of designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of HedgePath Pharmaceuticals, Inc. as of December 31, 2013 and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company incurred cumulative net losses since inception of approximately $28 million, of which approximately $1.5 million was incurred subsequent to the emergence from bankruptcy, as discussed in Note 1. Furthermore, the Company expects to continue to incur net losses through the foreseeable future and has significant negative working capital at December 31, 2013. These factors, among others as discussed in Note 2 to the financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Cherry Bekaert LLP

Tampa, Florida
April 15, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
HedgePath Pharmaceuticals, Inc.
(as successor to Commonwealth Biotechnologies, Inc.)
Tampa, FL

We have audited the accompanying balance sheet of HedgePath Pharmaceuticals, Inc. (as successor to Commonwealth Biotechnologies, Inc.) as of December 31, 2012 and the related statements of operations, stockholders' deficit, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of HedgePath Pharmaceuticals, Inc. (as successor to Commonwealth Biotechnologies, Inc.) as of December 31, 2012 and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company's recurring losses from operations and inability to generate sufficient cash flow to meet its obligations and sustain its operations raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 2 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PBMares, LLP

Richmond, Virginia
May 13, 2013

HEDGEPATH PHARMACEUTICALS, INC.
BALANCE SHEETS
DECEMBER 31, 2013 AND 2012

	December 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 217	$ 857,702
Other current assets	—	78,733
Prepaid assets	10,000	—
Total current assets	10,217	936,435
Total assets	$ 10,217	$ 936,435
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 287,072	$ 368,613
Notes payable, related party	68,428	—
Accrued payroll liabilities	—	191,340
Other liabilities	52,500	—
Accrued interest	1,923	—
Due to related party	366,130	—
Total current liabilities	776,053	559,953
Liabilities subject to compromise:		
Priority claims	—	23,450
Accounts payable and other unsecured creditors	—	422,316
Other liabilities	—	63,500
Total liabilities subject to compromise	—	509,266
Total liabilities	776,053	1,069,219
Commitments and contingencies (note 4)	—	—
Stockholders' deficit:		
Series A Preferred Stock, $0.0001 par value; 500,000 and no shares authorized in 2013 and 2012, respectively; 170,001 and no shares issued and outstanding in 2013 and 2012, respectively.	17	—
Undesignated Preferred Stock, $0.0001 par value in 2013 and no par value in 2012. 9,500,000 and 1,000,000 shares authorized in 2013 and 2012, respectively; no shares issued or outstanding in 2013 and 2012.	—	—
Common Stock, $0.0001 par value in 2013 and no par value in 2012; 340,000,000 and 100,000,000 shares authorized in 2013 and 2012, respectively; 18,888,971 and 15,560,504 shares issued and outstanding in 2013 and 2012, respectively	1,889	—
Additional paid-in capital	27,479,913	26,279,815
Accumulated deficit	(28,247,655)	(26,412,599)
Total stockholders' deficit	(765,836)	(132,784)
Total liabilities and stockholders' deficit	$ 10,217	$ 936,435

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2013 AND 2012

	Year Ended December 31,	
	2013	2012
Revenues:	$ —	$ —
Total revenues	—	—
Expenses:		
Chapter 11 expenses	117,324	—
Research and development	1,065,169	—
General and administrative	817,316	560,670
Total expenses	1,999,809	560,670
Loss from operations	(1,999,809)	(560,670)
Interest expense	(1,923)	—
Gain on reorganization:		
Realized gains	—	80,369
Gain on extinguishment of debt	—	666,667
Gain on settlement of pre-petition claims	166,676	—
	166,676	747,036
Net (loss) income	$ (1,835,056)	$ 186,366
Basic and diluted (loss) earnings per share	$ (0.10)	$ 0.01
Weighted average common stock shares outstanding	17,940,586	13,646,638

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED DECEMBER 31, 2013 AND 2012

	Preferred Stock Series A		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balances, January 1, 2012	—	$ —	12,660,504	$ —	$26,229,815	$(26,598,965)	$ (369,150)
Issuance of common stock	—	—	2,900,000	—	50,000	—	50,000
Net income	—	—	—	—	—	186,366	186,366
Balances, December 31, 2012	—	—	15,560,504	—	$26,279,815	$(26,412,599)	$ (132,784)
Issuance of preferred stock pursuant to the contribution agreement	170,001	17	—	—	1,049,987	—	1,050,004
Issuance of restricted stock in lieu of cash payment under the Bankruptcy Plan	—	—	3,328,467	—	152,000	—	152,000
Initiation of par value pursuant to agreement and plan of merger and reorganization	—	—	—	1,889	(1,889)	—	—
Net loss	—	—	—	—	—	(1,835,056)	(1,835,056)
Balances, December 31, 2013	170,001	$ 17	18,888,971	$ 1,889	$27,479,913	$(28,247,655)	$ (765,836)

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2013 AND 2012

	Year Ended December 31,	
	2013	2012
Operating activities:		
Net (loss) income	$(1,835,056)	$ 186,366
Adjustments to reconcile net (loss) income to net cash flows from operating activities:		
In-process research and development purchased with the issuance of preferred stock	1,020,004	—
Unrealized loss on investments	—	527
Gain on extinguishment of debt	—	(666,667)
Expenses paid with the issuance of stock	—	50,000
Changes in assets and liabilities:		
Other current assets	68,733	—
Accounts payable and other current liabilities	46,645	(34,492)
Net cash flows from operating activities before reorganization items	(699,674)	(464,266)
Reorganization items:		
Gain on reorganization	(166,676)	—
Decrease in liabilities subject to compromise	(357,265)	—
Net cash flows from operating activities	(1,223,615)	(464,266)
Financing activities:		
Proceeds from related party advances	366,130	—
Net cash flows from financing activities	366,130	—
Net change in cash and cash equivalents	(857,485)	(464,266)
Cash and cash equivalents at beginning of period	857,702	1,321,968
Cash and cash equivalents at end of period	$ 217	$ 857,702
Supplemental disclosure of non-cash financing activity:		
Reclassification of deposit to additional paid-in capital	$ 30,000	$ —
Promissory notes issued in payment of related party obligations	$ 68,428	$ —
Stock payments to officers and directors (liabilities subject to compromise) in lieu of cash payments under the Bankruptcy Plan	$ 152,000	$ —
Expenses satisfied with the issuance of stock	$ —	$ 50,000
Gain on extinguishment of debt	$ —	$ 687,500

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

1. Corporate overview:

Overview

The accompanying audited financial statements of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company", "HPPI", "we", "us" or similar terminology) as successor to Commonwealth Biotechnologies, Inc., a Virginia corporation ("CBI"), have been prepared by the Company as a going concern.

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

Nature of the Business

CBI was a specialized life sciences outsourcing business that offered certain peptide-based discovery chemistry and biology products and services through Mimotopes Pty Limited ("Mimotopes"), a wholly-owned subsidiary of CBI. On January 20, 2011, CBI filed a voluntary petition captioned *In re Commonwealth Biotechnologies, Inc., Case No. 11-30381-KRH* (the "Chapter 11 case") in the United States Bankruptcy Court for the Eastern District of Virginia (the "Bankruptcy Court") seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code"). On April 7, 2011, the Bankruptcy Court approved the private sale of the Mimotopes business unit for a net sales price of $850,000. The sale closed on April 29, 2011.

On August 12, 2013, in furtherance of CBI's emergence from bankruptcy as described further below, CBI effected a "short-form" reincorporation merger with HPPI, a newly created and wholly owned Delaware subsidiary of CBI, pursuant to which CBI merged with and into HPPI, with HPPI surviving the merger and with the effect of CBI becoming reincorporated as a Delaware corporation and changing its corporate name. Each outstanding share of CBI was converted into one share of HPPI. HPPI's Certificate of Incorporation (and thus the Certificate of Incorporation of the surviving company) authorizes the issuance of up to 340,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. The par value was changed from no par value to $0.0001, which par value is customary for newly formed Delaware corporations.

As described further below, the Company's present business is the development of the currently-marketed drug itraconazole (currently approved by the U.S. Food and Drug Administration ("FDA") as an anti-fungal agent) for the treatment of certain cancers.

Pre-Bankruptcy and Emergence from Bankruptcy

On January 4, 2013, CBI filed an Amended Plan of Reorganization (the "Plan") with the Bankruptcy Court. The Plan was approved by a vote of creditors and CBI stockholders on March 21, 2013. CBI received an auction fee of $30,000 from Hedgepath, LLC, a Florida limited liability company, (which fee was a binding, irrevocable offer for the purchase of a portion of CBI's equity interests) in addition to the contribution of Assets as described below. Hedgepath, LLC was the winning bidder for CBI, which is more fully described below in *Post-Bankruptcy Business of HPPI-General.* This auction fee was recognized as an increase in additional paid-in capital when the Contribution Agreement (as defined below) became effective.

On March 29, 2013, the Bankruptcy Court entered an order (the "Confirmation Order") confirming the Plan pursuant to Chapter 11 of the Bankruptcy Code. Under the terms of the Plan, and pursuant to the Contribution Agreement (as described further below), Hedgepath, LLC contributed and assigned the Assets (as such term is defined below) to HPPI, as the reorganized debtor, in exchange for the right to receive 90% of fully diluted voting equity in HPPI (in the form of the Series A Preferred Stock) on the date of issuance, with the prior stockholders of CBI retaining approximately 10% voting equity in HPPI, represented by 100% of the issued and outstanding shares of Common Stock.

Contribution Agreement

On August 13, 2013, the Company entered into a Contribution Agreement, dated as of August 13, 2013 (the "Contribution Agreement"), by and between the Company and Hedgepath, LLC pursuant to which, and subject to the terms and conditions contained therein, in exchange for the right to receive 170,001 shares of the Company's newly created Series A Convertible Preferred Stock (the "Series A Preferred Stock"), representing 90% of the fully diluted voting securities of the Company as of the date of issuance (or 170,000,739 shares of Common Stock on an as converted basis), Hedgepath, LLC contributed and/or assigned various assets and contract rights to the Company associated with the going forward business of the Company (collectively, the "Assets") to the Company as described below.

(i) U.S. Provisional Patent Application 61-813,122, "Prostate-Specific Antigen as Biomarker for Hedgehog Pathway Inhibitor Treatment and Prognostic Monitoring of Prostate Cancer" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

1. Corporate overview (continued):

(ii) U.S. Provisional Patent Application 61-813,823, "Treatment and Prognostic Monitoring of Cancer Using Hedgehog Pathway Inhibitors" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

(iii) Assignment of Patents, dated November 1, 2012, by Dr. Frank E. O'Donnell, Jr. in favor of Hedgepath, LLC;

(iv) Assignment of Patents, dated November 1, 2012, by Nicholas J. Virca in favor of Hedgepath, LLC;

(v) Consulting Agreement, dated and effective as of September 1, 2012, by and between HPPI (as successor to Hedgepath, LLC) and Emmanuel Antonarakis, MD ("Antonarakis").

(vi) Confidentiality and Intellectual Property Assignment Agreement, dated and effective September 1, 2012, between Antonarakis and HPPI (as successor to Hedgepath, LLC), which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Antonarakis under such agreement.

(vii) Consulting Agreement, effective as of April 11, 2013, by and between Hedgepath, LLC and Arianne Consulting, Inc. ("Arianne"); and

(viii) Confidentiality and Intellectual Property Assignment Agreement, dated and effective April 11, 2013, between Arianne and Hedgepath, LLC , which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Arianne under such agreement.

The Contribution Agreement was entered into to carry out the purposes and intent of the Plan filed by CBI and confirmed by the Bankruptcy Court in connection with the Chapter 11 case.

Hedgepath, LLC is a development stage pharmaceutical company. Since its formation in late 2011, Hedgepath, LLC has sought, among other pharmaceutical business opportunities, to acquire technology rights and to conduct activities related to the development of the currently-marketed drug itraconazole (currently FDA approved as an anti-fungal agent) for the treatment of certain cancers (the "Itra Business Opportunity"). Hedgepath, LLC has expended approximately $0.1 million acquiring assets and developing the ITRA Business Opportunity including approximately $82,500 on technical and medical consulting and $15,000 on option fees related to intellectual property agreement that has since expired.

In accordance with the Plan, and as a result of the transactions contemplated by the Contribution Agreement, from and after August 13, 2013, HPPI will be engaged in the Itra Business Opportunity. The Assets contributed to the Company by Hedgepath, LLC represent the assets and rights heretofore developed or acquired by Hedgepath, LLC related to the Itra Business Opportunity, and by virtue of the Contribution Agreement, the Company acquired all of Hedgepath, LLC's right, title and interest in and to the Assets.

As part of the Contribution Agreement, Hedgepath, LLC, which owned a certain claim against CBI in the amount of $52,500, payable to a third party service provider, contributed such claim to the Company. HPPI has agreed to issue to such service provider a number of restricted shares of its Common Stock to be determined based on the valuation of the shares to be issued to purchasers in connection with HPPI's planned $5 million offering of securities as described in the Plan. Such shares of Common Stock are to be issued to such service provider within five (5) business days of the final determination of such valuation (as memorialized in the final transaction documentation for such offering).

Hedgepath, LLC did not contribute any of its liabilities to the Company in connection with the Contribution Agreement, and retained all of its assets other than those related to the Itra Business Opportunity.

In conjunction with the execution of the Contribution Agreement, the Company has expensed, as in-process research and development cost, approximately $1.0 million. The value was calculated by taking 90% of the market capitalization on the date the assets were contributed to reflect the 90% ownership exchanged for the assets contributed by Hedgepath, LLC.

Post-Bankruptcy Business of HPPI—General

As a result of the aforementioned transactions, as of August 13, 2013 the Company is a clinical stage biopharmaceutical company that endeavors to discover, develop and commercialize innovative therapeutics for patients with certain cancers. The Company is currently

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

1. Corporate overview (continued):

focused on the development of therapies for certain cancers, with initial emphasis on skin, prostate and lung cancers in the U.S. market, based upon the use of the currently marketed anti-fungal drug itraconazole. The Company believes that itraconazole could affect the Hedgehog signaling pathway in cells, a major regulator of many fundamental cellular processes, which could, in turn, impact the development and growth of certain cancers.

Itraconazole is FDA approved for and extensively used to treat fungal infections and has an extensive history of safe and effective use in humans. The Company has developed, optioned and is seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole and has applied for patents to cover the Company's inventions.

Net (loss) income per common share

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per common share computations for the years ended December 31, 2013 and 2012.

	2013	2012
Basic:		
Net (loss) income attributable to common stockholders	$ (1,835,056)	$ 186,366
Weighted average common shares outstanding	17,940,586	13,646,638
Basic (loss) earnings per common share	$ (0.10)	$ 0.01
Diluted:		
Effect of dilutive securities:		
Net (loss) income attributable to common stockholders	$ (1,835,056)	$ 186,366
Adjustments to income for dilutive options and warrants	—	—
	(1,835,056)	186,366
Weighted average common shares outstanding	17,940,586	13,646,638
Effect of dilutive options and warrants	—	—
Diluted weighted average common shares outstanding	17,940,586	13,646,638
Diluted (loss) earnings per common share	$ (0.10)	$ 0.01

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. Common equivalent shares from stock options and warrants using the treasury stock method, are also included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the year ended December 31, 2012, outstanding stock options and warrants of 1,220,443 were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods.

2. Liquidity and management's plans:

A continued lack of adequate cash resulting from the Company's bankruptcy, the sale of CBI's principal assets, and the resulting inability to generate cash flow from operations or to raise capital from external sources forced the Company to substantially curtail or cease operations and, therefore, had a material adverse effect on its business. Consequently, during 2012 and 2013, the Company's business has undergone substantial reductions in relation to size, scale and scope of activities.

As a result of the foregoing circumstances, there is substantial doubt about the Company's ability to continue as a going concern. The Company's previous and current independent auditors have included a paragraph emphasizing "going concern" uncertainty in their report on the 2012 and 2013 financial statements. The financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

The Company currently has cash and cash equivalents of $217 as of December 31, 2013, and has and will therefore rely on loans from insiders and affiliates to fund its operations until the Company is able to raise additional capital. Subsequent to December 31, 2013, working capital advances as of the date of this Report from Hedgepath, LLC amounted to approximately $100,000, and have been used for officer and employee salaries, legal and professional fees.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

2. Liquidity and management's plans (continued):

The Company intends to finance its research and development, commercialization and distribution efforts and its working capital needs primarily through:

- partnering with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- licensing and joint venture arrangements with third parties, including other pharmaceutical companies where the Company would receive funding based on out-licensing its product to augment their product profile in the treatment of cancers;
- receiving government or private foundation grants which would be awarded to the Company to further develop our current and future anti-cancer therapies; and
- securing proceeds from public and private financings and other strategic transactions.

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

3. Summary of Significant Accounting Policies:

Recent accounting pronouncements

In July 2013, the FASB issued ASU 2013-11– Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists ("ASU 2013-11"). This guidance requires the unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset. When a deferred tax asset is not available, or the asset is not intended to be used for this purpose, an entity should present the unrecognized tax benefit in the financial statements as a liability. The guidance will become effective for us at the beginning of our first quarter of fiscal 2014. The Company does not expect the adoption of this guidance will have a material impact on its financial statements.

In January 2013, the FASB issued ASU 2013-01 – Clarifying the Scope of Disclosures about Offsetting Assets and Liabilities ("ASU 2013-01"). The amended guidance limits the scope of balance sheet offsetting disclosures to derivatives, repurchase agreements, and securities lending transactions to the extent that they are offset in the financial statements or subject to an enforceable master netting arrangement or similar agreement. The guidance became effective for us at the beginning of our fourth quarter of fiscal 2013. The adoption of this guidance had no impact on the Company's financial statements.

Estimates

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

Revenue Recognition

The Company currently has no ongoing source of revenues. Any miscellaneous income is recognized when earned by the Company.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts.

Research and Development Expenses

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

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

3. Summary of Significant Accounting Policies (continued):

Accounting for Enterprises in Reorganization

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 852—*Reorganizations* ("ASC Topic 852"), which is applicable to companies in Chapter 11, generally does not change the manner in which financial statements are prepared. However, it does require that the financial statements for periods subsequent to the filing of the Chapter 11 petition distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Revenues, expenses, realized gains and losses, and provisions for losses that can be directly associated with the reorganization and restructuring of the business must be reported separately as reorganization items in the statements of operations beginning in the quarter ending March 31, 2011. The balance sheet must distinguish prepetition liabilities subject to compromise from both those prepetition liabilities that are not subject to compromise and from post-petition liabilities. Liabilities that may be affected by a plan of reorganization must be reported at the amounts expected to be allowed by the Bankruptcy Court, even if they may be settled for lesser amounts. In addition, cash flows from reorganization items must be disclosed separately in the statement of cash flows. The Company became subject to ASC Topic 852 effective on January 20, 2011, and has segregated those items as outlined above for all reporting periods after such date. The Company officially emerged from bankruptcy on April 17, 2013, followed by the reincorporation merger, which satisfied the final condition to effectiveness of the Plan as detailed in Note 1.

Income taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. Management has evaluated the guidance relating to accounting for uncertainty in income taxes and has determined that the Company had no uncertain income tax positions that could have a significant effect on the consolidated financial statements for the years ended December 31, 2013 or 2012.

4. Supply and License Agreement

On September 3, 2013, the Company entered into an exclusive Supply and License Agreement (the "Supply and License Agreement") with Mayne Pharma International Pty Ltd., a company incorporated in Australia ("Mayne Pharma"), pursuant to which Mayne Pharma agreed to: (i) supply the Company with its patented formulation of the drug itraconazole, known as SUBA™-Itraconazole, in a particular dose formulation (the "Product") for the treatment of human patients with cancer via oral administration (the "Field") (with the initial areas of investigation being prostate, lung and skin cancer) in the United States (the "Territory"), (ii) provide the Company with an exclusive license to use and develop the intellectual property related to the Product in the Field and in the Territory and (iii) participate in a joint development committee with the Company ("JDC") to clinically develop the Product in the Field and in the Territory. The Company will pursue the development of the Product for treatment of a variety of cancers with a focus on clinical development, seeking regulatory approvals and, if regulatory approval is obtained, marketing in the United States.

Pursuant to the Supply and License Agreement, the Company, with the assistance of Mayne Pharma through the JDC and subject to certain approval rights of Mayne Pharma, will develop and exploit the Product through a development plan which will be authorized by the JDC and updated as necessary. The license granted to the Company under the Supply and License Agreement may only be assigned or sub-licensed with the prior approval of Mayne Pharma. In addition, in support of the exclusive nature of the Supply and License Agreement, during the term, Mayne Pharma is prohibited from directly or indirectly importing, promoting, marketing, distributing or selling the Product in the Territory and in the Field. If any other form of the Product manufactured by Mayne Pharma is sold as a result of any off label use, the Company shall be entitled to a royalty on such off-label sales. Further, the Company may not develop products that are competitive with the Product, which period extends for a certain period following the end of the term.

Under the Supply and License Agreement, the Company is responsible for obtaining all of its requirements for the Product from Mayne Pharma, including for use in clinical trials, importation, promotion, marketing, sale and distribution in the Territory. The Company and Mayne Pharma have established certain minimum floor prices that the Company must pay per unit of the Product and minimum order quantities for the Product.

Any intellectual property created by the Company, either on its own or jointly with Mayne Pharma, relating to the Product in the Field will be owned by the Company, except that the Company has granted Mayne Pharma an exclusive, perpetual, irrevocable, royalty free license to copy and exploit such developed intellectual property outside of the Territory.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

4. Supply and License Agreement (continued):

Although the Supply and License Agreement is effective immediately, it remained subject to early termination by Mayne Pharma if certain conditions (the "Conditions") were not met by December 16, 2013. Such Conditions include: (i) the Company shall have raised $5 million in an equity financing (or such lesser amount as may be agreed to by Mayne Pharma) (the "Equity Financing"); (ii) a representative of Mayne Pharma shall have been appointed to the Company's board of directors, and Mayne Pharma and the Company shall have entered into an agreement granting Mayne Pharma certain board appointment rights; (iii) Mayne Pharma shall, pursuant to customary definitive documentation to be negotiated by the parties, acquire from the Company, as part of the consideration under the Supply and License Agreement, 170,001 shares of the Company's Series A Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock"), representing, on an as fully converted, fully diluted basis, 45% of the issued and outstanding shares of capital stock of the Company (prior to the Equity Financing (as defined below) and the anticipated adoption by the Company of an equity incentive plan); (iv) Hedgepath, LLC (an affiliate of the Company who currently has the right to receive shares of Series A Preferred Stock), Nicholas J. Virca (the Company's President and Chief Executive Officer) ("Virca") and Mayne Pharma shall have entered into an agreement providing for certain restrictions on transfers and ownership of Company equity; (v) the Company and Mayne Pharma shall have entered into an agreement granting Mayne Pharma and accredited investors introduced to the Company by Mayne Pharma certain participation rights in future Company equity financings; (vi) the Company shall have (a) received a written estimate from a credible contract research organization reasonably acceptable to Mayne Pharma relating to the Company's proposed clinical trials and (b) provided reasonable assurances to Mayne Pharma that the Product will be available for commercial launch by a specified date; and (vii) Virca and Frank E. O'Donnell, Jr., the Company's Executive Chairman, shall have entered into customary agreements regarding their positions with the Company. Due to the contingent nature of the Supply and License Agreement, none of Series A Preferred Stock has been issued to Mayne Pharma as of the date of this Report and, therefore, there is no accounting treatment applicable.

Subject to earlier termination if the Conditions are not met as described above, the term of the Supply and License Agreement shall last until the later of: (i) 10 years from the target launch date of the Product for the treatment of human patients with cancer via oral administration or (ii) the date on which all issued patents of Mayne Pharma or any of its affiliates referred to in the Supply and License Agreement have lapsed or expired.

The Supply and License Agreement is further subject to termination in certain circumstances, including: (i) by either party in the event of (a) a material default that is not cured within a specified number of days after notice is received or is not capable of remedy, (b) if marketing authorizations for the Product are not obtained prior to the agreed upon target launch date for the Product or (c) a force majure event precluding performance by the other party for a specified period of time, (ii) the voluntary or involuntary bankruptcy of either party, (iii) by Mayne Pharma if either Hedgepath, LLC or Virca breach their respective agreements with Mayne Pharma to restrict the sale and or transfer of their shares of Company equity and such breach is not cured within a specified number of days after notice is received or such breach is not capable of remedy, (iv) by Mayne Pharma if the Company breaches certain of its obligations relating to the Conditions (once they are satisfied) and such breach is not cured within a specified number of days after notice is received or such breach is not capable of remedy, (v) by Mayne Pharma if, under certain circumstances, the Company fails to purchase the minimum agreed upon amounts of Product in any given year or (vi) by Mayne Pharma, under certain circumstances, upon a change of control of the Company.

On December 17, 2013, the Company entered into Amendment No. 1 to the Supply and License Agreement (the "Amended Supply and License Agreement") with Mayne Pharma. The Amended Supply and License Agreement amends the Agreement as follows:

(i) the date by which the Conditions (as defined below) must be met was extended from December 16, 2013 to February 28, 2014;

(ii) Mayne Pharma had agreed to reimburse all reasonable third party expenses incurred in the conduct of the activities set out in, and in accordance with, the development plan as set forth in the Agreement (the "Development Plan"), or otherwise related to the Product by the Company from the date of the Amended Supply Agreement through February 28, 2014; provided however that (i) such expenses may not exceed $100,000, (ii) the Company must receive prior written approval from Mayne Pharma prior to incurring such expenses, and (iii) any third party engaged to provide clinical or other services to the Company must first enter into an agreement with the Company to assign all intellectual property rights developed by or on behalf of it in providing such services to the Company. Furthermore, such reimbursement must be repaid by the Company to Mayne Pharma once the Conditions have been met or waived by Mayne Pharma; and

(iii) if Mayne Pharma terminated the Agreement, then the Company will assign to Mayne Pharma all intellectual property rights created or developed in the conduct of the activities set out in, and in accordance with, the Development Plan or

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

4. Supply and License Agreement (continued):

otherwise related to the Product that have been created or developed between the date of the Amended Supply and License Agreement and February 28, 2014. Such assignment will occur whether such rights were created or developed by or on behalf of the Company, its affiliates or any third party providing services to the Company or its affiliates; provided however, that: (i) all rights of the Company in the HP Patents (as defined in the Agreement) and all intellectual property rights of the Company created or developed (either by the Company or jointly with Mayne Pharma) prior to the date of the Amended Supply and License Agreement shall remain the exclusive property of the Company as provided for in the Agreement and (ii) if the Conditions have been waived by Mayne Pharma or satisfied as of or prior to the February 28, 2014, all provisions of the Agreement relating to the ownership of intellectual property rights relating to the Product shall be governed by the original provisions of the Agreement and this provision will be terminated upon the waiver by Mayne Pharma, or satisfaction, of the Conditions.

As provided for in the Agreement, as amended, Mayne Pharma could have terminated the Agreement since certain conditions were not met by February 28, 2014.

On March 5, 2014, the Company entered into Amendment No. 2 to the Supply and License Agreement (the "Amended Supply and License Agreement") with Mayne Pharma. The Amended Supply and License Agreement amends the Agreement as follows:

(i) the date by which the Conditions (as defined below) must be met was extended from February 28, 2014 to March 31, 2014;

(ii) the Company has agreed to use reasonable efforts to progress the conduct of the activities set out in, and in accordance with, the development plan as set forth in the Agreement (the "Development Plan"), and to seek reimbursement of relevant amounts in accordance with the Agreement;

(iii) the Company and Mayne Pharma acknowledged and agreed that warrants may be issued in connection with an Equity Financing (as defined below) and further agreed that in the event that warrants are issued in connection with an Equity Financing, Mayne Pharma will receive a warrant on the same terms as the warrants issued in the Equity Financing for such a number of shares that will ensure that Mayne Pharma will hold at least 30% of the issued and outstanding shares of capital stock of the Company on a fully diluted, fully converted basis following the Equity Financing;

(iv) if the Company does not (i) submit a complete Investigational New Drug ("IND") application to the United States Food and Drug Administration (the "FDA") for the Product for at least one indication in the Field and commence dosing patients in at least two phase II or phase II/III clinical trials across at least two indications in the Field by March 31, 2015 or (ii) submit an application for a new drug application to the FDA for at least one indication by March 31, 2016, then Mayne Pharma may, by notice to Frank E. O'Donnell, Jr. M.D., the Company's Executive Chairman, and Nicholas J. Virca, the Company's President and Chief Executive Officer, require each of them to resign from the Company, in which case each of Hedgepath LLC, Mr. Virca and Dr. O'Donnell will forfeit all of their respective unvested Company options, and Mayne Pharma will have the right to purchase all issued and outstanding shares of the Company's capital stock held by Mr. Virca and Dr. O'Donnell at market price, and neither Mr. Virca nor Dr. O'Donnell will be entitled to receive any severance or similar payments from the Company;

(v) in the event that Dr. O'Donnell or Mr. Virca are removed or resign from the Company's board of directors, any replacement appointees will need to obtain unanimous approval from the remaining board members; and

(vi) Mayne Pharma waived its right to require the Company to obtain a written estimate from a contact research organization relating to the timing and completion of phase II trials on the use of the Product in the Field and waived its right to reasonably expect that the Product would launch by a date agreed upon the Company and Mayne.

Mayne Pharma could have terminated the Agreement, as amended, if certain conditions were not met by March 31, 2014. That date was extended to April 25, 2014 by mutual agreements. The Company is continuing efforts to meet those conditions. No transactions under the original or amended Supply and License Agreement have transpired to date.

5. Gain on Reorganization:

The Company has recognized gains of $166,676 and $747,036, which are included in gain on reorganization in the accompanying statements of operations for the years ended December 31, 2013 and 2012, respectively, as a result of final payments under the Chapter 11 reorganization plan.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

6. Debt:

On September 4, 2008, CBI completed the issuance of a $500,000 convertible promissory note ("the Note") payable to Fornova Pharmaworld, Inc. ("the Holder"). On February 10, 2012, the CBI filed a claim against Fornova in Bankruptcy Court. CBI was disputing Fornova's claim that it was owed $500,000 plus accrued interest relating to a convertible note that was originated in 2007. CBI was seeking to have the claim disallowed in its entirety or, in the alternative, reclassified as an equity investment. In October 2012, CBI's claim against Fornova was approved by the Bankruptcy Court. Fornova's claim was disallowed in its entirety. Effective September 30, 2012, principal and accrued interest in the amount of $666,667 was written off and a gain on extinguishment of debt was recognized.

7. Property and Equipment:

Property and Equipment relating to CBI consisted of the following:

	December 31,	
	2013	2012
Furniture, fixtures, office and computer equipment	$—	$ 53,575
Other	—	9,077
	$—	$ 62,652
Less accumulated depreciation	—	(62,652)
	$—	$ —

There was no depreciation expense for the years ended December 31, 2013 and 2012.

8. Other Assets:

As of December 31, 2012, other current assets include $75,000 relating to cash held in escrow by the Company's bankruptcy attorneys. These funds were used to pay legal fees as approved by the Bankruptcy Court.

9. Income Taxes:

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

	December 31,	
	2013	2012
Income taxes (benefit) computed at statutory rate	$(627,319)	$ —
State income tax benefit, net	(63,688)	(347)
Change in valuation allowance	691,007	347
	$ —	$ —

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

	December 31,	
Deferred tax assets (liabilities)	2013	2012
In-process research and development	$ 346,801	$ —
Net operating loss carry forward	407,398	15,994,583
R&D credit	2,584	52,600
	756,783	16,047,183
Less: valuation allowance	(756,783)	(16,047,183)
	$ —	$ —

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

9. Income Taxes (continued):

In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, the Company recorded a valuation allowance with respect to all of the Company's deferred tax assets.

The Company has a federal net operating loss ("NOLs") of approximately $1.1 million as of December 31, 2013. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the NOLs and other deductions which are available to the Company. The portion of the NOLs incurred prior to August 12, 2013 is subject to this limitation. As such, the use of these NOLs to offset taxable income is limited to approximately $35,000 per year and the Company has written off the deferred tax assets associated with the NOLs limited due to the ownership change that occurred on August 12, 2013. The Company's State NOLS are approximately $1.1 million as of December 31, 2013. These loss carryforwards expire principally beginning in 2018 for federal and state purposes.

10. Chapter 11 Information:

During the year ended December 31, 2013, the Company settled all pre-petition claims associated with the bankruptcy in cash and Common Stock. The Company paid $357,265 in cash and $152,000 in Common Stock to settle the claims. The Common Stock was valued using the 30 day average of the Company's stock price. The $166,676 difference between pre-petition liabilities and the settled amount was recognized as gain on reorganization in the condensed statement of operations for the year ended December 31, 2013. During the year ended December 31, 2012, the Company sought to have a claim relating to a 2008 convertible promissory note disallowed. In October 2012, the claim was disallowed by the Bankruptcy Court. Consequently, principal and interest of approximately $500,000 and $166,667, respectively, were written off effective September 30, 2012. This write-off resulted in a gain on extinguishment of debt of $666,667. Other realized gains for 2012 were approximately $80,000 and resulted from changes in management's estimates regarding the expected settlement amounts of liabilities subject to compromise.

11. Stockholders' Deficit:

Employee Stock Plans

A 2002 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. However, all options were canceled on July 16, 2013, which was 90 days subsequent to the effective date of the emergence from bankruptcy.

A 2007 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. However, all options were canceled on July 16, 2013, which was 90 days subsequent to the effective date of the emergence from bankruptcy.

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

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

Stock-based compensation expense will be determined based on the fair value of the stock-based awards and recognized over the vesting period. No stock-based compensation expense related to employee stock options was recognized for the year ended December 31, 2013 or 2012. As of December 31, 2013 there was no unamortized stock-based compensation cost related to non-vested stock awards, as all such instruments were canceled upon emergence from bankruptcy. During the year ended December 31, 2013, no stock options were granted, exercised or forfeited.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

11. Stockholders' Deficit (continued):

Stock option activity for the years ended December 31, 2013 and 2012 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2012	245,443	$ 3.02	
Granted in 2012	—	—	
Exercised	—	—	
Outstanding at December 31, 2012	245,443	$ 3.02	$ —
Granted in 2013	—	—	
Exercised	—	—	
Canceled	(245,443)	3.02	
Outstanding at December 31, 2013	—	$ —	$ —

Issuance of Restricted Stock

In April 2013, restricted shares were issued to CBI's CEO, one CBI board member and one former CBI officer for a portion of their approved claims. The number of shares issued, which totaled 3,328,467, was determined by using a per share price equal to the average of the 30 day closing price of Common Stock and was valued at $152,000.

In September 2012, bonuses, in the form of restricted stock, were issued to a then current CBI employee. Total shares issued were 250,000. The market value of these shares was approximately $5,000.

In December 2010, the Board of Directors approved a resolution allowing former officers of the Company to receive restricted stock in lieu of cash compensation. In August 2012, restricted shares issued to the Company's CEO under this arrangement were 2,025,000. The market value of these shares was approximately $32,000. In September 2012, restricted shares issued to two independent directors under this arrangement were 625,000. The market value of these shares was approximately $13,000.

Warrants

In connection with a 2007 PIPE financing, CBI issued Class A warrants to purchase 975,000 shares of common stock at an exercise price of $2.85 per share that had an expiration date of May 2013. On March 20, 2013, CBI filed a motion to cancel all outstanding warrants under the terms of the Bankruptcy Code. This motion was approved and entered by the Bankruptcy Court in April 2013. As such, there are no warrants outstanding at December 31, 2013.

12. Related party transactions:

On August 1, 2013, the Company formalized amounts due to two former employees and a former director of CBI by issuing three non-interest bearing promissory notes. The two employee notes totaling approximately $62,000 were due on November 1, 2013. Interest will accrue at 18% per annum on any unpaid principal upon default. As of the date of this report, the Company is in default on the aforementioned notes. The Company is now accruing interest in accordance with the specified terms.

On January 31, 2014, the Company extended the two former employee notes. The amendments include additional principal of approximately $9,000 and are due on March 31, 2014.

The former director note of approximately $6,000 is due the later of five days following the date on which the Company has raised $1 million, or November 1, 2013. Default interest accrues at a rate of 5% per annum. Both the employee and director note amounts, including accrued interest, are included in notes payable, related party, in the accompanying balance sheet as of December 31, 2013.

As part of the short-form reincorporation merger with HPPI, certain expenses have been incurred for officer salary, travel, legal and patent expense. These expenses, totaling $366,130, were paid by Hedgepath, LLC on behalf of the newly formed HPPI and are included in due to related party in the accompanying balance sheet as of December 31, 2013. Subsequent to December 31, 3013, working capital advances as of the date of this report from Hedgepath, LLC approximate $100,000, and have been used for officer and employee salaries, legal and professional fees.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HEDGEPATH PHARMACEUTICALS, INC.

Date: April 15, 2014

By: /S/ NICHOLAS J. VIRCA
Name: **Nicholas J. Virca**
Title: **President and Chief Executive Officer**
(Principal Executive Officer)

By: /s/ Garrison J. Hasara
Name: Garrison J. Hasara
Title: **Chief Financial Officer and Treasurer**
(Principal Accounting Officer)

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/S/ DR. FRANCIS E. O'DONNELL, JR. **Dr. Francis E. O'Donnell, Jr.**	Executive Chairman and Director	April 15, 2014
/S/ NICHOLAS J. VIRCA **Nicholas J. Virca**	President, Chief Executive Officer and Director	April 15, 2014
/S/ SAMUEL P. SEARS, JR. **Samuel P. Sears, Jr.**	Director	April 15, 2014

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a)

I, Nicholas J. Virca, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of HedgePath Pharmaceuticals, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2014

/s/ Nicholas J. Virca
Nicholas J. Virca
President and Chief Executive Officer

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a)

I, Garrison J. Hasara, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of HedgePath Pharmaceuticals, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2014

/s/ Garrison J. Hasara

Garrison J. Hasara Chief Financial Officer and Treasurer

Exhibit 32.1

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of (18 U.S.C. 1350), the undersigned officer of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2013 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: April 15, 2014

/s/ Nicholas J. Virca
Nicholas J. Virca, President and Chief Executive Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.

Exhibit 32.2

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), the undersigned officer of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2013 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: April 15, 2014

/s/ Garrison J. Hasara
Garrison J. Hasara, Chief Financial Officer and Treasurer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.