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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, 2016

☐ **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 anon-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 30, 2016 was approximately $11,622,956 based on the closing sale price of the company's common stock on such date of $0.228 per share, as reported by the OTC Markets Group, Inc.

As of February 17, 2017, there were 353,447,172 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, 2016

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Unless we have indicated otherwise, or the context otherwise requires, references in this Report to "HPPI," 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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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:

- acceptance of our business model (namely the repurposing of a specialty formulation of the drug itraconazole for the treatment of cancer) by investors and potential commercial collaborators;
- our future capital requirements and our ability to satisfy our capital needs;
- our ability to commence and 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 owned or licensed 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

We are a clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. We may also explore acquiring or licensing other innovative therapeutics addressing unmet needs and orphan indications beyond cancer. Our preliminary focus is on the development of therapies for skin, lung and prostate cancers in the United States of America market, with the first indication targeting basal cell carcinoma (or BCC) in patients with Basal Cell Carcinoma Nevus Syndrome (or BCCNS, also known as Gorlin Syndrome). We are presently conducting an open label, Phase II(b) clinical trial of a proposed therapy for BCCNS, and in August 2016 and October 2016, we announced positive interim data from this trial.

Our proposed therapy is based upon SUBA™-Itraconazole, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole to which we hold an exclusive U.S. license as described below. We believe that the dosing of oral capsules of this formulation can affect the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration ("FDA") for, and has been extensively used to treat, fungal infections and has an extensive history of safe and effective use in humans.

"SUBA" (which stands for "super bioavailability") technology is designed to improve the bioavailability of orally administered drugs that are poorly soluble. In studies conducted by Mayne Pharma Ventures Pty Ltd. and its affiliates ("Mayne Pharma") relating to the anti-fungal use of SUBA-Itraconazole, SUBA-Itraconazole demonstrated improved absorption and significantly reduced variability within and between patients compared to the branded and generic forms of itraconazole in human studies. We believe this technology is well-suited for the exploration of the potential anti-cancer effects of itraconazole. Mayne Pharma is our majority stockholder and has also licensed to us the U.S. rights to SUBA-Itraconazole as a potential treatment for cancer. The predicted benefits of the SUBA-Itraconazole formulation are as follows:

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

The foregoing characteristics lead us to believe that SUBA-Itraconazole could be well-suited for chronic use in treating cancer due to its more predictable therapeutic levels and lower toxicity, and we are studying this theory in our current clinical trial.

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

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

Following a meeting between our management and representatives of the FDA in August 2014, we submitted to FDA an Investigational New Drug ("IND") application in November 2014 for the use of our product candidate to treat Gorlin Syndrome, which, among other conditions, causes the chronic formation of basal cell tumors. Our IND application was cleared by the FDA in December 2014, and we commenced patient recruiting during the third quarter of 2015 for our Phase II(b) clinical trial. We then began studying the safety and efficacy of the SUBA-Itraconazole formulation during the fourth quarter 2015 to determine how well it reduces basal cell carcinoma tumor burden in patients with Gorlin Syndrome.

In May 2016, we received notice of Orphan Drug Designation for treatment of patients with Gorlin Syndrome with our oral formulation of SUBA-Itraconazole Capsules. In August 2016, we announced positive interim data from our Phase II(b) trial. The data reported were derived from our analysis of results in 13 subjects who completed 16 weeks of SUBA-Itraconazole dosing. In October 2016, we announced additional positive interim data from our Phase II(b) trial for 18 subjects who completed 16 weeks of SUBA-Itraconazole dosing. Based on these encouraging interim results, we intend to continue collecting data on subjects being enrolled and treated at 5 centers in the U.S. while we interact with FDA regarding ongoing results demonstrating efficacy and tolerability for SUBA-Itraconazole the treatment of BCC in patients with Gorlin Syndrome.

In November 2016, we submitted a Breakthrough Therapy Designation Request (or BTDR) to the FDA for SUBA-Itraconazole for the treatment of non-metastatic basal cell carcinoma in patients with BCCNS. On January 19, 2017, we received a written communication from the FDA stating that our BTDR could not be granted at that time due to the FDA's determination that, based on the clinical endpoints for our ongoing Phase II(b) clinical trial of SUBA-Itraconazole for the treatment of BCCNS, we were not seeking to treat a life-threatening aspect of BCC associated with BCCNS. The FDA advised that, in lieu of meeting that requirement, we may submit a new BTDR at such time as we are able to provide further evidence that administration of SUBA-Itraconazole results in delay or avoidance of the need for surgical excision of BCC tumors in BCCNS subjects. The current study endpoint (as previously approved by the FDA) is a 30% or greater reduction in target tumor burden and, to-date only one subject in our current trial has required surgical intervention and only for a single tumor. The FDA further advised that, in order to submit a revised BTDR for SUBA-Itraconazole for the treatment of BCCNS, we must provide data for at least 24 weeks' duration of confirmed clinical responses for subjects being studied in our Phase II(b) trial according to a central independent review committee. As a result of this development, we intend to continue our planned recruitment and treatment of patients in our Phase II(b) trial in order to collect further data regarding duration of response for those subjects who have completed 24 weeks or more in the trial. Thirteen such subjects have qualified to date. We will continue to evaluate whether a revised BTDR submission is appropriate. Importantly, these developments are not expected to impact our overall anticipated timing for conclusion of the study (if primary endpoints are met) that would support the filing of a New Drug Application filing (or NDA) with the FDA later this year for potential approval of SUBA-Itraconazole for the treatment of BCCNS.

Our regulatory strategy is driven by the so called 505(b)(2) regulatory pathway, under which a drug (in our case, itraconazole) that has already been approved for use in humans in the United States by the FDA is developed for one or more new medical indications (in our case, as an anti-cancer agent). Due to the history of safe and efficacious use of itraconazole in humans for anti-fungal applications, we believe the 505(b)(2) pathway is available to us, which creates the potential for significantly reducing the risk and time to achieve FDA approval of our cancer therapy compared to new clinical entities.

Intellectual Property

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

We have developed, licensed and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole. We have exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole Capsules for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner and majority stockholder Mayne Pharma under a Supply and License Agreement, originally dated September 3, 2013, amended and restated on June 24, 2014 and May 15, 2015, and most recently amended on November 22, 2016 (the "Supply and License Agreement"). Mayne Pharma is an Australian specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes directly or through distribution partners and also provides contract development and manufacturing services. In addition to being our licensor and supply partner, under the Supply and License Agreement and related agreements, Mayne Pharma holds a majority equity stake in our company and holds important rights with respect to our company, such as the right to appoint members to our Board of Directors.

On September 2, 2015, we entered into a sublicense agreement with Mayne Pharma, pursuant to which Mayne Pharma sublicensed to us the exclusive U.S. rights to two patents regarding the use of itraconazole for treatment of cancer, namely US patent No 8,980,930 entitled "Angiogenesis Inhibitors", issued on March 17, 2015, and US patent No 8,653,083 entitled "Hedgehog Pathway Antagonists to Treat Disease", issued on February 28, 2014. Mayne Pharma is the sublicensee of the patents from Accelas Holdings, a British Virgin Islands company, who in turn is the licensee from The Johns Hopkins University, the owner of the patents. The patents relate to the use of itraconazole as a treatment for cancer and age-related macular degeneration. We paid a one-time license fee of $75,000 to Mayne Pharma upon entering into the sublicense agreement, which is included in research and development expenses in the accompanying 2015 statement of operations.

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

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

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

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

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

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

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

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

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

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

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

The Hedgehog Pathway

Based on the results of existing physician-sponsored studies conducted by others (including in vitro, animal and human studies), we believe that itraconazole affects the Hedgehog signaling pathway in cells, which could in turn impact the development and growth of certain cancers. The studies, conducted at prominent medical institutions, primarily in the United States, were published in the *Journal of Thoracic Oncology, The Oncologist and the Journal of Clinical Oncology* between May 2013 and February 2014. Based on these studies, it appears that itraconazole may have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of on-going research. These studies formed the basis of our interest in the clinical development of itraconazole for treatment of human cancers.

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

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

Repurposing Itraconazole for Treating Cancer

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

Itraconazole appears to have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of ongoing research. These anti-cancer effects have been demonstrated in various animal models and, subsequently in human studies over the last few years including our Phase II(b) clinical trial to treat BCC in patients with Gorlin Syndrome, all of which are the basis of our continued interest in the clinical development of SUBA-Itraconazole for treatment of human cancers.

We believe that our development of SUBA-Itraconazole as an anti-cancer therapy has demonstrated (as a result of the preliminary data from our ongoing Phase II(b) trial) its potential effective use as an inhibitor of the Hedgehog pathway, thereby retarding the progression of cancer.

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

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

Basal Cell Carcinoma

SUBA-Itraconazole may offer a significant alternative therapy to Genentech's drug, vismodegib, for treatment of basal cell carcinoma (known as BCC). Vismodegib is the first FDA-approved Hedgehog inhibitor based-therapy, yet has many reported toxicities and is associated with serious side effects that result in suspension of chronic dosing. As a result, basal cell tumors reoccur and patients are faced with the choice of returning to vismodegib therapy or, if possible, surgical alternatives. The SUBA-Itraconazole formulation of itraconazole may prove to be a more acceptable therapy for a larger number of patients or considered as a therapy which could easily be alternated with vismodegib, especially for patients who cannot endure vismodegib side-effects for extended periods of treatment. Additionally, recent reports indicate that vismodegib has led to resistance in some BCC patients, so use of SUBA-Itraconazole as an alternative therapy in this sub-population of patients could prove to be very useful for long term oral drug therapy. We believe it is for this reason that SUBA-Itraconazole has qualified for orphan drug designation for the treatment of patients with Gorlin Syndrome An orphan drug designation expedites review of drugs for the treatment of diseases that have relatively small patient populations. If SUBA-Itraconazole is approved as an orphan drug, there will be various commercial benefits to the Company such as 7 years of market exclusivity following FDA approval

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

Gorlin Syndrome is caused by a mutation in a gene called PTCH1. This mutation causes PTCH to lose its ability to inhibit SMO (a protein receptor of the Hedgehog pathway) which controls Hedgehog Pathway signaling. With SMO not being inhibited, BCCNS patients develop multiple BCC tumors over weeks, months and years on a continued basis. SUBA-Itraconazole is therefore being tested to study its ability to bind to SMO (itraconazole has demonstrated SMO binding in animal and human studies), thus inhibiting Hedgehog pathway activity which leads to the formation of the BCC tumors in these patients. The key objective of our ongoing Phase II(b) trial is to demonstrate patient benefit by reducing tumor burden that requires on-going intervention for tumor growth via surgery and/or use of more toxic Hedgehog inhibitor therapies.

Lung Cancer

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

Prostate Cancer

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

Our Potential Market

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

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

Cancer	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market*
Skin(1)	Patients with BCC (basal cell carcinoma) lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring surgery Follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures	Less toxic therapy than vismodegib for Gorlin Patients to delay surgeries; low toxicity therapy to delay or minimize surgical intervention for facial BCC tumors	10,000 Gorlin patients needing chronic BCC therapy; 65,000 BCC patients pending surgical treatment for facial tumors that require excision and potential plastic surgery	$300 million for Gorlin patients and $600 million for patients with BCC facial lesions requiring surgery based upon HedgePath estimates of ~ $4,000 - $5,000 monthly cost of therapy for target populations
Lung(2)	Patients with advanced non-squamous cell, non-small cell lung cancer (NSCLC) who will be placed on Cisplatin/Pemetrexed IV Therapy	Improve the current median 8-10 month survival achieved with best supportive care	56,000 men and women with late-stage disease on chemotherapy treatment	$1.7 billion based on HedgePath estimates of ~ $4,000 - $5,000 monthly cost of therapy
Prostate(3)	Patients with non metastatic castrate resistant prostate cancer (NMCRPC) and rising PSA levels on “off-label” androgen deprivation therapy (ADT)	Delay the progression to metastatic disease while preventing or reducing the use of ADT and its associated side-effects	45,000 high-risk men with prostate cancer which may lead to metastases of the bone	$1.5 billion based on HedgePath estimates of ~ $4,000 - $5,000 monthly cost of therapy

* HedgePath therapies based on 50% of patient populations

References:

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

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

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

Our Strategy

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

- *Rapidly Advance the Clinical Development of Our Therapies.* With the history of safe use of itraconazole in humans for anti-fungal indications, we bypassed each of the required pre-clinical animal studies for toxicity and Phase I human trials to establish safety, and therefore are able to move directly into Phase II human trials. We filed an IND to test SUBA-Itraconazole for the treatment of basal cell carcinoma in patients with Gorlin Syndrome, and the IND was cleared by FDA for human testing as of late December 2014. As a result, we began recruiting subjects for a Phase II(b) trial during the third quarter of 2015 and dosing subjects in fourth quarter of 2015. We announced positive interim data from this trial in August 2016 and October 2016. In addition, we may file individualized clinical protocols during 2017 and beyond to expand the study of SUBA-Itraconazole for other target cancer indications.

- *Seek FDA Programs to Expedite Drug Approvals.* The FDA has various programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. These expedited programs help ensure that therapies for serious conditions are available as soon as it can be concluded that the therapies' benefits justify their risks, taking into account the seriousness of the condition and the availability of alternative treatments. These programs include BTDR, 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. In May 2016, we received notice of Orphan Drug Designation for treatment of patients with Gorlin Syndrome with our oral formulation of SUBA-Itraconazole oral capsules. In January 2017, our initial BTDR request was denied by FDA, and we will continue to evaluate whether a revised BTDR submission is appropriate.

- *Commercialize and Market with Exclusivity.* We have opened clinical trial sites and commenced the clinical testing of SUBA-Itraconazole for treatment of basal cell carcinoma in an initial Phase II(b) trial for patients with Gorlin Syndrome, in order to later seek FDA approval based upon its efficacy for this new indication. In addition, should we gain FDA approval for treatment of BCC in patients with Gorlin Syndrome, for which we currently have an orphan designation, we would be entitled to 7 years of market exclusivity following FDA approval. We are also developing specific clinical trial designs to address different forms of cancer in order to pursue 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:

- financial support from our manufacturing and supply partner and majority stockholder, Mayne Pharma;

- proceeds from public and private financings and, potentially, from strategic transactions;

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

Background on Cancer

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

Cancer is the second leading cause of death in the United States, exceeded only by heart disease. The American Cancer Society estimates that in 2016 there were approximately 1.7 million new cases of cancer and approximately 596,000 deaths from cancer in the United States.

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

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

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

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

The Itraconazole Approach to Treating Cancer

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

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

Cancer and Hedgehog Inhibitors. The Hedgehog (also known as Hh) proteins comprise a group of secreted proteins that regulate cell growth, differentiation and survival. They are involved in organogenesis (the formation of organs), and have been shown to promote adult stem cell proliferation. Inappropriate activation of the Hh signaling pathway has been implicated in the development of several types of cancers including prostate, lung, pancreas, breast, brain and skin. Hedgehog pathway inhibitors are a relatively new class of therapeutic agents that act by targeting the proteins involved in the regulation of the Hh pathway. Many of these newly discovered inhibitors are currently undergoing preclinical testing and some have entered clinical studies as anti-cancer agents for a variety of cancers. Vismodegib was approved for treatment of locally advanced and metastatic basal cell carcinoma in early 2012 and sonidegib was approved for locally advanced BCC in mid-2015.

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

Manufacturing and Product Supply and Relationship with Mayne Pharma

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

Pursuant to the Supply and License Agreement, Mayne Pharma is obligated to: (i) supply us with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being skin, , lung and prostate cancer) in the United States, (ii) provide us with an exclusive license to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer via oral administration in the United States and (iii) participate in a joint development committee (or the JDC) with us to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States. The Supply and License Agreement may be terminated by Mayne Pharma if we fail to achieve regulatory approval to commercialize SUBA-Itraconazole in the U.S. by December 31, 2018, if we breach any provision of the Amended and Restated Equity Holders Agreement, as amended by Amendment No. 1 to Amended and Restated Equity Holders' Agreement (the "Equity Holders Agreement"), if we materially breach the Supply and License Agreement and do not cure such breach within a specified time period, or if either party files for bankruptcy or insolvency proceedings.

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

On June 24, 2014, we and Mayne Pharma, along with Nicholas J. Virca, our President and Chief Executive Officer, Frank E. O'Donnell, Jr., M.D., our former Executive Chairman, and Hedgepath, LLC, a Florida limited liability company and the then majority stockholder of our company which is controlled by Black Robe Capital LLC, consummated a series of related transactions to fulfill certain conditions of the Supply and License Agreement. In connection therewith, we and Mayne Pharma entered into an Amended and Restated Supply and License Agreement. In addition, on the June 24, 2014, in fulfillment of one of the conditions under the Supply and License Agreement, we entered into a Securities Purchase Agreement with Mayne Pharma (the "Mayne Purchase Agreement"). Pursuant to the terms of the Mayne Purchase Agreement, we issued to Mayne Pharma (i) 258,363.280 shares of our Series A Preferred Stock, and (ii) a warrant to purchase 10,250,569 shares of our common stock. The shares of Series A Preferred Stock converted into 87,843,897 shares of common stock on August 14, 2014. Such warrant has an exercise price of $0.0878 per share and expiration date of June 24, 2019, and was fully exercised during the twelve months ending December 31, 2016.

On May 15, 2015, we and Mayne Pharma, along with Mr. Virca and Dr. O'Donnell consummated a series of related transactions to fulfill certain conditions of the Supply and License Agreement. In connection therewith, we and Mayne Pharma entered into a Second Amended and Restated Supply and License Agreement. In addition, on May 15, 2015, we entered into a Securities Purchase Agreement with Mayne Pharma (the "2015 Mayne Purchase Agreement"). Pursuant to the terms of the 2015 Mayne Purchase Agreement, we issued to Mayne Pharma (i) 33,333,333 shares of our common stock and (ii) a warrant to purchase 33,333,333 shares of our common stock. Such warrant has an exercise price of $0.075 per share and expiration date of May 15, 2020, and was fully exercised during the twelve months ending December 31, 2016.

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

In connection with the Offering, and pursuant to an existing right of Mayne Pharma to purchase its pro rata share, on a fully-diluted basis, of new securities issuances (the "Mayne First Right of Refusal"), we entered into a definitive Securities Purchase Agreement ("SPA") (in substantially the same form as the SPA executed by other investors in the Offering) with Mayne Pharma, and in connection therewith issued an aggregate of 27,885,000 Units to Mayne Pharma, consisting of an aggregate of 27,885,000 shares of common stock and a Warrant to purchase up to an aggregate of 27,885,000 shares of common stock, for aggregate gross proceeds to us of $2,788,500.

In connection with the Offering, we engaged certain FINRA-member agents to help it secure investors for the Offering (the "Finders Arrangements"). Such agents secured investors for an aggregate of $582,500 for the Offering and received commissions equal to an aggregate of $46,600 in cash and warrants (in substantially the form of the Warrants) to purchase 466,000 shares of common stock. Pursuant to the Mayne Right of First Refusal, we issued and sold to Mayne Pharma a warrant to purchase 479,236 shares of common stock for a purchase price of $47,924 (the "Mayne Finders Warrant"), which constituted Mayne's pro rata share, on a fully-diluted basis, of all warrants issued in connection with the Finders Arrangements, inclusive of the Mayne Finders Warrant. For ease of administration, the 479,236 shares of common stock underlying the Mayne Finders Warrant were added to the Mayne Offering Warrant, resulting in the issuance to Mayne of a single Warrant to purchase 28,364,236 shares of common stock.

As a result of the Offering and subsequent warrant exercises by Mayne Pharma, Mayne Pharma owned approximately 50.5% of our equity securities on a fully diluted basis as of December 31, 2016.

See "Certain Relationships and Related Party Transactions" for further information.

Sales and Marketing

We are in the early stages of development and thus have not yet established a sales, marketing or product distribution infrastructure because our product candidate is still in clinical development. We may either license commercialization rights to our product candidate to larger third party partners, who will be responsible for sales, distribution and marketing efforts, or we may (assuming adequate resources are available) retain commercial rights for our product candidate, in which case we would seek to access the oncology market through a focused, specialized sales force of our own or in conjunction with a marketing partner under a co-promotion agreement. In December 2016, we entered into an agreement with a leading strategic advisory company, which specializes in the arena of orphan drugs, to provide us with additional assistance in the development of our commercial strategy for SUBA-Itraconazole for treatment of BCC in patients with BCCNS. This effort is intended to assist our determination of our pricing and launch strategy for 2018, assuming ultimate FDA approval of SUBA-Itraconazole as a treatment for BCCNS.

Competition

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

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

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

Names	Company	Description	Status
Taxotere® docetaxel	Sanofi-Aventis	Anti-tumor agent for MCRPC and late-stage NSCLC	Approved 2004; and new generics
Jevtana® cabazitaxel	Sanofi-Aventis	MCRPC following docetaxel failure	Approved 2010
Provenge® sipuleucel-T	Dendreon/Valient	Immunotherapy for asymptomatic MCRPC	Approved 2010
Zytiga® aberaterone	Janssen Biotech	Androgen synthesis inhibitor for MCRPC	Approved 2011
Xtandi® enzalutamide	Astellas	Androgen receptor inhibitor for MCRPC previously on docetaxel	Approved 2012
Erivedge® vismodegib	Roche Genentech	Hedgehog inhibitor for advanced and metastatic BCC	Approved 2012
Odomzo® - sonidegib	Sun Pharma	Hedgehog inhibitor for advanced and metastatic BCC	Approved 2015
Avastin® bevacizumab	Genentech	Angiogenesis inhibitor for NSCLC except squamous cell lung cancer	Approved for multiple cancers since 2004
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	Astellas	Epidermal growth factor inhibitor treatment for NSCLC - maintenance therapy after chemo or metastatic disease after chemo	Approved in 2013
Xalkori® crizotinib	Pfizer	Selective inhibitor for late-state NSCLC patients who express the ALK gene	Approved in 2011
Gilotrif® afatinib	Boehringer	NSCLC with mutations in EGFR	Approved 2013
Zykadia® certinib	Novartis	ALK-positive metastatic NSCLC for patients who progressed on Xalkori	Approved 2014
Opdivo® nivolumab	BMS	Metastatic squamous NSCLC	Approved 2015
Portrassa® necitumumab	Lilly	Metastatic squamous NSCLC	Approved 2015
Tagrisso® osimertinib	AstraZenica	EGFR mutation positive NSCLC	Approved 2015
Keytruda® pembrolizumab	Merck Oncology	Metastatic NSCLC expressing PD-L1	Approved 2015
Alecensa® alectinib	Genentech	Metastatic NSCLC ALK positive who could not tolerate crizotinib	Approved 2015
Iressa® gefitinib	As AstraZeneca	Metastatic NSCLC with EGFR deleture	Approved 2015
Tecentriq® atezolizumab	Genentech	Anti-PDL-1 for Metastatic NSCLC not responding to EGFR or ALK gene therapy or platinum-based chemotherapy	Approved 2016

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

Government Regulation and Product Approval

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

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending 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 ("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 ("cGMP") and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance; and
- FDA review and approval of the NDA.

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

We have successfully avoided pre-clinical studies or any Phase I studies to demonstrate safety based on the fact that itraconazole has an established history of safe and effective use in humans for anti-fungal indications and the fact that human data is already available and published regarding use of itraconazole in humans for anti-cancer indications, such as basal cell carcinoma, lung cancer and prostate cancer, at the Phase II level and the December 2014 clearance of our IND for human testing in a Phase II(b) clinical trial for which we began dosing patients during fourth quarter of 2015.

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

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

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. As mentioned previously, we have moved directly into Phase II trials with SUBA-Itraconazole for our targeted anti-cancer indications based upon the previous, well-established safety profile of itraconazole use in humans for treatment of anti-fungal indications and based upon the previous human data regarding the use of itraconazole for anti-cancer indications such as basal cell carcinoma, lung cancer and prostate cancer and the IND clearance by FDA which occurred in December 2014.

Marketing Approval. Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act ("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 ("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 ("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 (collectively, the "PPACA"), which, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. PPACA also created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. The federal Health Insurance Portability and Accountability Act of 1996 ("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 ("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 ("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 have obtained orphan drug designation for our product candidate for treatment of basal cell carcinoma in patients with Gorlin syndrome as of May 2016 and may, in the future, apply for orphan drug designation for other cancers such as 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. We do however intend to include sites outside the United States for our clinical trials in order to be able to recruit more patients for testing at a greater number of locations and in less time than if we were to focus only on US-based sites. For example, in the European Union, we would need to obtain authorization of a clinical trial application in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Employees

As of February 17, 2017, we have 3 full-time employees. One is involved in our clinical development program and operations and two handle our administration and accounting. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our clinical development and administrative functions. We currently have contracted a regulatory consultant and a Contract Research Organization to spearhead our efforts on clinical development. We consider relations with all of our employees to be good. Each of our employees has entered into confidentiality, intellectual property assignment and non-competition agreements with us.

Corporate History

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

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

We are a clinical stage biopharmaceutical company with no history of revenue-generating operations. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties inherent in a new business, in particular new businesses engaged in the development of pharmaceuticals. We still must establish and implement many important functions necessary to operate a business, including the clinical development of our product candidate and establishing our managerial and administrative structure.

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 potential commercial partners such as licensors of technology and suppliers.

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

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

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

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

Moreover, Hedgepath, LLC, from whom we acquired the itraconazole business opportunity as part of our plan of bankruptcy reorganization, was only formed in late 2011 and thus itself has a limited operating history. Our operations are presently limited to planning for clinical trials, conducting our current Phase II(b) clinical trial testing the efficacy and safety of SUBA-Itraconazole for treatment of basal cell carcinoma in patients with Gorlin Syndrome, and arranging for the raising of capital, developing our technology and identifying potential commercial partners. We have not yet demonstrated our ability to complete any clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for product commercialization. Consequently, any predictions you make about our future viability or ability to accomplish our business goals may not be as accurate as they could be if we had a longer operating history.

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

Under our Supply and License Agreement with Mayne Pharma which will terminate on December 31, 2018 if we have not received FDA approval for our product candidate (unless extended), we have secured exclusive rights to commercialize SUBA-Itraconazole for the treatment of patients with cancer via oral administration in the United States. Mayne Pharma is our sole source supplier of SUBA-Itraconazole, and under such agreement, we must obtain all required supply of SUBA-Itraconazole capsules for our clinical trials and commercialization of the product from Mayne Pharma, except in the limited circumstance where Mayne Pharma has established a secondary supplier and is unable to supply the product. In addition, Mayne Pharma is presently our majority stockholder, and as such has the power to exert significant control over our company. As such, our agreement and collaboration with Mayne Pharma are critical to our business. In the event that the Supply and License Agreement is terminated, whether due to our failure to obtain FDA approval by December 31, 2018 or otherwise, or Mayne Pharma is unable to supply the product, we may lose the ability to commercialize SUBA-Itraconazole, and our business prospects would be materially damaged.

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

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

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

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

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

Mayne Pharma currently owns approximately 55.9% of our outstanding common stock. Under the terms of our Equity Holders Agreement, Mayne Pharma has the right to purchase any shares of common stock being transferred or sold by the individual account of our current President and Chief Executive Officer and former Executive Chairman. In addition to Mayne Pharma's current common stock ownership, Mayne Pharma also has the right to designate one director to our Board of Directors (and to designate a second director if the size of the Board of Directors is increased to seven directors) until the earlier to occur of: (i) the date that the Supply and License Agreement is terminated or expires, or (ii) the date on which Mayne Pharma along with its affiliates ceases to own ten percent (10%) or more of our issued and outstanding common stock on a fully diluted basis. During this time frame, Mayne Pharma, through its representative on the Board of Directors, holds a veto right in the event that we want to increase or decrease the size of the Board of Directors or replace or remove our President and Chief Executive Officer (such veto right being the result of each of the foregoing Board of Director actions requiring the unanimous consent of the Board of Directors). Mayne Pharma's significant ownership of our common stock plus the existence of these additional rights will for the foreseeable future enable Mayne Pharma to exert influence over our company and matters requiring stockholder approval including the election of directors, financing activities or a merger or sale of our assets. An example of Mayne Pharma's exercise of its stockholder rights occurred in November 2016, when Mayne Pharma acted by written consent to remove two sitting members of our Board of Directors and replace such directors with appointees of Mayne Pharma's choosing. Mayne Pharma may elect in its discretion to exercise these or similar rights at any time. Additionally, these rights may limit the ability of our Board of Directors and our management team to make necessary personnel decisions, including adding independent directors to our Board of Directors, which may adversely affect the management of our company, particularly if disputes arise between us and Mayne Pharma (which disputes in and of themselves could have a material adverse effect on our ability to conduct business).

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

Our operations are dependent upon a relatively small group of individuals and, in particular, our current officers and directors, including most notably Nicholas J. Virca. We believe that our ability to implement our business plans depends on the continued service of these individuals and/or other officers and directors. We do presently have an employment agreement with Mr. Virca. However, the agreement is terminable upon 60 days' notice to us with or without good reason. The unexpected loss of the services of one or more of our directors or officers could have a detrimental effect on us.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities (including activities previously undertaken in a private company context) more difficult, time-consuming or costly and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our ability to implement our business plans. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

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

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

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

Risks Related to Our Financial Position and Need For Additional Capital

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

As of the date of this Report, we have cash on hand sufficient to run our planned operations into the quarter ending March 31, 2018. 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. In addition, there is a risk that we will be liable for a payroll tax liability arising from the payment of certain vested RSU awards that will be paid on or before March 15, 2017. Such withholding payment for related payroll taxes will be based upon the market value of approximately 26.5 million shares on the payment date of the RSUs, could be material and significantly reduce our cash resources and thus require us to raise additional capital earlier than planned to fund ongoing operations.

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

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

- the progress and results of our development efforts for SUBA-Itraconazole 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 of commercial success. Our commercial revenues, if any, will be derived from sales of a product that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

We currently do not generate any revenue from product sales or otherwise, and we therefore have a limited source of cash to meet our future capital requirements. We do not expect to generate revenues for the foreseeable future, and we may not be able to raise funds in the future, which would leave us without resources to continue operations and force us to resort to stockholder investments or loans, which may not be available to us. We may have difficulty raising needed capital in the near or longer term as a result of, among other factors, the very early stage of our company, the rights of certain of our stockholders to participate in our future financings and our lack of revenues as well as the inherent business risks associated with our company and present and future market conditions. Also, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. Our inability to raise funds could lead to decreases in the price of our common stock and the failure of our business.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Since we will be unable to generate any revenue from actual sales of products and expect to be in the development stage for the foreseeable future, we will need to seek equity or debt financing to provide the capital required to execute our business plan. We will need significant funding for developing our intellectual property, conducting clinical trials and entering into collaborations with third party partners as well as for working capital requirements and other operating and general corporate purposes.

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

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

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

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

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

Risks Related to the Clinical Development of Our Product Candidate

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

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

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

- positive commencement and completion of clinical trials;
- successful preparation of regulatory filings and receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and potential regulatory exclusivity for our product candidate and protecting our rights in our intellectual property portfolio;
- maintaining our agreement with Mayne Pharma to produce product needed for clinical testing, including obtaining FDA approval for our product prior to December 31, 2018, and, potentially if approvals are obtained, for commercial sale;
- launching commercial sales of our product, if and when approved for one or more indications, whether alone or in collaboration with others;
- acceptance of the product for one or more indications, if and when approved, by patients, the medical community and third party payors;

- protection from generic substitution based upon our own or licensed intellectual property rights;
- effectively competing with other therapies;
- obtaining and maintaining adequate reimbursement from healthcare payors; and
- maintaining a continued acceptable safety profile of our product following approval, if any.

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

In addition, given our current limited financial resources, we are currently focusing our efforts on one key cancer indication, namely basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome, also known as Gorlin Syndrome. We are thus faced with the risk that SUBA-Itraconazole could be ineffective in addressing this particular initial cancer indication, and if our efforts to demonstrate the efficacy of SUBA-Itraconazole in treating basal cell carcinoma in this target patient population are not positive, we may lack the resources to expand our efforts into other cancer indications.

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

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

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, which would be time consuming and costly;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of materials necessary to conduct clinical trials of our product candidate may be insufficient or inadequate;
- our product candidate may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials; and.
- interactions with other drugs.

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

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

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know which, if any, of our clinical trials other than our current Phase II(b) trial, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could lead to the termination of our agreement with Mayne Pharma to utilize SUBA-Itraconazole as a potential treatment for cancer (specifically, if we are not able to obtain FDA approval by December 31, 2018), 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. Enrollment delays may also lead to the termination of our agreement with Mayne Pharma to utilize SUBA-Itraconazole as a potential treatment for cancer (specifically, if we are not able to obtain FDA approval by December 31, 2018),

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

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

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

Because we have limited financial and managerial resources, we will focus for the foreseeable future only on the clinical development of SUBA-Itraconazole for the treatment of cancer as a therapy for basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome, also known as Gorlin Syndrome. As a result, we may forego or be unable to pursue opportunities with other product candidates or for indications other than those we intend to pursue that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs related to SUBA-Itraconazole for the treatment of cancer may not yield any commercially viable therapies. Because of this concentration of our efforts, our business will be particularly subject to significant risk of failure of our one current product candidate.

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

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

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

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

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

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

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

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

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

Moreover, we may be unable to maintain our agreement with Mayne Pharma, whether due to our failure to obtain FDA approval by December 31, 2018 or otherwise, or establish any agreements with other third party manufacturers or to do so on acceptable terms should we have the ability and the need to do so. Even though we have established an agreement with Mayne Pharma or if we are able to establish agreements with other third party manufacturers, reliance on third party manufacturers entails additional risks, including:

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

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

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

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

Risks Related to the Commercialization of Our Product Candidate

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

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

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

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

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

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

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

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

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

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

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs, and we may be unable to effectively compete with these companies for these or other reasons.

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

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

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

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

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

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

- decreased demand for any product candidates or products that we may develop;
- damage to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

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

Risks Related to Our Intellectual Property

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

Our business plan depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products, and in particular, the rights to develop SUBA-Itraconazole as an anti-cancer therapy. We seek to protect our proprietary position through our exclusive license for SUBA-Itraconazole with Mayne Pharma, through our sublicense of other itraconazole-related rights from 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.

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

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

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

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

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

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

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

We have and/or expect to enter into licenses with third parties that hold intellectual property, including patent rights, that are important or necessary to the development of itraconazole, and SUBA-Itraconazole in particular, as an anti-cancer therapy, and it may be necessary for us to use the patented or proprietary technology of third parties, such as Mayne Pharma, to commercialize itraconazole as an anti-cancer therapy, in which case we have or would be required to obtain a license from these third parties on commercially reasonable terms, or else our business could be harmed, possibly materially. Even though we have obtained exclusive rights to additional patents from Mayne Pharma during the second half of 2015 and early 2016, and have had a patent issued for our own inventions in the United States in November 2015, if we were not able to maintain or obtain our current or additional licenses, or were not able to maintain or obtain such licenses on commercially reasonable terms, our business could be harmed, possibly substantially if we are not able to maintain or obtain such licenses, or are not able to maintain or obtain such licenses on commercially reasonable terms, our business could be harmed, possibly substantially.

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

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

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

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

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

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

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

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

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

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

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

We will likely seek approval of SUBA-Itraconazole 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 an NDA with the FDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain preclinical testing or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product.

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

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

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

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

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

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that SUBA-Itraconazole as an anti-cancer therapy meets the criteria for designation as a breakthrough therapy for one or more indications, the FDA may disagree and instead determine not to make such designation. In fact, in January 2017, our initial breakthrough request related to SUBA-Itraconazole for the treatment of BCCNS was denied by FDA, and no assurances can be given that we will elect to again pursue breakthrough designation for this treatment.

Moreover, even if such designation is granted for one or more of our proposed therapies, of which no assurances may be given, the receipt of a breakthrough therapy designation for any product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if SUBA-Itraconazole as an anti-cancer therapy ultimately 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 have sought and been awarded orphan designation for our product candidate for treatment of non-metastatic BCC in BCCNS (Gorlin Syndrome) patients and if approved by the FDA, will then be entitled to orphan drug exclusivity. If our competitors are able to obtain orphan drug exclusivity for their products that are the same drug or a similar medicinal product as our product 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 SUBA-Itraconazole as an anti-cancer therapy after FDA approval, we may not be able to maintain it. For example, if a competitive product that is the same drug or a similar medicinal product as our product candidate is shown to be clinically superior to our product candidate, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. In addition, orphan drug exclusivity will not prevent the approval of a product that is the same drug as our product candidate if the FDA finds that we cannot assure the availability of sufficient quantities of the drug to meet the needs of the persons with the disease or condition for which the drug was designated. If one or more of these events occur, it could have a material adverse effect on our company.

Even if we obtain marketing approval for our product 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.

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 OTCQX 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 OTCQX market is a relatively unorganized, inter-dealer, over-the-counter market that provides significantly less liquidity than NASDAQ or the NYSE MKT (formerly known as the NYSE AMEX market). This illiquid trading market for our common stock may make it difficult for you to dispose of your common stock at desirable prices or at all. Moreover, there is a risk that our common stock could be delisted from the OTCQX, 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 OTCQX inclusion, and therefore you may be unable to sell your shares.

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

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

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

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;

- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

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

- changes in our relationship with Mayne Pharma
- any delay in or the results of our clinical trials;
- the announcements of clinical trial data, and the investment community's perception of and reaction to those data;
- the results of clinical trials conducted by others on products that would compete with our product candidate;
- any delay or failure to receive approval from the FDA and other regulatory agencies or bodies;
- our inability to commercially launch our product or market and generate sales of our product;
- failure of our product, even if approved for marketing, to achieve any level of commercial success;
- our failure to obtain or maintain patent protection for any of our technologies and product or the issuance of third party patents that cover our technologies or product;
- developments or disputes concerning our product's intellectual property rights;
- our competitors' technological innovations;
- general and industry-specific economic conditions that may affect our expenditures;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents;
- failure to adequately manufacture our product through third parties for purposes of clinical trials or actual sales;
- future sales of our common stock or other securities;
- period-to-period fluctuations in our financial results; and
- low trading volume of our common stock;

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

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

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

Collectively, our officers, our directors and two significant stockholders (Hedgepath, LLC and Mayne Pharma) own or exercise voting and investment control of approximately 88.8% of our common stock. As a result, investors may be prevented from affecting matters involving our company, including:

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

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

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

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

Our 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 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 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 Report. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our common stock to be limited, as you may be unable to resell your shares without the significant expense of state registration or qualification.

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

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

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

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

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

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

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

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

In addition, our certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. In particular, our certificate of incorporation and amended and restated bylaws, among other matters:

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

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

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in this 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, for which we currently pay a pro-rated portion of the rent of approximately $2,000 per month.

Item 3. Legal Proceedings.

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

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 OTCQX market under the symbol "HPPI". The range of reported high and reported low sales prices per share for our common stock for each fiscal quarter during 2016 and 2015, as reported by the OTC Markets Group, is set forth below.

Quarterly Common Stock Price Ranges

Fiscal Year 2016, Quarter Ended:	High	Low
March 31, 2016	$0.20	$0.08
June 30, 2016	$0.40	$0.11
September 30, 2016	$0.67	$0.20
December 31, 2016	$0.54	$0.32

Fiscal Year 2015, Quarter Ended:	High	Low
March 31, 2015	$0.30	$0.12
June 30, 2015	$0.24	$0.11
September 30, 2015	$0.19	$0.07
December 31, 2015	$0.20	$0.11

As of February 17, 2017, we had approximately 53 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

The following table provides information as of December 31, 2016 with respect to the shares of our common stock that may be issued under our existing equity compensation plan.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
Equity compensation plans approved by security holders (1)	27,191,738(2)	$ 0.24(2)	5,391,737

(1) The 2014 Equity Incentive Plan (the "EIP") was adopted by the Board of Directors and approved by a majority of our stockholders on September 30, 2014.

(2) Outstanding securities issued pursuant to our EIP are Restricted Stock Units ("RSUs') (26,541,738) and stock options (650,000). Each RSU represents a right to receive one share of our common stock. All stock options were issued on July 1, 2016 and have an exercise price of $0.24 per share. All RSUs and stock options vested in November 2016 upon a change in control. RSU shares will be issued on or before March 15, 2017.

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 is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. We may also explore acquiring or licensing other innovative therapeutics addressing unmet needs and orphan indications beyond cancer. Our preliminary focus is on the development of therapies for skin, lung and prostate cancers in the United States of America market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome). We are presently conducting an open label, Phase II(b) clinical trial of proposed therapy for Gorlin Syndrome, and in August 2016 and October 2016, we announced positive interim data from this trial.

We have developed, licensed and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole. We have exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole Capsules for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner and majority stockholder Mayne Pharma under a Supply and License Agreement, originally dated September 3, 2013, amended and restated on June 24, 2014 and May 15, 2015, most recently amended on November 22, 2016. Mayne Pharma is an Australian specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes directly or through distribution partners and provides contract development and manufacturing services. In addition to being our licensor and supply partner, under the Supply and License Agreement and related agreements, Mayne Pharma holds a majority equity stake in our company and holds important rights with respect to our company, such as the right (in its discretion) to appoint and remove members of our Board of Directors.

Following a meeting between our management and representatives of the FDA in August 2014, we submitted an IND application in November 2014 for the use of our product candidate to treat basal cell carcinoma in patients with Gorlin Syndrome, which, among other conditions, causes the chronic formation of basal cell tumors. Our IND application was cleared by the FDA in December 2014, and we commenced patient recruiting during the third quarter of 2015 for our open label Phase II(b) clinical trial. We then began studying the safety and efficacy of the SUBA-Itraconazole formulation during the fourth quarter 2015 to determine how well it reduces basal cell carcinoma tumor burden in patients with Gorlin Syndrome.

In May 2016, we received notice of Orphan Drug Designation for treatment of patients with Gorlin Syndrome with our oral formulation of SUBA-Itraconazole Capsules. Also, during 2017 and thereafter, we may file additional clinical trial protocols to expand the study of SUBA-Itraconazole for other target cancer indications.

In August 2016 and October 2016, we announced positive interim data from our Phase II(b) trial. The data reported was derived from our interim analysis of results in subjects who completed 16 weeks of SUBA-Itraconazole dosing. Based on these encouraging interim results, we intend to continue collecting data on subjects being enrolled and treated at 5 centers in the U.S. while we interact with FDA regarding ongoing results demonstrating efficacy and tolerability for SUBA-Itraconazole the treatment for Gorlin Syndrome.

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

Critical Accounting Policies and Estimates

Estimates

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

Revenue Recognition

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

Cash and Cash Equivalents

We consider all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, we may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts which is up to $250,000 for substantially all depository accounts. As of December 31, 2016, we had approximately $6.4 million in excess of the amount covered by Federal Deposit Insurance Corporation with one financial institution.

Research and Development Expenses

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

Stock-Based Compensation

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

In applying the Black-Scholes option pricing model for options issued in July 2016, the assumptions were as follows: expected price volatility of 113.16%; risk-free interest rate of 1.14%; weighted average expected life in years of 6; and no dividend yield. The value of these awards is based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

Income taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. We have evaluated the guidance relating to accounting for uncertainty in income taxes and determined that we had no uncertain income tax positions that could have a significant effect on the consolidated financial statements for the years ended December 31, 2016 or 2015. Deferred tax assets consists primarily of in-process research and development, net operating loss carryforward, and share-based compensation.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of Accounting Standards Codification ("ASC") Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard, as updated in 2015, will be effective for us in the first quarter of the year ending December 31, 2018 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. We will evaluate the impact of adoption of this standard on our financial statements upon commencement of revenue generating activities.

In April 2016, the FASB issued ASU2016-10, "*Revenue from Contracts with Customers* (Topic 606): Identifying Performance Obligations and Licensing." ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. This ASU applies to all companies that enter into contracts with customers to transfer goods or services. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, but not before interim and annual reporting periods beginning after December 15, 2016. Entities have the choice to apply the ASU either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. We will evaluate the impact of adoption of the new standard on its financial statements upon commencement of revenue generating activities.

In August 2014, the Financial Accounting Standards Board issued ASUNo. 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosure. This ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We evaluated the impact the revised guidance had on our financial statements and determined it had no significant impact.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification ("ASC") Topic 718, Compensation – Stock Compensation. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. We are currently evaluating the impact of adoption of the ASU on our financial statements.

Results of Operations

For the Year Ended December 31, 2016 Compared to the Year Ended December 31, 2015

Research and Development Expenses. We recognized $2,641,507 and $1,680,250 in research and development expenses during the years ended December 31, 2016 and 2015, respectively. For the year ended December 31, 2016, research and development expenses consisted primarily of approximately $1.5 million in direct clinical trial expense and approximately $1.1 million in salaries, non-cash stock-based compensation, and consulting expense related to clinical trial design and regulatory activities. For the year ended December 31, 2015, research and development expenses consisted of approximately $0.9 million in direct clinical trial expense and $0.8 million in salaries, non-cash stock-based compensation, and consulting expense related to clinical trial design and regulatory activities. The clinical trial began in late 2015 and continued throughout 2016, resulting in the increase in direct clinical trial expense of approximately $0.4 million during the year ended December 31, 2016. In addition, a revaluation of the stock-based compensation as a result of a change in vesting and payment terms of RSUs due to Mayne Pharma acquiring over 50% of our outstanding shares effecting a change in control that resulted in an increase of approximately $0.2 million in other research and development expenses.

General and Administrative Expenses. We recognized $4,380,695 and $2,269,335 in general and administrative expenses during the years ended December 31, 2016 and 2015, respectively. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, and consulting. The increase of approximately $2.1 million is primarily a result of the increase in non-cash stock-based compensation expense of $1.8 million during 2016. The increase in non-cash stock-based compensation was a result of the issuance, during 2016, of additional restricted stock units and stock options to certain employees and Directors under the EIP as well as a result of a change in vesting and payment terms of RSUs and stock options due to Mayne Pharma acquiring over 50% of our outstanding shares effecting a change in control that resulted in an increase of approximately $0.2 million in general and administrative expenses.

Interest Income. We recognized interest income during the year ended December 31, 2016 of $21,985 for interest earned on cash balances in our money market account. There was no interest income during the year ended December 31, 2015.

Liquidity and Capital Resources

We are presently developing and conducting our clinical and regulatory business plans. While we believe we have sufficient resources to complete our current clinical trial, our current cash on hand is insufficient to develop our full clinical and regulatory business plan as currently anticipated. We have not generated revenue since emerging from bankruptcy in 2013. In addition, we may be liable for a payroll tax liability arising from the payment of certain vested RSU awards that will be paid on or before March 15, 2017. Such withholding payment for related payroll taxes will be based upon the market value of approximately 26.5 million shares on the payment date of the RSUs, could be material and significantly reduce our cash resources and thus require us to raise additional capital earlier than planned to fund ongoing operations. A continued lack of cash resources resulting from an inability to generate cash flow from operations or to raise capital from external sources would force us to substantially curtail or cease operations and would, therefore, have a material adverse effect on our business and overall viability.

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

- public and private financings and, potentially, other strategic transactions;
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product to augment their product profile in the treatment of cancers; and
- seeking government or private foundation grants 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, 2016 are as follows:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Employment contracts	$1,000,000	$475,000	$525,000	$ —	$ —
Consulting agreements	$ 112,500	$112,500	$ —	$ —	$ —
Total contractual cash obligations	$1,112,500	$587,500	$525,000	$ —	$ —

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, are set forth beginning on page F-1 of this Report.

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

None.

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, 2016, 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 that, based on their evaluation as of the end of the period covered by this Report, 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, 2016 that have materially affected, 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 U.S. 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, 2016. 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, 2016.

Item 9B. Other Information.

On February 16, 2017, we entered into a second amendment to employment agreement with Nicholas J. Virca, our President and Chief Executive Officer. Pursuant to the terms of this second amendment, Mr. Virca's term of employment was extended through December 31, 2018 and will automatically renew for successive one year terms unless prior written notice is received from either party within 60 days prior to the end of the particular term. Additionally, Mr. Virca's base salary will be increased from $225,000 to $300,000 per annum effective on July 1, 2017 and he will now be eligible for a bonus in cash or in kind of up to 75% of his base salary (up from 50% of his base salary) based upon his achievement of certain goals as established by Mr. Virca and approved by the Board of Directors or a committee of the Board of Directors. The second amendment also revised Mr. Virca's severance package such that in the event that the employment agreement is terminated without cause by us or for good reason by Mr. Virca, Mr. Virca is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to twelve months of Mr. Virca's base salary. Aside from the changes above, there were no further material changes to Mr. Virca's employment agreement.

On February 16, 2017, we entered into a first amendment to employment agreement with Garrison J. Hasara, our Chief Financial Officer and Treasurer. Pursuant to the terms of this first amendment, Mr. Hasara's term of employment was extended through December 31, 2018 and will automatically renew for successive one year terms unless prior written notice is received from either party within 60 days prior to the end of the particular term. Additionally, Mr. Hasara's base salary will be increased from $200,000 to $225,000 per annum effective on July 1, 2017 and he will now be eligible for a bonus in cash or in kind of up to 75% of his base salary (up from 50% of his base salary) based upon his achievement of certain goals as established by Mr. Hasara and approved by the Board of Directors or a committee of the Board of Directors. The first amendment also revised Mr. Hasara's severance package such that in the event that the employment agreement is terminated without cause by us or for good reason by Mr. Hasara, Mr. Hasara is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to twelve months of his base salary. Aside from the changes above, there were no further material changes to Mr. Hasara's employment agreement.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of February 17, 2017 are as follows:

Name	Age	Position
E. Brendan Magrab	51	Chairman of the Board and Director
Nicholas J. Virca	70	President and Chief Executive Officer
Garrison J. Hasara, CPA	47	Chief Financial Officer and Treasurer
W. Mark Watson, CPA	66	Director
Stefan J. Cross	44	Director
Dr. R. Dana Ono	64	Director
Robert D. Martin	69	Director

Mayne Pharma has the right to designate one director to our Board of Directors and to designate a second director if the size of the Board of Directors is increased to seven directors until the earlier to occur of: (i) the date that the Supply and License Agreement is terminated or expires or (ii) the date on which Mayne Pharma ceases to own ten percent (10%) or more of our issued and outstanding common stock on a fully diluted basis. Mayne Pharma's current designee to our Board of Directors is Stefan J. Cross. On November 22, 2016, pursuant the EHA and further pursuant to Section 228 of the Delaware General Corporation Law, Mayne Pharma (as our majority stockholder) executed and delivered to us a written consent in lieu of a meeting of stockholders (i) removing Frank E. O'Donnell, Jr, M.D. as Executive Chairman of the Board of Directors and as a director (ii) electing E. Brendan Magrab, a consultant to Mayne Pharma, as Chairman of the Board of Directors and as a director. Mayne Pharma became the majority stockholder of HedgePath Pharmaceuticals in early November 2016 upon the exercise of certain common stock warrants. Mayne Pharma's action was undertaken unilaterally through the exercise of its rights under the EHA and Delaware law and without the prior knowledge or agreement of the independent members of our Board of Directors. Mayne Pharma did not provide the Board with any reasons for its actions. In connection with Mr. Magrab's election, an affiliate of Mayne Pharma has agreed to issue a certain number of ordinary shares of such affiliate to Mr. Magrab at future dates and to provide him with certain indemnification and related rights for any liability incurred by him in connection with his service with the Company. The Company does not believe that Mr. Magrab qualifies as an "independent director" as defined in the Equity Holders Agreement.

On November 30, 2016, pursuant to the EHA and further pursuant to Section 228 of the Delaware General Corporation Law, Mayne Pharma (as our majority stockholder) executed and delivered to us a written consent in lieu of a meeting of stockholders (i) removing Samuel P. Sears, Jr. as a director and (ii) electing Robert D. Martin as a director. Mayne Pharma's action was undertaken unilaterally through the exercise of its rights under the EHA and Delaware law and without the prior knowledge or agreement of the independent members of the Board of Directors. Mayne Pharma did not provide the Board with any reasons for its actions.

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

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

E. Brendan Magrab, age 51, is Chairman of the Board of Directors and a Director of our company. He has served as the President and CEO of Transpharmative Advisors, LLC since March 2013. Mr. Magrab has more than 20 years of experience in pharmaceutical development and marketing, including formulation development, clinical development, regulatory affairs, government affairs, marketing, managed care, legal and patents. Previously, from June 2012 to February 2013, he served as the President and CEO of URL Pharma, which was sold to Sun Pharmaceuticals in 2013. From October 2004 to June 2012, he held various positions of increasing responsibility at URL Pharma, including General Counsel and Executive Vice President of Commercial Operations. Prior to joining URL Pharma, from August 2000 to September 2004, Mr. Magrab served as Vice President of Intellectual Property at Alpharma, Inc. Prior to joining Alpharma, Inc., he served as an associate at a Washington D.C law firm, as a law clerk for the U.S. Court of Appeals for the Federal Circuit, and as a Patent Examiner at the U.S. Patent and Trademark Office. Mr. Magrab received his Bachelor's Degree in Biochemistry and Art History from the University of Virginia and his Juris Doctor from Georgetown University Law Center. Mr. Magrab is qualified to serve on our Board of Directors because of his extensive business experience in the pharmaceutical industry.

Nicholas J. Virca, age 70, has been our President and Chief Executive Officer since August 2013 and has been working on our business opportunity with Hedgepath, LLC since April 2012. From 2008 until April 2012, Mr. Virca served as the Chief Operating Officer for LamdaGen Corporation, a privately held company focused on monitoring assays for biopharmaceutical development and manufacturing applications, as well as high-sensitivity detection for human diagnostic biomarkers, such as oncoproteins related to cervical cancer. From 2005 to 2008, Mr. Virca was Vice President for Global Biotechnology at Pall Life Sciences where he was responsible for growth strategies and programs in the biotechnology arena, including new technology and product initiatives, joint ventures, licensing and acquisitions. He also founded the first Scientific Advisory Board for Pall's Biopharmaceuticals Division. From 1997 to 2004, Mr. Virca was COO, and later CEO and President of Adventrx Pharmaceuticals focusing on anti-cancer drug development in human clinical trials. He was instrumental in transitioning the company from a private corporation to a listing on the American Stock Exchange. Mr. Virca held various marketing and general management positions at Damon Biotech, Promega Corporation, Nicolet Imaging Systems, Ortho Diagnostic Systems, Fisher Scientific, Waters, Ross Laboratories and Pfizer Diagnostics. He previously served on the boards of Adventrx Pharmaceuticals between 2001 and 2004, and Diametrix Detectors between 1991 and 1997. He earned a bachelor's degree in Biology from Youngstown State University, is the co-inventor of packaging technology for enzyme research reagents, as well as co-inventor of therapy using itraconazole for treatment of cancer, and is a member of numerous biotechnology organizations for which he has been a speaker and organizer over the last two decades.

Garrison J. Hasara, CPA, age 47, has been our Chief Financial Officer and Treasurer since September 2013. From January 2011 to September 2013, he was the Acting Chief Financial Officer, Principal Financial Officer and Principal Accounting Officer of Accentia Biopharmaceuticals, Inc., 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.

W. Mark Watson, CPA, age 66, is a director of our company and Chairman of the Audit Committee. Mr. Watson is a Certified Public Accountant with over 40 years of experience in public accounting and auditing, having spent his entire career from January 1973 to June 2013 at Deloitte Touche Tohmatsu and its predecessor, most recently as Central Florida Marketplace Leader. Among other industries, he has a particular expertise in the health and life sciences sector, having played a significant role in the development of Deloitte's audit approach for health and life sciences companies and leading its national healthcare regulatory and compliance practice. He has served as lead audit partner and advisory partner on the accounts of many public companies ranging from middle market firms to Fortune 500 enterprises. Mr. Watson is a member of American Institute of Certified Public Accountants and the Florida Institute of Certified Public Accountants. Mr. Watson is qualified to serve on our Board of Directors due to his expertise in public accounting and his experience with pharmaceutical companies. He received his undergraduate degree in Accounting from Marquette University.

Stefan J. Cross, age 44, is a director of our company and the appointee of Mayne Pharma to our Board of Directors. Mr. Cross is currently serving as Chief Commercial Officer of Mayne Pharma Group Limited (ASX:MYX). Previously, Mr. Cross served as the President of the U.S. subsidiaries of Mayne Pharma Group Limited from November 2013 to January 2017. Mr. Cross has more than 20 years of experience in the pharmaceutical industry. He served since 2012 as the Vice President, Business and Corporate Development of Mayne Pharma's non-U.S. operations, where he was responsible for allin-licensing and out-licensing programs and research and development partnerships. Prior to joining Mayne Pharma, Mr. Cross was, from 2007 to 2012, Head of Marketing (Asia Pacific) for Hospira Inc., a leading global provider of pharmaceuticals and medical devices, where he was responsible for expansion of the new product portfolio and on-market product growth across all markets in the region. Prior to Hospira, Mr. Cross spent most of the period from 1991 to 2007 working in the pharmaceutical sector in the areas of strategy, business development/mergers and acquisitions, sales and marketing, human resources, finance and information technology. Mr. Cross is qualified to serve on our Board of Directors because of his extensive business experience in the pharmaceutical industry. Mr. Cross holds a Masters in Business in Administration from Swinburne University of Technology, Australia, and a degree in Business Information Systems from the University of South Australia.

Dr. R. Dana Ono, age 64, is a director of our company and Chairman of the Compensation Committee. Dr. Ono is aco-founder of, and since 2000 has been associated with, the VIMAC Milestone Medica Fund LP, a Boston-based early-stage life sciences fund co-sponsored by VIMAC Ventures LLC and RBC Technology Ventures, Inc. Dr. Ono has over 30 years of experience in managing public and private life science companies, including, from 1995 to 2000, serving as President and Chief Executive Officer of IntraImmune Therapies, Inc., which was sold to Abgenix, Inc. in 2000. Presently, Dr. Ono is an executive-in-residence at several universities in the United States advising their licensing offices in spin-outs and new company formation from promising technologies. Throughout his career, he has been engaged in the strategic planning, product management, technology acquisition, and commercial development of life science start-ups and has been involved in a number of pioneering milestones in biotechnology. He has founded several biotech companies in the U.S., including in the areas of drug discovery and development, nutraceuticals and cosmeceuticals. He is a founding director of the Massachusetts Biotechnology Council, Inc. and served on the Board of Trustees of the Marine Biological Laboratory in Woods Hole, Massachusetts. Dr. Ono is qualified to serve on our Board of Directors because of his medical and business expertise, particularly in the pharmaceutical industry. Dr. Ono received his AB in Earth & Planetary Sciences from The Johns Hopkins University and his AM and PhD in Biology from Harvard University, where he also completed a program in business administration.

Robert D. Martin, age 69, is a director of our company and Chairman of the Nominating and Governance Committee. Mr. Martin has over 30 years of finance and operations experience. Since 2006, Mr. Martin has been part of The Interlochen Group, LLC, a firm that provides chief financial officer personnel on a contract basis ("Interlochen"). Among other assignments, he was assigned to serve as Interim Chief Financial Officer of Tandy Brands Accessories Inc. from January 2011 to June 2011. Also, during 2015, he was a consultant/financial advisor to Intezyne Inc, a clinical stage biotechnology company. From 2004 to 2006, Mr. Martin served as President of RDMartin, LTD., a financial consulting firm, and from 2000 to 2004, Mr. Martin served as Senior Vice President and Chief Financial Officer of Russell Corporation, when it was a New York Stock Exchange listed company. Mr. Martin also previously served as divisional Chief Financial Officer of Sunbeam and in various finance roles, including divisional Chief Financial Officer, at Sara Lee Apparel. Mr. Martin earned a Masters of Business Administration from the University of North Carolina, Chapel Hill and a Bachelor's degree in Industrial Engineering from Georgia Tech. Mr. Martin qualifies for our Board of Directors because of his business expertise, particularly with publicly traded companies.

Board Committees and Director Independence

Director Independence

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

Board Committees

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

Audit Committee

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

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

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance anynon-audit service and fees therefor to be provided by the independent auditor;
- monitors the independence of the independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and reviews of our quarterly financial statements;
- provides oversight assistance in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the Board of Directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

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

Compensation Committee

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act 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 2016, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons.

Code of Ethics

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

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, 2016 and 2015. 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, 2016.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Nicholas J. Virca	2016	$187,500	$75,000	—	—	—	—	$ 11,637(2)	$274,137
President and Chief Executive Officer(1)	2015	$150,000	—	—	—	—	—	$ 10,009(2)	$160,009
Garrison J. Hasara, CPA	2016	$176,154	$37,500	—	—	—	—	$ 16,296(4)	$229,950
Chief Financial Officer and Treasurer(3)	2015	$135,000	—	—	—	—	—	$ 13,234(4)	$148,234

(1) Nicholas J. Virca was hired as Chief Executive Officer on August 1, 2013.
(2) Includes: $11,637 and $10,009 of health insurance premiums paid in 2016 and 2015, respectively.
(3) Garrison J. Hasara was hired as Chief Financial Officer on August 1, 2013.
(4) Includes: $16,296 and $13,234 of health insurance premiums paid in 2016 and 2015, respectively.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

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

Nicholas J. Virca, President and Chief Executive Officer - On June 24, 2014, Nicholas J. Virca entered into an employment agreement with us which was subsequently amended on May 15, 2015 and, as described in Item 9B above, on February 16, 2017. Pursuant to his employment agreement, Mr. Virca will act as our President and Chief Executive Officer through December 31, 2018. At the end of the term, the agreement will automatically renew for successive one year terms unless prior written notice is received from either party within 60 days prior to the end of the particular term. Mr. Virca originally earned a base salary of $150,000 per year for services rendered which was subsequently increased in June 2016 by the Board of Directors to $225,000 per year. Effective beginning on July 1, 2017, Mr. Virca's salary will increase to $300,000 per year. Mr. Virca has also historically been eligible for a bonus in cash or in kind of up to 50% of his base salary based upon his achievement of certain goals as established by the Board of Directors or a committee of the Board of Directors and in June 2016, Mr. Virca was awarded and paid a $75,000 bonus. As described in Item 9B above, beginning fiscal year 2017, Mr. Virca will be eligible for a bonus in cash or in kind of up to 75% of his base salary based upon his achievement of certain goals as established by Mr. Virca and approved by the Board of Directors or a committee of the Board of Directors. In addition, in July 2014, Mr. Virca was awarded 15,041,738 RSUs from the EIP, subsequently approved by our majority stockholders. Such RSUs have vested and the shares will be issued to Mr. Virca on or before March 15, 2017.

Mr. Virca's employment agreement may be terminated with or without cause by us or for or without good reason by Mr. Virca. In the event that the employment agreement is terminated for cause by us or without good reason by Mr. Virca, Mr. Virca is entitled to receive all accrued but unpaid salary and bonus amounts. In the event that the employment agreement is terminated without cause by us or for good reason by Mr. Virca (including following a change of control), Mr. Virca is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to twelve months of Mr. Virca's base salary. The employment agreement is also terminable upon death and disability and upon the terms as described in the Equity Holders Agreement between Hedgepath, LLC and Mayne Pharma described under "Certain Relationships and Related Party Transactions. Mr. Virca may not compete against us or solicit employees or customers from us for a period of one (1) year after termination of his employment for any reason as described in his employment agreement.

Garrison J. Hasara, Chief Financial Officer and Treasurer - On September 4, 2014, we and Garrison Hasara, our Chief Financial Officer and Treasurer, entered into an employment agreement, which was subsequently amended on February 16, 2017 as described in Item 9B above, to memorialize the terms under which Mr. Hasara will continue to serve in such capacity. The employment agreement has a term through December 31, 2018. At the end of the term, the agreement will automatically renew for successive one year terms unless prior written notice is received from either party within 60 days prior to the end of the particular term. For services rendered, Mr. Hasara was originally entitled to cash compensation of $135,000 per year, which increased to $180,000 per year upon closing on our follow-on public offering in May 2016 and increased further to $200,000 per year in June 2016. Effective beginning on July 1, 2017, Mr. Hasara's salary will increase to $225,000 per year. Mr. Hasara has historically been eligible for an annual bonus in cash or in securities of our company of up to 50% of Mr. Hasara's annual salary and in June 2016, Mr. Hasara was awarded and paid a bonus of $37,500. As described in Item 9B above, beginning fiscal year 2017, Mr. Hasara will be eligible for a bonus in cash or in kind of up to 75% of his base salary based upon his achievement of certain goals as established by Mr. Hasara and approved by the Board of Directors or a committee of the Board of Directors. Additionally on September 4, 2014, Mr. Hasara was awarded 7,000,000 RSUs from the EIP, subsequently approved by our majority stockholders. Such RSUs have vested and the shares will be issued to Mr. Hasara on or before March 15, 2017.

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

Outstanding equity awards

The following table summarizes outstanding unexercised options, unvested stocks and equity incentive plan awards held by each of our named executive officers, as of December 31, 2016:

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	OPTION AWARDS					STOCK AWARDS			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Prices ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Been Issued (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Been Issued ($)
Nicholas J. Virca	—	—	—	—	—	—	—	15,041,738(1)	$ 5,866,278
Garrison J. Hasara, CPA	—	—	—	—	—	—	—	7,000,000(2)	$ 2,730,000

(1) Includes stock awards consisting of Restricted Stock Units which are rights to acquire shares of our common stock. Mr. Virca's 15,041,738 Restricted Stock Units vested in November 2016 when Mayne Pharma became our majority stockholder (thus triggering a change of control acceleration of vesting under the EIP (as defined below)), and the underlying shares will be issued to Mr. Virca on or before March 15, 2017.

(2) Includes stock awards consisting of Restricted Stock Units which are rights to acquire shares of our common stock. Mr. Hasara's 7,000,000 Restricted Stock Units vested in November 2016 when Mayne Pharma became our majority stockholder (thus triggering a change of control acceleration of vesting under the EIP (as defined below)), and the underlying shares will be issued to Mr. Hasara on or before March 15, 2017.

2014 Equity Incentive Plan

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

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

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

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

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

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

Option Exercises and Stock Vested

There were no options exercised by the executive officers during the years ended December 31, 2016 or 2015.

All outstanding RSUs vested during the period upon the change in control as a result of Mayne Pharma's November 2016 warrant exercise, in connection with which Mayne Pharma became our majority stockholder. The shares associated with the vested RSUs will be issued on or before March 15, 2017. The total RSUs vested and to be paid on or before March 15, 2017 is 26,541,738.

Pension Benefits

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

Non-qualified Deferred Compensation

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

Compensation of Directors

The following table sets forth all compensation paid to our Board members during the year ended December 31, 2016:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Frank E. O'Donnell, Jr., MD(3)	$117,750(2)	$ —	$ —		$ —	$ —	$117,500
Stefan J. Cross	$ —	$ —	$ —		$ —	$ —	$ —
Dr. R. Dana Ono	$ 21,250	$34,500	$28,800		$ —	$ —	$ 84,550
Samuel P. Sears, Jr.(3)	$ 22,500	$34,500	$28,800		$ —	$ —	$ 85,800
W. Mark Watson, CPA	$ 25,000	$46,000	$38,400		$ —	$ —	$109,400
E. Brendan Magrab(4)	$ 1,250	—	—		$ —	$ —	$ 1,250
Robert D. Martin(4)	$ 708	—	—		$ —	$ —	$ 708

(1) Each Director serving on July 1, 2016 that was not the Executive Chairman or the Mayne Pharma appointed Board member received 150,000 Restricted Stock Units issued under the EIP which were to vest over 3 years. Mr. Watson received an additional 50,000 Restricted Stock Units with the same vesting terms under the EIP for his role as Chairman of the Audit Committee. In addition, each Director serving on July 1, 2016 that was not the Executive Chairman or the Mayne Pharma appointed Board member received 150,000 common stock options issued under the EIP which were to vest over 3 years. Mr. Watson received an additional 50,000 Restricted Stock Units with the same vesting terms under the EIP for his role as Chairman of the Audit Committee. Upon Mayne Pharma exercising Common Stock warrants and owning (as a result) more than 50% of our outstanding Common Stock, all outstanding RSUs and stock options vested. The shares related to the vested RSUs will be issued on or before March 15, 2017.

(2) Compensation for serving as Executive Chairman.

(3) Served as a member of the Board of Directors through December 25, 2016

(4) Board compensation began on December 26, 2016

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

The following table sets forth, as of February 1, 2017, 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)
Mayne Pharma Ventures Pty Ltd.(2)	221,010,368	58.6%
Hedgepath, LLC(3)	92,377,638	25.4%
Nicholas J. Virca(4)	15,041,738	4.3%
Garrison J. Hasara, CPA(5)	7,000,000	1.9%
Stefan J. Cross(6)	600,000	*
Dr. R. Dana Ono(7)	900,000	*
W. Mark Watson, CPA(8)	2,110,000	*
E. Brendan Magrab(9)	—	—
Robert D. Martin(10)	—	—
All directors and executive officers as a group (7 persons)	25,651,738	7.2%

* Less than 1%

(1) Applicable percentages are based on 353,447,172 shares outstanding as of the date of this filing. This table is based upon information supplied by officers, directors, and principal stockholders and Schedule 13G(s) filed with the SEC. Unless indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

(2) Includes 197,506,132 shares of our common stock and warrants to purchase an additional 23,504,236 shares of our common stock. The address for Mayne Pharma Ventures Pty Ltd is Level 14, 474 Flinders Street, Melbourne Vic 3000, Australia.

(3) Includes 82,127,069 shares of our common stock and a warrant to purchase an additional 10,250,569 shares of our common stock. Our Corporate Secretary, James A. McNulty, CPA, has sole voting and dispositive power over the securities held by Hedgepath, LLC. The address for Hedgepath, LLC is 324 S. Hyde Park Avenue, Suite 350, Tampa, FL 33606.

(4) Mr. Virca is our Chief Executive Officer and President. Includes 15,041,738 vested restricted stock units issued under our 2014 Equity Incentive Plan for which shares will be issued to Mr. Virca on or before March 15, 2017. Mr. Virca's address is 449 South 12th Street, Unit 1105, Tampa, FL 33602.

(5) Mr. Hasara is our Chief Financial Officer and Treasurer. Excludes 7,000,000 vested restricted stock units issued under our 2014 Equity Incentive Plan for which shares will be issued to Mr. Hasara on or before March 15, 2017. Mr. Hasara's address is 16904 Melissa Ann Drive, Lutz, FL 33558.

(6) Mr. Cross is a director of our company. Includes 600,000 vested restricted stock units issued under our 2014 Equity Incentive Plan for which shares will be issued to Mr. Cross on or before March 15, 2017. Mr. Cross' address is c/o Mayne Pharma at Level 1, 99 King Street, Melbourne, Victoria 3000, Australia.

(7) Dr. Ono is a director of our company. Includes 600,000 vested restricted stock units issued under our 2014 Equity Incentive Plan for which shares will be issued to Dr. Ono on or before March 15, 2017. Also includes 150,000 vested stock options. Dr. Ono's address is c/o HedgePath Pharmaceuticals at 324 S. Hyde Park Ave., Suite 350, Tampa, FL 33606.

(8) Mr. Watson is a director of our company. Includes 900,000 vested restricted stock units issued under our 2014 Equity Incentive Plan for which shares will be issued to Mr. Watson on or before March 15, 2017. Also includes 200,000 vested stock options. Mr. Watson's address is c/o HedgePath Pharmaceuticals at 324 S. Hyde Park Ave., Suite 350, Tampa, FL 33606.

(9) E. Brendan Magrab is the Chairman and a director of our company. Mr. Magrab's address is c/o HedgePath Pharmaceuticals at 324 S. Hyde Park Ave., Suite 350, Tampa, FL 33606.

(10) Robert D. Martin is a director of our company. Mr. Martin's address is c/o HedgePath Pharmaceuticals at 324 S. Hyde Park Ave., Suite 350, Tampa, FL 33606.

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

The following is a listing of our related party transactions:

Mayne Pharma

Second Amended and Restated Supply and License Agreement

Pursuant to our Supply and License Agreement with Mayne Pharma, which was originally entered into on September 3, 2013, amended and restated on June 24, 2014 and May 15, 2015, and most recently amended on November 22, 2016, Mayne Pharma is obligated to: (i) supply us with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being prostate, lung and skin cancer) in the United States, (ii) provide us with an exclusive license to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer via oral administration in the United States and (iii) participate in the JDC with us to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States. Mayne Pharma will also provide certain services to us (in accordance with the development plan and budget for our product) including to direct clinical programming (subject to the oversight and approval by the JDC and, in certain circumstances, the Board of Directors), and to direct the regulatory approval process and intellectual property strategy related to the product. Any services provided to us by Mayne Pharma in this regard will be provided at Mayne Pharma's expense (other than third party costs agreed to by us and Mayne Pharma), and such services will be subject to our prior approval. The Supply and License Agreement may be terminated by Mayne Pharma if we fail to achieve regulatory approval to commercialize SUBA-Itraconazole in the U.S. by June 30, 2017 (see below for amendment), if we breach any provision of our Equity Holders Agreement or purchase agreements with Mayne Pharma, if we materially breach the Supply and License Agreement and do not cure such breach within a specified time period, or if either party files for bankruptcy or insolvency proceedings.

On June 24, 2014 and again on May 15, 2015, we and Mayne Pharma, along with Nicholas J. Virca, our President and Chief Executive Officer, Frank E. O'Donnell, Jr., M.D., our former Executive Chairman, and Hedgepath, LLC consummated a series of related transactions to fulfill certain conditions of the original Supply and License Agreement and Amended and Restated Supply and License Agreements, respectively. In connection therewith, we and Mayne Pharma entered into the Second Amended and Restated Supply and License Agreement. On November 22, 2016, we entered into Amendment No. 1 to Second Amended and Restated Supply and License Agreement (the "Amendment") with Mayne Pharma. The Amendment, which amends that certain Second Amended and Restated Supply and License Agreement, dated May 15, 2015, extends the date on which we must achieve regulatory approval in the U.S. to commercialize SUBA-Itraconazole to December 31, 2018 from June 30, 2017. There were no further changes to the Supply and License Agreement.

Securities Purchase Agreements with Mayne Pharma

On May 15, 2015, we entered into the 2015 Mayne Purchase Agreement pursuant to which we issued to Mayne Pharma (i) 33,333,333 shares of our common stock and (ii) a warrant to purchase 33,333,333 shares of our common stock. Such warrant has an exercise price of $0.075 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on May 15, 2020.

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

In connection with the Offering, and pursuant to an existing right of our license and manufacturing partner and now majority stockholder Mayne Pharma to purchase its pro rata share, on a fully-diluted basis, of new securities, we entered into a definitive Securities Purchase Agreement ("SPA") (in substantially the same form as the SPA executed by other investors in the Offering) with Mayne Pharma, and in connection therewith issued an aggregate of 27,885,000 Units to Mayne Pharma, consisting of an aggregate of 27,885,000 shares of common stock and a Warrant to purchase up to an aggregate of 27,885,000 shares of common stock, for aggregate gross proceeds to us of $2,788,500.

In connection with the Offering, we engaged certain FINRA-member agents to help it secure investors for the Offering (the "Finders Arrangements"). Such agents secured investors for an aggregate of $582,500 for the Offering and received commissions equal to an aggregate of $46,600 in cash and warrants (in substantially the form of the Warrants) to purchase 466,000 shares of common stock. Pursuant to the Mayne Right of First Refusal, we issued and sold to Mayne Pharma a warrant to purchase 479,236 shares of common stock for a purchase price of $47,924 (the "Mayne Finders Warrant"), which constituted Mayne's pro rata share, on a fully-diluted basis, of all warrants issued in connection with the Finders Arrangements, inclusive of the Mayne Finders Warrant. For ease of administration, the 479,236 shares of common stock underlying the Mayne Finders Warrant were added to the Mayne Offering Warrant, resulting in the issuance to Mayne of a single Warrant to purchase 28,364,236 shares of common stock.

As a result of the Offering and subsequent warrant exercises by Mayne Pharma, Mayne Pharma owned approximately 50.5% of our equity securities on a fully diluted basis as of December 31, 2016.

Frank E. O'Donnell, Jr., MD

Consulting Agreement

In December 2016, we entered into a consulting agreement which became effective January 1, 2017 with our former Executive Chairman, Francis E. O'Donnell Jr., MD. Pursuant to the terms of the agreement, Dr. O'Donnell will consult with us regarding various aspects of our clinical development programs. The agreement has a one-year term and may be terminated on 30 days' notice of breach (with an opportunity to cure).

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 years ended December 31, 2016 and 2015 totaled $86,000 and $89,365, respectively.

Audit-Related Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services were $21,250 and $3,000 related to our S-1 filings for the years ended December 31, 2016 and 2015, respectively

Tax Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for tax compliance, for the years ended December 31, 2016 and 2015 totaled $9,900 and $5,000, respectively.

All Other Fees. None.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Exhibit No.	Description
3.1	Certificate of Incorporation of the Company (1)
3.2	Amended and Restated Certificate of Designation for Series A Preferred Stock (5)
3.3	Certificate of Amendment to the Company's Certificate of Incorporation (6)
3.4	Second Amended and Restated Bylaws of the Company (2)
3.5	Certificate of Amendment to the Company's Certificate of Incorporation (9)
4.1	Warrant, dated June 24, 2014 issued to Hedgepath, LLC (3)
4.2	Form of Warrant issued in the 2016 Private Placement (10)
10.1	Securities Purchase Agreement, dated June 24, 2014, by and between the Company and Mayne Pharma Ventures Pty Ltd. (3)
10.2	Amended and Restated Equity Holders Agreement, dated May 15, 2015, by and between the Company, Mayne Pharma Ventures Pty Ltd., Hedgepath, LLC, Nicholas J. Virca and Frank O'Donnell, Jr. M.D. (7)+
10.3	Amendment No. 1 to Amended and Restated Equity Holders Agreement, dated December 17, 2015, Company, Mayne Pharma Ventures Pty Ltd., Hedgepath, LLC., Nicholas J. Virca and Frank O'Donnell (11)
10.4	Employment Agreement, dated June 24, 2014, between the Company and Nicholas J. Virca (3)+
10.5	First Amendment to Employment Agreement, dated May 15, 2015, between the Company and Nicholas J. Virca (7)
10.6	Second Amendment to Employment Agreement, dated February 16, 2017, between the Company and Nicholas J. Virca*
10.7	Executive Chairman Agreement, dated June 24, 2014, between the Company and Frank O'Donnell, Jr. M.D. (3)
10.8	First Amendment to Executive Chairman Agreement, dated May 15, 2015, between the Company and Frank O'Donnell, Jr. M.D. (7)
10.9	Second Amended and Restated Supply and License Agreement, dated May 15, 2015, by and among the Company and Mayne Pharma. (7)+
10.10	Employment Agreement, dated September 4, 2014, between the Company and Garrison J. Hasara (4)
10.11	First Amendment to Employment Agreement, dated February 16, 2017, between the Company and Garrison J. Hasara*
10.12	Securities Purchase Agreement, dated May 15, 2015, by and between the Company and Mayne Pharma Ventures Pty Ltd. (7)
10.13	Master Clinical Services Agreement, dated June 15, 2015, by and between the Company and SciQuus, Inc. (7)+
10.14	Sublicense Agreement, entered into effective as of September 2, 2015, by and between Mayne Pharma International Pty Ltd and the Company. (8)+
10.15	Form of Securities Purchase Agreement issued in the 2016 Private Placement (10)
10.16	Amendment No. 1 to Second Amended and Restated Supply and License Agreement, dated November 22, 2016, by and among the Company and Mayne Pharma.*
14	Code of Ethical Conduct (12)
23.1	Consent of Cherry Bekaert LLP *
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.sch	XBRL Taxonomy Extension Schema Document
101.cal	XBRL Taxonomy Calculation Linkbase Document
101.def	XBRL Taxonomy Definition Linkbase Document
101.lab	XBRL Taxonomy Label Linkbase Document
101.pre	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) and240.24b-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 8-K, dated August 16, 2013.
(2) Previously filed with Form 8-K, dated May 21, 2015.
(3) Previously filed with Form 8-K, dated June 30, 2014.
(4) Previously filed with Form 8-K, dated September 9, 2014.
(5) Previously filed with Form 8-K, dated September 10, 2013.
(6) Previously filed with Form S-1/A on July 22, 2015.
(7) Previously filed with Form 10-Q on August 14, 2015.
(8) Previously filed with Form 8-K, dated September 9, 2015.

(9) Previously filed with Form 8-K, dated May 26, 2016.

(10) Previously filed with Form 8-K, dated April 15, 2016.
(11) Previously filed with Form 8-K, dated December 22, 2015.
(12) Previously filed with Form 10-K on February 13, 2015

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 sheets of HedgePath Pharmaceuticals, Inc. (the "Company") as of December 31, 2016 and 2015 and the related statements of operations, stockholders' equity and cash flows for the years then ended. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of HedgePath Pharmaceuticals, Inc. as of December 31, 2016 and 2015 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Cherry Bekaert LLP

Tampa, Florida
February 17, 2017

HEDGEPATH PHARMACEUTICALS, INC.
BALANCE SHEETS
DECEMBER 31, 2016 AND 2015

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,885,422	$ 601,445
Prepaid expenses	61,097	34,414
Deposit	250,000	—
Total current assets	7,196,519	635,859
Other long term assets	141,576	250,000
Total assets	$ 7,338,095	$ 885,859
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 297,826	$ 383,356
Other liabilities	10,307	78,524
Total current liabilities	308,133	461,880
Total liabilities	308,133	461,880
Commitments and contingencies	—	—
Stockholders' equity:		
Series A Preferred Stock, $0.0001 par value; 500,000 shares authorized; no shares issued and outstanding.	—	—
Undesignated Preferred Stock, $0.0001 par value; 9,500,000 shares authorized; no shares issued or outstanding.	—	—
Common Stock, $0.0001 par value; 500,000,000 and 340,000,000 shares authorized in 2016 and 2015, respectively; 353,447,172 and 245,353,270 shares issued and outstanding in 2016 and 2015, respectively	35,345	24,535
Additional paid-in capital	50,167,372	36,571,982
Accumulated deficit	(43,172,755)	(36,172,538)
Total stockholders' equity	7,029,962	423,979
Total liabilities and stockholders' equity	$ 7,338,095	$ 885,859

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2016 AND 2015

	Year Ended December 31,	
	2016	2015
Revenues:	$ —	$ —
Total revenues	—	—
Expenses:		
Research and development	2,641,507	1,680,250
General and administrative	4,380,695	2,269,335
Total expenses	7,022,202	3,949,585
Loss from operations	(7,022,202)	(3,949,585)
Interest income	21,985	—
Net loss	$ (7,000,217)	$ (3,949,585)
Basic and diluted loss per share	$ (0.02)	$ (0.02)
Weighted average common shares outstanding	288,752,723	232,616,649

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2016 AND 2015

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balances, December 31, 2014	211,419,937	$21,142	$ 32,263,890	$ (32,222,953)	$ 62,079
Sale of common stock and common stock warrants, related party	33,333,333	3,333	2,496,667	—	2,500,000
Common shares issued for payment of trade payables	600,000	60	89,940	—	90,000
Stock-based compensation	—	—	1,721,485	—	1,721,485
Net loss	—	—	—	(3,949,585)	(3,949,585)
Balances, December 31, 2015	245,353,270	24,535	36,571,982	(36,172,538)	423,979
Sale of common stock and common stock warrants	27,115,000	2,712	2,662,188	—	2,664,900
Sale of common stock and common stock warrants, related party	27,885,000	2,788	2,785,712	—	2,788,500
Sale of warrants for cash to related party	—	—	47,924	—	47,924
Issuance of common stock upon warrant exercise	4,650,000	465	557,535	—	558,000
Issuance of common stock upon warrant exercise, related party	48,443,902	4,845	3,978,356	—	3,983,201
Stock-based compensation	—	—	3,563,675		3,563,675
Net loss	—	—	—	(7,000,217)	(7,000,217)
Balances, December 31, 2016	**353,447,172**	**$35,345**	**$ 50,167,372**	**$ (43,172,755)**	**$ 7,029,962**

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2016 AND 2015

	Year Ended December 31,	
	2016	2015
Operating activities:		
Net loss	$ (7,000,217)	$ (3,949,585)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Stock-based compensation	3,563,675	1,721,485
Changes in assets and liabilities:		
Prepaid expenses and other assets	(168,259)	(186,597)
Accounts payable and current liabilities	(153,747)	150,981
Net cash flows used in operating activities	(3,758,548)	(2,263,716)
Financing activities:		
Proceeds from sale of common stock and common stock warrants	2,664,900	—
Proceeds from sale of common stock and common stock warrants, related party	2,836,424	2,500,000
Proceeds from exercise of common stock warrants	558,000	—
Proceeds from exercise of common stock warrants, related party	3,983,201	—
Net cash flows from financing activities	10,042,525	2,500,000
Net increase in cash and cash equivalents	6,283,977	236,284
Cash and cash equivalents at beginning of year	601,445	365,161
Cash and cash equivalents at end of year	$ 6,885,422	$ 601,445
Cash paid for interest	$ —	$ —
Supplemental disclosure of non-cash financing activities:		
Issuance of common stock in payment of trade payables	$ —	$ 90,000

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2016 AND 2015

1. Corporate overview:

Overview

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

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

Nature of the Business

The Company is a clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. The Company may also explore acquiring or licensing other innovative therapeutics addressing unmet needs and orphan indications beyond cancer. The Company's preliminary focus is on the development of therapies for skin, lung and prostate cancers in the U.S. market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome) for which the Company has begun dosing its Phase II(b) clinical trial. The Company's proposed therapy is based upon the use of SUBA-Itraconazole, which is a patented, oral formulation of the currently marketed anti-fungal drug itraconazole. The Company believes that the dosing of oral capsules of this formulation can affect the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration (the "FDA") for, and has been extensively used to, treat fungal infections and has an extensive history of safe and effective use in humans. The Company has developed, optioned and licensed intellectual property and know-how related to the treatment of cancer patients using itraconazole.

Second Amended and Restated Supply and License Agreement

Pursuant to the Company's Supply and License Agreement with Mayne Pharma Ventures Pty Ltd. and its affiliates ("Mayne Pharma") which was originally entered into on September 3, 2013, amended and restated on June 24, 2014 and May 15, 2015, most recently amended on November 22, 2016, Mayne Pharma is obligated to: (i) supply the Company with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being prostate, lung and skin cancer) in the United States, (ii) provide the Company with an exclusive license to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer via oral administration in the United States and (iii) participate in a joint development committee (the "JDC") with the Company to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States. Mayne Pharma will also provide certain services (in accordance with the development plan and budget for the Company's product) including to direct clinical programming (subject to the oversight and approval by the JDC and, in certain circumstances, the Board of Directors), and to direct the regulatory approval process and intellectual property strategy related to the product. Any services provided to the Company by Mayne Pharma in this regard will be provided at Mayne Pharma's expense (other than third party costs agreed to by the Company and Mayne Pharma), and such services will be subject to the Company's prior approval. The Supply and License Agreement could have been terminated by Mayne Pharma if the Company failed to achieve regulatory approval to commercialize SUBA-Itraconazole in the U.S. by June 30, 2017 (see below for amendment), if the Company breaches any provision of the Equity Holders Agreement or purchase agreements with Mayne Pharma (each as described below), if the Company materially breaches the Supply and License Agreement and do not cure such breach within a specified time period, or if either party files for bankruptcy or insolvency proceedings.

On June 24, 2014 and again on May 15, 2015, the Company and Mayne Pharma, along with Nicholas J. Virca, President and Chief Executive Officer, Frank E. O'Donnell, Jr., M.D., former Executive Chairman, and Hedgepath, LLC consummated a series of related transactions to fulfill certain conditions of the original Supply and License Agreement and Amended and Restated Supply and License Agreements, respectively. In connection therewith, the Company and Mayne Pharma entered into the Second Amended and Restated Supply and License Agreement. On November 22, 2016, the Company entered into Amendment No. 1 to the Second Amended and Restated Supply and License Agreement (the "Amendment") with Mayne Pharma. The Amendment, which amends that certain Second Amended and Restated Supply and License Agreement, dated May 15, 2015, extends the date on which the Company must achieve regulatory approval in the U.S. to commercialize SUBA-Itraconazole to December 31, 2018 from June 30, 2017. There were no further changes to the Supply and License Agreement.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2016 AND 2015

1. Corporate overview (continued):

Mayne Pharma Sublicense Agreement

On September 2, 2015, the Company entered into a sublicense agreement with Mayne Pharma. Pursuant to the Agreement, Mayne Pharma sublicensed to the Company the exclusive U.S. rights to two additional patents regarding the use of Itraconazole for treatment of cancer, namely US patent No 8,980,930 entitled "Angiogenesis Inhibitors", issued on March 17, 2015, and US patent No 8,653,083 entitled "Hedgehog Pathway Antagonists to Treat Disease", issued on February 28, 2014. Mayne Pharma is the sublicensee of the patents from Accelas Holdings, a British Virgin Islands company, who in turn is the licensee from The Johns Hopkins University, the owner of the patents. The patents relate to the use of itraconazole as a treatment for cancer and age-related macular degeneration. The Company paid a one-time license fee of $75,000 to Mayne Pharma upon entering into the sublicense agreement, which is included in research and development expenses in the accompanying 2015 statement of operations.

Mayne Pharma Securities Purchase Agreement – May 2015

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

May 2016 Financing

On May 25, 2016, the Company conducted the final closing of its previously announced "best efforts/no minimum" private placement offering to accredited investors (the "Offering") of the Company's units (each a "Unit") at a price of $0.10 per Unit, with each Unit consisting of: (i) one (1) share of the Company's common stock, par value $0.0001 per share ("Common Stock"), and (ii) a five-year warrant to purchase one (1) share of Common Stock at an exercise price of $0.12 per share (each a "Warrant"). No actual Units were issued, and each investor received shares of Common Stock and Warrants only. During the course of the Offering, which began on March 30, 2016, the Company sold all 55,000,000 Units reserved for the Offering for aggregate gross proceeds of $5,500,000 including the units sold to Mayne Pharma as described below.

The Company has granted the investors certain registration rights requiring the Company, following the Final Closing, to file a registration statement with the Securities and Exchange Commission covering the resale by the investors of the shares of Common Stock issued in the Offering and the shares of Common Stock underlying the Warrants issued in the Offering. The Company is required to use its commercially best efforts to cause the registration statement to be declared effective. The Company filed the registration statement with the Securities and Exchange Commission in June 2016, and it was declared effective on July 22, 2016.

In connection with the Final Closing, and pursuant to an existing right of the Company's license and manufacturing partner and significant stockholder Mayne Pharma to purchase its pro rata share, on a fully-diluted basis, of new securities issuances of the Company (the "Mayne Right of First Refusal"), the Company entered into a definitive Securities Purchase Agreement ("SPA") (in substantially the same form as the SPA executed by other investors in the Offering) with Mayne Pharma, and in connection therewith issued an aggregate of 27,885,000 Units to Mayne Pharma, consisting of an aggregate of 27,885,000 shares of Common Stock and a Warrant to purchase up to an aggregate of 27,885,000 shares of Common Stock, for aggregate gross proceeds to the Company of $2,788,500.

In connection with the Offering, the Company engaged certain FINRA-member agents to help it secure investors for the Offering (the "Finders Arrangements"). Such agents secured investors for an aggregate of $582,500 for the Offering and received commissions equal to an aggregate of $46,600 in cash and warrants (in substantially the form of the Warrants) to purchase 466,000 shares of Common Stock. Pursuant to the Mayne Right of First Refusal, the Company issued and sold to Mayne a warrant to purchase 479,236 shares of Common Stock for a purchase price of $47,924 (the "Mayne Finders Warrant"), which constituted Mayne's pro rata share, on a fully-diluted basis, of all warrants issued in connection with the Finders Arrangements, inclusive of the Mayne Finders Warrant. For ease of administration, the 479,236 shares of Common Stock underlying the Mayne Finders Warrant were added to the Mayne Offering Warrant, resulting in the issuance to Mayne of a single Warrant to purchase 28,364,236 shares of Common Stock.

See Note 8 regarding Mayne common stock warrant exercises during the year ended December 31, 2016.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2016 AND 2015

2. Liquidity and management's plans:

At December 31, 2016, the Company had approximately $6.9 million in cash and cash equivalents. Based on the Company's current operational plan and budget, the Company expects that it has sufficient cash to manage its business into approximately the first quarter of 2018, although this estimation assumes the Company does not accelerate the development of the existing product candidate, acquire other drug development opportunities, or otherwise face unexpected events, costs or contingencies, any of which could affect the Company's cash requirements. Available resources may be consumed more rapidly than anticipated, potentially resulting in the need for additional funding. Moreover, the Company may be liable for a payroll tax liability arising from the payment of certain vested RSU awards on or before March 15, 2017. Such withholding payment for related payroll taxes will be based upon the market value of approximately 26.5 million shares on the payment date of the RSUs, could be material and significantly reduce the Company's cash resources and thus require the Company to raise additional capital earlier than planned to fund ongoing operations.

3. Summary of Significant Accounting Policies:

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of Accounting Standards Codification ("ASC") Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard, as updated in 2015, will be effective for the Company in the first quarter for the year ending December 31, 2018 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. The Company will evaluate the impact of adoption of the new standard on its financial statements upon commencement of revenue generating activities.

In April 2016, the FASB issued ASU2016-10, "*Revenue from Contracts with Customers* (Topic 606): Identifying Performance Obligations and Licensing." ASU2016-10 clarifies the implementation guidance on identifying performance obligations. These ASUs apply to all companies that enter into contracts with customers to transfer goods or services. This ASUs is effective for public entities for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, but not before interim and annual reporting periods beginning after December 15, 2016. Entities have the choice to apply the ASUs either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. The Company will evaluate the impact of adoption of the new standard on its financial statements upon commencement of revenue generating activities.

In August 2014, the Financial Accounting Standards Board issued ASUNo. 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosure. This ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company evaluated the impact of the revised guidance on its financial statements and determined it had no significant impact.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification ("ASC") Topic 718, Compensation – Stock Compensation. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of the ASU on its financial statements.

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

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2016 AND 2015

3. Summary of Significant Accounting Policies (continued):

Estimates

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

Revenue Recognition

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

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts of $250,000 for substantially all accounts. As of December 31, 2016, the Company had approximately $6.4 million in excess of the amount covered by Federal Deposit Insurance Corporation with one financial institution.

Research and Development Expenses

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

Stock-Based Compensation

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

In applying the Black-Scholes options pricing model for options issued in July 2016 (see Note 8), the assumptions were as follows: expected price volatility of 113.16%; risk-free interest rate of 1.14%; weighted average expected life in years of 6; and no dividend yield. The value of these awards is based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

Income taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. See Note 7 for details. Management has evaluated the guidance relating to accounting for uncertainty in income taxes and has determined that the Company had no uncertain income tax positions that could have a significant effect on the financial statements for the years ended December 31, 2016 or 2015.

4. Prepaid Expenses:

At December 31, 2016, prepaid expenses of $61,097 consisted primarily of approximately $41,000 of directors and officers insurance and clinical trial insurance and $20,000 in market exchange fees. At December 31, 2015, prepaid expenses of $34,414 consisted primarily of approximately $27,000 in prepaid directors and officers insurance and clinical trial insurance.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2016 AND 2015

5. Other Long-term Assets:

At December 31, 2016, other long-term assets consisted of approximately $142,000 of prepaid directors and officers insurance associated with asix-year tail policy purchased during 2016. Other long-term assets at December 31, 2015 consisted of a $250,000 deposit with the Company's independent contract research organization. The deposit is fully refundable at the conclusion of the clinical trial which targets basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome. The deposit was reclassified to short-term at December 31, 2016 in anticipation of the completion of the trial and return of the deposit during 2017.

6. Other Liabilities:

At December 31, 2016, other liabilities consisted of accrued payroll of approximately $10,000. At December 31, 2015, other liabilities included approximately $73,000 of accrued legal expenses of which $52,500 was payable to a third party service provider which was to be settled in stock upon the completion of at least a $5 million stock offering. That liability was renegotiated and settled in May 2016 resulting in a gain of $27,500 which is included as a reduction of general and administrative expenses in the accompanying 2016 condensed statements of operations.

7. Income Taxes:

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

	December 31,	
	2016	2015
Income taxes benefit computed at statutory rate	$(2,380,073)	$(1,342,859)
State income tax benefit, net	(241,633)	(136,332)
Other	74,355	20,950
Change in valuation allowance	2,547,351	1,458,241
Total	$ —	$ —

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

	December 31,	
Deferred tax assets (liabilities)	**2016**	**2015**
In-process research and development	$ 996,154	$ 996,154
Net operating loss carry forward	2,995,024	1,681,549
R&D credit	142,721	60,213
Share-based compensation	2,010,742	841,524
Accrued expenses	—	17,850
	6,144,641	3,597,290
Less: valuation allowance	(6,144,641)	(3,597,290)
Total	$ —	$ —

In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. At December 31, 2016 and 2015, the Company recorded a 100% valuation allowance against its deferred tax assets as it has determined such amounts will not be realizable.

The Company has a federal net operating loss ("NOLs") of approximately $8.0 million as of December 31, 2016. 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 $7.8 million as of December 31, 2016. The loss carryforwards begin to expire in 2018.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2016 AND 2015

8. Stockholders' Equity:

Employee Stock Plans

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

On July 18, 2014, the EIP was adopted by the Company's Board of Directors. On September 30, 2014, the EIP was approved by the majority of stockholders. The 2014 EIP authorizes the issuance of up to 32,583,475 shares of the Company's common stock. In July 2014, 15,041,738 restricted stock units ("RSUs") were granted to the Company's Chief Executive Officer, Nicholas J. Virca, and were to vest upon the earlier to occur of (i) September 3, 2016 or (ii) the acceptance by the FDA of a New Drug Application ("NDA") by the Company for any Company product candidate with a cancer indication utilizing the Company's licensed SUBA-itraconazole technology, provided that Mr. Virca is actively employed by the Company on the earlier of such date. An additional 1.5 million RSUs were issued to various Board members and officers with the same vesting schedule. In August 2014, 7,000,000 RSUs were issued to the Company's Chief Financial Officer, Garrison J. Hasara. Of those RSUs, 50% were to vest upon the earlier to occur of (i) September 3, 2016 or (ii) the acceptance by the FDA of a NDA by the Company for any Company product candidate with a cancer indication utilizing the Company's licensed SUBA-itraconazole technology, provided that Mr. Hasara is actively employed by the Company on the earlier of such date. Mr. Hasara's balance of RSUs were to vest September 3, 2017.

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

On July 1, 2016, the three independent members of the Board of Directors and the Secretary received a total grant of 650,000 RSUs and 650,000 common stock options with an exercise price of $0.24 per share. Stock option activity for the year ended December 31, 2016 is as follows:

	Number of Shares	Weighted Average Exercise Price per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2016	—	**n/a**	**n/a**
Granted to Directors and Officers in 2016	650,000	$ 0.24	
Exercised	—	—	
Forfeitures	—	—	
Outstanding at December 31, 2016	**650,000**	**$ 0.24**	**$ 97,500**

In November 2016, pursuant to the change in control provision in the EIP, all outstanding RSUs and stock options vested when Mayne Pharma exercised Common Stock warrants and exceeded 50% ownership the of outstanding Common Stock. The RSU shares will be issued no later than March 15, 2017. No stock options have been exercised as of December 31, 2016.

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

Stock-based compensation expense is determined based on the fair value of the stock-based awards and recognized over the vesting period. The Company recognized $3,563,675 and $1,721,485 in stock-based compensation expense related to Restricted Stock Units and stock options for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, there was approximately $1.8 million in unamortized stock-based compensation cost related to the unissued shares associated with the unpaid RSUs and will be recognized through the payment date to be no later than March 15, 2017.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2016 AND 2015

8. Stockholders' Equity (continued):

Common Stock Issuances

See Note 1 for discussion of Common Stock issued in conjunction with the Mayne Pharma Purchase Agreement and the May 2016 Financing.

Warrants

See Note 1 for discussion of warrants issued in conjunction with the Mayne Pharma Purchase Agreement and the May 2016 Financing.

During the twelve months ended December 31, 2016, common stock warrants were exercised resulting in the issuance of 53,093,902 common shares. There were no common stock warrants exercised in 2015. Details of the warrant exercises during 2016 can be found in the chart below:

Warrant Holder	# of Warrants	Exercise Price	Total Proceeds
Mayne	10,250,569	$ 0.0878	$ 900,000
Mayne	33,333,333	$ 0.075	2,500,001
Mayne	4,860,000	$ 0.12	583,200
Total Mayne exercises	48,443,902		3,983,201
May 2016 Financing Finders	150,000	$ 0.12	18,000
May 2016 Financing Investors	4,500,000	$ 0.12	540,000
Total common stock warrant exercises for the twelve months ended December 31, 2016	**53,093,902**		**$ 4,541,201**

There were 56,685,805 outstanding common stock warrants at December 31, 2016 with a weighted average exercise price of $0.11 and a weighted average remaining life of 3.99 years.

9. Related party transactions:

The Company has significant contractual agreements with majority stockholder Mayne Pharma as discussed in Note 1. There were no amounts due to or from Mayne Pharma at December 31, 2016.

10. Legal Proceedings:

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

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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: February 17, 2017

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/ BRENDAN MAGRAB **Brendan Magrab**	Chairman and Director	February 17, 2017
/S/ STEFAN J. CROSS **Stefan J. Cross**	Director	February 17, 2017
/S/ DR. R. DANA ONO **Dr. R. Dana Ono**	Director	February 17, 2017
/S/ ROBERT MARTIN **Robert Martin**	Director	February 17, 2017
/S/ W. MARK WATSON, CPA **W. Mark Watson, CPA**	Director	February 17, 2017

Exhibit 10.6

SECOND AMENDMENT TO EMPLOYMENT AGREEMENT

THIS SECOND AMENDMENT TO EMPLOYMENT AGREEMENT (the **"Amendment"**), is dated and effective as of February 16, 2017 by and between HedgePath Pharmaceuticals, Inc., a Delaware corporation (the **"Company"**), and Nicholas J. Virca (the **"Executive"**). The Company and the Executive are referred to collectively herein as the **"Parties."**

WHEREAS, the Parties entered into that certain Employment Agreement dated as of June 24, 2014, as amended by that certain First Amendment to Employment Agreement, dated May 15, 2015 (collectively, the **"Agreement"**); and

WHEREAS, the Parties wish to amend the Agreement in accordance with Section 11(g) thereof.

NOW THEREFORE, in consideration of the mutual premises, covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt, and legal adequacy of which is hereby acknowledged, the Parties, intending to be legally bound, hereby agree to amend the Agreement as follows:

1. Amendment to Section 1. The Parties hereby completely amend and restate Section 1 of the Agreement and replace such Section in its entirety with the following:

"1. **Term**. The Company hereby agrees to continue to employ the Executive, and the Executive hereby agrees to continue his employment with the Company, as the Company's President and Chief Executive Officer. The term of the Executive's employment shall be for a period ending on December 31, 2018 (the **"Initial Term"**). At the conclusion of the Initial Term, this Agreement shall automatically renew for successive one (1) year terms (each, a **"Renewal Term"**) unless either party gives the other written notice of non-renewal at least sixty (60) days' prior to the end of the Initial Term or a Renewal Term (as the case may be) and subject to earlier termination as provided in Section 7 hereof. When used herein, the term **"Employment Term"** shall mean the Initial Term together with any Renewal Terms (if any)."

2. Amendment to Section 2(a). The Parties hereby amend Section 2(a) of the Agreement to delete the following proviso at the conclusion of such Section: "*provided, however*, that the Executive will not be responsible for leading any capital raising initiatives on behalf of the Company."

3. Amendment to Sections 3(a), (b) and (c). The Parties hereby completely amend and restate Sections 3(a), (b) and (c) of the Agreement and replace such Sections in their entirety with the following:

"(a) Salary. The Company shall pay to the Executive an annual cash salary in the gross amount of $225,000 (the "**Base Salary**") for services rendered hereunder, payable in accordance with prevailing Company policy. The Base Salary may only be adjusted with the approval of the Board or a designated committee thereof; *provided, however*, that the Base Salary will automatically increase, on a prospective basis, to $300,000 effective July 1, 2017 and shall thereafter be subject to annual review based upon Company policy as set by the Board or a designated committee thereof.

(b) Bonus. The Executive shall be eligible to receive an annual bonus (based on the Company's fiscal year, beginning with the fiscal year ending December 31, 2017) in cash or in securities of the Company or otherwise as determined and approved by the Board or a designated committee thereof and paid to the Executive by no later than March 15 of the succeeding fiscal year. Such bonus, if any, shall be in an amount up to 75% of the Base Salary based on the achievement of such criteria as shall be approved by the Board or a designated committee thereof. Prior to January 31 of each fiscal year, Executive shall be required to provide the Board or a designated committee thereof with a set of corporate and/or individual goals for each fiscal year (to be approved by the Board or a designated committee thereof) on which Executive's performance shall be evaluated for the purpose of determining Executive's bonus. For the avoidance of doubt, Executive shall not be entitled to any bonus for the fiscal year ending December 31, 2016.

(c) Grant of Restricted Stock Units.

(i) The Executive has heretofore been awarded 15,041,738 restricted stock units (the "**Initial Grant**") under the Company's 2014 Equity Incentive Plan (the "**EIP**"). The Initial Grant vested on September 3, 2016 and will be paid on or before March 15, 2017.

(ii) Beyond the Initial Grant, the Executive shall be entitled to receive annual or other equity awards under the EIP or such other compensation plans commensurate with his position as shall be adopted by the Board or a designated committee thereof from time to time.

(iii) This Section 3(c) and any participation by the Executive in the EIP is to be read in conjunction with, and is subject to, the terms of the EHA.

4. Amendment to Section 8(b). The Parties hereby completely amend and restate Section 8(b) of the Agreement and replace such Sections in its entirety with the following:

"(b) Upon termination of the Executive's employment hereunder pursuant to Sections 7(d) or 7(e)(ii) for Good Reason, the Executive shall be entitled to receive the following: (x) all items set forth in Section 8(a) hereof and (y) a cash payment in an amount equal to twelve (12) months Base Salary."

5. Deletion of Section 8(c). The Parties hereby delete Sections 8(c) of the Agreement in its entirety.

6. No Other Amendments. Nothing in this Amendment is intended to amend any language of the Agreement other than as specifically set forth above, and the remainder of the Agreement shall be unmodified and in full force and effect.

[Remainder of page intentionally left blank.]
[Signature page immediately follows.]

IN WITNESS WHEREOF, each of the Company and the Executive has executed this Second Amendment to Employment Agreement as of the date first above written.

HedgePath Pharmaceuticals, Inc.

By: /s/ Garrison J. Hasara
Name: Garrison J. Hasara
Title: Chief Financial Officer and Treasurer

/s/ Nicholas J. Virca
Nicholas J. Virca

Exhibit 10.11

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

THIS FIRST AMENDMENT TO EMPLOYMENT AGREEMENT (the **"Amendment"**), is dated and effective as of February 16, 2017 by and between HedgePath Pharmaceuticals, Inc., a Delaware corporation (the **"Company"**), and Garrison J. Hasara (the **"Executive"**). The Company and the Executive are referred to collectively herein as the **"Parties."**

WHEREAS, the Parties entered into that certain Employment Agreement dated as of September 4, 2014 (the **"Agreement"**); and

WHEREAS, the Parties wish to amend the Agreement in accordance with Section 11(g) thereof.

NOW THEREFORE, in consideration of the mutual premises, covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt, and legal adequacy of which is hereby acknowledged, the Parties, intending to be legally bound, hereby agree to amend the Agreement as follows:

1. Amendment to Section 1. The Parties hereby completely amend and restate Section 1 of the Agreement and replace such Section in its entirety with the following:

"1. **Term**. The Company hereby agrees to continue to employ the Executive, and the Executive hereby agrees to continue his employment with the Company, as the Company's Chief Financial Officer and Treasurer. The term of the Executive's employment shall be for a period ending on December 31, 2018 (the **"Initial Term"**). At the conclusion of the Initial Term, this Agreement shall automatically renew for successive one (1) year terms (each, a **"Renewal Term"**) unless either party gives the other written notice of non-renewal at least sixty (60) days' prior to the end of the Initial Term or a Renewal Term (as the case may be) and subject to earlier termination as provided in Section 7 hereof. When used herein, the term **"Employment Term"** shall mean the Initial Term together with any Renewal Terms (if any)."

2. Amendment to Sections 3(a), (b) and (c). The Parties hereby completely amend and restate Sections 3(a), (b) and (c) of the Agreement and replace such Sections in their entirety with the following:

"(a) Salary. The Company shall pay to the Executive an annual cash salary in the gross amount of $200,000 (the "**Base Salary**") for services rendered hereunder, payable in accordance with prevailing Company policy. The Base Salary may only be adjusted with the approval of the Board or a designated committee thereof; *provided, however*, that the Base Salary will automatically increase, on a prospective basis, to $225,000 effective July 1, 2017 and shall thereafter be subject to annual review based upon Company policy as set by the Board or a designated committee thereof.

(b) Bonus. The Executive shall be eligible to receive an annual bonus (based on the Company's fiscal year, beginning with the fiscal year ending December 31, 2017) in cash or in securities of the Company or otherwise as determined and approved by the Board or a designated committee thereof and paid to the Executive by no later than March 15 of the succeeding fiscal year. Such bonus, if any, shall be in an amount up to 75% of the Base Salary based on the achievement of such criteria as shall be approved by the Board or a designated committee thereof. Prior to January 31 of each fiscal year, Executive shall be required to provide the Board or a designated committee thereof with a set of corporate and/or individual goals for each fiscal year (to be approved by the Board or a designated committee thereof) on which Executive's performance shall be evaluated for the purpose of determining Executive's bonus. For the avoidance of doubt, Executive shall not be entitled to any bonus for the fiscal year ending December 31, 2016.

(c) Grant of Restricted Stock Units.

(i) The Executive has heretofore been awarded 7,000,000 restricted stock units (the "**Initial Grant**") under the Company's 2014 Equity Incentive Plan (the "**EIP**"). The Initial Grant vested on September 3, 2016 and will be paid on or before March 15, 2017.

(ii) Beyond the Initial Grant, the Executive shall be entitled to receive annual or other equity awards under the EIP or such other compensation plans commensurate with his position as shall be adopted by the Board or a designated committee thereof from time to time.

3. Amendment to Section 8(b). The Parties hereby completely amend and restate Section 8(b) of the Agreement and replace such Sections in its entirety with the following:

"(b) Upon termination of the Executive's employment hereunder pursuant to Sections 7(d) or 7(e)(ii) for Good Reason, the Executive shall be entitled to receive the following: (x) all items set forth in Section 8(a) hereof and (y) a cash payment in an amount equal to twelve (12) months Base Salary."

4. No Other Amendments. Nothing in this Amendment is intended to amend any language of the Agreement other than as specifically set forth above, and the remainder of the Agreement shall be unmodified and in full force and effect.

[Remainder of page intentionally left blank.]
[Signature page immediately follows.]

IN WITNESS WHEREOF, each of the Company and the Executive has executed this First Amendment to Employment Agreement as of the date first above written.

HedgePath Pharmaceuticals, Inc.

By: /s/ Nicholas J. Virca
Name: Nicholas J. Virca
Title: President and Chief Executive Officer

/s/ Garrison J. Hasara
Garrison J. Hasara

Exhibit 10.16

AMENDMENT NO. 1 TO
SECOND AMENDED AND RESTATED SUPPLY AND LICENSE AGREEMENT

THIS AMENDMENT NO. 1 TO SECOND AMENDED AND RESTATED SUPPLY AND LICENSE AGREEMENT (the "Amendment"), dated effective as of November 22, 2016 (the "Effective Date"), is by and among:

(i) **MAYNE PHARMA VENTURES PTY LTD**, an Australian company ACN 168 896 357 ("Mayne Pharma"); and

(ii) **HEDGEPATH PHARMACEUTICALS, INC.**, a Delaware corporation ("HPPI").

WHEREAS, Mayne Pharma and HPPI (collectively, the "Parties") are parties to that certain Second Amended and Restated Supply and License Agreement, dated May 15, 2015 (the "SLA"); and

WHEREAS, the Parties now desire to amend the SLA on the terms and conditions set forth herein.

NOW THEREFORE, for good and valuable consideration, the receipt, and legal adequacy of which is hereby acknowledged, and pursuant to Section 26.8 of the SLA, the parties, intending to be legally bound, hereby agree to amend the SLA as of the Effective Date as follows:

1. **Defined Terms**. Unless otherwise defined herein, all capitalized terms used herein shall have the meanings ascribed to them in the SLA.

2. **Extension to the Target Launch Date**. The parties agree to extend the Target Launch Date to 31 December 2018.

3. **No Further Amendment**. Except as amended hereby, the SLA shall remain unmodified and in full force and effective.

4. **Governing Law**. This Amendment shall be governed by and construed and enforced in accordance with the laws of the State of Delaware applicable to agreements made and to be performed wholly within such State, without regard to its conflict of law rules.

5. **Headings; Counterparts**. The headings contained in this Amendment are inserted for reference purposes only and shall not in any way affect the meaning, construction or interpretation of this Amendment. This Amendment may be executed in two (2) counterparts, each of which, when executed, shall be deemed to be an original, but both of which, when taken together, shall constitute one and the same document. Such counterparts may be executed and delivered by facsimile/e-mail transmission, which shall constitute valid execution and delivery.

IN WITNESS WHEREOF, each of the Parties has executed this Amendment as of the date first above written.

MAYNE PHARMA VENTURES PTY LTD

By: /s/ Scott A. Richards
Name: Scott A. Richards
Title: Director

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca
Name: Nicholas J. Virca
Title: President and Chief Executive Officer

[Signature Page to Amendment No. 1 to
Second Amended and Restated Supply and License Agreement]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-214207) of our report dated February 17, 2017 included in this Annual Report on Form 10-K of HedgePath Pharmaceuticals, Inc. (the "Company"), relating to the balance sheets of the Company as of December 31, 2016 and 2015, and the related statements of operations, stockholders' equity and cash flows for the years then ended.

/s/ Cherry Bekaert LLP

Tampa, Florida
February 17, 2017

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: February 17, 2017

/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 Rules13a-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: February 17, 2017

/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 Form10-K for the year ended December 31, 2016 (the "Form10-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 Form10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: February 17, 2017

/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 Form10-K for the year ended December 31, 2016 (the "Form10-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 Form10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: February 17, 2017

/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.