FORM 10-K

HedgePath Pharmaceuticals, Inc. - HPPI

Filed: March 07, 2019 (period: December 31, 2018)

Annual report with a comprehensive overview of the company

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, 2018

☐ **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.)**
4830 W. Kennedy Blvd., Suite 600 Tampa, FL	**33609**
(Address of principal executive offices)	**(Zip Code)**

Issuer's telephone number: 813-830-7489

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 every Interactive Data File required to be submitted 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 such files) Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, a smaller reporting company or an emerging growth company. See definition of "large accelerated filer", "accelerated filer," "smaller reporting company" and "emerging

growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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, 2018 was approximately $24,879,000 based on the closing sale price of the company's common stock on such date of $0.32 per share, as reported by the OTC Markets Group, Inc.

As of March 7, 2019, there were 370,446,185 shares of company common stock issued and outstanding.

HedgePath Pharmaceuticals, Inc.

Annual Report on Form 10-K

For the fiscal year ended December 31, 2018

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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 Securities and Exchange Commission (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, and the potential acquisition or license of other pharmaceutical technologies) by investors and potential commercial collaborators;
- our future capital requirements and our ability to satisfy our capital needs;
- our ability to commence and complete required clinical trials of our product candidate and obtain approval from the U.S. Food and Drug Administration or other regulatory agencies in different jurisdictions;
- matters associated with the fact that Mayne Pharma is our majority stockholder and key licensor;
- our ability to secure and maintain key development and commercialization partners for our product candidate;
- our ability to obtain, maintain or protect the validity of our owned or licensed patents and other intellectual property;
- our ability to internally develop, acquire or license 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 pharmaceutical development company that is seeking to discover, develop and ultimately commercialize innovative therapeutics for patients with certain cancers and non-cancerous proliferation disorders. We also have explored and expect to continue to explore acquiring or licensing other innovative preclinical and clinical stage therapeutics addressing unmet needs and orphan indications for the treatment of cancer and other diseases.

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

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

SUBA-Itraconazole

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

"SUBA" (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 relating to the anti-fungal use of SUBA-Itraconazole, SUBA-Itraconazole demonstrated improved absorption and significantly reduced variability within and between patients compared to the branded and generic forms of itraconazole in human studies. We believe this technology is well-suited for the exploration of the potential anti-cancer effects of itraconazole. The predicted benefits of the SUBA-Itraconazole formulation are as follows:

- polymer drug dispersion technology (which is utilized in SUBA-Itraconazole) has been demonstrated to deliver itraconazole with 90% bioavailability;
- Itraconazole absorption is not dependent on an acidic stomach;
- SUBA-Itraconazole is released in the lower pH conditions found in the intestine, thus improving drug delivery and bioavailability;
- SUBA-Itraconazole levels have been demonstrated to be more consistent within patients and between patients compared to generic or branded itraconazole;

- SUBA-Itraconazole can be taken with or without food or acidic beverages; and
- there are no restrictions regarding achlorhydric patients (low acid stomach) or patients with acid reflux (requiring proton-pump inhibitors).

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

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

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

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

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

Based on this meeting with FDA, we concluded that our estimated timeline for submitting the SUBA-Itraconazole BCCNS NDA would need to be revised from sometime during the fourth quarter of 2018 to sometime during the first quarter of 2019. However, under our Supply and License Agreement, Mayne Pharma had the right to assume control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS if we were unable to have the SUBA-Itraconazole BCCNS NDA accepted by FDA for filing by December 31, 2018 (subject to a possible maximum extension of 30 days if the NDA was filed in December). As a result of unexpected FDA guidance, we determined that we would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this

deadline, and thus we commenced negotiations with Mayne Pharma to allow Mayne Pharma to assume such control of the SUBA-Itraconazole BCCNS program on an expedited basis in December 2018 in exchange for (among other consideration) a 9% quarterly cash royalty on future net sales, if any, of SUBA-Itraconazole BCCNS in the United States. See "Certain Relationships and Related Party Transactions" for further information.

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

University of Connecticut Itraconazole Analogue Technology

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

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

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

Intellectual Property

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

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

On September 2, 2015, we entered into a sublicense agreement with an affiliate of Mayne Pharma (which was most recently amended on December 17, 2018 and which we refer to as the Sublicense Agreement), pursuant to which such affiliate sublicensed to us the exclusive U.S. rights to two patents regarding the use of itraconazole for treatment of cancer, namely US patent No 8,980,930 entitled "Angiogenesis Inhibitors", issued on March 17, 2015, and US patent No 8,653,083 entitled "Hedgehog Pathway Antagonists to Treat Disease", issued on February 28, 2014 in the licensed filed. Such affiliate is the sublicensee of the patents from Accelas Holdings, a British Virgin Islands company, who in turn is the licensee from The Johns Hopkins University, the owner of the patents. The patents relate to the use of itraconazole as a treatment for cancer and age-related macular degeneration.

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

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

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

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

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

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

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

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

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

HedgePath Intellectual Property: We were issued a patent by the US Patent and Trademark Office (or USPTO) on November 24, 2015 (US Patent 9,129,609, *Treatment and Prognostic Monitoring of Proliferation Disorders Using Hedgehog Pathway Inhibitors, expires 02-05-2034*). On May 8, 2018, we were issued a patent by the USPTO for US Patent 9,962,381, *Treatment and Prognostic Monitoring of Cancerous Proliferation Disorders Using Hedgehog Pathway Inhibitors, expires 02-05-2034*; and on May 15, 2018, we were issued a patent by the USPTO for US Patent 9,968,600, *Treatment and Prognostic Monitoring of Non-Cancerous Proliferation Disorders Using Hedgehog Pathway Inhibitors, expires 02-05-2034.*

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

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

The Hedgehog Pathway

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

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

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

Repurposing Itraconazole for Treating Cancer

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

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

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

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

Prostate Cancer

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

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

Lung Cancer

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

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

Basal Cell Carcinoma

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

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

Our Potential Market

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

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

Cancer Type	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market*
Prostate (1)	Patients with metastatic castrate resistant prostate cancer (mCRPC) and rising PSA levels no longer responding to androgen deprivation therapy (ADT)	Delay the progression of metastatic disease	23,000 high-risk men with metastatic prostate cancer who are no longer responding to ADT due to biochemical resistance	$215Million at Yr 5 ($843M cumulative from launch) based on HedgePath estimates of ~ $4,000 - $5,000 monthly cost of 2nd line therapy
Lung (2)	Patients with advanced non-squamous cell, non-small cell lung cancer (NSCLC) who will be placed on Platinum Doublet/Pemetrexed IV Therapy	Improve the current median 8 -10 month survival achieved with best supportive care for patients who are not eligible for treatment with tyrosine kinase or checkpoint inhibitors	45,000 men and women with late-stage disease who may be treated with chemotherapy if not eligible for other therapies	$270Million at Yr 5 ($945M cumulative from launch based on HedgePath estimates of ~ $4,000 - $5,000 monthly cost of 2nd or 3rd line therapy
Skin (3)	Patients with BCC (basal cell carcinoma) lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring surgery Potential for follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures	Less toxic therapy than vismodegib or sonidegib for Gorlin Patients to delay surgeries; low toxicity therapy to delay or minimize surgical intervention for head and neck BCC tumors	10,000 Gorlin patients needing chronic BCC therapy; 65,000 BCC patients pending surgical treatment for facial tumors that require excision and potential plastic surgery	$300M for Gorlin patients for which HPPI receives a 9% royalty on net sales in the US based upon licensing the indication to Mayne Pharma; and $600M for patients with BCC facial lesions requiring surgery based upon HedgePath/Mayne Pharma estimates of ~ $4,000 - $5,000 monthly cost of therapy for target populations

*** Estimated**

References:

(1) *J. Urology, 2003; Oncology, 2004; American J. Hematologic Oncology, 2014; NIH NCI SEER 2014; Medscape, 2015; Future Oncology 2015; Global Data2015; Pennside Partners 2017*

(2) *STATS MGU, 2009; Global Industry Analysts, 2010; World Health Organization, 2015; Cost of Treating Lung Cancer, 2012; LUNGevity Foundation 2017; NEJM 2015; Pennside Partners 2017*

(3) *J Am Academy Dermatology, 2006; Skin Cancer Foundation, 2009; International Medicine News, 2011; Seeking Alpha, 2017; BCCNS Life Support Network 2017, Genetics Home Reference 2015; Pennside Partners 2016*

Our Strategy

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

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

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

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

- proceeds from public and private financings (including, most recently, financing from our majority shareholder, Mayne Pharma) and, potentially, from strategic transactions;
- advances from Mayne Pharma of potential future royalties on the SUBA-Itraconazole BCCNS product available under the Supply and License Agreement;
- royalty revenue from Mayne Pharma from sales of SUBA-Itraconazole BCCNS upon and assuming approval by FDA (after earned royalties have been applied to any advances due under the Supply and License Agreement);
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including potentially, warrants held by our Mayne Pharma, our majority stockholder);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive milestone and royalty payments;

- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and/or
- seeking government or private foundation grants or loans which would be awarded to us to further develop our current and future anti-cancer therapies.

Background on Cancer

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

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

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

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

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

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

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

The Itraconazole Approach to Treating Cancer

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

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

Cancer and Hedgehog Inhibitors. The Hedgehog (also known as Hh) proteins comprise a group of secreted proteins that regulate cell growth, differentiation and survival. They are involved in organogenesis (the formation of organs), and have been shown to promote adult stem cell proliferation. Inappropriate activation of the Hh signaling pathway has been implicated in the development of several types of cancers including prostate, lung, pancreas, breast, brain and skin. Hedgehog pathway inhibitors are a relatively new class of therapeutic agents that act by targeting the proteins involved in the regulation of the Hh pathway. Many of these newly discovered inhibitors are currently undergoing preclinical testing and some have entered clinical studies as anti-cancer agents for a variety of cancers. Vismodegib was approved for treatment of locally advanced and metastatic basal cell carcinoma in early 2012, sonidegib was approved for locally advanced BCC in mid-2015 and gladegib was approved in late 2018 for treatment of acute myeloid leukemia

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

Manufacturing and Product Supply and Relationship with Mayne Pharma

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

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

Sales and Marketing

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

Competition

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

Below are some examples of companies with approved and potentially competitive anti-cancer therapies or related products, though the examples are not all-inclusive. Many of these entities have significantly greater research and development capabilities than do we, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' research, financial, marketing, manufacturing and other resources. Such potential competitive anti-cancer therapies may ultimately prove to be safer, more effective or less costly than any product candidates that we are currently developing or may be able to develop. Additionally, our competitive position may be materially 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
Trexall® methotrexate	Teva	Antimetabolite therapy to slow cancer cell growth	Approved before 1984
Taxotere® docetaxel	Sanofi-Aventis	Anti-tumor agent for MCRPC and late-stage NSCLC	Approved 2004; and new generics
Gemzar® gemcitabine	Lilly	Cytotoxic chemotherapy agent for NSCLC in combination with platinum drugs	Approved for multiple cancers since 1996
Avastin® bevacizumab	Genentech	Angiogenesis inhibitor for NSCLC except squamous cell lung cancer	Approved for multiple cancers since 2004
Jevtana® cabazitaxel	Sanofi-Aventis	MCRPC following docetaxel failure	Approved 2010
Provenge® sipuleucel-T	Dendreon/Valeant	Immunotherapy for asymptomatic MCRPC	Approved 2010
Zytiga® aberaterone	Janssen Biotech	Androgen synthesis inhibitor for metastatic and non-metastatic CRPC	Approved 2011
Xalkori® crizotinib	Pfizer	Selective inhibitor for late-state NSCLC patients who express the ALK gene	Approved in 2011

Names	Company	Description	Status
Xtandi® enzalutamide	Astellas	Androgen receptor inhibitor for MCRPC previously on docetaxel	Approved 2012
Erivedge® vismodegib	Roche Genentech	Hedgehog inhibitor for advanced and metastatic BCC	Approved 2012
Odomzo® - sonidegib	Sun Pharma	Hedgehog inhibitor for advanced and metastatic BCC	Approved 2015
Avastin® bevacizumab	Genentech	Angiogenesis inhibitor for NSCLC except squamous cell lung cancer	Approved for multiple cancers since 2004
Tarceva® erlotinib	Astellas	Epidermal growth factor inhibitor treatment for NSCLC - maintenance therapy after chemo or metastatic disease after chemo	Approved in 2013
Gilotrif® afatinib	Boehringer	NSCLC with mutations in EGFR	Approved 2013
Zykadia® certinib	Novartis	ALK-positive metastatic NSCLC for patients who progressed on Xalkori	Approved 2014
Cyrazma® ramucirumab	Lilly	VEGF antagonist NSCLC	Approved 2014
Opdivo® nivolumab	BMS	Metastatic squamous NSCLC	Approved 2015
Portrassa® necitumumab	Lilly	Metastatic squamous NSCLC	Approved 2015
Tagrisso® osimertinib	AstraZenica	EGFR mutation positive NSCLC	Approved 2015
Keytruda® pembrolizumab	Merck Oncology	Metastatic NSCLC expressing PD-L1	Approved 2015
Alecensa® alectinib	Genentech	Metastatic NSCLC ALK positive who could not tolerate crizotinib	Approved 2015
Iressa® gefitinib	AstraZeneca	Metastatic NSCLC with EGFR deleture	Approved 2015
Tecentriq® atezolizumab	Takeda	Anti-PDL-1 for Metastatic NSCLC not responding to EGFR or ALK gene therapy or platinum-based chemotherapy	Approved 2016
Alunbrig® brigatinib	Genentech	ALD positive metastatic NSCLC	Approved 2017
Erleada™ apalutamide	Janssen	AR inhibitor for non-MCRPC	Approved 2018

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

Government Regulation and Product Approval

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

United States Government Regulation

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

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

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

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

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

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

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. We moved directly into Phase 2 trials with SUBA-Itraconazole BCCNS based upon the previous, well-established safety profile of itraconazole use in humans for treatment of anti-fungal indications and based upon the previous human data regarding the use of itraconazole for anti-cancer indications such as basal cell carcinoma, lung cancer and prostate cancer.

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

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

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

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

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

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS (Risk Evaluation Mitigation Strategy) which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

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

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

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

Moreover, under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A

breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

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

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

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

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

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

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

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

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

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

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

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

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

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act (or HITECH) and its implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH

makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any

product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

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

Exclusivity and Approval of Competing Products

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

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

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

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

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

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

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

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

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

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

Employees

As of March 7, 2019, we have 2 full-time employees. One is involved in our clinical development program and operations and one handles our administration and accounting. Neither of our employees is 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 regulatory consultants, two regulatory

advisory firms, a scientific advisor 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 when such reports are available on the SEC website. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers like us 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 is highly speculative and 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 pharmaceutical development company and are thus subject to the risks associated with early stage businesses in that industry.

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

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

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

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

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

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

Our operations are presently limited to planning and conducting of pre-clinical testing and clinical trials, arranging for the raising of capital, developing our technology or seeking technology licenses or acquisitions, and

identifying potential commercial partners. We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for product commercialization. Consequently, any predictions you make about our future viability or ability to accomplish our business goals may not be as accurate as they could be if we had a longer operating history.

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

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

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

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

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

As of the date of this Report, Mayne Pharma beneficially owns approximately 59.1% of our outstanding voting securities (including shares of our common stock and Series B Preferred Stock). Under the terms of our Equity Holders Agreement, Mayne Pharma has the right to designate one director to our Board of Directors (and to designate a second director if the size of the Board of Directors is increased to seven directors) until the earlier to occur of: (i) the date that the Supply and License Agreement is terminated or expires, or (ii) the date on which Mayne Pharma along with its affiliates ceases to own ten percent (10%) or more of our issued and outstanding common stock on a fully diluted basis. During this time frame, Mayne Pharma, through its representative on the Board of Directors, holds a veto right in the event that we want to increase or decrease the size of the Board of Directors or replace or remove our President and Chief Executive Officer (such veto right being the result of each of the foregoing Board of Director actions requiring the unanimous consent of the Board of Directors).

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

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

Pursuant to our agreements with Mayne Pharma, Mayne Pharma and its affiliates have been granted certain rights to purchase a pro rata share of any new securities issued by us, which pro rata share would be determined

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

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

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

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

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

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

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

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

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

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We

intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from business development activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

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

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

Risks Related to Our Financial Position and Need For Additional Capital

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

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

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

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

- the progress and results of our development efforts for SUBA-Itraconazole;
- the progress and results of our pre-clinical development efforts with product candidates other than SUBA-Itraconazole;
- the progress and results of Mayne Pharma's efforts effort to commercialize SUBA-Itraconazole BCCNS for which we will receive a quarterly cash royalty of 9% of net sales if such sales are achieved;
- the costs, timing and outcome of clinical trials of our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- competing technological and market developments;
- market acceptance of our product candidates as a treatment;

- the costs and timing of our potential future acquisitions or licenses of additional pharmaceutical technologies;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidate for which we receive marketing approval;
- the revenue, if any, received from commercial sales or licensing royalty from a commercial partner of any product candidate for which we may receive marketing approval;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Clinical Development of Our Product Candidate

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

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

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

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

- maintaining a continued acceptable safety profile of our product following approval, if any.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;

- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

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

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

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

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

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

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

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

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

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

- collaborators may not perform their obligations as expected;

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

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

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

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third-party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and

- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

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

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

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

Risks Related to the Commercialization of Our Product Candidate

Even if any of our product candidates receive marketing approval for any indication, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

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

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

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

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

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

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

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

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

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

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

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

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove 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 a therapy for cancer and non-cancerous proliferation disorders. We seek to protect our proprietary position through our exclusive license for SUBA-Itraconazole with Mayne Pharma, through our sublicense of other itraconazole-related rights from Mayne Pharma, our own patents for treating cancer with SUBA-Itraconazole and by filing patent applications in the United States related to our novel technologies and product candidate and also our expectation to license additional applicable patents from third parties. We will also need to obtain and maintain patent protection for any technologies we may acquire or license (including the UConn technology to which we currently have an option).

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The process of obtaining marketing approvals in the United States is very expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We experienced unexpected complexities of this nature in the regulatory development of SUBA-Itraconazole BCCNS (which ultimately led to Mayne Pharma to assume control of that product), and may experience similar complexities in the future, which could harm our prospects

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

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

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

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

- the federal HIPAA and HITECH laws, which govern the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

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

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

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

It is our intention to seek to avail ourselves of the FDA's 505(b)(2) approval procedure where it is appropriate to do so, particularly for SUBA-Itraconazole as a therapy to treat cancer and non-cancerous proliferation disorders since itraconazole has previously been approved for another indication. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act permits an applicant to file an NDA with the FDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain preclinical testing or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- restrictions on such product, our manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of the product;
- restrictions of product distribution use;
- requirements to conduct post-marketing studies or clinical trials;
- 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 OTCQB marketplace operated by OTC Markets Group, Inc., trading has been very limited, and we cannot predict whether an active market for our common stock will ever develop in the future. In the absence of an active trading market:

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

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

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

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

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

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

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

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

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

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

- changes in our relationship with Mayne Pharma
- any delay in or the results of our clinical trials;
- the announcements of clinical trial data, and the investment community's perception of and reaction to those data;
- the results of clinical trials conducted by others on products that would compete with our product candidate;

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

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

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

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

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

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

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

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

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

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

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

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

Our common stock is considered a "penny stock" as it does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Securities Exchange Act of 1934. Our common stock will be a "penny stock" for so long as it meets one or more of the following conditions: (i) the stock trades at a price less than $5 per share; (ii) it is not traded on a "recognized" national exchange; or (iii) is issued by a company (such as ours) that has been in business less than three years with net tangible assets less than $5 million.

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

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

FINRA rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status and investment objectives, among other things. Under interpretations

of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares, have an adverse effect on the market for our shares, and thereby depress our share price.

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

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

We do not know whether our securities will be registered or exempt from registration under the laws of any state. A determination regarding registration will be made by those broker-dealers, if any, who agree to serve as market makers for our common stock. We have not yet applied to have our securities registered in any state and will not do so until we receive expressions of interest from investors resident in specific states after they have viewed this 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 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 common stock. We currently intend to retain any future earnings and do not expect to pay any dividends for the foreseeable future. Therefore, you should not invest in our common stock in the expectation that you will receive dividends.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Description of Property.

We currently lease our corporate office in Tampa, Florida for approximately $3,500 per month. Prior to February 1, 2019, we leased space at the offices of Hedgepath, LLC in Tampa, Florida for which we paid a prorated portion of the rent of approximately $1,400 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 OTCQB market under the symbol "HPPI", but an established public trading market for our common stock does not exist. The range of reported high and reported low sales prices per share for our common stock for each fiscal quarter during 2018 and 2017, as reported by the OTC Markets Group, is set forth below.

Quarterly common stock Price Ranges

Fiscal Year 2018, Quarter Ended:	High	Low
March 31, 2018	$0.36	$0.22
June 30, 2018	$0.36	$0.26
September 30, 2018	$0.38	$0.27
December 31, 2018	$0.32	$0.04

Fiscal Year 2017, Quarter Ended:	High	Low
March 31, 2017	$0.41	$0.24
June 30, 2017	$0.46	$0.27
September 30, 2017	$0.47	$0.30
December 31, 2017	$0.42	$0.19

As of March 7, 2019, we had approximately 64 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, 2018 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)	3,424,000 (2)	$ 0.28 (2)	2,417,737

(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. The Board of Directors approved an increase to the number of shares available for issuance under the EIP of 11,000,000 shares which was subsequently approved by our majority shareholder in December 2018. As of January 2019, there are now 13,417,737 shares available for issuance under the EIP.

(2) Outstanding securities issued pursuant to our EIP are 3,424,000 stock options. 650,000 stock options were issued on July 1, 2016 with an exercise price of $0.24 per share and vested upon a change in control in November 2016. 1,862,000 stock options were issued on March 13, 2018 with an exercise price of $0.2722 per share. 758,000 of those March 13, 2018 options vested on the grant date with the balance vesting on March 13, 2019. 912,000 stock options were issued on June 15, 2018 with an exercise price of $0.33 per share and vest on June 15, 2019.

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

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

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

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

Critical Accounting Policies and Estimates

Estimates

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

Revenue Recognition

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

Cash and Cash Equivalents

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

Research and Development Expenses

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

Stock-Based Compensation

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

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

Income taxes

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

Recent accounting pronouncements

In May 2014, FASB issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of ASC Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the new

standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. We have evaluated the impact of adoption of this standard on our financial statements, which was effective January 1, 2018, and determined it had no material impact.

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

In April 2016, the FASB issued ASU 2016-10, "*Revenue from Contracts with Customers* (Topic 606): Identifying Performance Obligations and Licensing." ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. This ASU applies to all companies that enter into contracts with customers to transfer goods or services. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2017. We have evaluated the potential impact of this guidance, which was effective January 1, 2018, and determined it had no material impact on our financial statements.

Results of Operations

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

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

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

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

Liquidity and Capital Resources

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

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

- public and private financings and, potentially, other strategic transactions (including, most recently, financings from our majority shareholder, Mayne Pharma);
- advances from Mayne Pharma of potential future royalties on the SUBA-Itraconazole BCCNS product available under the Supply and License Agreement;

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

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

Contractual Obligations and Commercial Commitments

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

Off Balance Sheet Arrangements

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

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, 2018, 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, 2018 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, 2018. 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, 2018.

Item 9B. Other Information.

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of March 7, 2019 are as follows:

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

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

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

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

E. Brendan Magrab, age 53, has been Chairman of the Board of Directors and a Director of our company since December 2016. 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. On February 11, 2019, Mr. Magrab notified our Board of Directors that he had executed an agreement to become the Chief Executive Officer of a privately-held biotechnology company (Epalex Corporation) and that, pursuant to such agreement, Mr. Magrab was afforded a period of six (6) months to transition off our Board of Directors. In his notification, Mr. Magrab did not resign from our Board of Directors. In light of Mr. Magrab's notification, during the contemplated transition period, the Board of Directors or its designated committee will be evaluating options in light of the potential vacancy on the Board of Directors.

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

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

W. Mark Watson, CPA, age 68, is a director of our company and Chairman of the Audit Committee of our Board of Directors. Mr. Watson has been a director since June 2014. Mr. Watson is a Certified Public Accountant with over 40 years of experience in public accounting and auditing, having spent his entire career from January 1973 to June 2013 at Deloitte Touche Tohmatsu and its predecessor, most recently as Central Florida Marketplace Leader. Among other industries, he has a particular expertise in the healthcare and life sciences sector, having played a significant role in the development of Deloitte's audit approach for health and life sciences companies and leading its national healthcare regulatory and compliance practice. He has served as lead audit partner and lead client service partner on the accounts of many public companies ranging from middle market firms to Fortune 500 enterprises. Mr. Watson was elected to the Board of Directors of Sykes Enterprises Inc. in May 2018 and serves on its Audit Committee. Mr. Watson was elected to the Board of Directors of BioDelivery Sciences International, Inc. in December 2017 and was appointed Chairman of its Audit Committee. Mr. Watson is a member of American Institute of Certified Public Accountants and the Florida Institute of Certified Public Accountants. Mr. Watson is qualified to serve on our Board of Directors due to his expertise in public accounting and his experience with life science and pharmaceutical companies. He received his undergraduate degree in Accounting from Marquette University.

Stefan J. Cross, age 46, is a director of our company and the appointee of Mayne Pharma to our Board of Directors. Mr. Cross has been a director since June 2014. Mr. Cross is currently serving as President, International Operations of Mayne Pharma Group Limited (ASX:MYX). Previously, Mr. Cross served as the President of the U.S. subsidiaries of Mayne Pharma Group Limited from November 2013 to January 2017. Mr. Cross has more than 20 years of experience in the pharmaceutical industry. He served since 2012 as the Vice President, Business and Corporate Development of Mayne Pharma's non-U.S. operations, where he was responsible for all in-licensing and out-licensing programs and research and development partnerships. Prior to joining Mayne Pharma, Mr. Cross was, from 2007 to 2012, Head of Marketing (Asia Pacific) for Hospira Inc., a leading global provider of

pharmaceuticals and medical devices, where he was responsible for expansion of the new product portfolio and on-market product growth across all markets in the region. Prior to Hospira, Mr. Cross spent most of the period from 1991 to 2007 working in the pharmaceutical sector in the areas of strategy, business development/mergers and acquisitions, sales and marketing, human resources, finance and information technology. Mr. Cross is qualified to serve on our Board of Directors because of his extensive business experience in the pharmaceutical industry. Mr. Cross holds a Masters in Business in Administration from Swinburne University of Technology, Australia, and a degree in Business Information Systems from the University of South Australia.

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

Robert D. Martin, age 71, is a director of our company and Chairman of the Compensation Committee of our Board of Directors. Mr. Martin has been a director since December 2016. Mr. Martin has over 30 years of finance and operations experience. Most recently, Mr. Martin was appointed President and Chief Operating Officer of Specicare, a company that arranges for storage of cancer patients' live tumor tissue from surgery to be used for specialized and precision treatment. Since 2006, Mr. Martin has been part of The Interlochen Group, LLC, a firm that provides chief financial officer personnel on a contract basis. Among other assignments, he was assigned to serve as Interim Chief Financial Officer of Tandy Brands Accessories Inc. from January 2011 to June 2011. Also, during 2015, he was a consultant/financial advisor to 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 established in accordance with Section 3(a)(58)(A) of the Exchange Act, composed of W. Mark Watson, Robert D. Martin and Dr. R. Dana Ono. All members are

independent directors as defined in accordance with Rule 10A-3 of the Exchange Act and the rules of the NASDAQ Stock Market. Mr. Watson serves as chairman of the committee. The Board of Directors has determined that Mr. Watson is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K.

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

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

Nominating and Corporate Governance Committee

Our Board of Directors has a Nominating and Corporate Governance Committee composed of Robert D. Martin, Dr. R. Dana Ono, and W. Mark Watson. Mr. Martin served as the chairman of the committee for 2018. As of January 23, 2019, Dr. Ono was appointed as the chairman of this 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. Dr. Ono served as chairman of this committee for 2018. As of January 23, 2019, Mr. Martin was appointed as the 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 2018, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons except that Mayne Pharma, the beneficial owner of more than ten percent of our common stock, filed one Form 4 disclosing one transaction late.

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, 2018 and 2017. Individuals we refer to as our "named executive officers" include our Chief Executive Officer and our most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2018.

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

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

Narrative Disclosure to Summary Compensation Table

Employment Agreements

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

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

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

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

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

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

Pursuant to the New Hasara Employment Agreement, Mr. Hasara will earn a base salary of $225,000 per annum (his prior salary level), payable in accordance with our regular payroll practices. Mr. Hasara will also receive a cash bonus for the fiscal year ended December 31, 2018 ($67,500 approved in February 2019 and payable by March 15, 2019), the amount of such bonus to be determined by our Compensation Committee of the Board of Directors in accordance with the bonus potential under the Prior Hasara Employment Agreement and the Compensation Committee's determination of corporate objectives met. Mr. Hasara is also eligible for a bonus in cash and/or equity awards for the period covered by the New Hasara Employment Agreement, any such bonus to be granted at the discretion of the Board of Directors or the Compensation Committee. Pursuant the New Hasara Employment Agreement, Mr. Hasara will continue to receive customary benefits. The New Hasara Employment Agreement may be terminated by the Company or by Mr. Hasara, in each case on 30 days' notice, and we may terminate the New Hasara Employment Agreement immediately for Cause (as such term is defined in the New Hasara Employment Agreement). We shall have no severance payment obligation to Mr. Hasara in the event of any termination of the New Hasara Employment Agreement. The New Hasara Employment Agreement also provides that Mr. Hasara may not compete against us or solicit employees or customers from us for a period of six (6) months after termination of his employment for any reason.

Outstanding equity awards

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

	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	310,000	—	—	$0.2722	March 13, 2028	—	—	—	—
Garrison J. Hasara, CPA	260,000	—	—	$0.2722	March 13, 2028	—	—	—	—

2014 Equity Incentive Plan

In July 2014, our Board of Directors adopted our EIP. On September 30, 2014, the EIP was approved by the majority of stockholders pending delivery of required notice to all Company stockholders. At December 31, 2018, the EIP was comprised of 32,583,475 shares. In December 2018, the Board of Directors approved an increase to the number of shares available for issuance under the EIP of 11,000,000 shares which was subsequently approved by our majority shareholder in December 2018. As of January 2019, the EIP is comprised of 43,583,475 shares and there are now 13,417,737 shares available for issuance under the EIP (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, 2018 or 2017.

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

Pension Benefits

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

Non-qualified Deferred Compensation

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

Compensation of Directors

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

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

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

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

The following table sets forth, as of March 7, 2019, 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., 4830 W. Kennedy Blvd, Suite 600, Tampa, Florida 33609.

Name and address of beneficial owners	Amount and nature of beneficial ownership of Common Stock	Approximate percentage of outstanding common stock(1)
Mayne Pharma Ventures Pty Ltd.(2)	248,244,247	59.1%
Hedgepath, LLC(3)	89,877,638	23.6%
Nicholas J. Virca(4)	9,037,519	2.4%
Garrison J. Hasara, CPA(5)	4,219,044	1.1%
Stefan J. Cross(6)	—	*
Dr. R. Dana Ono(7)	912,000	*
W. Mark Watson, CPA(8)	2,082,600	*
E. Brendan Magrab(9)	410,000	*
Robert D. Martin(10)	369,000	*
All directors and executive officers as a group (7 persons)	17,030,163	4.6%

* Less than 1%

(1) Applicable percentages are based on 370,446,185 shares outstanding as of the date of this filing. This table is based upon information supplied by officers, directors, and principal stockholders and Schedule 13D(s) and Schedule 13G(s) filed with the SEC. Unless indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

(2) Includes 198,653,051 shares of our common stock, 17,391,306 shares of common stock upon conversion of Series B Preferred Stock, and warrants to purchase 32,199,890 shares of our common stock. The address for Mayne Pharma Ventures Pty Ltd is Level 14, 474 Flinders Street, Melbourne Vic 3000, Australia.

(3) Includes 79,627,069 shares of our common stock and a warrant to purchase 10,250,569 shares of our common stock. Our former Corporate Secretary, James A. McNulty, CPA, has sole voting and dispositive power over the securities held by Hedgepath, LLC. The address for Hedgepath, LLC is 324 S. Hyde Park Avenue, Suite 350, Tampa, FL 33606.

(4) Mr. Virca is our Chief Executive Officer and President. Includes 8,727,519 shares of our common stock and 310,000 vested stock options. Mr. Virca's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.

(5) Mr. Hasara is our Chief Financial Officer and Treasurer. Includes 3,959,044 shares of our common stock and 260,000 vested stock options. Mr. Hasara's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.

(6) Mr. Cross is a director of our company. Mr. Cross' address is c/o Mayne Pharma at Level 1, 99 King Street, Melbourne, Victoria 3000, Australia.

(7) Dr. Ono is a director of our company. Includes 453,000 shares of our common stock and 459,000 vested stock options. Dr. Ono's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.

(8) Mr. Watson is a director of our company. Includes 1,053,600 shares of our common stock, warrants to purchase 500,000 shares of our common stock, and 529,000 vested stock options. Mr. Watson's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.

(9) E. Brendan Magrab is the Chairman and a director of our company. Includes 65,000 shares of our common stock and 345,000 vested stock options. Mr. Magrab's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.

(10) Robert D. Martin is a director of our company. Includes 60,000 shares of our common stock and 309,000 vested stock options. Mr. Martin's address is c/o HedgePath Pharmaceuticals at 4830 W. Kennedy Blvd., Suite 600, Tampa, FL 33609.

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

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

On December 17, 2018 (the "Effective Date"), we entered into the following related agreements (collectively, the "Transaction Documents"): (i) an agreement, by and among us, Mayne Pharma and Mayne Pharma International Pty Ltd ("Mayne Pharma International") (the "Agreement"), (ii) Third Amended and Restated Supply and License Agreement, dated December 17, 2018, by and between us and Mayne Pharma (referred to in this Item 13 as the "Third Amended SLA") and (iii) Amended and Restated Sublicense Agreement, by and between the us and Mayne Pharma International, which amends and restates that certain Sublicense Agreement, dated August 31, 2015, between us and Mayne Pharma International, as amended (referred to in this Item 13 as the "Amended and Restated Sublicense Agreement"). In addition, pursuant to the terms of the Agreement, we and Mayne Pharma agreed to the terms and provisions of an Amended and Restated Certificate of Designation of Series B Convertible Preferred Stock of Company (the "Amended and Restated COD"), which amends and restates the Certificate of Designation of Series B Convertible Preferred Stock of the Company, dated January 8, 2018 (as corrected, the "Original COD"), to remove certain features thereof as described below. As of the Effective Date, all outstanding shares of Series B Preferred Stock are held by Mayne Pharma. Mayne Pharma owns approximately 54.4% of our equity securities on a fully-diluted basis and beneficially owned 59.1% of our outstanding voting securities (including shares of our common stock and Series B Preferred Stock) as of the date of this Report.

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

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

Agreement

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

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

In addition, pursuant to the Agreement, for the period beginning on the Effective Date and ending three (3) years from the Effective Date, in the event that we asks our stockholders (whether at a meeting of stockholders or pursuant to a written consent of stockholders) to vote on or approve a proposal to effect a reverse split of our capital stock for the purpose of uplisting our common stock to a U.S. national securities exchange (a "Reverse Stock Split Proposal"), Mayne Pharma (on behalf of itself and its affiliates) has agreed to vote or cause to be voted (in

person, by proxy or by action by written consent, as applicable) all shares of our voting capital stock that either Mayne Pharma then owns or over which Mayne Pharma has voting control in favor of the adoption and approval of any such Reverse Stock Split Proposal. The Agreement further provides that the Reverse Stock Split Proposal may take the form of an authorization based on a range of ratios for the reverse stock split, with authority being granted to our Board of Directors (or a designated committee thereof) to determine the final ratio of the reverse stock split, provided such range is reasonable in connection with the uplisting of the common stock to a U.S. national securities exchange. No assurances are given that we will seek an uplisting to a U.S. national securities exchange or implement a reverse stock split of our common stock.

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

Third Amended and Restated Supply and License Agreement

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

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

- Mayne Pharma has agreed to pay us a 9% quarterly cash royalty on future net sales, if any, of SUBA-Itraconazole BCCNS in the United States (the "Royalty"), from which certain royalties owed by us to Mayne Pharma for access to certain patents would be funded.
- Mayne Pharma has agreed to advance funds to us in an aggregate amount of up to $5 million (each, an "Advance", and collectively, the "Advances") on the following terms and conditions:
    - on the Effective Date, Mayne Pharma made an Advance to us of $500,000;
    - within three (3) business days following the completion of the agreed upon activities associated with transferring the SUBA-Itraconazole BCCNS product to Mayne Pharma, Mayne Pharma made an Advance to the Company of $1,000,000 (subsequently received in January 2019);
    - if, and only if, our SUBA-Itraconazole BCCNS Phase 2(b) clinical trial data have been provided to Mayne Pharma in all material respects so as to allow Mayne Pharma to assume control of SUBA-Itraconazole BCCNS in the United States, upon the earlier of June 30, 2019 or the acceptance for filing by FDA of an NDA for the SUBA-Itraconazole BCCNS, Mayne Pharma must make an Advance to the Company of $1,500,000; and
    - If we raise aggregate gross proceeds of more than $3 million from the sale of new common stock, preferred stock equity subordinate to the preferred stock held by Mayne Pharma or warrants ("New Securities") to third parties in one or more equity financings by June 30, 2021 (the "Equity Funding Achievement"), we may request additional Advances of up to an amount equal to $2 million less the amount of aggregate gross proceeds received by us from Mayne Pharma from the sale of New Securities if Mayne Pharma elects to participate in such equity financings pursuant to contractual pro rata participation rights contained in the Third Amended SLA.
- The field covered by the Third Amended SLA was amended to specifically include only the following indications: (i) any prostate cancer, prostatic intraepithelial neoplasia and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia, and (iii) familial adenomatous polyposis, colorectal polyps and Barett's esophagus (the licensed field). Our continued right to work on these indications will no longer be tied to the achievement of clinical or commercial target dates as they were under the Second Amended SLA.

- Mayne Pharma will continue to provide quantities of SUBA-Itraconazole drug and placebo oral capsules without charge for our SUBA Itraconazole prostate clinical studies and for future indications as agreed to by the parties.
- Pursuant to the Third Amended SLA, unlike under the Second Amended SLA, Mayne Pharma has licensed to the Company the right to use all pre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to the Product anywhere in the world for its activities under the Third Amended SLA.

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

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

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

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

Amended and Restated Sublicense Agreement

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

January 2018 Series B Preferred Stock Purchase Agreement

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

(i) up to 7,246,377 shares of our Series B Preferred Stock at $0.69 per share of Series B Preferred Stock (with each share of Series B Preferred Stock being convertible into three (3) shares of our common stock for an effective price per share of common stock of $0.23), for potential gross proceeds of $5,000,000;

(ii) Series A warrants (the "Series A Warrants") to purchase up to an aggregate 5,434,783 shares of common stock, with a two-year term from the date of issuance and an exercise price per share of $0.23; and

(iii) Series B warrants (the "Series B Warrants") to purchase up to an aggregate of 5,434,783 shares of common stock, with a five-year term from the date of issuance and an exercise price per share of $0.275 (which we refer to together with the Series A Warrants as, the "Warrants").

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

(i) $2.4 million was funded at an initial closing of the Financing that occurred on January 10, 2018;

(ii) $1.6 million was funded on July 5, 2018; and

(iii) $1.0 million may be funded on or before December 31, 2018 (the "Third Closing") did not occur.

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

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

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

Mayne Pharma owns approximately 54.4% of our equity securities on a fully-diluted basis and beneficially owns approximately 59.1% of our outstanding voting securities (including shares of our common stock and Series B Preferred Stock) as of the date of this filing.

Equity Holders Agreement

On June 24, 2014, we, Mayne Pharma, Hedgepath, LLC, Dr. Francis O'Donnell and Mr. Virca (who for these purposes we refer to together as the Equity Holder Parties) entered into an Amended and Restated Equity Holders Agreement. On May 15, 2015, the Equity Holder Parties entered into the Second Amended and Restated Equity Holders Agreement. The Equity Holders Agreement governs the rights and obligations of each of the parties as they pertain to our securities and to the present and future governance of our company. Pursuant to the Equity Holders Agreement:

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

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

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, 2018 and 2017 totaled $65,000 and $70,000, respectively.

Audit-Related Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services were $1,750 related to our S-1 filings for both the years ended December 31, 2018 and December 31, 2017.

Tax Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for tax compliance, for the years ended December 31, 2018 and 2017 totaled $4,600 and $6,300, 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 (2)
3.3	Certificate of Amendment to the Company's Certificate of Incorporation (3)
3.4	Second Amended and Restated Bylaws of the Company (4)
3.5	Certificate of Amendment to the Company's Certificate of Incorporation (5)
3.6	Amended and Restated Certificate of Designation of Series B Preferred Stock of the Company, dated February 1, 2019 (6)
4.1	Warrant, dated June 24, 2014 issued to Hedgepath, LLC (7)
4.2	Form of Warrant issued in the 2016 Private Placement (8)
4.3	Form of Warrant issued in the January 2018 Series B Preferred Stock Financing (9)
10.1	Amended and Restated Equity Holders Agreement, dated May 15, 2015, by and between the Company, Mayne Pharma Ventures Pty Ltd., Hedgepath, LLC, Nicholas J. Virca and Frank O'Donnell, Jr. M.D. (10)+
10.2	Amendment No. 1 to Amended and Restated Equity Holders Agreement, dated December 17, 2015, Company, Mayne Pharma Ventures Pty Ltd., Hedgepath, LLC., Nicholas J. Virca and Frank O'Donnell (11)
10.3	Employment Letter Agreement, dated December 31, 2018, between the Company and Nicholas J. Virca (12)
10.4	Employment Letter Agreement, dated December 31, 2018, between the Company and Garrison J. Hasara (12)
10.5	Third Amended and Restated Supply and License Agreement, dated December 17, 2018, by and among Mayne Pharma, Mayne Pharma International and the Company *^
10.6	Amended and Restated Sublicense Agreement, dated December 17, 2018, by and among Mayne Pharma, Mayne Pharma International and the Company *^
10.7	Agreement, dated December 17, 2018, by and among Mayne Pharma, Mayne Pharma International and the Company *
10.8	Master Clinical Services Agreement, dated June 15, 2015, by and between the Company and SciQuus, Inc. (10)+
10.9	Securities Purchase Agreement, dated January 8, 2018, between the Company and Mayne Pharma (9)
14	Code of Ethical Conduct (13)
23.1	Consent of Cherry Bekaert LLP *
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. *#

Exhibit No.	Description
101.ins	XBRL Instance Document
101.sch	XBRL Taxonomy Extension Schema Document
101.cal	XBRL Taxonomy Calculation Linkbase Document
101.def	XBRL Taxonomy Definition Linkbase Document
101.lab	XBRL Taxonomy Label Linkbase Document
101.pre	XRL Taxonomy Presentation Linkbase Document

* Filed herewith
\+ Confidential treatment has been granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
^ Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
# A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
(1) Previously filed with Form 8-K, dated August 16, 2013.
(2) Previously filed with Form 8-K, dated September 10, 2013.
(3) Previously filed with Form S-1/A on July 22, 2015.
(4) Previously filed with Form 8-K, dated May 21, 2015.
(5) Previously filed with Form 8-K, dated May 26, 2016.
(6) Previously filed with Definitive Information Statement, filed on January 8, 2019.
(7) Previously filed with Form 8-K, dated June 30, 2014.
(8) Previously filed with Form 8-K, dated April 15, 2016.
(9) Previously filed with Form 8-K, dated January 11, 2018.
(10) Previously filed with Form 10-Q on August 14, 2015.
(11) Previously filed with Form 8-K, dated December 22, 2016.
(12) Previously filed with Form 8-K, dated December 31, 2018.
(13) Previously filed with Form 10-K on February 13, 2015.

Item 16. Form 10-K Summary.

We have elected not to include a summary pursuant to this Item 16.

HEDGEPATH PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of HedgePath Pharmaceuticals, Inc. (the "Company") as of December 31, 2018 and 2017 and the related statements of operations, stockholders' equity and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board of the United States of America ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to fraud or error. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ Cherry Bekaert LLP

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

Tampa, Florida
March 7, 2019

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

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

See notes to financial statements

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

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

See notes to financial statements

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

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

See notes to financial statements

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

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

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018 AND 2017

1. Corporate overview:

Overview

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

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

Nature of the Business

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

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

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

Overview of December 2018 Transactions with Mayne Pharma

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

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

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

The Transaction Documents resulted from negotiations regarding the existing right of Mayne Pharma under the Second Amended SLA to elect to assume control of the regulatory and clinical development program for SUBA-Itraconazole for the treatment of

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
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1. Corporate overview (continued):

BCCNS (such product candidate "SUBA-Itraconazole BCCNS") in exchange for a royalty on any future net sales of SUBA-Itraconazole BCCNS by Mayne Pharma in the United States if and FDA New Drug Application ("NDA") was not accepted for filing by FDA by December 31, 2018 (subject to limited extension if the NDA were filed in December 2018). Based on unforeseen requirements imposed by FDA in September 2018, the Company determined that it would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus the Company commenced negotiations with Mayne Pharma to transfer SUBA-Itraconazole BCCNS in advance of December 31, 2018 on negotiated terms deemed beneficial to the Company.

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

December 2018 Agreement with Mayne Pharma

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

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

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

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

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

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

(a) a 9% quarterly cash royalty (the "Royalty") on future net sales, if any, of SUBA-Itraconazole product in the BCCNS field in the United States, from which certain royalties owed by the Company to Mayne Pharma for access to certain patents would also be funded.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018 AND 2017

1. Corporate overview (continued):

(b) Mayne Pharma's agreement to advance funds to the Company in an aggregate amount of up to $5 million on the following terms and conditions:

(i) As of the Effective Date, Mayne Pharma shall make an Advance to the Company of $500,000; the Company received this first Advance on December 18, 2018;

(ii) Within three (3) business days following the completion of the agreed upon activities associated with transferring the SUBA-Itraconazole BCCNS product to Mayne Pharma, Mayne Pharma must make an Advance to the Company of $1 million; the Company received this Advance in January 2019;

(iii) If, and only if, the Company's Phase 2(b) clinical trial data have been provided to Mayne Pharma in all material respects so as to allow Mayne Pharma to assume control of SUBA-Itraconazole BCCNS in the United States, upon the earlier of June 30, 2019 or the acceptance for filing by FDA of an NDA for the SUBA-Itraconazole BCCNS, Mayne Pharma must make an Advance to the Company of $1,500,000; and

(iv) If the Company raises aggregate gross proceeds of more than $3 million from the sale of new common stock, preferred stock equity subordinate to the Series B Preferred Stock held by Mayne Pharma or warrants to third parties ("New Securities") in one or more equity financings by June 30, 2021 (the "Equity Funding Achievement"), the Company may request additional Advances of up to an amount equal to $2 million less the amount of aggregate gross proceeds received by the Company from Mayne Pharma from the sale of New Securities if Mayne Pharma elects to participate in such equity financings pursuant to contractual pro rata participation rights contained in the Third Amended SLA.

(c) The field covered by the Third Amended SLA was amended to specifically include only the following indications: (i) any prostate cancer, prostatic intraepithelial neoplasia and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia, and (iii) familial adenomatous polyposis, colorectal polyps and Barett's esophagus (the "Field"). The Company's work on these indications will no longer be tied to the achievement of clinical or commercial target dates as they were under the Second Amended SLA.

(d) Mayne Pharma will continue to provide quantities of SUBA-Itraconazole drug and placebo oral capsules without charge for the Company's SUBA-Itraconazole Prostate clinical studies and for future indications as agreed to by the parties.

(e) Pursuant to the Third Amended SLA, Mayne Pharma has licensed to the Company the right to use all pre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to SUBA-Itraconazole anywhere in the world for its activities under the Third Amended SLA.

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

December 2018 Amended and Restated Sublicense Agreement

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

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
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1. Corporate overview (continued):

January Series B Preferred Stock Purchase Agreement

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

(i) up to 7,246,377 shares of the Company's then newly designed Series B Preferred Stock at $0.69 per share of Series B Preferred Stock (with each share of Series B Preferred Stock being convertible into three (3) shares of the Company's common stock for an effective price per share of common stock of $0.23), for potential gross proceeds of $5,000,000;

(ii) Series A Warrants to purchase up to an aggregate 5,434,783 shares of common stock, with a two-year term from the date of issuance and an exercise price per share of $0.23; and

(iii) Series B Warrants to purchase up to an aggregate of 5,434,783 shares of common stock, with a five-year term from the date of issuance and an exercise price per share of $0.275 (together with the Series A Warrants, the "Warrants").

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

(i) $2.4 million was funded at an initial closing of the Financing that occurred on January 10, 2018 (the "Initial Closing");

(ii) $1.6 million was funded in July 2018 (the "Second Closing"); and

(iii) $1.0 million that was to be funded on or before December 31, 2018 (or the "Third Closing") did not occur.

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

Terms of the Series B Preferred Stock

The Series B Preferred Stock carries the following provisions:

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

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

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

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

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

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018 AND 2017

1. Corporate overview (continued):

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

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

Terms of the Warrants

The Warrants are divided equally between the Series A Warrants and the Series B Warrants (i.e., with each being exercisable for an aggregate of 5,434,783 shares of common stock if all Closings had occurred), which represents fifty percent (50%) warrant coverage on the shares of common stock underlying the Series B Preferred Stock. The Warrants were issued, pro rata in relation to the total investment in the Series B Preferred Stock, at each Closing. Since the Third Closing did not occur, only 4,347,827 were issued of each the Series A Warrants and the Series B Warrants.

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

2. Liquidity and management's plans:

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

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

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018 AND 2017

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

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

3. Summary of Significant Accounting Policies:

Recent accounting pronouncements

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

In April 2016, the FASB issued ASU 2016-10, "*Revenue from Contracts with Customers* (Topic 606): Identifying Performance Obligations and Licensing." ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. These ASUs apply to all companies that enter into contracts with customers to transfer goods or services. This 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 March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification ("ASC") Topic 718, Compensation – Stock Compensation. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. The Company evaluated the impact of the revised guidance on its financial statements and determined it had no significant impact.

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

Estimates

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

Revenue Recognition

The Company currently has no ongoing source of revenues. Miscellaneous income, including interest, is recognized when earned by the Company. Deferred revenue represents cash received for royalties in advance of being earned. Such payments are reflected as deferred revenue until recognized under the Company's revenue recognition policy. Deferred revenue would be classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date. Deferred revenue will be recognized when the product is sold and the royalty is earned. Since all deferred revenue is related to the BCCNS product which is yet to be approved by FDA, the Company has determined that 100% of the advances of the royalty received by Mayne Pharma should be classified as non-current. At December 31, 2018, Deferred Revenue consisted of $0.5 million of royalties advanced by Mayne Pharma under the Third Amended SLA. There was no Deferred Revenue at December 31, 2017.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018 AND 2017

3. Summary of Significant Accounting Policies (continued):

Cash and Cash Equivalents

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

Research and Development Expenses

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

Stock-Based Compensation

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

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

Income taxes

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

HEDGEPATH PHARMACEUTICALS, INC.
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4. Income Taxes:

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

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

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

	December 31,	
Deferred tax assets (liabilities)	2018	2017
In-process research and development	$ 736,325	$ 736,325
Net operating loss carry forward	5,807,112	4,759,727
R&D credit	310,682	211,461
Share-based compensation	33,943	9,424
Other	2,607	5,825
	6,890,669	5,722,762
Less: valuation allowance	(6,890,669)	(5,722,762)
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, 2018 and 2017, the Company recorded a 100% valuation allowance against its deferred tax assets as it has determined such amounts will not be currently realizable.

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

5. Stockholders' Equity:

Employee Stock Plans

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

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

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018 AND 2017

5. Stockholders' Equity (continued):

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

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

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

Options outstanding at December 31, 2018 are as follows:

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

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018 AND 2017

5. Stockholders' Equity (continued):

Options exercisable at December 31, 2018 are as follows:

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

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

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

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

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

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

Preferred Stock Issuances

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

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018 AND 2017

5. Stockholders' Equity (continued):

Warrants

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

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

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

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

6. Related party transactions:

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

7. Legal Proceedings:

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

8. Subsequent Events:

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

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

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: March 7, 2019

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, Secretary, 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	March 7, 2019
/S/ STEFAN J. CROSS **Stefan J. Cross**	Director	March 7, 2019
/S/ DR. R. DANA ONO **Dr. R. Dana Ono**	Director	March 7, 2019
/S/ ROBERT MARTIN **Robert Martin**	Director	March 7, 2019
/S/ W. MARK WATSON, CPA **W. Mark Watson, CPA**	Director	March 7, 2019

Exhibit 10.5

*****CONFIDENTIAL TREATMENT REQUESTED*****

Note: Confidential treatment requested with respect to certain portions hereof denoted with "***"

Third Amended and
Restated Supply and
License Agreement

Mayne Pharma Ventures Pty Ltd (**Mayne Pharma**)
HedgePath Pharmaceuticals, Inc. (**HPPI**)

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Details

Date	**December 17, 2018**

Parties

Name	**Mayne Pharma Ventures Pty Ltd**, an Australian company ACN 168 896 357
Short form name	**Mayne Pharma**
Notice details	1538 Main North Road, Salisbury South, SA 5106 Australia Facsimile: +61 3 9614 7022 Attention: General Counsel
Name	**HedgePath Pharmaceuticals, Inc.**, a company incorporated in Delaware, successor in interest by merger to Commonwealth Biotechnologies, Inc, a Virginia corporation
Short form name	**HPPI**
Notice details	324 South Hyde Park Avenue #350, Tampa, FL 33606, United States Facsimile: +1 813-527-0500 Attention: Nicholas Jon Virca, President & CEO

Background

A Mayne Pharma International Pty Ltd, a company incorporated in Australia (ACN 007 870 984) (**MPI**) and HPPI entered into that certain Supply and License Agreement dated on or about September 3, 2013 (the "**Original Agreement**").

B MPI and HPPI entered into that certain Amendment No. 1 to the Original Agreement, dated on or about December 17, 2013 ("**Amendment No. 1**").

C MPI and HPPI entered into that certain Amendment No. 2 to the Original Agreement, dated on or about March 6, 2014 ("**Amendment No. 2**").

D MPI assigned, and Mayne Pharma assumed, the rights and obligations under the Original Agreement as amended by Amendment No. 1 and Amendment No. 2.

E Mayne Pharma had the right to terminate the Original Agreement (as amended), if HPPI did not obtain equity funding of at least Five Million Dollars (USD5 million) or lesser amount as agreed to by the parties, on or before May 30, 2014. In consideration of Mayne Pharma not exercising such termination right, HPPI agreed to issue to Mayne Pharma in a private placement certain stock under the Mayne Pharma Purchase Agreement (as defined) and to enter into related agreements with Mayne Pharma, Hedgepath, LLC (as defined) and others.

F Pursuant to clause 26.8 of the Original Agreement, Mayne Pharma and HPPI amended and replaced, in their entirety, their agreements as set forth in the Original Agreement, Amendment No. 1 and Amendment No. 2, with the agreements, terms, conditions, representations and warranties set forth in that certain Amended and Restated Supply and License Agreement, dated on or about June 24, 2014 ("**First Amended and Restated Supply and License Agreement**").

G MPI and HPPI entered into that certain Amendment No. 1 to the First Amended and Restated Supply Agreement, with effect from September 19, 2014 ("**Amendment No. 1 to the First Amended and Restated Supply and License Agreement**").

H Pursuant to clause 26.8 of the First Amended and Restated Supply and License Agreement, in connection with Mayne Pharma's investment of Two Million Five Hundred Thousand Dollars (USD2.5 million) in HPPI under the 2015 SPA (as defined), Mayne Pharma and HPPI desire to amended and replaced, in their entirety, their agreements as set forth in the First Amended and Restated Supply and License Agreement and Amendment No. 1 to the First Amended and Restated Supply and License Agreement, with the agreements, terms, conditions, representations and warranties set forth in that certain Second Amended and Restated Supply and License Agreement, dated on or about May 15, 2015 ("**Second Amended and Restated Supply and License Agreement**").

I The Second Amended and Restated Supply and License Agreement was amended by Amendment No. 1 on November 22, 2016 ("**Amendment No. 1 to the Second Amended and Restated Supply and License Agreement**").

J In exchange for Mayne Pharma agreeing to invest up to Five Million Dollars (USD5,000,000) in HPPI under a Securities Purchase Agreement dated January 8, 2018 (as amended, the "**2018 SPA**"), the Second Amended and Restated Supply and License Agreement was amended by Amendment No. 2 on January 10, 2018 ("**Amendment No. 2 to the Second Amended and Restated Supply and License Agreement**").

K Pursuant to that certain Agreement, dated as of even date herewith, by and among, HPPI, Mayne Pharma and MPI (**December 2018 Agreement**) and clause 26.8 of the Second Amended and Restated Supply and License Agreement, as amended, Mayne Pharma and HPPI desire to amend and replace, in their entirety, their agreements as set forth in the Second Amended and Restated Supply and License Agreement, Amendment No. 1 to the Second Amended and Restated Supply and License Agreement and Amendment No. 2 to the Second Amended and Restated Supply and License Agreement, with the agreements, terms, conditions, representations and warranties set forth herein.

1. Defined terms & interpretation

1.1 Defined terms

In this Agreement:

Accountant means a certified accountant who is independent and from a nationally recognised accounting firm.

Actual Launch Date means the date of the first commercial sale of the Product in any part of the Field, directly or indirectly, by HPPI.

Adverse Drug Event means any untoward medical occurrence in a patient or clinical investigation subject administered with the Product, including any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the Product, whether or not considered related to the Product.

Affected Obligations is defined in clause 21.1(a)(ii).

Affiliate means, with respect to a party, any person which, directly or indirectly, is Controlled by, Controls or is under common Control with that party. Notwithstanding this definition, but solely for purposes of this Agreement and not applicable laws, rules and regulations generally, if Mayne Pharma controls HPPI:

(a) Affiliates of HPPI will not include Mayne Pharma nor any person that would otherwise be an Affiliate of HPPI as a result of Mayne Pharma's Control of HPPI; and

(b) Affiliates of Mayne Pharma will not include HPPI nor any person that would otherwise be an Affiliate of Mayne Pharma as a result of Mayne Pharma's Control of HPPI.

Agreement means this Third Amended and Restated Supply and License Agreement.

Alternate Product means any product ***.

Angiogenesis and Hedgehog Patent Sublicense means that certain Amended and Restated Sublicense Agreement dated on or around the Effective Date, by and between Mayne Pharma International, and HPPI, as amended from time to time.

API means active pharmaceutical ingredient.

BCCNS means Basal Cell Carcinoma Nevus (Gorlin) Syndrome.

BCCNS Field means the treatment of human patients with BCCNS via oral administration.

Budget means a budget, in customary form, for HPPI to conduct its activities relating to the development of the Product in the Field (including the implementation of the Development Plan).

Business Day means:

(a) for receiving a notice under clause 22, a day that is not a Saturday, Sunday, public holiday or bank holiday in the place where the notice is received; and

(b) for performing an obligation or exercising a right by Mayne Pharma, a day that is not a Saturday, Sunday, bank holiday or public holiday in Melbourne, Australia;

(c) for performing an obligation or exercising a right by HPPI, a day that is not a Saturday, Sunday, bank holiday or public holiday in New York, New York, USA; and

(d) for all other purposes, a day that is not a Saturday, Sunday, bank holiday or public holiday in Melbourne, Australia.

Business Hours means the hours between 9am and 5pm on a Business Day.

Business Plan is the business plan provided by HPPI under clause 12.1 and updated from time to time in accordance with that clause.

Certificate of Analysis means a document which is signed and dated by an authorised representative of Mayne Pharma containing analysis results and certifying that the Product conforms with the Product Specification.

Commercial Year means a year starting at the start of the first Quarter after the Actual Launch Date.

Competing Product means ***.

Confidential Information is defined in clause 17.1.

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

CPI means the 'Price Indexes of Materials Used in Manufacturing Industries, Australia' issued by the Australian Bureau of Statistics using the index figure for chemicals.

Defective Product is defined in clause 9.2.

Delivery Date is defined in clause 6.2(c).

Developed Intellectual Property Rights is defined in clause 18.5.

Development Plan means the plan for the research, development and registration activities relating to the Product **(*******)** to be provided by HPPI to Mayne Pharma under clause 4.1, and as may be updated from time to time in accordance with this Agreement.

Disclosing Party is defined in clause 17.1.

Effective Date means December 17, 2018.

Equity Holders Agreement means the amended and restated equity holders agreement dated as of May 15, 2015, between Mayne Pharma, HPPI, Hedgepath, LLC, Frank E. O'Donnell, Jr., M.D. and Nicholas J. Virca, as amended by Amendment No. 1 to the Amended and Restated Equity Holders Agreement dated December 17, 2015, as amended from time to time.

Field means treatment of human patients with any of the following indications via oral administration:

(a) any prostate cancer, prostatic intraepithelial neoplasia (IEN) and benign prostatic hyperplasia,

(b) any lung cancer and atypical adenomatous hyperplasia, and

(c) familial adenomatous polyposis, colorectal polyps and Barett's esophagus.

The Field excludes the BCCNS Field and any indications not expressly listed above.

Force Majeure Event means, in relation to a party, anything outside the reasonable control of the party, including:

(a) any act or omission of a third person (except for an act or omission of any Affiliate or contractor, or in relation to HPPI, any Sub Licensee);

(b) fire, flood, earthquake, elements of nature or act of God; or

(c) riot, civil disorder, rebellion or revolution.

Forecast is defined in clause 6.1(a).

Forecast Period is set out in Schedule 5.

Good Distribution Practice means the guidelines for the proper distribution of medicinal products for human use in the Territory, including in accordance with 21 CFR 210/211 and USP 1079, as each may be amended from time to time.

Good Manufacturing Practice means the guidelines for the proper manufacture of medicinal products for human use in the Territory, including in accordance with in accordance with 21 CFR 210/211, as may be amended from time to time.

Hedgepath, LLC means Hedgepath, LLC, a limited liability company organised in the State of Florida.

HP LLC Patents means each of US patent 9,192,609 (Treatment and prognostic monitoring of proliferation disorders), US patent 9,968,600 and US patent application 15/966,613 (Treatment and prognostic monitoring of non-cancerous proliferation disorders using Hedgehog pathway inhibitors), and US patent 9,962,381 and US patent application 15/966,844 (Treatment and prognostic monitoring of cancerous proliferation disorders using hedgehog pathway inhibitors) in the name of HPPI but claiming priority from patent applications filed by Hedgepath LLC and any other resulting issued patents whether or not in the Territory, and all continuations-in-part, continuations or divisions of any such patent or patents, or substitutes of it, and any reissues, re-examinations, extensions, or renewals of it, whether or not in the Territory.

HPPI Licensed Rights is defined in item 1 of Schedule 7.

HPPI Patents means each of US patent application *** in the name of HPPI and any resulting issued patents whether or not in the Territory, and all continuations-in-part, continuations or divisions of any such patent or patents, or substitutes of it, and any reissues, re-examinations, extensions, or renewals of it, whether or not in the Territory.

IND means investigational new drug.

Initial Term is set out in Schedule 1.

Intellectual Property Rights or **IPR** means all intellectual property rights subsisting anywhere in the world, including:

(a) inventions, know how, patents, copyrights, designs, trade and service marks, logos, rights to data and any right to have information kept confidential; and

(b) any application or right to apply for registration of any of the rights referred to in paragraph (a),

whether or not such rights are registered or capable of being registered.

JDC is defined in clause 4.2.

Licensed IPR means Intellectual Property Rights included within the HPPI Licensed Rights or MP Licensed Rights.

Marketing Authorisation means a registration, approval or licence from a Relevant Regulatory Authority in the Territory for the importation, storage, promotion, sale or distribution of the Product in the Field.

Mayne Pharma International means Mayne Pharma International Pty Ltd, an Australian company ACN 007 870 984.

Mayne Pharma Purchase Agreement is defined in the Equity Holders Agreement.

Minimum Annual Volume for the Product is as agreed by the parties in accordance with item 1.2 of Schedule 5.

Minimum Order Quantity means the batch size for the Product as set out in Schedule 5**.**

MP Licensed Rights means all Intellectual Property Rights in the Product relevant to the Product in the Field owned by Mayne Pharma or its Affiliates:

(a) comprising, in respect of patent rights, ***, all in the name of Mayne Pharma, together with and any resulting issued patents in the Territory, and all continuations-in-part, continuations or divisions of any such patent or patents, or substitutes of it, and any reissues, re-examinations, extensions, or renewals of the same, in the Territory;

(b) comprising raw or audited pre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to the Product anywhere in the world, or licensed by Mayne Pharma with the right to sublicense to HPPI;

(c) comprising any Intellectual Property Rights in the Field relating to the Product that are jointly developed by HPPI and Mayne Pharma and their respective Affiliates and Personnel after the Effective Date; and

(d) excluding rights in respect of trade and service marks and logos.

MP Marketing Authorisation means a registration, approval or licence from a Relevant Regulatory Authority for the importation, storage, promotion, sale or distribution of any MP Product:

(a) outside the Territory in any field, or

(b) in the Territory outside the Field.

MP Product means the Product or another SUBA-Itraconazole product.

NDA means a New Drug Application filed or to be filed with the FDA.

New Securities means (i) common stock of HPPI, (ii) preferred stock of HPPI that is subordinate in liquidation preference to the preferred stock of HPPI held by Mayne Pharma and that has no voting or approval rights senior to the preferred stock of HPPI held by Mayne Pharma and (iii) warrants to purchase common stock of HPPI; provided, however, that New Securities does not include any common stock of HPPI that is issuable upon exercise of warrants that are outstanding as of the Effective Date.

Off Label Sales is defined in clause 7.3(a).

Original Field means treatment of human patients with cancer via oral administration.

Order is defined in clause 6.2(a).

Personnel, of a party, means its employees, officers, directors, agents, consultants and contractors (to avoid doubt, such contractors not including the other party).

Precluded Extent is defined in clause 21.1.

Precluded Party is defined in clause 21.1.

Price is set out in Schedule 5.

Product means the product set out in Schedule 4, and any other product agreed by the parties in writing for the purposes of this Agreement from time to time (at which time the parties must also agree in writing related amendments to Schedule 4 and Schedule 5). The parties acknowledge and agree that the term "Product" may include products covering different medical indications developed under the Development Plan, provided the same are included within the scope of the Field, and ***.

Product Specification means the specification with respect to the manufacture, packaging, quality and characteristics (including the raw materials and product specification) and testing of the Product, as set out in Schedule 4.

Proposed Publication means any proposed scientific public disclosure (including a manuscript or abstract intended for publication, a paper or abstract intended to be orally presented, any poster presentation, or oral disclosure) that includes, describes or refers to the use of the Product for the treatment of human patients with cancer via oral administration.

Quality Agreement means the technical agreement between the parties detailing the specification and technical terms for the manufacture of the Product as set out in the Marketing Authorisation.

Quarter means a 3 month period starting 1 January, 1 April, 1 July or 1 October.

reasonable commercial efforts means ***.

Recipient is defined in clause 17.2.

Relevant Regulatory Authority, in relation to a country or region, means any governmental authority (whether federal, state or local) regulating the manufacture, importation, storage, promotion, sale, distribution or use of therapeutic substances, and in the case of Australia and the USA includes the Therapeutic Goods Administration (**TGA**) and the Food and Drug Administration (**FDA**) respectively, or any successor body.

Safety Data Exchange Agreement (SDEA) means the agreement between the parties setting out the rules and procedures for exchanging information concerning certain safety and pharmacovigilance issues.

Sales Forecast is set out in item 1.2 of Schedule 5.

Start Date is set out in Schedule 1.

Sub Licensee is defined in clause 3.4.

Tax means any tax (including any GST or VAT), withholding tax, duties, levies, charges, fees and other imposts of any kind (including any fine, interest, penalty and expenses in connection with those items) levied, assessed, charged or collected in connection with this Agreement or the performance of services under this Agreement, but does not include any income or capital gains tax.

Term means the Initial Term and any extensions under clause 2.2.

Territory is set out in Schedule 1.

Trade Mark means US trade mark (number 77793077) "SUBA" for goods and services in class 5 (pharmaceutical and veterinary preparations having enhanced bioavailability excluding pharmaceutical products for the treatment of opioid addiction) and any other trademarks (whether registered or unregistered) notified in writing by Mayne Pharma to HPPI for the purposes of this Agreement from time to time.

2015 SPA is defined in the Equity Holders Agreement.

1.2 Interpretation

In this Agreement, except where the context otherwise requires:

(a) the singular includes the plural and vice versa, and a gender includes other genders;

(b) another grammatical form of a defined word or expression has a corresponding meaning;

(c) a reference to a clause, paragraph, schedule or annexure is to a clause or paragraph of, or schedule or annexure to, this Agreement, and a reference to this Agreement includes any schedule or annexure;

(d) a reference to a document or instrument includes the document or instrument as novated, altered, supplemented or replaced from time to time;

(e) a reference to AUD is to Australian dollars, to USD is to United States dollars, to GBP is to British pounds and to EUR is to euros;

(f) a reference to time is to Melbourne, Australia time;

(g) a reference to a party is to a party to this Agreement, and includes the party's executors, administrators, successors and permitted assigns and substitutes;

(h) a reference to a person includes a natural person, partnership, corporation, limited liability company, trust, association, governmental or local authority or agency or other entity;

(i) a reference to a statute, ordinance, code or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them;

(j) the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions;

(k) a rule of construction does not apply to the disadvantage of a party because the party was responsible for the preparation of this Agreement or any part of it;

(l) if a day on or by which an obligation must be performed or an event must occur is not a Business Day, the obligation must be performed or the event must occur on or by the next Business Day;

(m) headings are for ease of reference only and do not affect interpretation; and

(n) clauses 1 and 26 prevail over a Schedule to the extent of any inconsistency.

1.3 Amendment and Restatement

Mayne Pharma and HPPI hereby agree by their mutual execution hereof that this Agreement amends, restates and supersedes, in their entirety, effective as of the Effective Date, each and all their agreements as set forth in the Second Amended and Restated Supply and License Agreement, Amendment No. 1 to the Second Amended and Restated Supply and License Agreement and Amendment No. 2 to the Second Amended and Restated Supply and License Agreement.

2. Term

2.1 Initial Term

This Agreement starts effective as of the Start Date and continues for the Initial Term unless terminated in accordance with its terms and conditions.

2.2 Extension

This Agreement automatically continues after the Initial Term for additional periods of ***, unless a party gives notice of its wish not to extend this Agreement *** before the end of the Initial Term or any extended term under this clause 2.2 or this Agreement is terminated in accordance with its terms and conditions.

LICENCE

3. Licence

3.1 Licence to exploit the Product in the Territory

Mayne Pharma grants to HPPI an exclusive licence to exploit the Product in the Field in the Territory, including:

(a) to conduct the activities in the Territory in the Field under the Development Plan; and

(b) to import, promote, market, sell and distribute the Product in the Territory in the Field,

which licence:

(c) comprises the right to copy and exploit the MP Licensed Rights and to use the Trade Mark, to the extent reasonably necessary or desirable to exploit the Product in the Field in the Territory;

(d) may only be assigned or sub licensed in accordance with this Agreement or otherwise with the prior written consent of Mayne Pharma; and

(e) excludes the right to manufacture, except by a Backup Manufacturer in accordance with Schedule 6.

3.2 HPPI obligations

HPPI must:

(a) obtain from Mayne Pharma all its requirements for the Product, including for clinical trials, importation, promotion, marketing, sale or distribution in the Territory;

(b) not directly itself, or indirectly through any third party:

(i) research, develop, manufacture, import, promote, market, sell, distribute or otherwise have any commercial interest or involvement in any Competing Product in the Territory during the Term and for *** after the end of the Term; or

(ii) sell or distribute the Product to any other party which it knows, or has reasonable grounds for suspecting, will sell or distribute the Product outside the Territory or outside the Field;

(iii) import, promote, market, sell or distribute the Product outside the Territory or outside the Field; and

(c) refer to Mayne Pharma all enquiries, sales leads, prospects and other information HPPI may receive concerning sales and prospective sales of the Product outside the Territory or the Field.

3.3 Supporting the exclusive licence

Mayne Pharma must not, directly itself or indirectly through any third party, import, promote, market, distribute or sell the Product or any Competing Product in the Territory in the Field during the Term, other than as a result of any off label use of an Alternate Product which the parties acknowledge is outside the reasonable control of Mayne Pharma (but subject to the provisions of clause 7.3 hereof).

3.4 Sub licensing the MP Licensed Rights

HPPI may only grant a sub licence of the MP Licensed Rights and the Trade Mark to a third party (including any Affiliate or approved contractor) (**Sub Licensee**) with the prior written consent of Mayne Pharma under a written agreement that:

(a) includes obligations on that third party that relate to use and disclosure of Intellectual Property Rights and Confidential Information at least equivalent to those imposed on the HPPI under this Agreement, without any right of further disclosure or sub license;

(b) ends at the same time as this Agreement ends (whether by expiry or termination); and

(c) includes an assignment to HPPI of all Intellectual Property Rights that relate to the Product,

and HPPI remains responsible for ensuring its Sub Licensees comply with such written agreement.

3.5 BCCNS Field

Notwithstanding anything to the contrary in this Agreement, effective upon Mayne Pharma making the advance of Five Hundred Thousand United States dollars (USD 500,000) contemplated by item 2(b)(i) of Schedule 2, each of Mayne Pharma and HPPI agrees to comply with Schedule 2.

3.6 Copies of documents, data and other information embodying the MP Licensed Rights

Promptly in response to a request by HPPI at any time during the Term, Mayne Pharma must provide to HPPI a copy of any documents, data and other information embodying the MP Licensed Rights since the most recent request by HPPI under this clause 3.6. Without limiting the generality of the foregoing, Mayne Pharma agrees to provide HPPI, at Mayne Pharma's expense, access to any Drug Master File (should one exist from time to time), all pre-clinical or clinical data included as part of the MP Licensed Rights, and all chemistry, manufacturing and control sections of the Product dossier to support pre-IND, IND and NDA activities, in each case as relevant to the Product in the Field and set out in the Development Plan.

4. Development

4.1 Development Plan and Budget

(a) On ***, HPPI will provide to Mayne Pharma a Development Plan and Budget, that reasonably demonstrates HPPI's compliance with its obligations under clauses 5.1(a) and 12.3.

(b) HPPI will conduct the activities set out in, and in accordance with, the Development Plan and further in accordance with the Budget.

(c) ***, the JDC will review the Development Plan and Budget and acting in good faith, may provide recommendations to HPPI for amendment.

4.2 JDC

(a) From and after the Effective Date, the parties will continue to utilize a joint development committee (**JDC**):

(i) to make recommendations to HPPI on research, development and registration activities relating to the exploitation of the Product in the Field in the Territory, including medico regulatory strategy;

(ii) to review progress against the current Development Plan and Budget and recommend amendments to HPPI;

(iii) to review HPPI clinical trial protocols relating to the Product in the Field before they are finalised (which protocols HPPI must provide to the JDC);

(iv) to review the progress of any clinical trial relating to the Product; and

(v) to share and discuss clinical data and developments related to the Licensed IPR, including without limitation in furtherance of clause 3.6 and item 2 of Schedule 7,

which JDC will continue until the Actual Launch Date. The parties acknowledge and agree that the JDC is solely advisory in nature, shall have no power or authority to legally bind HPPI or Mayne Pharma, and at all times shall remain subject to the authority of the board of directors of HPPI.

(b) Each of the parties will appoint two representatives to the JDC. In addition, from time to time the parties may, by agreement in writing, invite additional representatives from either party, or industry experts or consultants, to participate in certain meetings on specific issues as needed, at HPPI's cost and expense. A representative of and designated by HPPI will be the chairperson of the JDC.

(c) Each of the parties may change its representatives at any time during the term of this Agreement by notice to the other party, except that Nicholas J. Virca will be a representative of HPPI from the Start Date unless or until it is no longer possible for reasons outside HPPI's reasonable control.

(d) Each member of the JDC (including the chairperson) shall be entitled to one (1) vote on all matters which must be presented under this Agreement (or which are otherwise presented) to the JDC for approval, with the chairperson to have a casting vote that resolves any deadlock. The JDC shall fully abide by such vote or action in the conduct of its affairs, subject always to clause 4.2(a) and the continuing authority of the board of directors of HPPI.

(e) The JDC may hold meetings in person, by teleconference or by video conference:

(i) on a regular basis until the Actual Launch Date, but not less than one per Quarter;

(ii) as otherwise reasonably requested by the parties.

The JDC may also take action by written consent of the JDC members, and a majority of the JDC members may act by written consent on any matter which must be presented under this Agreement (or which are otherwise presented) to the JDC for approval.

(f) The site, date and proposed agenda of any meeting of the JDC must be determined by agreement of the members of the JDC.

4.3 Development decisions

If any proposed activity of HPPI relating to the Product at the IND enabling or clinical stages would be outside the scope of cGLP, cGCP or customary practices for drug development or is reasonably likely to have a material adverse impact outside the Field, then Mayne Pharma has the right to veto such proposed activity by notice to HPPI, in which case HPPI agrees not to engage in such activity. In all other cases, HPPI has the right to make decisions regarding research, development and registration activities relating to the exploitation of the Product in the Field in the Territory, provided that, for any material decisions, it first consults with the JDC.

4.4 Previous Mayne Pharma support

(a) From May 15, 2015 until December 31, 2015, HPPI acknowledges that Mayne Pharma provided to HPPI the following services in connection with the exploitation of the Product in the Territory in the Field and the conduct of the Development Plan, comprising:

(i) coordinating the JDC meetings;

(ii) directing the conduct of the entire clinical program for the Product, subject to the oversight and approval by the JDC and, as applicable hereunder or for other matters binding on HPPI, the HPPI board of directors;

(iii) medico regulatory strategy, including directing a third party to prepare the regulatory documents to progress and file any Marketing Authorisation, including any application for, maintenance of or variation of, any Marketing Authorisation, for the Product;

(iv) intellectual property strategy; and

(v) other administrative services as agreed with HPPI,

but excluding, without limitation, the provision of legal, tax, accounting or other professional advice.

5. Marketing Authorisation

5.1 Obtaining and maintaining Marketing Authorisations in the Field

HPPI must:

(a) actively seek, in coordination with the JDC and Mayne Pharma and at its own cost and expense, and use reasonable commercial efforts to obtain all Marketing Authorisations in its own name;

(b) pay fees or charges in respect of the application for all Marketing Authorisations, maintenance of all Marketing Authorisations and the making of any variation to all Marketing Authorisations; and

(c) comply with the requirements of any Relevant Regulatory Authority within the Territory, including in connection with any Marketing Authorisation and all reporting obligations.

5.2 Obtaining and maintaining Marketing Authorisations in the BCCNS Field

Mayne Pharma must:

(a) actively seek, at its own cost and expense, and use reasonable commercial efforts to obtain an MP Marketing Authorisation in the Territory for an MP Product in the BCCNS Field in its own name;

(b) pay fees or charges in respect of the application for any MP Marketing Authorisations, maintenance of all MP Marketing Authorisations and the making of any variation to all MP Marketing Authorisations; and

(c) comply with the requirements of any Relevant Regulatory Authority within the Territory, including in connection with any MP Marketing Authorisation and all reporting obligations.

5.3 Assistance by Mayne Pharma

Mayne Pharma will, at HPPI's cost and expense:

(a) assist HPPI in connection with any Marketing Authorisation, including any application for, maintenance of or variation of, any Marketing Authorisation; and

(b) in response to a request by HPPI, provide any documents required by HPPI in connection with any Marketing Authorisation.

5.4 Assistance by HPPI

HPPI will, at Mayne Pharma's cost and expense:

(a) assist Mayne Pharma in connection with any MP Marketing Authorisation, including any application for, maintenance of or variation of, any MP Marketing Authorisation; and

(b) in response to a request by Mayne Pharma, provide any documents required by Mayne in connection with any MP Marketing Authorisation.

5.5 Failure to obtain an approved NDA in the Field

If the FDA has not approved an NDA filed by HPPI for the Product in part of the Field within eight (8) years from the Effective Date, then Mayne Pharma may, with immediate effect by notice to HPPI, elect:

(a) to convert the licence in clause 3.1 to a non-exclusive licence; and

(b) to take a non-exclusive, perpetual, irrevocable royalty free licence to copy and exploit the HPPI Licensed Rights inside the Territory in the Field,

in which case (i) HPPI's obligations under clauses 5.1(a) and 12.1 will terminate and be of no further force and effect and (ii) the parties will cooperate with each other to execute and deliver such further amendments to this Agreement, instruments or documents and to take any such further action as is appropriate to carry out the intent of this clause 5.5.

OBLIGATIONS RELATING TO SUPPLY OF PRODUCT

6. Manufacture and supply of Product

6.1 Forecasts

(a) Starting *** before the anticipated Actual Launch Date, ***, HPPI must provide Mayne Pharma with a forecast of its monthly requirements for the Product for the following Forecast Period (**Forecast**).

(b) The first Forecast will include ***. For each subsequent Forecast:

(i) ***; and

(ii) ***.

6.2 Orders

(a) HPPI must provide Mayne Pharma with a purchase order setting out the quantities of the Product, desired delivery date and delivery instructions (**Order**), at least ***.

(b) Each Order must be for at least the Minimum Order Quantity, and any amount above the Minimum Order Quantity for whole multiples of any incremental order quantity specified in item 1 of Schedule 5, unless the parties agree otherwise in writing before an Order is placed.

(c) Within *** of receipt by Mayne Pharma of an Order, Mayne Pharma must confirm its acceptance in writing and notify HPPI of the expected date of delivery (**Delivery Date**) of the Product. Without limitation, Mayne Pharma may refuse to confirm any quantity of Orders in a Quarter to the extent they exceed ***% of the most recent Forecast provided by HPPI for that Quarter.

(d) Mayne Pharma agrees to use reasonable commercial efforts:

(i) to provide a Delivery Date *** after the delivery date specified in the Order; and

(ii) to supply the Order by the Delivery Date.

(e) No Order amends this Agreement unless HPPI expressly states in the Order that it seeks to amend this Agreement, and Mayne Pharma agrees in writing to the Order.

6.3 Manufacture; Failure to Supply

(a) Mayne Pharma will manufacture the Product in accordance with all confirmed Orders received from HPPI.

(b) In the situation where Mayne Pharma is not able to supply Product, or Mayne Pharma anticipates that it will be unable to supply Product to HPPI in satisfaction of HPPI's Orders or forecasted Orders, Mayne Pharma shall use reasonable commercial efforts:

(i) to inform HPPI in a timely manner about such situation and the details causing such situation; and

(ii) to provide HPPI with a reasonable estimate of the length and extent of production interruption or other issue affecting Mayne Pharma's satisfaction of HPPI's Product demand.

6.4 Backup manufacturer

HPPI is entitled to qualify an alternate manufacturer of the Product in accordance with Schedule 6.

7. Payments

7.1 HPPI Payments

In consideration for Mayne Pharma manufacturing and delivering the Products in accordance with this Agreement, HPPI must make the payments set out in, and comply with, Schedule 5.

7.2 Review of Prices

(a) Mayne Pharma has the right to review and vary any Floor Price set out in Schedule 5 by giving *** notice to HPPI, to reflect any changes in:

(i) ***;

(ii) ***;

(iii) ***.

(b) Mayne Pharma will consult with HPPI during the *** period of notice of a variation under clause 7.2.

7.3 Mayne Pharma Payments

(a) The parties acknowledge that notwithstanding clause 3.3, there is a risk that Mayne Pharma may, directly itself or indirectly through any third party, sell an Alternate Product in the Territory in the Field as a result of off label use (**Off Label Sales**).

(b) If HPPI becomes aware of any Off Label Sales in any ***, it must notify Mayne Pharma promptly, and in any event, no later than ***, and provide Mayne Pharma with its evidence of such Off Label Sales.

(c) Prior to a Marketing Authorisation being obtained by HPPI, any Affiliate or Sub Licensee, within *** after receipt of a notice from HPPI under clause 7.3(b), Mayne Pharma must pay to HPPI a cash royalty of *** on gross sales up to *** and *** on gross sales over *** for the relevant Quarter for the Alternate Product sold through Off Label Sales ***.

(d) After a Marketing Authorisation is obtained by HPPI, any Affiliate or Sub Licensee, if Off Label Sales of any Alternate Product exceed ***, then the parties agree to enter into a good faith negotiation to enter into an arrangement under which they will share profits from Off Label Sales of any Alternate Product ***.

7.4 Payment terms

Each party must make payments due under this Agreement:

(a) in the currency specified in Schedule 5 and where necessary, converted:

(i) in respect of any payment covering a Quarter, at the average daily exchange rate for the applicable Quarter as published by the financial institution specified in Schedule 5; and

(ii) otherwise, at the daily exchange rate quoted by the financial institution specified in Schedule 5 on the date of payment;

(b) to the bank account of the other party listed on the relevant invoice, with the party making payment to bear the costs of any such remittance; and

(c) in the case of payments due to Mayne Pharma, to Mayne Pharma or its nominee as specified on the relevant invoice.

7.5 Reimbursement

Where a party agrees to reimburse to the other party any costs or expenses, then it will reimburse these amounts within *** from receipt of the other party's invoice for, and reasonable evidence of, such costs or expenses.

8. Delivery, risk and title

8.1 Delivery

Mayne Pharma must deliver the Product to HPPI in accordance with the delivery terms set out in item 3 of Schedule 5. Any Product that HPPI is paying for must have the minimum shelf life specified in item 4 of Schedule 5.

8.2 Risk

All risk of loss or of damage to the Product will pass to HPPI upon delivery of the Product in accordance with the delivery terms set out in item 3 of Schedule 5.

8.3 Title

Title to the Product will pass to HPPI upon payment in full of the Price payable for that Product or if no amount is payable, then on delivery.

9. Acceptance of Product

9.1 Certificate of Analysis

Each delivery of the Product will be accompanied by a Certificate of Analysis from Mayne Pharma in respect of the Product so delivered.

9.2 Defective Product

(a) HPPI must notify Mayne Pharma within *** of delivery of the Product if HPPI reasonably believes any of the Product does not conform to the Product Specification (**Defective Product**).

(b) If HPPI gives notice under clause 9.2(a), the parties agree to consult with each other to resolve the issue (during which time Mayne Pharma may conduct its own retention sample testing). If the discrepancy is not resolved within a further *** from the receipt of the notice, the parties agree to appoint (at HPPI's expense) an independent analyst, acceptable to both parties, that will carry out tests on representative samples taken from such shipment, and the results of such tests will be binding on the parties.

(c) If HPPI does not notify Mayne Pharma in accordance with clause 9.2(a), then HPPI will be deemed to have accepted the Product at the end of the *** period after delivery of the Product.

(d) If the independent analyst determines that the Defective Product does not conform to the Product Specification and as long as the Product has been transported, handled and stored in accordance with the Marketing Authorisation and all reasonable directions of Mayne Pharma once the Product has left Mayne Pharma's facility, then:

(i) Mayne Pharma must, at its expense, replace any such Defective Product and reimburse HPPI for the costs of the independent analyst; and

(ii) all quantities of Defective Product must, at Mayne Pharma's election and expense be either:

(A) returned to Mayne Pharma at an address notified by Mayne Pharma, and packed and shipped according to instructions provided by Mayne Pharma; or

(B) destroyed by HPPI under Mayne Pharma's direction.

(e) If:

(i) the independent analyst determines that the Defective Product does conform to the Product Specification; or

(ii) the Product has not been transported, handled and stored in accordance with the Marketing Authorisation and all reasonable directions of Mayne Pharma once the Product has been delivered to HPPI in accordance with this Agreement,

then HPPI is deemed to have accepted the Product and will reimburse Mayne Pharma for any costs and expenses incurred by Mayne Pharma in attempting to resolve the issue, including the costs of any retention sample testing conducted by Mayne Pharma.

9.3 Sole remedy

Despite any other provision in this Agreement, HPPI's sole remedy in respect of Product which fails to conform to the Product Specification is, and Mayne Pharma's liability to HPPI under this Agreement will be, limited as set out in clauses 9.2 and 16.3.

10. Complaints

10.1 Handling customer complaints

HPPI must handle all customer complaints relating to any Product supplied, directly or indirectly, by HPPI in the Territory and any related activities associated with reporting or management of customer complaints.

10.2 Notification of complaints

If HPPI becomes aware of any material complaint in connection with the Product supplied, directly or indirectly, by HPPI, it must promptly notify Mayne Pharma of the complaint and provide details.

10.3 Adverse Drug Events

HPPI must advise Mayne Pharma as soon as reasonably practicable after becoming aware of any Adverse Drug Event from any Product supplied, directly or indirectly, by HPPI.

10.4 Supplementary agreements

(a) For Product supplied for clinical trial use, the parties will enter into an agreement outlining the party's responsibilities with respect to the use of the Product for that purpose.

(b) The parties must execute a Safety Data Exchange Agreement and Quality Agreement at least *** before the Actual Launch Date.

(c) This Agreement prevails to the extent of any inconsistency between it and the Safety Data Exchange Agreement or the Quality Agreement. To avoid doubt, clause 10.1 to 10.3 do not limit any obligations under the Safety Data Exchange Agreement and Quality Agreement.

11. Recalls

11.1 Notice of recall

If a party determines any quantity of the Product supplied, directly or indirectly, by HPPI in the Territory should be recalled for any reason, or a party is notified of a recall, that party must give the other party notice within the time frames set out in the Safety Data Exchange Agreement of its request to recall that quantity and specify its reasons. If a party determines that to avoid an immediate perceived threat to health, time does not permit the provision of notice, such notice may be made by telephone or e-mail transmission to the other party's medical affairs liaison and quality contact person to be confirmed in writing after such notice.

11.2 Directing that the Product be recalled

If, within *** of the receipt of notice under clause 11.1, the parties are unable to agree on the need to undertake a recall (including after HPPI discusses the issue with the Relevant Regulatory Authority), then either party may direct that the Product be recalled, with or without the agreement of the other party, if it reasonably determines that such recall is necessary to protect the public health or is necessary to ensure compliance with applicable laws, rules and regulations.

11.3 Administering a recall

HPPI must administer any recall of the Product supplied, directly or indirectly, by HPPI in the Territory.

11.4 Cost of the recall

If the cause of the recall is because the Product does not conform to the Product Specification, and it is as a result of a breach of warranty or negligence by Mayne Pharma, then Mayne Pharma must, at its expense, reimburse to HPPI for all its reasonable costs and expenses of any recall and the costs of any independent analyst engaged under clause 11.5. Otherwise, all costs and expenses in respect of the recall and the independent analyst are payable by HPPI.

11.5 Submission to independent analysis

If the parties cannot agree on whether the Product conformed to the Product Specification, then the parties agree to submit a sample of the Product to an independent analyst, acceptable to both parties, for a report. Absent manifest error, the finding of the independent analyst is binding on the parties

PERFORMANCE OBLIGATIONS

12. Performance obligations

12.1 Business Plan

(a) At least *** before the anticipated Actual Launch Date, HPPI must provide a business plan to Mayne Pharma in connection with the distribution of Product in the Territory in the Field outlining the sales and marketing of the Product in the Territory from the Actual Launch Date until the end of *** later, which plan must include market situational analysis, market segmentation, targeting and position, marketing strategies and selling strategies.

(b) After the Actual Launch Date, the parties must meet *** to review HPPI's Business Plan outlining the sales and marketing of the Product in the Territory in the Field for the following ***. In developing the Business Plan, HPPI will use *** or similar locally sourced data, provided such data are available. The parties will discuss such Business Plan in good faith and HPPI may amend such Business Plan following the discussions.

(c) If HPPI fails to update the Business Plan in accordance with clause 12.1(b), the then current Business Plan will continue until updated in accordance with that clause.

(d) HPPI will use reasonable commercial efforts to achieve the objectives in the Business Plan.

12.2 Promotional Material

(a) HPPI is responsible for all sales, distribution, public relations, medical education and similar expenses related to HPPI's promotion and marketing of the Product in the Territory in the Field.

(b) Mayne Pharma will, at its own expense, provide to HPPI information relating to the Product and promotional information available to Mayne Pharma which HPPI reasonably requires for the promotion and marketing of the Product in the Territory in the Field but only to the extent that Mayne Pharma has the right to provide such information.

(c) HPPI will provide to Mayne Pharma at Mayne Pharma's expense information relevant to Mayne Pharma's business outside the Territory and in the Territory, outside the Field.

(d) HPPI must make available to Mayne Pharma samples of all materials (including all advertisements, promotions and other marketing material) used by it in respect of the Product, and grants to Mayne Pharma a non-exclusive, perpetual, irrevocable, royalty free licence to use those materials in connection with the importation, promotion, marketing, sale or distribution of the Product outside the Territory and in the Territory, outside the Field, which licence is capable of sub license to any Affiliate or licensee of Mayne Pharma.

12.3 Efforts to maximise sales

After HPPI obtains any Marketing Authorisation for any Product in the Territory in the Field, HPPI must use reasonable commercial efforts to maximise the sale of the Product in the Field in the Territory (including, without limitation, through maintaining all warehousing, sales, personnel and facilities required to perform its obligations under this Agreement with respect to Products in the Field in the Territory).

12.4 Minimum Annual Volumes

(a) HPPI will purchase in each Commercial Year at least the Minimum Annual Volumes as agreed to by the parties in accordance with Schedule 5 hereof.

(b) If, in any Commercial Year, HPPI purchases less than the Minimum Annual Volumes, HPPI may elect to pay to Mayne Pharma the difference between the aggregate Prices paid for the volume of Product actually purchased for that Commercial Year and the value of the Minimum Annual Volumes for that Commercial Year, within *** of the end of that Commercial Year.

(c) If, in any Commercial Year, HPPI purchases less than the Minimum Annual Volumes and has not elected to pay to Mayne Pharma the amount under clause 12.4(b) within *** of the end of the Commercial Year, then Mayne Pharma may, with immediate effect by notice to HPPI, terminate this Agreement.

13. Compliance with laws and regulations

13.1 HPPI's obligations

HPPI must:

(a) promptly obtain and maintain as and when required all necessary registrations, permits, approvals and licences in respect of HPPI's activities under this Agreement;

(b) advise Mayne Pharma of any matters necessary or relevant to be known by Mayne Pharma to ensure that it manufactures the Product in compliance with all applicable laws, rules and regulations;

(c) conduct the activities under the Development Plan, and import, promote, market, sell and distribute the Product in accordance with all laws, rules and regulations, Good Distribution Practice and any Marketing Authorisation; and

(d) transport, handle and store the Product in accordance with any Marketing Authorisation and all reasonable directions specified by Mayne Pharma not inconsistent with any Marketing Authorisation.

13.2 Mayne Pharma's obligations

Mayne Pharma must:

(a) obtain and maintain, as and when required, all necessary registrations, permits, approvals and licences in respect of Mayne Pharma's activities under this Agreement, including in respect of the manufacture of the Product in Australia;

(b) manufacture the Product in accordance with all laws in Australia (or such other jurisdiction in which the Product is manufactured) and the Marketing Authorisation;

(c) manufacture the Product in accordance with Good Manufacturing Practices;

(d) ensure that Mayne Pharma's premises comply with standards stipulated by relevant State or Commonwealth authorities of Australia; and

(e) transport, handle and store the Product in accordance with all laws and Marketing Authorisations.

13.3 Anti-corruption

(a) Without limitation, each party represents that it is now in compliance with, and will at all times remain in compliance with, all applicable laws and regulations relating to anti-corruption in Australia and in the Territory (including the US Foreign Corrupt Practice Act), as well as the UK Bribery Act 2010 and related regulations, and any other applicable anti-corruption laws prohibiting bribery or other forms of corruption, including money laundering, within the public and private sectors.

(b) Except as disclosed in writing, each party warrants that:

(i) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and

(ii) it will maintain arms-length relations with all third parties (including government officials) with which it deals for, or on behalf of, the other party.

14. Inspection

Each party must procure that the other party or its authorised representative may, at the other party's expense and on reasonable notice, visit and inspect the facilities of the first party, its Affiliates, sub licensees or its contractors used in respect of the Product (not more than once per year), to ensure compliance with this Agreement.

LIABILITY

15. Representations and warranties

15.1 Legal capacity and relationships

Each party represents and warrants that:

(a) it is a corporation organised and validly existing under the laws of its jurisdiction of incorporation and has the legal capacity and authority to enter this Agreement and perform its obligations under this Agreement; and

(b) this Agreement is a valid and binding obligation of that party enforceable in accordance with its terms, and it will not become a party to any agreement in conflict with this Agreement.

15.2 Mayne Pharma warranties

(a) Mayne Pharma represents and warrants that the Product supplied to HPPI under this Agreement:

(i) will conform in all material respects to the Product Specification; and

(ii) will be manufactured in conformity with Good Manufacturing Practice, in accordance with all Marketing Authorisations and in accordance with all laws in Australia.

(b) Mayne Pharma represents and warrants that it is the lawful and exclusive owner of the entire right, title and interest in and to all MP Licensed Rights (except to the extent such rights are licensed to Mayne Pharma with the right to grant sub licenses).

(c) To the extent permitted by law, Mayne Pharma makes no other representations or warranties, express or implied, with respect to the Product or this Agreement. In particular:

(i) Mayne Pharma does not warrant that the importation or sale of the Product in the Territory will not infringe the Intellectual Property Rights of any third party; and

(ii) except as expressly provided for in clause 4.4, Mayne Pharma provides no warranties in respect of the provision of the services referred to in clause 4.4.

15.3 HPPI warranties

HPPI represents and warrants that:

(a) as at the Start Date:

(i) HPPI is successor by merger to Commonwealth Biotechnologies, Inc, a Virginia corporation;

(ii) the Amended Plan of Reorganization of CBI (the **Plan**), dated January 4, 2013, and filed in In re: Commonwealth Biotechnologies, Inc., Case No. 11-30381-KRH, U.S. Bankruptcy Court, E.D. Virginia (the **Case**), has been confirmed pursuant to a final and non-appealable order of the bankruptcy court;

(iii) HPPI has delivered a true, correct and complete copy of the Plan with all amendments to Mayne Pharma;

(iv) the "Effective Date", as defined in the Plan, has occurred and is August 12, 2013 and HPPI has taken all actions reasonable and necessary to formally close the Case;

(v) there are no voting trusts, proxies, or other agreements or understandings with respect to the voting of the capital stock of HPPI; and

(vi) the HP LLC Patents have been irrevocably assigned to HPPI on a royalty free basis;

(b) it will use reasonable commercial efforts to maintain all warehousing, sales, personnel and facilities required to perform its obligations under this Agreement; and

(c) it is the lawful and exclusive owner of the entire right, title and interest in and to all HPPI Licensed Rights (except to the extent such rights are licensed to HPPI with the right to grant sub licenses).

16. Liability, indemnity and insurance

16.1 No exclusion or limitation

HPPI may have certain rights and remedies that cannot be excluded, restricted or modified by agreement. Nothing in this Agreement operates to exclude, restrict or modify the application of any implied condition or warranty, provision, the exercise of any right or remedy, or the imposition of any liability under any law where to do so would contravene that law or cause any term of this Agreement to be void (**Non-excludable Obligation**).

16.2 Exclusion and disclaimer of implied obligations

Except for the Non-excludable Obligations and the express covenants, representations and warranties set out in this Agreement, MAYNE PHARMA MAKES NO OTHER COVENANTS, REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, THE WARRANTY OF NON INFRINGEMENT, OR ANY OTHER MATTER, ANY SUCH COVENANTS, REPRESENTATIONS AND WARRANTIES BEING EXPRESSLY DISCLAIMED.

16.3 Limitation of liability regarding matters other than Non-Excludable Obligations

Mayne Pharma's liability to HPPI arising directly or indirectly under or in connection with this Agreement or the performance or non-performance of this Agreement and whether arising under any indemnity, statute, in tort (including for negligence or otherwise (except as provided for below in this clause 16.3)), or on any other basis in law or equity is limited as follows:

(a) ***;

(b) ***; and

(c) ***,

***.

16.4 Indemnity

HPPI must indemnify and hold harmless and keep indemnified and held harmless Mayne Pharma and each of its Personnel from and against all actions, claims, demands, losses, damages, costs and expenses (including legal expenses as between a solicitor and their own client) howsoever and wheresoever arising, whether during or after the Term, which arise directly or indirectly from or in respect of:

(a) the research, development or registration activities relating to the Product, directly or indirectly, by HPPI;

(b) the importation, promotion, marketing, sale or distribution of the Product, directly or indirectly, by HPPI;

(c) the use or effects of such Product;

(d) to avoid doubt and without limitation, any actual or alleged infringement of Intellectual Property Rights (but excluding the MP Licensed Rights) arising from any of activities, use or effects referred to in clauses 16.4(a) to 16.4(c),

except to the extent that such action, claim, demand, loss, damage, cost or expense is caused by a breach of an express warranty given under this Agreement by Mayne Pharma or the gross negligence, fraud or wilful misconduct of Mayne Pharma or its Affiliates or Personnel.

16.5 HPPI Insurance

(a) HPPI must take out, at its own cost, adequate insurance cover for the Term (and in the case of a claims based policy, for *** after), with reputable insurers to the reasonable satisfaction of Mayne Pharma, in respect of its liabilities under this Agreement and its activities contemplated by this Agreement, which:

    (i) covers each of HPPI, Mayne Pharma and its Personnel for their respective rights, interests and liabilities (to avoid doubt, in whatever country the liability arises); and

(ii) notes Mayne Pharma's interest under the policy.

(b) Without limiting clause 16.5(a):

(i) for such period as there is a Mayne Pharma appointee to the board of directors of HPPI, HPPI must take out, at its own cost, adequate director and officer liability insurance cover;

(ii) clinical trial insurance which provides coverage for at least *** for each occurrence and *** in the aggregate or such other level of cover as agreed in writing by the parties, acting reasonably, and which covers each of HPPI, Mayne Pharma and its Personnel for their respective rights, interests and liability arising directly or indirectly from or in respect of the conduct of any clinical trial conducted by or on behalf of HPPI for the Product; and

(iii) from the Actual Launch Date, HPPI must effect product and public liability insurance which provides coverage for at least *** for each occurrence, and which covers each of HPPI, Mayne Pharma and its Personnel for their respective rights, interests and liabilities arising directly or indirectly from or in respect of:

(A) the research, development or registration activities relating to the Product, directly or indirectly, by HPPI;

(B) the importation, promotion, marketing, sale or distribution of the Product, directly or indirectly, by HPPI; and

(C) the use or effects of such Product.

16.6 Mayne Pharma Insurance

Mayne Pharma must effect and maintain product and public liability insurance, with reputable insurers, which provides coverage for at least *** for each occurrence.

16.7 Maintain insurance

Each party must maintain the insurance policies referred to in clause 16.5 or 16.6 (as applicable) throughout the Term and, in the case of a claims-based policy, until *** after the termination or expiry of this Agreement.

16.8 Evidence of insurance

Promptly in response to a request by a party, the other party must provide to the requesting party evidence of the currency of the insurance policies referred to in clause 16.5 or 16.6 (as applicable).

CONFIDENTIALITY AND IPR

17. Confidentiality and publication

17.1 Definition

Subject to clause 17.3, **Confidential Information** of a party (in this context, the **Disclosing Party**) means all information regardless of its form:

(a) treated by the Disclosing Party as confidential or in which it would be reasonable to expect that the Disclosing Party has an expectation of confidentiality (even if not specifically identified as confidential); and

(b) disclosed by the Disclosing Party to the other party or of which the other party becomes aware, whether before or after the Start Date,

and any derived information from which that information can reasonably be ascertained. Without limiting the generality of the foregoing, Confidential Information shall include, information and materials related to Product, processes, formulations, procedures, tests, equipment, data, batch records, reports, know-how, patent positioning, relationships with consultants and employees, business plans and business developments, and information concerning the existence, scope or activities of any research, design, development, manufacturing, marketing or other activities hereunder or otherwise relating to the Disclosing Party or its business.

17.2 Restrictions on disclosure and use

Subject to the exceptions and permitted disclosures set out below, each party (**Recipient**) agrees:

(a) to keep the Confidential Information of the Disclosing Party strictly secret and confidential from third parties (including any patent office); and

(b) to use the Confidential Information only for the purposes of this Agreement or exercise of the rights granted under this Agreement, and not for any other activity (including the purchase or sale or securities of the Disclosing Party in the public markets) without the prior written approval of the other party,

except that each party may share such Confidential Information:

(c) with any Affiliate, sub licensee or approved contractors to the extent necessary or reasonably desirable for the purposes of this Agreement, provided each party remains responsible for ensuring such Affiliates, sub licensees or contractors comply with restrictions on use and disclosure of information which are at least equivalent to those set out in this Agreement, without any right of further disclosure;

(d) to the extent reasonably necessary to seek, obtain or maintain (in the case of HPPI) a Marketing Authorisation or (in the case of Mayne Pharma) an MP Marketing Authorisation; and

(e) to the extent reasonably necessary to prepare, file, maintain, enforce or defend patents or patent applications.

17.3 Exceptions

The restrictions on use and disclosure set out above do not apply to the extent the Recipient can show the information:

(a) was public knowledge or generally known at the date of its disclosure or which subsequently becomes public knowledge or generally known through no act or failure to act on the part of the Recipient;

(b) is or was already in the Recipient's possession and was not acquired directly or indirectly from the Disclosing Party (in each case as shown by the Recipient's written records);

(c) is or was acquired by the Recipient in good faith from a third party who was not under an obligation of confidence with respect to that Confidential Information; or

(d) to the extent it is required by law, rule or regulation to be disclosed (including the U.S. federal securities laws and the rules and regulations of the U.S. Securities and Exchange Commission and the listing rules of the Australian Stock Exchange).

17.4 Scientific publication

(a) Notwithstanding clauses 17.1 to 17.3, each party has the right to publish Proposed Publications, subject to this clause 17.4.

(b) Each party (**Publishing Party**) must provide the other party with a copy of any Proposed Publication 30 days before the intended date of publication.

(c) The other party may review the Proposed Publication within the 30 day period and put any reasonable requests it requires to the Publishing Party:

(i) to prevent the disclosure of the other party's Confidential Information, by amending the Proposed Publication to remove the other party's Confidential Information or any information from which such Confidential Information can reasonably be ascertained; and/or

(ii) to delay publishing the Proposed Publication to prevent prejudicing the other party's ability to protect or commercially exploit any of its Intellectual Property Rights, up to a maximum further period of *** (for a total period of ***).

(d) For the avoidance of doubt, nothing in this clause prevents a party from ultimately publishing a publication that does not include any other Confidential Information of the other party.

18. Intellectual Property Rights

18.1 Intellectual Property Rights in the Product as at the Start Date

HPPI acknowledges and agrees that Mayne Pharma owns all Intellectual Property Rights in the Product existing as at the Start Date other than the HP LLC Patents, HPPI Licensed Rights or any Intellectual Property Rights developed exclusively by HPPI or its Affiliates or Personnel prior to the Start Date.

18.2 Reserved

18.3 Reserved

18.4 *

18.5 Development of Intellectual Property Rights and Licence of HPPI Licensed Rights

(a) All Intellectual Property Rights relating to the Product:

(i) from the Start Date to the Effective Date, for its use in the Original Field, that are or have been developed:

(A) by HPPI, its Affiliates or Personnel (solely or with any third party);

(B) jointly by HPPI and Mayne Pharma and their respective Affiliates and Personnel; or

(C) solely by Mayne Pharma and its Affiliates and Personnel in providing the services referred to in clause 4.4, and

(ii) from the Effective Date, for its use in the Field, that are or have been developed by HPPI, its Affiliates or Personnel (solely or with any third party),

(collectively, **Developed Intellectual Property Rights**) shall be the sole and exclusive property of HPPI, and, to the extent created in part by Mayne Pharma, its Affiliates or Personnel, Mayne Pharma hereby irrevocably transfers and assigns to HPPI without additional consideration all such Intellectual Property Rights. Notwithstanding the foregoing, the parties agree with Schedule 7 applies to Developed Intellectual Property Rights. All such Intellectual Property Rights are included in the HPPI Licensed Rights.

(b) All Intellectual Property Rights relating to the Product, whether or not for its use in the Field, that are or have been developed:

(i) by Mayne Pharma, its Affiliates or Personnel (solely or with any third party) from and after the Start Date, or

(ii) from the Effective Date, jointly by HPPI and Mayne Pharma and their respective Affiliates and Personnel,

shall be the sole and exclusive property of Mayne Pharma (but without limiting clause 3.3 of this Agreement), and, to the extent created in part by HPPI, its Affiliates or Personnel, HPPI hereby irrevocably transfers and assigns to Mayne Pharma without additional consideration all such Intellectual Property Rights. All such Intellectual Property Rights are included in the MP Licensed Rights to the extent relevant to the Product in the Field.

18.6 Notification of infringement or invalidity claim

Each party will immediately notify the other party if it becomes aware of any potential or actual:

(a) infringement or misappropriation of the other party's Intellectual Property Rights;

(b) the infringement of third party rights as a result of the research, development and registration activities relating to the Product, or the manufacture, importation, promotion, marketing, sale or distribution of the Product, as contemplated under this Agreement; or

(c) declaratory judgment or equitable relief action or similar proceeding alleging invalidity of any of the Licensed IPR.

18.7 Right to take action

Mayne Pharma will have the first right (but not the obligation) at its own cost and expense to pursue any remedies against any third party infringement or misappropriation of any Licensed IPR or to defend any Licensed IPR against a claim of invalidity. If Mayne Pharma decides not to pursue such remedies or defences within:

(a) *** after notice of the alleged infringement, misappropriation or claim; or

(b) *** before any deadline imposed by the Hatch-Waxman Act or similar laws (whichever comes first) with respect to an infringement or misappropriation of any HPPI Licensed Rights, or an infringement or misappropriation of any MP Licensed Rights within the scope of the grant of license from Mayne Pharma to HPPI under this Agreement,

then HPPI will have the right (but not the obligation) at its own cost and expense to pursue any remedies against the infringing or misappropriating third party or defences against claims of invalidity. A party taking action pursuant to this clause will be an **Enforcing Party**.

18.8 Consultation and assistance

The Enforcing Party will regularly consult with the other party with respect to any action or proceeding it undertakes and will consider the other party's position in good faith, and keep the other party informed of developments in any such action or proceeding. The other party will assist and cooperate fully with the Enforcing Party including, if required or reasonably requested, entering into a common interest agreement, bringing or joining in any action or proceeding, taking any action or providing a power of attorney, in each case, at the cost and expense of the Enforcing Party.

18.9 Disposition of damages

Any damages or other amounts collected will be distributed, first, to the Enforcing Party to cover its costs and expenses and, second, to the other party to cover its costs and expenses, if any, relating to the assistance and cooperation in the pursuit of such remedies; and any remaining amount will be distributed to the Enforcing Party.

19. Branding

19.1 Directions regarding use of the Trade Mark

HPPI may use the Trade Mark in connection with its promotion, marketing, sale and distribution of the Product in the Territory, and must observe all directions notified to it by Mayne Pharma regarding the depiction of its Trade Marks.

19.2 Samples of marketing materials

HPPI must submit to Mayne Pharma samples of all materials (including all advertisements, promotions and other marketing material for the Product) that depict the Trade Mark for approval by Mayne Pharma before use.

19.3 Use of the Trade Mark

HPPI must not, whether during the Term or after the end of this Agreement:

(a) use the Trade Mark as part of its corporate, business or trading name;

(b) use any other trade mark or name in conjunction with or in close proximity to the Trade Mark;

(c) use the Trade Mark in a manner which would jeopardise or invalidate any registration (or prejudice any application for registration) of the Trade Mark or could assist or give rise to an application to terminate, revoke or dilute any such registration; or

(d) use the Trade Mark in a manner which might prejudice the right or title of Mayne Pharma to the Trade Mark.

19.4 Goodwill

HPPI acknowledges that any goodwill and other such rights in the Trade Marks that may otherwise accrue to HPPI as a result of its use of the Trade Mark, accrue to the benefit of Mayne Pharma.

19.5 No right for HPPI to register the Trade Mark

HPPI must not, whether during the Term or after the end of this Agreement, apply to register anywhere in the Territory or the world any trade mark, or apply to register or use any business name, company name or Internet domain name that comprises or contains the Trade Mark or any words or images that are similar to the Trade Mark without the prior written consent of Mayne Pharma.

TERMINATION

20. Termination

20.1 Termination for breach by a party

A party may terminate this Agreement with immediate effect by notice in the manner set forth below to the other party if:

(a) that other party breaches any material provision of this Agreement and fails to remedy the breach within *** after receiving notice requiring it to do so;

(b) that other party breaches a material provision of this Agreement where that breach is not capable of remedy; or

(c) any event referred to in clause 20.3 happens to that other party (whether or not notification has been provided under clause 20.3).

20.2 Termination by Mayne Pharma for cause arising under a related agreement

Mayne Pharma may terminate this Agreement with immediate effect by notice to HPPI if:

(a) HPPI breaches a material provision of the Equity Holders Agreement, and:

(i) fails to remedy the breach within *** after receiving notice requiring it to do so; or

(ii) that breach is not capable of remedy;

(b) HPPI breaches a material provision of the Mayne Pharma Purchase Agreement, the 2015 SPA, the 2018 SPA, the Angiogenesis and Hedgehog Patent Sublicense or the December 2018 Agreement and:

(i) fails to remedy the breach within *** after receiving notice requiring it to do so; or

(ii) that breach is not capable of remedy.

20.3 Notification of insolvency events

Each party must notify the other party immediately if:

(a) that party ceases to carry on its business operations;

(b) that party ceases to be able to pay its debts as they become due;

(c) any step is taken by a mortgagee or secured party to take possession or dispose of the whole or part of that party's assets, operations or business;

(d) that party makes a general assignment for the benefit of creditors;

(e) that party becomes the subject of the filing or institution of bankruptcy, liquidation or receivership proceedings;

(f) any step is taken to appoint a receiver, a receiver and manager, a trustee in bankruptcy, a provisional liquidator, a liquidator, an administrator or other like person of the whole or part of that party's assets, operations or business; or

(g) an order is made for winding up or dissolution without winding up of that party or an effective resolution is passed for the winding up of that party.

20.4 Change of Control and disposal of assets or business by HPPI

(a) For so long as this Agreement is in effect, HPPI must seek the prior written consent of Mayne Pharma before it disposes of the whole or a substantial part of its assets, operations or business, such consent not to be unreasonably withheld, conditioned or delayed. HPPI must, at its own reasonable expense, provide to Mayne Pharma such information as Mayne Pharma reasonably requires to consider such a request for consent, including an independent third party opinion on valuation that has been approved by the board of HPPI. Without limitation, a breach of this clause is a breach of a material provision of this Agreement not capable of remedy.

(b) For so long as this Agreement is in effect, HPPI must notify Mayne Pharma before it undergoes any change in its direct or indirect Control. If, acting reasonably, Mayne Pharma considers that such change will have a material, negative impact on its rights under this Agreement, it may terminate this Agreement by giving *** notice to HPPI. Mayne Pharma agrees that HPPI is not deemed to have undergone a change in its direct or indirect Control for purposes of this clause 20.4(b) if Mayne Pharma ceases to own more than 50% of the outstanding voting power of HPPI solely as a result of (i) HPPI's issuance of New Securities in an equity financing with respect to which Mayne Pharma has preemptive or similar contractual rights to participate on the same terms and conditions as investors in the financing and (ii) Mayne Pharma's election not to participate in such financing on the same terms and conditions as investors in the financing.

20.5 Impact of claims of infringement

(a) If Mayne Pharma becomes subject to, or acting in its discretion, considers it is at risk of becoming subject to, any litigation, arbitration or similar proceeding claiming its activities under this Agreement with respect to the Product infringe the Intellectual Property Rights of any third party (the **Third Party IPR**), then Mayne Pharma may, at any time while such proceeding or risk remains, with immediate effect by notice to HPPI, elect not to supply Product for commercial sales until:

(i) Mayne Pharma enters into written agreement under which it obtains an exclusive license to copy and exploit all Intellectual Property Rights in the applicable Third Party IPR; or

(ii) all rights arising from the applicable Third Party IPR in the Territory have expired, lapsed or been invalidated by action of Mayne Pharma, HPPI or otherwise.

(b) During any period that Mayne Pharma has elected not to supply Product for commercial sale under clause 20.5(a):

(i) Mayne Pharma will supply Product:

(A) for uses reasonably related to the development and submission of information under a US Federal law which regulates the manufacture, use, or sale of drugs for clinical trials that have already started at the date of the notice until those clinical trials have completed;

(B) at the Floor Price in accordance with item 5.2(a) of Schedule 5, in which case item 5.1 of Schedule 5 shall no longer apply;

(ii) HPPI may allow any Backup Manufacturer to manufacture the Product for commercial sale, in accordance with Schedule 6 except that notwithstanding item 3.1 of Schedule 6, the parties will use their reasonable commercial efforts to Qualify a Backup Manufacturer (both as defined in Schedule 6) within 6 months after consent is provided by Mayne Pharma under item 2 of Schedule 6;

(iii) recognizing that the exercise by Mayne Pharma of its election under this clause 20.5 to not provide Product for commercial supply would materially impact the timing for any planned commercial launch of the Product in the Field, should Mayne Pharma exercise its rights under this clause 20.5, HPPI and Mayne Pharma shall, with input from the JDC, promptly take action to amend the Development Plan. The parties shall use reasonable commercial efforts to approve such revised Development Plan within *** of Mayne Pharma's election; and

(iv) in consideration for Mayne Pharma allowing such manufacture by a Backup Manufacturer, at the end of each Quarter:

(A) HPPI must notify Mayne Pharma of the quantities of any Product manufactured by the Backup Manufacturer in that Quarter under clause 20.5(b)(ii); and

(B) HPPI must pay to Mayne Pharma:

Mayne Pharma Sales Share Rate x (the Total Net Sales for that Quarter minus the reasonable cost of goods (per unit) incurred by HPPI to obtain the Product sold in that Quarter from the Backup Manufacturer),

within *** of the date of Mayne Pharma's notice under clause 20.5(a).

20.6 Accrued rights and remedies

The termination or expiry of this Agreement does not affect any accrued rights or remedies of either party.

20.7 Sell down or repurchase

At the termination or expiry of this Agreement except for termination by Mayne Pharma under clause 20.1 or 20.2:

(a) Mayne Pharma will fill any Orders provided they are placed *** before the date of the termination or expiry of this Agreement; and

(b) HPPI may promote, market, sell and distribute any Product for a period of *** from the termination or expiry of this Agreement (in which case, to avoid doubt, the provisions of clause 7, 10 and 11 continue to apply), subject to HPPI meeting its contractual obligations after the termination or expiry of this Agreement.

20.8 Return of Confidential Information

At the termination or expiry of this Agreement for any reason whatsoever:

(a) each party will, as soon as practicable, return to the other party all of the other party's Confidential Information (other than Confidential Information comprising part of the HPPI Licensed Rights), whether in permanent or magnetic/computer disk form or any other form provided that each party may:

(i) provide one copy of that Confidential Information to its legal advisers, to be held by them solely for the purpose of determining the scope of that party's obligations under this clause; and

(ii) retain one copy of such of that Confidential Information that is required by the Relevant Regulatory Authority, to be retained by that party.

(b) HPPI must, within *** after the termination or expiry of this Agreement, deliver to Mayne Pharma, at Mayne Pharma's option, all advertising, promotional or sales materials relating to the Product which are still in the power, possession or control of HPPI, any of its Affiliates or any Sub Licensee.

GENERAL

21. Force majeure

21.1 Occurrence of Force Majeure Event

If a Force Majeure Event affecting a party precludes that party (**Precluded Party**) partially or wholly from complying with its obligations (except its payment obligations) under this Agreement then:

(a) as soon as reasonably practicable after that Force Majeure Event arises, the Precluded Party must notify the other party in writing of:

(i) the Force Majeure Event;

(ii) which obligations the Precluded Party is precluded from performing (**Affected Obligations**);

(iii) the extent to which the Force Majeure Event precludes the Precluded Party from performing the Affected Obligations (**Precluded Extent**); and

(iv) the expected duration of the delay arising directly out of the Force Majeure Event;

(b) the Precluded Party's obligation to perform the Affected Obligations will, to the Precluded Extent, be suspended for the duration of the actual delay arising directly out of the Force Majeure Event; and

(c) the other party's obligations to perform any obligations dependent on the Affected Obligations will be suspended until the Precluded Party resumes performance.

21.2 Termination

If the suspension under clause 21.1(b) continues for more than ***, the other party may terminate this Agreement with immediate effect by giving notice to the Precluded Party.

22. Notices and other communications

22.1 Service of notices

A notice, demand, consent, approval or communication under this Agreement (**Notice**) must be:

(a) in writing, in English and signed by a person duly authorised by the sender; and

(b) hand delivered or sent by reputable international courier, prepaid post or by facsimile transmission to the recipient's address for Notices specified in the Details, as varied by any Notice given by the recipient to the sender.

22.2 Effective on receipt

A Notice given in accordance with clause 22.1 takes effect when taken to be received (or at a later time specified in it), and is taken to be received:

(a) if hand delivered or sent by reputable international courier, on delivery;

(b) if sent by prepaid post, on the second Business Day after the date of posting (or on the seventh Business Day after the date of posting if posted to or from a place outside Australia);

(c) if sent by facsimile, when the sender's facsimile system generates a message confirming successful transmission of the entire Notice unless, within 8 Business Hours after the transmission, the recipient informs the sender that it has not received the entire Notice,

but if the delivery, receipt or transmission is not on a Business Day or is after 5.00pm on a Business Day, the Notice is taken to be received at 9.00am on the next Business Day.

23. Dispute resolution

In the event of any action, question or disagreement arising from or relating to this Agreement, the parties hereto agree to settle such action, question or disagreement by arbitration before three arbitrators in New York, New York, selected by, and such arbitration to be administered by, the American Arbitration Association ("AAA") in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Each of the parties hereto agrees and acknowledges that all actions, questions or disagreements between or among them arising from or relating to this Agreement are subject to the alternative dispute resolution procedures of this clause 23. Each of the parties hereto agrees that any aspect of alternative dispute resolution not specifically covered in this Agreement shall be covered, without limitation, by the applicable AAA rules and procedures. Each of the parties hereto further agrees that any determination by the arbitrator regarding any action, question or disagreement arising from or relating to this Agreement shall be final and binding upon the parties hereto and shall not be subject to further appeal.

24. GST

24.1 Interpretation

(a) Words or expressions used in this clause 24 which are defined in the *A New Tax System (Goods and Services Tax) Act 1999* (Cth) have the same meaning in this clause.

(b) Clause 25 prevails over this clause 24 to the extent of any inconsistency.

24.2 Consideration is GST exclusive

Any consideration to be paid or provided to the Supplier for a supply made by it under or in connection with this Agreement, unless specifically described in this Agreement as 'GST inclusive', does not include an amount on account of GST.

24.3 Gross up of consideration

(a) Despite any other provision in this Agreement, if the Supplier makes a taxable supply under or in connection with this Agreement (not being a supply the consideration for which is specifically described in this Agreement as 'GST inclusive'):

(i) the consideration payable or to be provided for that supply under this Agreement but for the application of this clause ('**GST exclusive consideration**') is increased by, and the Recipient must also pay to the Supplier, an amount equal to the GST payable on the supply ('**GST Amount**'); and

(ii) the GST Amount must be paid to the Supplier by the Recipient without set off, deduction or requirement for demand, at the same time as the GST exclusive consideration is payable or to be provided.

24.4 The sale of the Product is intended to be a GST-free export of goods

(a) Mayne Pharma and HPPI acknowledge that the supply of the Product under this Agreement is intended to constitute a GST-free supply of exported goods under item 1 of section 38-185(1) of the GST Act.

(b) HPPI warrants that in relation to each delivery of the Product, it will it satisfy the requirements under:

(i) Item 1 of section 38-185(1) and section 38-185(3) the GST Act; and

(ii) The interpretation of those provisions in paragraph (i) as outlined by the Australian Taxation Office in its Public Goods and Services Tax Ruling '*GSTR 2002/6, Goods and Services Tax: Exports of goods, items 1 to 4A of the table in subsection 38-185(1) of the A New Tax System (Goods and Services Tax) Act 1999'.*

(c) HPPI must provide written evidence to the Supplier that it has satisfied the requirements in clause 24.4(b) within *** of the Supplier issuing an invoice for the relevant Product.

(d) In the event HPPI fails to satisfy the requirements in clause 24.4(b), clause 24.4(c) or the Australian Taxation Office otherwise determines that the sale of the Product by Mayne Pharma constitutes a taxable supply, HPPI must immediately pay to Mayne Pharma the GST Amount payable in relation to the supply of the Product in accordance with clause 24.3 and any applicable interest, fines and penalties payable by Mayne Pharma as a result of the supply of the Product being treated as a GST-free supply.

24.5 Reimbursements (net down)

If a payment to a party under this Agreement is a reimbursement or indemnification or otherwise calculated by reference to a loss, cost or expense incurred by that party, then the payment will be reduced by the amount of any input tax credit to which that party, or the representative member of the GST group that party is a member of (as the case may be), is entitled in respect of that loss, cost or expense.

24.6 Tax invoices

The Supplier will give the Recipient a tax invoice in respect of a taxable supply made under or in connection with this Agreement**.**

24.7 Adjustments

If and to the event an adjustment event arises in respect of a supply made under or in connection with this Agreement, then:

(a) if the Supplier's corrected GST Amount is less than the previously attributed GST Amount, the Supplier shall refund the difference to the Recipient;

(b) if the Supplier's corrected GST Amount is greater than the previously attributed GST Amount, the Recipient shall pay the difference to the Supplier;

(c) the Supplier must issue an adjustment note to the Recipient within *** of the adjustment event occurring or otherwise as soon as it becomes aware of the adjustment event; and

(d) any payment under clauses 24.7(a) or 24.7(b) must be paid to the Supplier or Recipient (as the case may be) within *** of the adjustment note being issued by the Supplier.

24.8 Similar goods and services taxes or value added taxes

Clauses 24.2, 24.3 and 24.5 to 24.7 apply with the necessary changes in respect of any similar goods and services taxes or value added taxes levied in jurisdictions outside Australia**.**

25. Tax

25.1 Payments free of taxes; obligations to withhold; payments on account of taxes

(a) Any and all payments to be made to Mayne Pharma under this Agreement must be, to the extent permitted by law, be made free and clear or and without reduction or withholding for any Tax. HPPI acknowledges and agrees that any amount (in cash, securities or property in kind) received by Mayne Pharma or its nominee from HPPI as consideration arising under or related to this Agreement, is deemed to be a payment made to Mayne Pharma under this Agreement.

(b) Whenever HPPI is required by law to make a deduction or withholding in respect of Tax from any payment to be made to Mayne Pharma under this Agreement, then HPPI will:

(i) make that deduction or withholding from the payment;

(ii) promptly pay an amount equal to the amount deducted or withheld as required by law and by the date that Tax is due to be paid to the appropriate governmental or regulatory agency having jurisdiction over HPPI;

(iii) if requested by Mayne Pharma, within *** of that request, deliver to Mayne Pharma official relevant receipts issued by such Tax authority, if any, received by HPPI or other documentation of HPPI evidencing payment of that amount; and

(c) pay Mayne Pharma such additional amounts as necessary to ensure Mayne Pharma receives when due a net amount (after deduction or withholding of any Taxes in respect of such additional amounts) equal to the full amount which Mayne Pharma would have received if no deduction or withholding had been made.

25.2 Refunds

Mayne Pharma has no obligation to file or otherwise pursue any refund of Taxes withheld or deducted from funds paid to Mayne Pharma.

26. Miscellaneous

26.1 Survival of Obligations

Any indemnity or any obligation of confidence under this Agreement is independent and survives termination of this Agreement. Any other term by its nature intended to survive termination of this Agreement survives termination of this Agreement, to avoid doubt, including clause 3.2(b)(i), 5.3, 7.1, 7.4, 7.5, 12.2(d), 16, 17, 18.1, 18.7, 19.3 to 19.5, 20.6 to 20.8, 23, 24, 25, 26.1, 26.11 and 26.14, Schedule 2 (except to the extent otherwise provided therein) and Schedule 7.

26.2 Approvals and consents

Except where this Agreement expressly provides otherwise, a party may, in its discretion, give conditionally or unconditionally or withhold any approval or consent under this Agreement.

26.3 Announcements

Without limiting clause 17, a public announcement by HPPI in connection with this Agreement or any transaction contemplated by it must be approved in writing by Mayne Pharma before it is made, except if required by law or a regulatory body (including any relevant stock exchange), in which case HPPI must, to the extent practicable, first consult with and take into account the reasonable requirements of Mayne Pharma.

26.4 Subcontracting

Each party may appoint contractors to perform its obligations under this Agreement, except that HPPI must obtain the prior written consent of Mayne Pharma before appointing a contractor to perform a material part of the HPPI's obligations under this Agreement. The appointment of any contractor by a party does not relieve that party of any of its obligations under this Agreement.

26.5 Assignment

(a) HPPI may assign any of its rights or obligations under this Agreement only with the prior written consent of Mayne Pharma.

(b) Mayne Pharma may assign any of its rights or obligations under this Agreement to:

(i) an Affiliate or any entity to whom Mayne Pharma has disposed the whole or a substantial part of its assets, operations or business; or

(ii) otherwise with the prior written consent of HPPI.

26.6 Costs

Each party must pay its costs and expenses of negotiating, preparing and executing this Agreement.

26.7 Relationship

The relationship of principal and agent does not exist between the parties. Each party is an independent contractor and not an agent of HPPI. Neither party has any authority to act, execute any documents or warrant or represent on behalf of or otherwise bind the other party.

26.8 No modification

This Agreement cannot be modified except in writing and signed by each party.

26.9 Non waiver

A party's failure to exercise any right conferred on it under this Agreement will not be deemed to be a waiver of that right, unless it is in writing signed by that party. A party's waiver of any right under this Agreement at any given time is not deemed to be a waiver for any other time.

26.10 Entire agreement

This Agreement (as amended and restated as of the Effective Date), including its schedules, the Equity Holders Agreement, the 2014 Transaction Documents (as defined in the Equity Holders Agreement) and the 2015 Transaction Documents (as defined in the Equity Holders Agreement), the 2018 SPA, the Angiogenesis and Hedgehog Patent Sublicense, the December 2018 Agreement and the exhibits, annexes, instruments and the documents contemplated thereby, constitute the entire agreement between the parties in connection with its subject matter and supersedes all previous or contemporaneous agreements, promises or understandings between the parties in connection with its subject matter.

26.11 Further Action

Each party must do, at its own expense, everything reasonably necessary (including executing documents) to give full effect to this Agreement and any transaction contemplated by it.

26.12 Severability

If any term or provision of this Agreement is held to be invalid or unenforceable, it is to be read down so as to be valid or enforceable or, if such reading down is not possible, severed and the remaining terms hereof will not be affected but will be valid and enforced to the fullest extent permitted by law.

26.13 Counterparts

This Agreement may be executed in counterparts, including electronic counterparts. All executed counterparts constitute one document. Delivery of an executed signature page of this Agreement by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

26.14 Governing law

This Agreement is governed by the laws of Delaware, USA, without regard to the conflicts of laws principles thereof.

26.15 Embodiments of IIPR

All rights and licenses granted by HPPI to Mayne Pharma under this Agreement (including, without limitation, pursuant to Clause 5.5 and Schedule 7) are and shall be deemed to be rights and licenses to "intellectual property" and the subject matter of this Agreement, including all Intellectual Property Rights, is and shall be deemed to be "embodiment[s]" of "intellectual property" in each case, as such terms are used in and interpreted under Section 365(n) of the United States Bankruptcy Code (the "Code") (11 U.S.C. § 365(n)). Mayne Pharma shall have all rights, elections and protections under the Code and all other applicable bankruptcy, insolvency and similar laws with respect to this Agreement (including, without limitation, pursuant to Clause 5.5 and Schedule 7) and the subject matter hereof and thereof. Without limiting the generality of the foregoing, HPPI acknowledges and agrees that, if HPPI or its estate becomes subject to any bankruptcy or similar proceeding: (A) subject to Mayne Pharma's rights of election under Section 365(n), all rights, licenses and privileges granted to Mayne Pharma under this Agreement (including, without limitation, pursuant to Clause 5.5 and Schedule 7) will continue subject to the respective terms and conditions hereof and thereof, and will not be affected, even by HPPI's rejection of this Agreement (including, without limitation, pursuant to Clause 5.5 and Schedule 7) and (B) Mayne Pharma shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property and embodiments of intellectual property, which, if not already in Mayne Pharma's possession, shall be promptly delivered to Mayne Pharma or its designee, unless HPPI elects to and does in fact continue to perform all of its obligations under this Agreement (including, without limitation, pursuant to Clause 5.5 and Schedule 7).

[Schedules Follow Beginning on Next Page]

Schedule 1 – Agreement details

1. Start Date

   3 September 2013

2. Initial Term

   Starts on the Start Date and continues until the later of:

   (a) 10 years from the Actual Launch Date;

   (b) all issued patents of Mayne Pharma or any of its Affiliates referred to in paragraph (a) of the definition of MP Licensed Rights (and all continuations-in-part, continuations or divisions of any such patent or patents, or substitutes of it, and any reissues, re-examinations, extensions, or renewals of the same) have lapsed or expired.

3. Territory

   United States of America, including all of its commonwealths, territories and possessions.

1. Transfer Activities

(a) From the Effective Date, HPPI, in collaboration with Mayne Pharma, must immediately commence all activities necessary or reasonably required to implement the transfer of all of HPPI's rights to the Product to Mayne Pharma in the Territory in the BCCNS Field (**Transfer Activities**), including:

(i) the assignment to Mayne Pharma (subject to obtaining applicable third party agreements and consents as necessary) of all relevant contracts and other agreements related to HPPI's activities in the BCCNS Field in the Territory which are deemed necessary by Mayne Pharma for the future conduct of its activities in the BCCNS Field in the Territory (provided that HPPI shall provide Mayne Pharma copies of all agreements with contract research organisations, clinical trial investigators and key opinion leaders and any other agreements as requested in writing by Mayne Pharma);

(ii) the transfer of IND *** and the sponsorship of such IND to Mayne Pharma;

(iii) the transfer of all relevant regulatory files relating to the Product in the BCCNS Field to Mayne Pharma, including PDF and word versions of all HPPI correspondence and IND related submissions sent by HPPI to the FDA and PDF copies of all correspondence received from the FDA; and

(iv) the transfer to Mayne Pharma of all audited or raw clinical data related to HPPI's Phase 2b trial in the possession of HPPI or its contractors as of the Effective Date , including the Trial Master File as described in Schedule 3 and a copy of the *** study database in Excel and/or SAS format ("**Scoring Study Clinical Data**").

(b) To avoid doubt, the rights to the Product in the Territory in the BCCNS Field which are the subject of the Transfer Activities shall not include a transfer or assignment of the HPPI Patents, the HP LLC Patents or any other patents or patent applications owned or licensed by HPPI themselves, which patents and applications are subject to the license granted by HPPI hereunder.

(c) Mayne Pharma designates *** as its point person in the United States to interface with HPPI management on a frequent basis to coordinate and ensure the efficient execution of the Transfer Activities.

(d) HPPI may not communicate with the FDA after the Effective Date with regard to the MP Product in the BCCNS Field, except to give effect to the transfer as set out above.

(e) From the Effective Date, Mayne Pharma is:

(i) responsible for all expenses related to exploiting the MP Product in the BCCNS Field (including, with respect to third party consulting if Mayne Pharma determines to engage such services); and

(ii) responsible (save for HPPI's Transfer Activity obligations) for compiling the integrated safety study required for any MP Marketing Authorisation in the BCCNS Field.

(f) HPPI is responsible for all liabilities related to the Product in the Territory in the treatment of human patients with cancer via oral administration prior to the Effective Date.

(g) Each of HPPI and Mayne Pharma must use its reasonable commercial efforts to complete all Transfer Activities detailed in clause 1(a) on or prior to December 31, 2018 (subject to any required consents of or negotiations with third party contractors), other than the transfer of the Scoring Study Clinical Data and the IND transfer. Each of HPPI and Mayne Pharma must use its reasonable commercial efforts to complete the transfer of all *** and IND *** to Mayne Pharma on or prior to January 31, 2019.

2. Advancement of Funds

(a) In consideration of HPPI's execution and delivery of this Agreement, and HPPI's performance of its obligations under this Agreement, Mayne Pharma agrees to advance funds to HPPI in an aggregate amount of up to Five Million United States dollars (USD 5,000,000) (each, an **Advance**, and collectively, the **Advances**), as set out in this item 2 of Schedule 2.

(b) *Base Advances*

(i) Tranche One – On the Effective Date, Mayne Pharma must make an Advance to HPPI of Five Hundred Thousand United States dollars (USD 500,000);

(ii) Tranche Two – Within three (3) Business Days following the completion of the Transfer Activities (as evidenced by the completion in all material respects of the actions set forth in items 1(a)(i) to 1(a)(iii) of this Schedule 2), Mayne Pharma must make an Advance to HPPI of One Million United States dollars (USD 1,000,000); and

(iii) Tranche Three – If, and only if, the Scoring Study Clinical Data has been provided to Mayne Pharma in all material respects so as to allow Mayne Pharma to assume control of the Product in the Territory in the BCCNS Field, upon the earlier of June 30, 2019 or the acceptance for filing by FDA of an NDA for the Product in the BCCNS Field, Mayne Pharma must make an Advance to HPPI of One Million Five Hundred Thousand United States dollars (USD 1,500,000).

(c) *Top-Up Right; Elected Advance*

(i) If, from Effective Date until June 30, 2021, HPPI proposes to issue New Securities in any transaction that would result in HPPI having received aggregate gross proceeds since the Effective Date of more than Three Million United States dollars (USD 3,000,000) (**Threshold**) from the issuance of New Securities to one or more investors other than Mayne Pharma, whether in one or a series of related or unrelated financings (collectively, an **Equity Issuance**), then, Mayne Pharma will have the right, at its option, to purchase concurrently with the most recent Equity Issuance that results in the Threshold being met, up to or equal to the same New Securities being sold to the investors in such Equity Issuance, on terms and conditions the same as the most favourable terms contemplated in any such financing, such that following the Equity Issuance and the exercise of such option Mayne Pharma will own up to the same percentage of equity in HPPI that it owned immediately prior to the Equity Issuance (**Top-Up Right**).

(ii) If Mayne Pharma does not purchase its entire allocation pursuant to the Top-Up Right then, promptly following delivery of notice by HPPI (at its election) to Mayne Pharma requesting a further Advance of up to an amount equal to the difference between Two Million United States dollars (USD 2,000,000) and the amount of aggregate gross proceeds received by HPPI from Mayne Pharma from the sale of New Securities to Mayne Pharma pursuant to the Top-Up Right (**Elected Advance**), ***.

(iii) To avoid doubt, if HPPI receives aggregate proceeds of at least Two Million United States dollars (USD 2,000,000) from Mayne Pharma from the sale of New Securities to Mayne Pharma pursuant to the Top-Up Right, then HPPI is not entitled to request the Elected Advance and Mayne Pharma has no obligation to make the Elected Advance to HPPI.

(d) Additional terms and conditions

(i) Notwithstanding anything to the contrary in this Agreement, Mayne Pharma shall not be required to make any Advance under this item 2 of Schedule 2 if: (A) this Agreement has expired, has been terminated or is not otherwise in full force and effect, or (B) any event referred to in clause 20.3 has happened to HPPI.

(ii) HPPI may use the proceeds from each Advance as determined by HPPI in its discretion.

(iii) With respect to any Equity Issuance, Mayne Pharma hereby agrees to waive its right to approve any such Equity Issuance pursuant to Section 5.3 of the 2018 SPA.

(e) *Optional Conversion in Certain Circumstances*

(i) If Mayne Pharma does not obtain FDA approval of an NDA for the MP Product in the BCCNS Field by December 31, 2023, then, from and after December 31, 2023, at any time and from time to time, Mayne Pharma may convert, at its option by notice to HPPI and without the payment of additional consideration by Mayne Pharma, all or any portion of the Advances Amount (as defined below) made under this item 2 of Schedule 2 into such number of fully paid and non-assessable restricted shares of common stock of HPPI as is determined by dividing the amount of Advances Amount being converted by the Per Share Market Price.

(ii) No fractional shares of common stock of HPPI shall be issued upon conversion of Advances Amount under this item 2(e) of Schedule 2. In lieu of any fractional shares to which Mayne Pharma would otherwise be entitled, HPPI shall pay cash equal to such fraction multiplied by the Per Share Market Price.

(iii) In order for Mayne Pharma to voluntarily convert all or any portion of the Advances Amount into common stock of HPPI pursuant to this item 2(e) of Schedule 2, Mayne Pharma shall provide written notice to HPPI that Mayne Pharma elects to convert all or any portion of the Advances Amount and specify the amount of Advances Amount that is being so converted (a **Conversion Notice**).

(iv) HPPI shall, as soon as practicable after receipt of a Conversion Notice (i) issue and deliver to Mayne Pharma, or to its nominees, a certificate or certificates for the number of full shares of HPPI common stock issuable upon such conversion in accordance with the provisions hereof and an acknowledgement as to the remaining amount of Advances Amount that have not converted into HPPI common stock and (ii) pay in cash such amount as provided in item 2(e)(ii) of Schedule 2 in lieu of any fraction of a share of HPPI common stock otherwise issuable upon such conversion.

(v) For the purposes of this item 2(e) of Schedule 2:

(A) **Advances Amount** means a USD value determined by multiplying (1) the amount of Advances proposed to be converted into HPPI common stock by (2) 1.10.

(B) **Per Share Market Price** means (1) if HPPI common stock is then traded primarily on the New York Stock Exchange or Nasdaq Stock Market, the per share volume weighted average trading price of HPPI common stock over the thirty (30) consecutive trading days ending on the trading day immediately prior to HPPI's receipt of the applicable Conversion Notice (calculated by dividing the total value by the total volume of HPPI common stock traded for the trading days included in such thirty (30) trading day period), (2) if HPPI common stock is then listed or traded on other exchanges, markets and systems, the per share volume weighted average trading price of HPPI common stock over the ninety (90) consecutive trading days ending on the trading day immediately prior to HPPI's receipt of the applicable Conversion Notice (calculated by dividing the total value by the total volume of HPPI common stock traded for the trading days included in such ninety (90) trading day period) and (3) if HPPI common stock is not then publicly traded, the per share fair market value of HPPI common stock as determined by an appraiser mutually selected by Mayne Pharma and HPPI that is independent of Mayne Pharma and HPPI and their respective Affiliates that is skilled in preparing appraisals of the value of non-publicly traded stock, provided that (i) if Mayne Pharma and HPPI are unable to agree on a single appraiser, then each party must select a qualified independent appraiser and the two qualified independent appraisers must then determine the per share fair market value of HPPI common stock, (ii) if the two qualified independent appraisers cannot agree on the per share fair market value of HPPI common stock within 30 days after their selection, they must, within 30 days, mutually select a third qualified independent appraiser, (iii) the mutually selected qualified independent appraiser (or, if applicable, the third qualified independent appraiser) must determine the per share fair market value of HPPI common stock within 30 days of selection, and such determination is conclusive and binding upon Mayne Pharma and HPPI and (iv) Mayne Pharma and HPPI must bear equally the fees and expenses of such appraisers.

(vi) HPPI shall have no obligation to reserve and keep available out of its authorized but unreserved and unissued capital stock any shares of HPPI common stock or other HPPI securities for the purpose of effecting the conversion of Advances pursuant to this item 2(e) of Schedule 2; provided, however, that if at the applicable date of desired conversion of any Advances (**Conversion Date**), HPPI shall have an insufficient number of authorized, unreserved shares of HPPI common stock available for issuance upon conversion of all of such Advances, Mayne Pharma may elect to convert the applicable amount of such Advances it is permitted to convert based on the then authorized, unreserved shares of HPPI common stock and, with respect to any deficiency amount, to either (A) require HPPI to take, and HPPI shall take, all corporate action within *** of the Conversion Date as may be necessary to increase its authorized but unissued and unreserved shares of HPPI common stock to such number of shares as shall be sufficient for purposes of converting the remaining Advances or (B) recoup the Advances that is unable to be converted as of the Conversion Date in the form of

an unsecured promissory note issued by HPPI which will (1) not contain any affirmative or negative covenants restricting the corporate activities of HPPI, (2) contain customary event of default and other provisions for a simple promissory note, (3) will mature on the one (1) year anniversary of the Conversion Date, (4) will carry an interest rate of *** per annum and (5) will be prepayable by HPPI at any time prior to maturity without penalty.

(vii) Any such portion of Advances so converted under this item 2(e) of Schedule 2 shall not be credited and set off against royalty payments, if any, due by Mayne Pharma to HPPI under item 4.1 of Schedule 2 as contemplated by item 4.3 of Schedule 2.

(viii) With respect to any and all shares of common stock of HPPI issued upon conversion of Advances under this item 2(e) of Schedule 2, HPPI agrees to provide to Mayne Pharma the same rights and privileges that are set forth in Annex G to the 2018 SPA applicable to Registrable Securities (as defined therein).

3. Mayne Pharma's performance obligation for the BCCNS Field

After Mayne Pharma obtains any MP Marketing Authorisation for any MP Product in the Territory in the BCCNS Field, Mayne Pharma must use reasonable commercial efforts to maximise the sale of the MP Product in the BCCNS Field in the Territory (including, without limitation, through maintaining all warehousing, sales, personnel and facilities required to perform its obligations under this Agreement with respect to Products in the BCCNS Field in the Territory).

4. Royalty

4.1 Payment each Quarter

Subject to items 4.2 and 4.3 of Schedule 2, within 60 days of the end of each Quarter, Mayne Pharma must pay to HPPI a cash royalty (**HPPI BCCNS Royalty**) of 9% on the aggregate of the actual gross invoice price for the MP Product sold by Mayne Pharma, its Affiliates or any sub licensee to third parties in the Territory in the BCCNS Field, less the following deductions (whether or not separately stated on invoices) to the extent reasonable and customary in the market for the MP Product or any product similar to or substitutable for the MP Product:

(a) ***;

(b) ***; and

(c) ***.

4.2 Calculation of the royalty

In respect of the amounts payable under item 4.1 of Schedule 2:

(a) if such amount is negative in any Quarter, then no royalty is payable for that Quarter and that amount will be carried forward and included as a deduction from the aggregate of the gross invoice price in any subsequent Quarter (as applicable);

(b) Mayne Pharma may reduce the amount of the royalty owed to HPPI under item 4.1 of Schedule 2 by the value of any milestone payments forfeited by Mayne Pharma International under the Angiogenesis and Hedgehog Patent Sublicense;

(c) Mayne Pharma must submit to HPPI a report setting out, in reasonable detail, the calculation of the royalty amount (including the aggregate actual gross invoice price for the MP Product sold by Mayne Pharma, its Affiliates or any sub licensee during the applicable Quarter) at the same time as it makes payment; and

(d) Mayne Pharma must, and must ensure that its Affiliates and any sub licensee must, promptly process any deduction and in any event, process such deductions no later than one Quarter after they are allowed (in the case of discounts, bonuses, commissions and rebates) applied or the Products sold by Mayne Pharma, its Affiliates or any sub licensee are rejected or returned.

4.3 Credit for payment of the Advance

Each Advance made by Mayne Pharma under item 2 of Schedule 2 (other than any portion of such Advance that has been converted under item 2(d) of Schedule 2) will be credited and set off against royalty payments, if any, due by Mayne Pharma to HPPI under item 4.1 of Schedule 2, as follows (for the avoidance of doubt, any funds invested by Mayne Pharma in consideration of New Securities pursuant to the Top-Up Right shall not be credited and set off against royalty payments, if any, due by Mayne Pharma to HPPI under item 4.1 of Schedule 2 as contemplated hereby):

(a) With respect to each Advance made by Mayne Pharma prior to the receipt of FDA approval of an NDA for the MP Product in the BCCNS Field, each USD 0.75 increment of each such Advance will be credited and set off against each USD 1.00 increment of royalty due by Mayne Pharma to HPPI under item 4.1 of Schedule 2; and

(b) With respect to each Advance made by Mayne Pharma on or after the receipt of FDA approval of an NDA for the MP Product in the BCCNS Field, each USD 0.85 increment of each such Advance will be credited and set off against each USD 1.00 increment of royalty due by Mayne Pharma to HPPI under item 4.1 of Schedule 2.

4.4 Books of account

(a) Mayne Pharma will maintain books of account and records with respect to sales and stocks of the Product in the Territory in the BCCNS Field by Mayne Pharma, its Affiliates and any sub licensee (including stock records) (**Mayne Pharma Books of Account**).

(b) HPPI will have the right to appoint, on reasonable notice, an Accountant to inspect and examine the Mayne Pharma Books of Account.

(c) HPPI will bear the fees of such Accountant unless an error equivalent to 5% or more (in favor of HPPI) of the amounts payable under item 4.1 of Schedule 2 in any calendar year is discovered, in which case the fees will be borne by Mayne Pharma.

(d) Mayne Pharma will maintain the Mayne Pharma Books of Account in accordance with business accounting standards in the Territory.

5. Option to buy out the royalty

If, prior to June 30, 2021, HPPI has not successfully consummated the Equity Issuance, then Mayne Pharma has the right, at its option, to satisfy all of its remaining obligations under item 4 of this Schedule 2 by making a single lump sum payment to HPPI (**Royalty Buyout Option**) in an amount equal to seventy percent (70%) of the fair market value of the remaining royalties payable under item 4 of this Schedule 2 (**Royalty Fair Market Value**) within 60 days of the determination of the Royalty Fair Market Value becoming conclusive and binding upon Mayne Pharma and HPPI as set out below. Within 30 days following delivery by Mayne Pharma of notice of the exercise of the Royalty Buyout Right to HPPI (**Royalty Buyout Notice**), Mayne Pharma and HPPI must mutually select an appraiser independent of Mayne Pharma and HPPI and

their respective Affiliates that is skilled in preparing appraisals of the future value of pharmaceutical products (a **Qualified Independent Appraiser**) to determine the Royalty Fair Market Value. If Mayne Pharma and HPPI are unable to agree on a single Qualified Independent Appraiser, then each party must select a Qualified Independent Appraiser and the two Qualified Independent Appraisers must then determine the Royalty Fair Market Value. If the two Qualified Independent Appraisers cannot agree on the Royalty Fair Market Value within 30 days after their selection, they must, within 30 days, mutually select a third Qualified Independent Appraiser. The mutually selected Qualified Independent Appraiser (or, if applicable, the third Qualified Independent Appraiser) must determine the Royalty Fair Market Value within 30 days of selection, and such determination is conclusive and binding upon Mayne Pharma and HPPI. Mayne Pharma and HPPI must bear equally the fees and expenses of the Qualified Independent Appraisers.

6. Indemnity

Subject to clause 16.3, Mayne Pharma must indemnify and hold harmless and keep indemnified and held harmless HPPI and each of its Personnel from and against all actions, claims, demands, losses, damages, costs and expenses (including legal expenses as between a solicitor and their own client) howsoever and wheresoever arising, whether during or after the Term, to the extent arising from or in respect of any of the following activities:

(a) the research, development or registration activities relating to the MP Product in the Territory in the BCCNS Field, directly or indirectly, by Mayne Pharma;

(b) the importation, promotion, marketing, sale or distribution of the MP Product in the Territory in the BCCNS Field, directly or indirectly, by Mayne Pharma;

(c) the use or effects of such MP Product in the Territory in the BCCNS Field; and

(d) to avoid doubt and without limitation, any actual or alleged infringement of Intellectual Property Rights arising from any activities, use or effects referred to above,

except to the extent that such action, claim, demand, loss, damage, cost or expense is caused by a breach of an express warranty given under this Agreement by HPPI or the gross negligence, fraud or willful misconduct of HPPI or its Personnel.

Schedule 3 – Trial Master File for Study ***

***

Schedule 4 – Product and Product Specification

Product: SUBA-Itraconazole 50mg hard capsules

1. **Description of the dosage form**

Hard gelatin capsules, size ***_body and cap printed *** in *** on the cap. ***

2. **Composition**

The qualitative composition for SUBA-Itraconazole Capsules is presented in Table 1 below.

***

3. **Container Closure System**

SUBA-Itraconazole Capsules 50 mg will be packaged ***.

SUBA-Itraconazole Capsules 50 mg may be packaged ***.

Schedule 5 – Economic details

1. Floor Price, Minimum Order Quantity and Minimum Annual Volumes

1.1 Floor Price and Minimum Order Quantity

Product	Floor Price per unit (USD)	Minimum Order Quantity (MOQ) (capsules)	Incremental Order Quantity (after the MOQ) (capsules)
SUBA-Itraconazole 50mg hard capsule	***	***	***

1.2 Minimum Annual Volumes

***

2. Forecast Period

***

3. Delivery terms

EXW (Incoterms 2010), Salisbury, South Australia, Australia.

4. Minimum shelf life

***

5. Price

5.1 Product Mayne Pharma provides *

Mayne Pharma will provide Product and placebo for the conduct of the activities in the applicable Development Plan and any other activities relating to the research, development or registration activities relating to the Product approved by Mayne Pharma, acting reasonably.

***

5.2 Product for which Mayne Pharma *

HPPI *** Mayne Pharma for:

(a) any Product required for the conduct of the activities in the Development Plan and any other activities relating to the research, development or registration activities relating to the Product:

(i) above the amount specified in item 5.1 of this Schedule 5; or

(ii) ***,

at the Floor Price, and payable by HPPI within *** of the date of Mayne Pharma's invoice, to be issued on or after shipment of the Product; and

(b) all other Product, in accordance with this item 5 of this Schedule 5.

5.3 Definitions

In this Schedule 5:

Actual ASP means for any ***.

Floor Price means the floor price set out in the table above.

Forecast ASP means the forecasted ***.

***

Price is calculated under item 5.6 of this Schedule 5.

Total Net Sales means ***

Transfer Price has the meaning given to it in item 5.5 of this Schedule 5.

Total Units Sold means ***.

5.4 Forecast ASP

At least *** before the start of each ***, the parties will use reasonable commercial efforts to agree on the forecasted Total Net Sales on a per Product basis and the forecasted Total Units Sold for that ***, which will be used to calculate the Forecast ASP.

5.5 Transfer Price

The Transfer Price must be reviewed by the parties, and if necessary, revised at least *** before the start of each ***. The Transfer Price for the Product at the time of invoice is ***.

5.6 Price

The Price to be paid by HPPI for the Product in the Territory is:

(a) the Transfer Price, payable by HPPI within *** of the date of Mayne Pharma's invoice, to be issued on or after shipment of the Product; and

(b) as adjusted by a reconciliation of the Actual ASP in relation to the Forecast ASP ***.

5.7 Timely accounting for deductions

HPPI must, and must ensure that its Affiliate and any Sub Licensee must, promptly process any deduction from Total Net Sales and in any event, process such deductions no later than *** after they are allowed (in the case of discounts, bonuses, commissions and rebates), applied or the Products are rejected or returned.

5.8 Books of Account

(a) HPPI will maintain books of account and records with respect to sales and stocks of the Product supplied by Mayne Pharma under this Agreement in the Territory by HPPI, its Affiliates and Sub Licensee (including stock records) (**HPPI Books of Account**).

(b) Mayne Pharma will have the right to appoint, on reasonable notice, an Accountant to inspect and examine the Books of Account.

(c) Mayne Pharma will bear the fees of the such Accountant unless an error equivalent to *** or more of the Total Net Sales in any calendar year is discovered, in which case the fees will be borne by HPPI.

(d) HPPI will maintain the HPPI Books of Account in accordance with business accounting standards in the Territory and at a standard sufficient to facilitate any Product recall.

(e) HPPI will have the right to appoint on reasonable notice an Accountant to inspect and examine Mayne Pharma's manufacturing costs, including Mayne Pharma's cost of goods as such is relevant to the calculation of the Floor Price.

5.9 Reporting requirements

Within *** from the end of each month of each Quarter, HPPI must use reasonable commercial efforts to submit to Mayne Pharma an estimated reconciliation report in reasonable detail.

6. Currency and exchange rate

6.1 Currency

USD

6.2 Financial institution for exchange rate

National Bank of Australia Limited

Schedule 6 – Qualification of Backup Manufacturer

1. Definitions

In this Schedule 6:

***

1. Licence of HPPI Licensed Rights

1.1 Grant of licence

From the Start Date, HPPI grants to Mayne Pharma an exclusive, perpetual, irrevocable licence to copy and exploit:

(a) outside the Territory in any field, and

(b) inside the Territory outside the Field,

any Intellectual Property Right (including all Developed Intellectual Property Right subject to clause 18.5 of the Agreement, but excluding rights in respect of trade and service marks and logos) that satisfies all of the following criteria:

(i) relates to, or has potential application in connection with, the Product, including any dossier containing technical or clinical information relating to the Product; and

(ii) is owned by HPPI or its Affiliates or Sub Licensees, or licensed by HPPI, its Affiliates or Sub Licensees (without restriction as to license or sub license) at any time during the period starting at the Start Date until the earlier of:

(A) ***; or

(B) the termination or expiry of this Agreement,

(**HPPI Licensed Rights**) including the HP LLC Patents and the HPPI Patents and also including, in respect of Intellectual Property Rights not yet in existence at the Start Date but created before the earlier of the dates referred to in items 1.1(ii)(A) and (B) of this Schedule 7), by way of a grant of a licence of future Intellectual Property Rights, which takes effect from the date of creation of those rights. The license granted pursuant to this item 1.1 of Schedule 7 shall be royalty free, except to the expressly provided in Schedule 2.

1.2 HPPI to ensure it remains free to licence the HPPI Licensed Rights

HPPI must:

(a) ensure that, in respect of any Intellectual Property Rights comprising the HPPI Licensed Rights owned by it, its Affiliates or any Sub Licensee; and

(b) use reasonable commercial efforts to ensure that, in respect of any Intellectual Property Rights comprising the HPPI Licensed Rights licensed by it, its Affiliates and any Sub Licensee,

HPPI is free to grant to Mayne Pharma an exclusive, perpetual, irrevocable, royalty free licence to copy and exploit such Intellectual Property Rights outside the Territory in any field or in the Territory outside the Field. Promptly on becoming aware of any restriction on such right to grant such licence, HPPI must notify Mayne Pharma.

1.3 Restriction on assignment or sub licence

The licence under item 1.1 of this Schedule 7 may only be assigned or sub licensed in accordance with this Agreement or otherwise with the prior written consent of HPPI.

1.4 Survival

To avoid doubt, the licenses granted under item 1.1 of this Schedule 7 survive termination of this Agreement.

2. Copies of documents, data and other information embodying the HPPI Licensed Rights

Promptly in response to a request by Mayne Pharma at any time during the Term or a reasonable period after the termination or expiry of this Agreement, HPPI must provide to Mayne Pharma a copy of any documents, data and other information embodying the HPPI Licensed Rights since the most recent request by Mayne Pharma under this item 2 of Schedule 7. Without limiting the generality of the foregoing, HPPI agrees to provide Mayne Pharma, at HPPI's expense, access to any Drug Master File (should one exist from time to time) and all pre-clinical or clinical data included as part of the HPPI Licensed Rights.

3. Intellectual property protection for HPPI Licensed Rights

(a) HPPI will consult with Mayne Pharma regarding intellectual property protection for such rights outside the Territory.

(b) In particular, HPPI must give at least *** prior notice before it, or any of its Affiliates:

(i) discloses any Confidential Information comprised in the HPPI Licensed Rights to any third party unless subject to equivalent restrictions on use and disclosure as those under clause 18, without any right of further disclosure; and

(ii) without limitation, discloses any Confidential Information comprised in the HPPI Licensed Rights to any patent office, including as part of a patent application.

(c) If HPPI decides not to file, prosecute or maintain patent protection for any invention comprised in the HPPI Licensed Rights in any country outside the Territory, it must promptly give notice to Mayne Pharma (with such notice to be given at least *** before any deadline for decisions relating to such filing, prosecution or maintenance).

(d) Mayne Pharma may, by notice to HPPI, request that HPPI make a decision in respect of the filing, prosecution or maintenance of patent protection for any invention comprised in the HPPI Licensed Rights in any country outside the Territory, in which case HPPI must respond before any deadline referred to in item 3(c) of this Schedule 7 but in any event no later than *** after the request by Mayne Pharma.

(e) If HPPI gives notice to Mayne Pharma under item 3(c) or (d) of this Schedule 7 of its intention not to file, prosecute or maintain patent protection of any invention comprised in the HPPI Licensed Rights in any country outside the Territory, Mayne Pharma may decide to take over such filing, prosecution or maintenance at its cost by giving notice to HPPI before the relevant deadline, in which case:

(i) HPPI will, or will procure that its Affiliate (as applicable) will, promptly assign to Mayne Pharma or its nominee all rights in respect of the invention (including under any patent application or issued patent); and

(ii) from the date of such assignment, HPPI acknowledges that:

(A) such rights no longer form part of the HPPI Licensed Rights;

(B) Mayne Pharma or its nominee may, in its discretion and at its cost, file, prosecute, maintain, enforce and defend any assigned patent application or issued patent; and

(C) any information in respect of the invention that is not public knowledge is deemed to be Confidential Information of Mayne Pharma.

4. Sub-licensing and assignment

4.1 Sub-licensing

Upon notice to HPPI, Mayne Pharma may grant a sub licence of the HPPI Licensed Rights to a third party without the prior written consent of HPPI under a written agreement that includes obligations on that third party that relate to use and disclosure of Intellectual Property Rights of HPPI and Confidential Information of HPPI at least equivalent to those imposed on Mayne Pharma under this Agreement.

4.2 Assignment

Despite clause 26.5(b), Mayne Pharma may assign any of its rights or obligations under this Schedule 7 without the prior written consent of HPPI.

[Signature page follows]

Signed as an **AGREEMENT** by authorised officers of each party.

Signed for **Mayne Pharma Ventures Pty Ltd**
by an authorised officer

/s/ Nick Freeman
Signature of officer

Nick Freeman
Name of officer (print)

Company Secretary
Office held

December 17, 2018
Date

Signed for **HedgePath Pharmaceuticals, Inc.**
by an authorised officer

/s/ Nicholas J. Virca
Signature of officer

Nicholas J. Virca
Name of officer (print)

President and CEO
Office held

December 17, 2018
Date

Confidential Treatment Requested by HedgePath Pharmaceuticals, Inc.,
IRS Employer Identification No. 30-0793665

Exhibit 10.6

*****CONFIDENTIAL TREATMENT REQUESTED*****
Note: Confidential treatment requested with respect to certain portions hereof denoted with "***"

December 17, 2018

AMENDED AND RESTATED SUBLICENSE AGREEMENT

BETWEEN

MAYNE PHARMA INTERNATIONAL PTY LTD

&

HEDGEPATH PHARMACEUTICALS, INC.

Confidential Treatment Requested by HedgePath Pharmaceuticals, Inc.,
IRS Employer Identification No. 30-0793665

AMENDED AND RESTATED SUBLICENSE AGREEMENT

THIS AMENDED AND RESTATED SUBLICENSE AGREEMENT (this "**Agreement**") is entered into effective as of December 17, 2018 by and between MAYNE PHARMA INTERNATIONAL PTY LTD, ABN 88 007 870 984, an Australian body corporate having an address at 1538 Main North Road, Salisbury South, SA 5106, Australia ("**Mayne Pharma**"), and HEDGEPATH PHARMACEUTICALS, INC., a company incorporated in Delaware having an address at 324 South Hyde Park Avenue #350, Tampa, Florida, 33606, United States ("**HPPI**") with respect to the following:

RECITALS

WHEREAS, valuable inventions entitled "New Angiogenesis Inhibitors" (JHU Ref No C04494; hereinafter referred to as the "**ANGIOGENESIS PATENT**"), and "New uses for old drugs: Identification of Hedgehog Pathway Antagonists previously tested in Humans" (JHU Ref No C04820; hereinafter referred to as the "**HEDGEHOG PATENT**") have heretofore been developed during the course of research conducted by Drs Jun Liu, Curtis Chung, David Sullivan, Schrindar Bhat, Jin Xu and Philip Beachy (all hereinafter "**INVENTORS**");

WHEREAS, THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation having an address at 3400 N. Charles Street, Baltimore, Maryland, 21218-2695 ("**JHU**"), has acquired through assignment all rights, title and interest, with the exception of certain retained rights by the United States Government, in said valuable inventions;

WHEREAS, JHU has granted to Accelas Holdings, a BVI corporation having an address at Rm 1228,12/F, One Grand Tower, 639 Nathan Road, Kowloon, Hong Kong ("**ACCELAS"**) an exclusive license to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions throughout the world under an exclusive license agreement effective on 14 December 2009, as varied by a first amendment effective on 22 May 2012 and a second amendment effective on 23 January 2014 (hereinafter referred to as the "**HEAD LICENSE**");

WHEREAS, Mayne Pharma obtained from Accelas a sublicense effective August 26, 2015 to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions (hereinafter referred to as the "**ACCELAS SUBLICENSE**");

WHEREAS, HPPI and Mayne Pharma are parties to that certain Sublicense Agreement, dated as of August 31, 2015, under which HPPI obtained from Mayne Pharma a sub-sublicense to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions in the United States of America, including all commonwealths, territories and possessions thereof, on the terms and conditions set forth herein (hereinafter referred to as the "**ORIGINAL AGREEMENT**");

WHEREAS, HPPI and Mayne Pharma Ventures Pty Ltd ACN 168 896 357 ("**MPV**"), an affiliate of Mayne Pharma, are entering into that certain Third Amended and Restated Supply and License Agreement dated as of even date herewith under which MPV agrees to supply HPPI with SUBA-Itraconazole hard capsules and provide a license to certain intellectual property rights (hereinafter referred to as the "**THIRD SLA**"); and

WHEREAS, pursuant to that certain Agreement, dated as of even date herewith, by and among, HPPI, MPV and Mayne Pharma, the parties hereto desire to amend and restate the ORIGINAL AGREEMENT to effect certain amendments, upon the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

All references to particular Exhibits, Articles or Paragraphs shall mean the Exhibits to, and Paragraphs and Articles of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

1.1 "AFFILIATED COMPANY" as used herein in either singular or plural shall mean any corporation, company, partnership, joint venture or other entity, which controls, is controlled by or is under common control with HPPI. For purposes of this Paragraph 1.1, control shall mean the direct or indirect ownership of at least fifty- percent (50%).

1.1A "BCCNS FIELD" shall mean the treatment of human patients with Basal Cell Carcinoma Nevus (Gorlin) Syndrome via oral administration.

1.2 "EFFECTIVE DATE" of this License Agreement shall mean August 31, 2015.

1.3 "EXCLUSIVE LICENSE" shall mean a grant by Mayne Pharma to HPPI of its entire right and interest as a licensee in the PATENT RIGHTS subject to rights retained by the United States Government, if any, in accordance with the Bayh-Dole Act of 1980 (established by P.L. 96-517 and amended by P.L. 98-620, codified at 35 USC § 200 et. seq. and implemented according to 37 CFR Part 401), and subject to the retained right of JHU under the Head License to make, have made, provide and use for its and The Johns Hopkins Health Systems' purposes LICENSED PRODUCT(S) and LICENSED SERVICE(S), including the ability to distribute any biological material disclosed and/or claimed in PATENT RIGHTS for nonprofit academic research use to non-commercial entities as is customary in the scientific community.

1.3A "FIRST COMMERCIAL SALE" shall mean the first day of the calendar quarter that occurs after the first sale for use or consumption by the general public of a LICENSED PRODUCT in the LICENSED FIELD in the TERRITORY after all required marketing and pricing approvals have been granted by the US Food and Drug Administration ("**FDA**").

1.4 "LICENSED FIELD" shall mean (i) for the ANGIOGENESIS PATENT: itraconazole racemic mixture, for the treatment of human patients with any of the LICENSED INDICATIONS via oral administration under the PATENT RIGHTS (and specifically excluding TOPICAL USE); and (ii) for the HEDGEHOG PATENT: SYSTEMIC USE and OCULAR USE of the racemic mixture of itraconazole for the treatment of human patients with any of the LICENSED INDICATIONS via oral administration. The LICENSED FIELD excludes the BCCNS FIELD and any fields not expressly listed above. ***.

1.4A "LICENSED INDICATIONS" shall mean the following to the extent they are oncology and age-related macular degeneration indications (i) any prostate cancer, prostatic intraepithelial neoplasia (IEN) and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia and (iii) familial adenomatous polyposis, colorectal polyps and Barett's esophagus. The LICENSED INDICATIONS exclude the BCCNS FIELD and any indications not expressly listed above.

1.5 "LICENSED PRODUCT(S)" as used herein in either singular or plural shall mean any process or method, material, compositions, drug, or other product, the manufacture, use or sale of which would constitute, but for the license granted to HPPI pursuant to this Agreement, an infringement of a claim of PATENT RIGHTS (infringement shall include, but is not limited to, direct, contributory, or inducement to infringe).

1.6 "LICENSED SERVICE(S)" as used herein in either singular or plural shall mean the performance on behalf of a third party of any method or the manufacture of any product or the use of any product or composition which would constitute, but for the license granted to HPPI pursuant to this Agreement, an infringement of a claim of the PATENT RIGHTS, (infringement shall include, but not be limited to, direct, contributory or inducement to infringe).

1.7 "NET SALES" shall mean ***.

1.8 "NET SERVICE REVENUES" shall mean ***.

1.9 "PATENT RIGHTS" shall mean (i) US Provisional Application No 60/583,076 (JHU Ref No C04494) entitled "New Angiogenesis Inhibitors", subsequently filed as PCT/US05/23015 on June 27, 2005 (hereinafter referred to as "the ANGIOGENESIS PATENT"); and (ii) US patent No 8,653,083 entitled "Hedgehog Pathway Antagonists to Treat Disease", filed on August 22, 2005, and subsequently filed as PCT/US2006/32952 on August 22, 2006 (hereinafter referred to as "the HEDGEHOG PATENT"); and (iii) the inventions disclosed and claimed therein, and all continuations, divisions and reissued based thereof, and any patents issuing, granted or registered therefrom. HPPI acknowledges and agrees that PATENT RIGHTS do not include ***.

1.10 "SUBLICENSEE" shall mean any person or entity to which LICENSEE has granted a sublicense with the approval of Mayne Pharma and JHU under Paragraph 2.2 of this Agreement.

1.11 Not used.

1.12 "OCULAR USE" shall mean application to the membranes, cornea or conjunctiva of the eye.

1.13 "SYSTEMIC USE" shall mean internal application throughout the whole body and not confined to a specific localized external area, including ingested or injected formulations of drugs, but excluding intradermal and subcutaneous injected formulations of drugs designed to locally treat external areas of the body and having a predominately local effect.

1.14 "TOPICAL USE" shall mean application to an external area of the body and affecting mostly the area to which it is applied, including intradermal and subcutaneous injection designed to locally treat such external area, including but not limited to the skin, ear and accessible mucous membranes including but not limited to those of the mouth, vagina and anus. TOPICAL USE shall comprise of drug formulations and delivery mechanisms including but not limited to lotions, creams, ointments, gels, powders (talc), patches, nanoparticles, microneedles and solutions (liquids) but shall exclude systemic uses, such as ingested or injected formulations of drugs. For the purpose of this agreement, TOPICAL USE shall specifically exclude OCULAR USE.

1.15 Not used.

1.16 "TERRITORY" shall mean the United States of America, including all commonwealths, territories and possessions thereof.

1.17 "THIRD PARTY" shall mean any entity other than HPPI or any SUBLICENSEE.

ARTICLE 2
LICENSE GRANT

2.1 Grant. Subject to the terms and conditions of this Agreement, Mayne Pharma hereby grants to HPPI an EXCLUSIVE LICENSE to make, have made, use, import, offer for sale and sell the LICENSED PRODUCT(S) and to provide the LICENSED SERVICE(S) in the TERRITORY under the PATENT RIGHTS in the LICENSED FIELD.

2.2 No right of Sublicense. HPPI may not sublicense to others (including any AFFILIATED COMPANY) under this Agreement, except with prior written consent of Mayne Pharma and JHU, which each may withhold or grant subject to conditions, in its discretion.

2.3 Government Rights. The United States Government may have acquired a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the inventions described in PATENT RIGHTS throughout the world. The rights granted herein are additionally subject to: (i) the requirement that any LICENSED PRODUCT(S) produced for use or sale within the United States shall be substantially manufactured in the United States (unless a waiver under 35 USC § 204 or equivalent is granted

by the appropriate United States government agency), (ii) the right of the United States government to require JHU, or its licensees, including HPPI, to grant sublicenses to responsible applicants on reasonable terms when necessary to fulfill health or safety needs, and, (iii) other rights acquired by the United States government under the laws and regulations applicable to the grant/contract award under which the inventions were made. HPPI will reimburse to Mayne Pharma all costs and expenses reasonably incurred in connection with an application for a waiver under 35 USC § 204 or equivalent by the appropriate United States government agency to the extent it relates to the LICENSED FIELD, within *** of the receipt of an invoice from Mayne Pharma and reasonable evidence of payment.

ARTICLE 3
FEES, ROYALTIES, PAYMENTS

3.1 License Fee. HPPI shall pay to Mayne Pharma within thirty (30) days of the EFFECTIVE DATE of this Agreement a license fee as set forth in Exhibit A. The license fee is nonrefundable and shall not be credited against royalties or other fees.

3.2 Minimum Annual Royalties. HPPI shall pay to Mayne Pharma minimum annual royalties as set forth in Exhibit A. These minimum annual royalties shall be due within *** after the FIRST COMMERCIAL SALE of a LICENSED PRODUCT occurs. Running royalties accrued under Paragraph 3.3 and paid to Mayne Pharma during the *** of the FIRST COMMERCIAL SALE shall be credited against the minimum annual royalties due on that date. Minimum annual royalties cease to be payable on the earlier of (i) the expiry or lapse of all PATENT RIGHTS that have been granted, issued or registered in the TERRITORY; or (ii) there is no longer a marketing authorization in place for sale of a LICENSED PRODUCT in the LICENSED FIELD in the TERRITORY.

3.3 Running Royalties. HPPI shall pay to Mayne Pharma a running royalty as set forth in Exhibit A, for each LICENSED PRODUCT(S) sold, and for each LICENSED SERVICE(S) provided, by HPPI and any SUBLICENSEE(S), based on NET SALES and NET SERVICE REVENUES for the term of this Agreement. Such payments shall be made quarterly from the FIRST COMMERCIAL SALE of a LICENSED PRODUCT occurs.

3.4 Not used.

3.5 Milestone Payments. HPPI shall pay to Mayne Pharma milestone payments as set forth in Exhibit A, upon the occurrence of the milestone events described therein whether achieved by (a) HPPI or any SUBLICENSEE with respect to a LICENSED PRODUCT in the LICENSED FIELD, or (b) Mayne Pharma or any of its sublicensees with respect to a LICENSED PRODUCT in the BCCNS FIELD. HPPI shall provide written notice to Mayne Pharma within *** of achievement of the milestones numbered 1, 2 and 3 in Exhibit A in the LICENSED FIELD. These milestone payments shall be due within *** following receipt by HPPI of an invoice therefor.

3.6 Patent Reimbursement. In accordance with Paragraph 4.1 below, HPPI will reimburse Mayne Pharma, within *** of the receipt of an invoice from Mayne Pharma and reasonable evidence of payment, for all costs associated with the preparation, filing, maintenance, and prosecution of the PATENT RIGHTS in the TERRITORY incurred by Accelas subsequent to the EFFECTIVE DATE of the Accelas Sublicense (which costs are to be reimbursed by Mayne Pharma to Accelas under the Accelas Sublicence).

3.7 Payment. All payments under this Agreement (including payments under this Article 3 and Paragraph 4.1) shall be payable within *** after HPPI receives an invoice or at any time specified for payment in this Agreement, whichever is the later. Amounts are payable in USD, and where necessary, converted at an average daily exchange rate to buy USD for the applicable calendar quarter to which that payment relates, as published in the Wall Street Journal.

3.8 Payment Information. All check payments from HPPI to Mayne Pharma shall be sent to such address which Mayne Pharma may designate in writing from time to time. Checks are to be made payable to "Mayne Pharma". Wire transfers may be made to the account which Mayne Pharma may designate in writing from time to time. HPPI shall be responsible for any and all costs associated with wire transfers.

3.9 Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the *** following the due date thereof, calculated at the annual rate of the sum of (a) *** plus (b) ***, provided however, that in no event shall said annual interest rate exceed the maximum legal interest rate for corporations. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of any party to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to termination of this Agreement as set forth in Paragraph 9.2.

3.10 Withholding tax.

(a) If any payment or deliverable under this Agreement is subject to any tax, duties, levies, charges, fees or other imposts of any kind ("**Taxes**") which HPPI is required at law to withhold, then HPPI will withhold that amount and deduct it from the payments required to be made to Mayne Pharma under this Agreement. HPPI will promptly provide to Mayne Pharma certificates or any other form of documentary evidence issued by any authority regarding the payment of any such Taxes. HPPI will sign all lawful documents as reasonably requested by Mayne Pharma as is necessary to able Mayne Pharma to take advantage of any applicable legal provision or any double taxation treaties that would result in limiting the amount of any such Taxes.

(b) Where any sum due to be paid to Mayne Pharma hereunder is subject to any withholding or similar tax, HPPI shall use its commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable it to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, HPPI shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount paid to Mayne Pharma and secure and send to Mayne Pharma the best available evidence of such payment.

(c) For any period during the term of this Agreement where there is no applicable double taxation agreement or treaty, to the extent that Mayne Pharma, acting reasonably, is not able to obtain the benefit of any amounts withheld or deducted by HPPI under this Agreement, then Mayne Pharma shall give notice of this to HPPI and HPPI must pay Mayne Pharma such additional amounts as necessary to ensure Mayne Pharma receives, when due, a net amount (after deduction or withholding of Taxes in respect of such additional amounts) equal to the full amount which Mayne Pharma would have received if no deduction or withholding had been made.

ARTICLE 4
PATENT PROSECUTION, MAINTENANCE, & INFRINGEMENT

4.1 Prosecution & Maintenance.

4.1.1 Title to all PATENT RIGHTS pursuant to this Agreement shall reside in JHU.

4.1.2 The parties acknowledge that, under the Head License, JHU shall take primary responsibility for the prosecution and maintenance of all PATENT RIGHTS in the TERRITORY. JHU shall have primary responsibility for the PATENT RIGHTS prosecuted and maintained in any jurisdiction in the TERRITORY, and at HPPI's expense, shall file, prosecute and maintain all such patents and patent applications that, subject to the terms and conditions of this Agreement, HPPI has obtained a license hereunder. Notwithstanding the forgoing, JHU shall have full and complete control over all patent prosecution matters in connection therewith under the PATENT RIGHTS in the TERRITORY, provided however, that Mayne Pharma shall (a) timely provide to HPPI copies of non-confidential official actions and written correspondence with the USPTO regarding the PATENT RIGHTS in the TERRITORY, and (b) consult with HPPI and allow HPPI an opportunity to comment, which comments Mayne Pharma will consider and as appropriate, pass onto JHU.

4.1.3 Provided Mayne Pharma has provided HPPI with at least *** advance written notice of any filing or response deadline or fee due date, by written notification to Mayne Pharma at least *** of any filing or response deadline, or fee due date (or where Mayne Pharma has not provided sufficient advance notice, such shorter period such that HPPI has at least *** to consider its election), HPPI may elect not to have a patent application filed or not to pay expenses associated with prosecuting or maintaining any patent application or patent comprising the PATENT RIGHTS, provided that HPPI pays for all costs incurred up to receipt of such notification. Failure to provide such notification can be considered to be HPPI's authorization to proceed at HPPI's expense. Upon such notification, on behalf of Mayne Pharma, JHU may file, prosecute, and/or maintain such patent applications or patent at its own expense and for its own benefit and any rights or license granted hereunder held by HPPI or any SUBLICENSEE(S) relating to the PATENT RIGHTS which comprise the subject of such patent applications or patent and/or apply to the TERRITORY, shall terminate.

4.2 Notification. Each party will notify the other promptly in writing when any infringement by another is uncovered or suspected.

4.3 Infringement.

(a) Mayne Pharma shall have the first right to enforce any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY. Subject to Paragraph 4.5A, *** will pay all reasonable costs and expenses (including reasonable attorney fees for litigation and opinion) incurred by *** in connection with such enforcement (**Enforcement Costs**). Before Mayne Pharma commences an action with respect to any infringement of such patents, HPPI acknowledges and agrees that Mayne Pharma shall give careful consideration to the views of JHU and to potential effects on the public interest in making its decision whether or not to sue. HPPI acknowledges and agrees that no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld. This right to sue for infringement shall not be used in an arbitrary or capricious manner. HPPI shall reasonably cooperate in any such litigation at *** expense, including in accordance with Paragraph 4.6. Should HPPI seek the first right to enforce any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY, then it shall notify Mayne Pharma who will seek the consent of JHU (which consent HPPI acknowledges may be withheld or granted subject to conditions by JHU acting in its discretion).

(b) If HPPI elects not to pay Enforcement Costs in respect of a particular infringement in the TERRITORY, then it shall so notify Mayne Pharma in writing within *** of receiving notice that an infringement exists, and Mayne Pharma may, in its sole judgment and at its own expense, take steps to enforce any patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover, for its own account, any damages, awards or settlements resulting therefrom, or may allow JHU to do so.

4.4 Patent Invalidity Suit. Mayne Pharma shall have the first right to defend any declaratory judgment action or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS within LICENSED FIELD in the TERRITORY. Subject to Paragraph 4.5A, *** will pay all reasonable costs and expenses (including reasonable attorney fees for litigation and opinion) incurred by *** in connection with such defense. HPPI acknowledges and agrees that no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld. Should HPPI seek the first right to defend any declaratory judgment action or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS within LICENSED FIELD in the TERRITORY, then it shall notify Mayne Pharma who will seek the consent of JHU (which consent HPPI acknowledges may be withheld or granted subject to conditions by JHU acting in its discretion).

4.5 Recovery. Any recovery by Mayne Pharma under Paragraph 4.3 shall be paid:

(a) first to *** to reimburse its Enforcement Costs; and

(b) following *** recovery of its Enforcement Costs, the Parties shall share equally in the recovery. If the Enforcement Costs exceed the recovery, then *** shall be credited against royalties payable by HPPI to Mayne Pharma hereunder in connection with sales of LICENSED PRODUCT covered in the PATENT RIGHTS which are the subject of the infringement suit in the TERRITORY, provided, however, that any such credit under this Paragraph shall not exceed *** of the royalties otherwise payable to Mayne Pharma with regard to sales in the TERRITORY in any one calendar year, with any excess credit being carried forward to future calendar years.

4.5A Joint litigation committee. Mayne Pharma shall manage the conduct of any enforcement of any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY or defense of any declaration judgment or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS within LICENSED FIELD in the TERRITORY at its sole discretion, subject to:

(a) consulting with HPPI through a joint litigation committing comprising two appointees of each of Mayne Pharma and HPPI, which committee will discuss the management and course of action with respect to such enforcement or defense, including without limitation, the selection of outside counsel, legal strategy, staff, the engagement of any third party consultants, experts or vendors, the advancement of any legal theory or basis for infringement or defense, scope of discovery, deadlines or extensions for discovery, filing of motions, taking of depositions, providing admission or stipulations, schedule for hearings, proceedings before the court, filing of appeals, commencement and conduct of settlement negotiations or any other actions affecting a Party's rights or obligations or entailing the incurring of cost or expense; and

(b) Mayne Pharma obtaining the express consent of HPPI prior to selecting counsel, bringing any suit in HPPI's name, or entering into any settlement, consent judgment or other voluntary final disposition of the suit, such consent not be unreasonably withheld, except that if JHU consents to HPPI enforcing any patent within the PATENT RIGHTS or defending any declaratory judgment action or similar proceeding alleging invalidity of any of the PATENT RIGHTS then HPPI shall manage the conduct of any such enforcement or defense but will consult with Mayne Pharma on the same terms as would have applied under Paragraph 4.5A(a) and obtain the prior written consent of Mayne Pharma prior to the events referred to in Paragraph 4.5A(b), such consent not be unreasonably withheld.

4.6 Conduct of litigation where HPPI is a party. Where it is necessary or desirable for HPPI to be named as a party in any litigation referred to in Paragraph 4.3 or 4.4, HPPI will do all acts and execute such legal papers as are reasonably requested by Mayne Pharma in connection with such litigation. The counsel selected by Mayne Pharma for the litigation (subject to the express consent of HPPI, not to be unreasonably withheld) shall represent both

HPPI and Mayne Pharma. Notwithstanding the foregoing, if due to legal conflict, the parties cannot be represented by the same counsel, then each of JHU and Mayne Pharma shall have the right to retain its own separate legal counsel, in which case, the fees of such separate legal counsel shall still be paid by HPPI.

4.7 Listing on the FDA Orange Book. At the applicable time, HPPI must use reasonable commercial efforts to list all patents comprised in the PATENT RIGHTS promptly in the FDA Orange Book for the LICENSED PRODUCT in the LICENSED FIELD.

ARTICLE 5
OBLIGATIONS OF THE PARTIES

5.1 Reports. HPPI shall provide to Mayne Pharma the following written reports according to the following schedules.

(a) HPPI shall provide quarterly Royalty Reports, substantially in the format of Exhibit B and due within *** the FIRST COMMERCIAL SALE occurs. Royalty Reports shall disclose the amount of LICENSED PRODUCT(S) and LICENSED SERVICE(S) sold, the total NET SALES and NET SERVICE REVENUES of such LICENSED PRODUCT(S) and LICENSED SERVICE(S), and the running royalties due to Mayne Pharma as a result of NET SALES and NET SERVICE REVENUES by HPPI or any SUBLICENSEE thereof. Payment of any such royalties due shall accompany such Royalty Reports.

(b) Until HPPI or any SUBLICENSEE has achieved a first commercial sale of a LICENSED PRODUCT or LICENSED SERVICE in the TERRITORY, or received FDA market approval, HPPI shall provide to Mayne Pharma semiannual Diligence Reports, due within *** following the EFFECTIVE DATE of this Agreement. These Diligence Reports shall describe the technical efforts of HPPI or SUBLICENSEE towards meeting its obligations under the terms of this Agreement.

(c) HPPI shall provide to Mayne Pharma Annual Reports within *** following the EFFECTIVE DATE of this Agreement. Annual Reports shall include:

(i) evidence of insurance as required under Paragraph 10.4, or, a statement of why such insurance is not currently required, and

(ii) notice of all FDA approvals of any LICENSED PRODUCT(S) or LICENSED SERVICE(S) obtained by HPPI or any SUBLICENSEE, the patent(s) or patent application(s) licensed under this Agreement upon which such product or service is based, and the commercial name of such product or service, or, in the alternative, a statement that no FDA approvals have been obtained.

5.2 Records. HPPI shall make and retain, for a period of *** following the period of each report required by Paragraph 5.1, true and accurate records, files and books of account containing all the data reasonably required for the full computation and verification of sales and other information required in Paragraph 5.1. Such books and records shall be in accordance with generally accepted accounting principles consistently applied. HPPI shall permit the inspection and copying of such records, files and books of account by Mayne Pharma, Accelas or their agents during regular business hours upon *** written notice to HPPI. Such inspection shall not be made more than once each calendar year. All costs of such inspection and copying shall be paid by ***, provided that if any such inspection by Mayne Pharma shall reveal that an error has been made in the amount equal to *** of such payment, such costs shall be borne by ***.

5.3 Best Efforts. HPPI is responsible for the commercialization of the LICENSED PRODUCT(S) and LICENSED SERVICE(S) in the LICENSED FIELD in the TERRITORY, including the conduct of all development programs, the submission and approval of the marketing authorizations, and payment of all associated fees and expenses, provided that JHU and Mayne Pharma must provide any assistance reasonably requested by HPPI in seeking marketing authorizations (at HPPI's expense). HPPI shall exercise best efforts to develop and to introduce the LICENSED PRODUCT(S) in the LICENSED FIELD into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgement; thereafter, until the expiration or termination of this Agreement, HPPI shall endeavor to keep LICENSED PRODUCT(S) in the LICENSED FIELD reasonably available to the public. HPPI shall also exercise reasonable efforts to develop LICENSED PRODUCT(S) suitable for different indications within the LICENSED FIELD, so that the PATENT RIGHTS can be commercialized as broadly and as speedily as good scientific and business judgement would deem possible.

5.4 Patent Acknowledgement. HPPI agrees that all packaging containing individual LICENSED PRODUCT(S) sold by HPPI or any SUBLICENSEE will be marked with the number of the applicable patent(s) licensed hereunder in accordance with patent laws in the TERRITORY.

ARTICLE 6
REPRESENTATIONS

6.1 Duties of the Parties. JHU is not a commercial organization. It is an institute of research and education. Therefore, JHU has no ability to evaluate the commercial potential of any PATENT RIGHTS or LICENSED PRODUCT or other license or rights granted in this Agreement. It is therefore incumbent upon HPPI to evaluate the rights and products in question, to examine the materials and information provided by JHU, and to determine for itself the validity of any PATENT RIGHTS, its freedom to operate, and the value of any LICENSED PRODUCTS or SERVICES or other rights granted.

6.2 PATENT RIGHTS PROVIDED "AS IS"; Representations by JHU. JHU has warranted via the Head License that it has good and marketable title to the inventions claimed under PATENT RIGHTS with the exception of certain retained rights of the United States Government, which may apply if any part of the JHU research was funded in whole or in part by the United States Government. JHU does not warrant the validity of any patents or that practice under such patents shall be free of infringement. EXCEPT AS EXPRESSLY SET FORTH IN THIS PARAGRAPH 6.2, EACH OF HPPI AND ANY SUBLICENSEE AGREE THAT THE PATENT RIGHTS ARE PROVIDED "AS IS", AND THAT EACH OF JHU, ACCELAS AND

MAYNE PHARMA MAKE NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE PERFORMANCE OF LICENSED PRODUCT(S) AND LICENSED SERVICE(S) INCLUDING THEIR SAFETY, EFFECTIVENESS, OR COMMERCIAL VIABILITY. EACH OF JHU, ACCELAS AND MAYNE PHARMA DISCLAIM ALL WARRANTIES WITH REGARD TO PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, ALL WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, JHU ADDITIONALLY DISCLAIMS ALL OBLIGATIONS AND LIABILITIES ON THE PART OF JHU AND INVENTORS, AND EACH OF ACCELAS AND MAYNE PHARMA ADDITIONALLY DISCLAIM ALL OBLIGATIONS AND LIABILTIES ON THE PART OF ACCELAS AND MAYNE PHARMA FOR DAMAGES, INCLUDING, BUT NOT LIMITED TO, DIRECT, INDIRECT, SPECIAL, AND CONSEQUENTIAL DAMAGES, ATTORNEYS' AND EXPERTS' FEES, AND COURT COSTS (EVEN IF ANY OF JHU, ACCELAS OR MAYNE PHARMA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, FEES OR COSTS), ARISING OUT OF OR IN CONNECTION WITH THE MANUFACTURE, USE, OR SALE OF THE PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT. HPPI AND ANY SUBLICENSEE ASSUME ALL RESPONSIBILITY AND LIABILITY FOR LOSS OR DAMAGE CAUSED BY A PRODUCT AND/OR SERVICE MANUFACTURED, USED, OR SOLD BY HPPI OR ANY SUBLICENSEE WHICH IS A LICENSED PRODUCT(S) OR LICENSED SERVICE(S) AS DEFINED IN THIS AGREEMENT.

6.3 Representations and Covenants of Mayne Pharma.

(a) Mayne Pharma warrants to HPPI that (i) it is entitled to grant HPPI the sublicence of the PATENT RIGHTS on the terms and conditions set out in this Agreement; and (ii) Exhibit C (with commercial in confidence information redacted) is a true and complete copy of the Accelas Sublicense; and (iii) it has not, and will not during the term of this Agreement, impose in favor of any third party any mortgage, pledge, lien, encumbrance, charge or other security interest over the Sublicense or any PATENT RIGHTS, whether that mortgage, pledge, lien, encumbrance, charge or other security interest has a material, adverse impact on HPPI's rights under this Agreement.

(b) Mayne Pharma covenants to HPPI that it will use reasonable commercial efforts to comply with its obligations under the Accelas Sublicense and will not terminate the Accelas Sublicense without cause except with the prior written consent of HPPI, such consent not to be unreasonably withheld or delayed.

ARTICLE 7
INDEMNIFICATION

7.1 Indemnification. HPPI shall be responsible for injuries or losses to third parties arising from or related to HPPI's own acts or omissions, or caused by arising from HPPI's use or third party use of LICENSED PRODUCT(S) sold by HPPI or any SUBLICENSEE and LICENSED SERVICE(S) performed by HPPI or any SUBLICENSEE, or arising as a

consequence of the exercise by HPPI or any SUBLICENSEE(S) of any rights granted in this Agreement. JHU and the Inventors will have no legal liability exposure to third parties if JHU does not license the LICENSED PRODUCT(S) and LICENSED SERVICE(S), and any royalties JHU and the Inventors may receive under the Head License is not adequate compensation for such legal liability exposure. Therefore, JHU requires HPPI to protect JHU and Inventors from such exposure to the same manner and extent to which insurance, if available, would protect JHU and Inventors. Furthermore, JHU and the Inventors will not, under the provisions of the Head License, this Agreement or otherwise, have control over the manner in which HPPI or any SUBLICENSEE(S) or those operating for its account or third parties who purchase LICENSED PRODUCT(S) or LICENSED SERVICE(S) from any of the foregoing entities, develop, manufacture, market or practice the inventions of LICENSED PRODUCT(S) and LICENSED SERVICE(S). Therefore, HPPI and any SUBLICENSEE shall indemnify, defend with counsel reasonably acceptable to JHU, and hold JHU, The Johns Hopkins Health Systems, their present and former trustees, officers, Inventors of PATENT RIGHTS, agents, faculty, employees and students harmless as against any judgments, fees, expenses, or other costs arising from or incidental to any product liability or other lawsuit, claim, demand or other action brought as a consequence of the practice of said inventions by any of the foregoing entities, whether or not JHU or said Inventors, either jointly or severally, is named as a party defendant in any such lawsuit and whether or not JHU or the Inventors are alleged to be negligent or otherwise responsible for any injuries to persons or property. Practice of the inventions covered by LICENSED PRODUCT(S) and LICENSED SERVICE(S), by an agent or any SUBLICENSEE(S) or a third party on behalf of or for the account of HPPI or by a third party who purchases LICENSED PRODUCT(S) and LICENSED SERVICE(S) from HPPI, shall be considered HPPI's practice of said inventions for purposes of this Paragraph. The obligation of HPPI to defend and indemnify as set out in this Paragraph shall survive the termination of this Agreement, shall continue even after assignment of rights and responsibilities to an AFFILIATED COMPANY (but not any other assignment by HPPI in accordance with Paragraph 10.8), and shall not be limited by any other limitation of liability elsewhere in this Agreement.

7.2 Indemnification Procedure. A party intending to claim indemnification under this Agreement ("**Indemnitee**") shall promptly notify the indemnifying party ("**Indemnitor**") in writing of any lawsuit, claim, demand or other action, or any judgments, fees, expenses or other costs in respect of which the Indemnitee intends to claim such indemnification. The Indemnitee reasonably shall cooperate with the Indemnitor in the defense of the lawsuit, claim, demand or other action, and the Indemnitor shall have the right to control the defense and/or settlement of the lawsuit, claim, demand or other action; provided, however, that any such settlement shall not require the Indemnitee to admit any liability or pay any amounts without the prior written consent of such Indemnitee. The Indemnitee shall use reasonable efforts to mitigate any fees, expenses or other costs.

ARTICLE 8
CONFIDENTIALITY

8.1 Confidentiality. If necessary, the parties will exchange information in respect of the subject matter of this Agreement, which they consider to be confidential. The recipient of such information agrees to keep it confidential provided such information is marked as confidential at the time it is sent to the recipient, or if it is disclosed orally, summarised in writing and identified as 'confidential' within *** after its presentation (provided that a failure to do so shall not detract from the obligations in this Paragraph where it was reasonably apparent that such information was confidential in nature). Without limitation, the recipient agrees to employ all reasonable efforts to maintain the information secret and confidential, such efforts to be no less than the degree of care employed by the recipient to preserve and safeguard its own confidential information. The information shall not be disclosed or revealed to anyone except employees of the recipient who have a need to know the information and who have entered into a secrecy agreement with the recipient under which such employees are required to maintain confidential the proprietary information of the recipient and such employees shall be advised by the recipient of the confidential nature of the information and that the information shall be treated accordingly.

The obligations of this Paragraph 8.1 shall also apply to any SUBLICENSEE(S) provided such information by HPPI. Mayne Pharma's, HPPI's, and SUBLICENSEES' obligations under this Paragraph 8.1 shall extend until *** after the termination of this Agreement.

The obligations of this Paragraph 8.1 shall apply to confidential information exchanged prior to, on or after the EFFECTIVE DATE in connection with this Agreement or the transactions contemplated under it. To avoid doubt, the parties agree that nothing in this Agreement detracts from the restrictions on use and disclosure of confidential information under the Second Amended and Restated Supply and License Agreement, dated May 15, 2015, by and between Mayne Pharma Ventures Pty Ltd., an Affiliated Company of Mayne Pharma, and HPPI.

8.2 Exceptions. The recipient's obligations under Paragraph 8.1 shall not extend to any part of the information:

(a) that can be demonstrated to have been in the public domain or publicly known and readily available to the trade or the public prior to the date of the disclosure; or

(b) that can be demonstrated, from written records to have been in the recipient's possession or readily available to the recipient from another source not under obligation of secrecy to the disclosing party prior to the disclosure; or

(c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by the recipient; or

(d) that is demonstrated from written records to have been developed by or for the receiving party without reference to confidential information disclosed by the disclosing party.

(e) that is required to be disclosed by law, government rule or regulation or court or arbitration order, or any applicable stock exchange.

8.3 Right to Publish. JHU may publish manuscripts, abstracts or the like describing the PATENT RIGHTS and inventions contained therein provided confidential information of HPPI as contemplated in Paragraph 8.1, is not included or without first obtaining approval from HPPI to include such confidential information. Otherwise, JHU and the Inventors shall be free to publish manuscripts and abstracts or the like directed to the work done at JHU related to the licensed technology without prior approval.

ARTICLE 9
TERM & TERMINATION

9.1 Term. The term of this Agreement shall commence on the EFFECTIVE DATE and shall continue until the earlier of: (a) the date of expiration of the last to expire patent included within PATENT RIGHTS in the TERRITORY; or (b) notice by Mayne Pharma with immediate effect promptly after termination or expiry of the Head License or Accelas Sublicense in circumstances where Mayne Pharma no longer has the right to obtain an EXCLUSIVE LICENSE to make, have made, use, import, offer for sale and sell the LICENSED PRODUCT(S) and to provide the LICENSED SERVICE(S) in the TERRITORY under the PATENT RIGHTS in the LICENSED FIELD.

9.2 Termination By Either Party. This Agreement may be terminated by either party giving written notice to the other party, with effect immediately (or any later date specified in the notice), in the event that the other party (a) files or has filed against it a petition under the Bankruptcy Act, makes an assignment for the benefit of creditors, has a receiver appointed for it or a substantial part of its assets, otherwise takes advantage of or has any action taken in respect of it under any statute or law designed for relief of debtors, or (having regard to its legal structure and the jurisdiction in which it is incorporated or operates) any event analogous to one of the foregoing events happens to it or (b) fails to perform or otherwise breaches any of its obligations hereunder, if either (i) following the giving of notice by the terminating party of its intent to terminate and stating the grounds therefor, the party receiving such notice shall not have cured the failure or breach within *** or (ii) that failure to perform or breach is not capable of being cured. In no event, however, shall such notice or intention to terminate be deemed to waive any rights to damages or any other remedy which the party giving notice of breach may have as a consequence of such failure or breach.

9.3 Termination by Mayne Pharma. Mayne Pharma may terminate this Agreement with immediate effect by notice to HPPI if the THIRD SLA expires or is terminated.

9.4 Obligations and Duties upon Termination. If this Agreement is terminated, both parties shall be released from all obligations and duties imposed or assumed hereunder to the extent so terminated, except as expressly provided to the contrary in this Agreement. Upon termination, both parties shall cease any further use of the confidential information disclosed to the receiving party by the other party. Termination of this Agreement, for whatever reason, shall not affect the obligation of either party to make any payments for which it is liable prior to or upon such termination. Termination shall not affect Mayne Pharma's right to recover unpaid royalties, fees, reimbursement for patent expenses, or other forms of financial compensation incurred prior to termination. Upon termination HPPI shall submit a final royalty report to Mayne Pharma and any royalty payments, fees, unreimbursed patent expenses and other financial compensation due Mayne Pharma shall become immediately payable. Furthermore, upon termination of this Agreement, as between Mayne Pharma and HPPI, all rights in and to the licensed technology shall revert immediately to Mayne Pharma at no cost to Mayne Pharma.

ARTICLE 10
MISCELLANEOUS

10.1 Use of Name. HPPI and any SUBLICENSEE shall not use the name of The Johns Hopkins University or The Johns Hopkins Health System or any of its constituent parts, such as the Johns Hopkins Hospital or any contraction thereof or the name of Inventors in any advertising, promotional, sales literature or fundraising documents without prior written consent from an authorized representative of JHU. HPPI and any SUBLICENSEE(S) shall allow at least *** notice of any proposed public disclosure for JHU's review and comment or to provide written consent.

10.2 No Partnership. Nothing in this Agreement shall be construed to create any agency, employment, partnership, joint venture or similar relationship between the parties other than that of a licensor/licensee. Neither party shall have any right or authority whatsoever to incur any liability or obligation (express or implied) or otherwise act in any manner in the name or on the behalf of the other, or to make any promise, warranty or representation binding on the other.

10.3 Notice of Claim. Each party shall give the other or its representative immediate notice of any suit or action filed, or prompt notice of any claim made, against them arising out of the performance of this Agreement or arising out of the practice of the inventions licensed hereunder.

10.4 Product Liability. Prior to initial human testing or first commercial sale of any LICENSED PRODUCT(S) or LICENSED SERVICE(S) in the LICENSED FIELD in the TERRITORY, HPPI shall establish and maintain product liability or other appropriate insurance coverage in the minimum amount of *** per claim and will annually present evidence to JHU or Mayne Pharma that such coverage is being maintained. Upon JHU's or Mayne Pharma's request, HPPI will furnish it with a Certificate of Insurance of each product liability insurance policy obtained. JHU shall be listed as an additional insured in HPPI's said insurance policies. If such Product Liability insurance is underwritten on a 'claims made' basis, HPPI agrees that any change in underwriters during the term of this Agreement will require the purchase of 'prior acts' coverage to ensure that coverage will be continuous throughout the term of this Agreement.

10.5 Governing Law. For consistency with the Head License which is with JHU (a Maryland corporation) and are governed by the laws of the State of Maryland, and for consistency with the Accelas Sublicense which is governed by the laws of the State of Maryland, this Agreement shall be construed, and legal relations between the parties hereto shall be determined, in accordance with the laws of the State of Maryland applicable to contracts solely executed and wholly to be performed within the State of Maryland without giving effect to the principles of conflicts of laws. EACH PARTY WAIVES ALL RIGHTS TO ANY TRIAL BY JURY IN ALL LITIGATION RELATING TO OR ARISING OUT OF THIS AGREEMENT.

10.5A Resolution of Disputes. A party must not start court proceedings (except proceedings seeking interlocutory relief for the protection of intellectual property or confidential information, or proceedings in relation to debt recovery) for a dispute arising out of this Agreement, including the breach, termination or invalidity of this Agreement, (**"Dispute"**) unless it has complied with this Paragraph 10.5A. A party claiming that a Dispute has arisen must notify the other party giving details of the Dispute. When such a notice is given, each party's respective representatives must first attempt to resolve the Dispute and, if they cannot resolve the Dispute within *** after the notice is given, they must refer the Dispute to each party's chief executive officer who must then attempt to resolve it. If the parties cannot resolve the Dispute within six weeks after the notice of the Dispute is given (or longer period if the parties to the Dispute agree in writing), either party may refer the Dispute to arbitration. If either party exercises that right, the Dispute must be settled by arbitration in accordance with the expedited procedure set out in the Singapore International Arbitration Centre Rules for Arbitration, as at present in force and as may be amended by the rest of this Paragraph 10.5A. The place of arbitration will be Singapore. There will only be one arbitrator. The arbitration must be conducted in English. The decision of the arbitrator shall be final and binding and any award rendered thereon may be entered in any court having jurisdiction. The parties hereby waive any and all objections and defenses to such jurisdiction regardless of the nature of such objection or defense.

10.6 Notice. All notices or communication required or permitted to be given by either party hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, to the other party at its respective address set forth below or to such other address as one party shall give notice of to the other from time to time hereunder.

If to Mayne Pharma:	General Counsel Mayne Pharma International Pty Ltd 1538 Main North Road, Salisbury South, SA 5106 Melbourne Vic 3000 Australia Facsimile: +61 3 9614 7022
If to HPPI:	President and CEO HedgePath Pharmaceuticals, Inc. 324 South Hyde Park Avenue Suite 350 Tampa, FL 33606, United States Facsimile: +1 813-527-0500

A notice given in accordance with Paragraph 10.6 takes effect when taken to be received (or at a later time specified in it), and is taken to be received: (i) if hand delivered or sent by reputable international courier, on delivery; (ii) if sent by prepaid post, on the second business day after the date of posting (or on the seventh business day after the date of posting if posted to or from a place outside Australia); or (iii) if sent by facsimile, when the sender's facsimile system generates a message confirming successful transmission of the entire notice unless, within 8 business hours after the transmission, the recipient informs the sender that it has not received the entire notice, but if the delivery, receipt or transmission is not on a business day or is after 5.00pm on a business day, the notice is taken to be received at 9.00am on the next business day.

10.7 Compliance with All Laws. In all activities undertaken pursuant to this Agreement, both Mayne Pharma and HPPI covenant and agree that each will in all material respects comply with such Federal, state and local laws and statutes, as may be in effect at the time of performance and all valid rules, regulations and orders thereof regulating such activities.

10.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein, except for the right to receive any remuneration hereunder, may be assigned or novated by either party, in whole or in part, without the prior written consent of the other party (which consent must not be unreasonably withheld or delayed), except that either party shall be free to assign or novate this Agreement in connection with any sale of substantially all of its assets without the consent of the other and Mayne Pharma shall be free to assign or novate this Agreement to an AFFILIATED COMPANY who is an assignee of Mayne Pharma's rights and obligations under the Accelas Sublicense. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the parties hereto.

10.9 No Waivers; Severability. No waiver of any breach of this Agreement shall constitute a waiver of any other breach of the same or other provision of this Agreement, and no waiver shall be effective unless made in writing. Any provision hereof prohibited by or unenforceable under any applicable law of any jurisdiction shall as to such jurisdiction be deemed ineffective and deleted herefrom without affecting any other provision of this Agreement. It is the desire of the parties hereto that this Agreement be enforced to the maximum extent permitted by law, and should any provision contained herein be held by any governmental agency or court of competent jurisdiction to be void, illegal and unenforceable, the parties shall negotiate in good faith for a substitute term or provision which carries out the original intent of the parties.

10.10 Entire Agreement; Amendment. HPPI and Mayne Pharma acknowledge that they have read this entire Agreement and that this Agreement, including the attached Exhibits constitutes the entire understanding and contract between the parties hereto and supersedes any and all prior or contemporaneous oral or written agreements or communications with respect to the subject matter hereof, all of which agreements and communications are merged herein. It is expressly understood and agreed that (i) there being no expectations to the contrary between the parties hereto, no usage of trade, verbal agreement or another regular practice or method dealing within any industry or between the parties hereto shall be used to modify, interpret, supplement or alter in any manner the express terms of this Agreement; and (ii) this Agreement shall not be modified, amended or in any way altered except by an instrument in writing signed by both of the parties hereto.

10.11 Delays or Omissions. Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any party hereto, shall impair any such right, power or remedy to such party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or in any similar breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or

approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

10.12 Force Majeure. If either party fails to fulfill its obligations hereunder (other than an obligation for the payment of money), when such failure is due to an act of God, or other circumstances beyond its reasonable control, including but not limited to fire, flood, civil commotion, riot, war (declared and undeclared), revolution, or embargoes, then said failure shall be excused for the duration of such event and for such a time thereafter as is reasonable to enable the parties to resume performance under this Agreement, provided however, that in no event shall such time extend for a period of more than ***. If a failure to perform continues for more than ***, the other party may terminate this Agreement immediately by giving notice to the affected party.

10.13 Further Assurances. Each party shall, at any time, and from time to time, prior to or after the EFFECTIVE DATE of this Agreement, at reasonable request of the other party, execute and deliver to the other such instruments and documents and shall take such actions as may be required to more effectively carry out the terms of this Agreement.

10.14 Survival. All representations, warranties, covenants and agreements made herein and which by their express terms or by implication are to be performed after the execution and/or termination hereof, or are prospective in nature, shall survive such execution and/or termination, as the case may be. This shall include Paragraph 3.7 (Payment), 3.10 (Withholding tax) 5.2 (Records), and Articles 6, 7, 8, 9.4 and 10, and Paragraphs 4.3 to 4.6 where Mayne Pharma elects to continue with such litigation after execution and/or termination.

10.15 No Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any person, firm, corporation or other entity, other than the parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof, except as expressly set out in this Agreement.

10.16 Headings. Article headings are for convenient reference and not a part of this Agreement. All Exhibits are incorporated herein by this reference.

10.17 Counterparts. This Agreement may be executed in counterparts (including electronic counterparts), each of which shall be deemed an original and all of which when taken together shall be deemed but one instrument. Delivery of an executed signature page of this agreement by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

10.18 Costs. Each party must bear its own costs of preparing and executing this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, Mayne Pharma and HPPI have duly executed this Amended and Restated Sublicense Agreement as of the date first written above.

MAYNE PHARMA INTERNATIONAL PTY LTD

/s/ Nick Freeman
Scott Richards
Director

December 17, 2018
(Date)

HEDGEPATH PHARMACEUTICALS, INC.

/s/ Nicholas J. Virca
Nicholas J. Virca
President and CEO

December 17, 2018
(Date)

EXHIBIT A

License fee: ***.

Minimum annual royalty: *** per year, commencing in accordance with Paragraph 3.2.

Royalty: *** of NET SALES of an itraconazole LICENSED PRODUCT in the LICENSED FIELD and NET SERVICE REVENUES in the LICENSED FIELD in the TERRITORY where a patent comprised in the PATENT RIGHTS is and remains registered at the time the relevant sales revenues and fees are billed.

Where an itraconazole LICENSED PRODUCT has exclusivity in the LICENSED FIELD in the TERRITORY due solely to the PATENT RIGHTS, a further royalty supplement of *** of NET SALES and NET SERVICE REVENUES in the TERRITORY except that where Accelas, itself or through any third party, imports, promotes, distributes or sells any product substantially the same as, or similar to, or substitutable for, the LICENSED PRODUCT or providers services substantially the same as, or similar to, the LICENSED SERVICES, in each case in the LICENSED FIELD in the TERRITORY, in which case no royalty supplement applies. .

Milestone Payments: HPPI shall pay to Mayne Pharma the milestone payments set forth below**, in each case payable only** provided that any claim in the HEDGEHOG PATENT in the TERRITORY directed to administering orally itraconazole remains valid at the time payment falls due**:**

***

EXHIBIT B

Royalty Report

***

EXHIBIT C

Accelas Sublicense

AGREEMENT

This **AGREEMENT** (this "Agreement") is entered into by and among **HEDGEPATH PHARMACEUTICALS, INC.**, a Delaware corporation ("HPPI"), **MAYNE PHARMA VENTURES PTY LTD**, an Australian company ACN 168 896 357 ("Mayne Pharma"), and **MAYNE PHARMA INTERNATIONAL PTY LTD**, an Australian company ACN 007 870 984 ("Mayne Pharma International" and together with Mayne Pharma, collectively, the "Mayne Pharma Companies" and each, a "Mayne Pharma Company"), effective December 17, 2018 (the "Effective Date"). Any capitalized term used herein but not otherwise defined shall have the meaning ascribed to such term in the Existing Supply and License Agreement (as hereinafter defined).

RECITALS

WHEREAS, HPPI and Mayne Pharma are parties to that certain Second Amended and Restated Supply and License Agreement, dated as of May 15, 2015, as amended by that certain Amendment No. 1 to Second Amended and Restated Supply and License Agreement, effective as of November 22, 2016 and that certain Amendment No. 2 to Second Amended and Restated Supply and License Agreement and Amendment No. 1 to Sublicense Agreement, effective as of January 10, 2018 (the "Existing Supply and License Agreement");

WHEREAS, HPPI and Mayne Pharma International are parties to that certain Sublicense Agreement, dated August 31, 2015, as amended by that certain Amendment No. 2 to Second Amended and Restated Supply and License Agreement and Amendment No. 1 to Sublicense Agreement, effective as of January 10, 2018 (the "Existing Angiogenesis and Hedgehog Patent Sublicense Agreement");

WHEREAS, pursuant to that certain Securities Purchase Agreement, dated as of January 8, 2018, by and between HPPI and Mayne Pharma, HPPI (i) filed with the Secretary of State of Delaware a Certificate of Designation of Series B Convertible Preferred Stock of HedgePath Pharmaceuticals, Inc., as corrected by a Certificate of Correction of Certificate of Designation of Series B Convertible Preferred Stock of HedgePath Pharmaceuticals, Inc. (the "Series B Certificate of Designation"), and (ii) issued to Mayne Pharma 5,797,102 shares (the "Series B Preferred Shares") of Series B Convertible Preferred Stock, par value $0.0001 per share (the "Series B Preferred Stock"), of HPPI;

WHEREAS, pursuant to Section 5.3 of the Existing Supply and License Agreement and Section 10.19 of the Existing Angiogenesis and Hedgehog Patent Sublicense Agreement, within sixty days from the date Mayne Pharma receives written notice of a Target Failure or, failing timely provision of such notice, on Mayne Pharma becoming aware of such Target Failure, Mayne Pharma, among other things, may, by notice to HPPI elect to assume the right to, on its own and at its sole cost and expenses, exploit any Product solely in the BCCNS Field in the Territory and Mayne Pharma International may, by notice to HPPI elect to exclude the BCCNS Field from the Licensed Field (as defined in the Existing Angiogenesis and Hedgehog Patent Sublicense Agreement) (collectively, the "Mayne BCCNS Assumption Right");

WHEREAS, each of the Existing Supply and License Agreement and the Existing Angiogenesis and Hedgehog Patent Sublicense Agreement provides that a "Target Failure" means the earlier to occur of (i) December 31, 2018, if the FDA has not accepted the filing of the NDA by

such date; provided that such date shall be automatically extended in the event that the NDA is filed with the FDA during December 2018 to a date which is 30 days from the date of such filing and (ii) the Target Launch Date, if the commercial launch of Licensed Product in the Territory in the BCCNS Field has not been achieved by HPPI by such date;

WHEREAS, on October 9, 2018, HPPI publicly announced that it anticipated filing its NDA for SUBA BCCNS with the FDA in the first quarter of 2019;

WHEREAS, while exploring alternatives to file the NDA for SUBA BCCNS so as to avoid a "Target Failure", the Board of Directors of HPPI formed a committee comprised of disinterested directors who are independent of Mayne Pharma (the "Independent Committee") to evaluate, negotiate and approve or disapprove of any potential transaction with Mayne Pharma with respect to the Mayne BCCNS Assumption Right and related matters;

WHEREAS, after exploring all alternatives in the exercise of their business judgment, the Independent Committee has (i) negotiated the terms and conditions of this Agreement and the agreements and transactions contemplated hereby on behalf of HPPI, (ii) determined that it is advisable and in the best interests of HPPI and its stockholders other than Mayne Pharma to enter into this Agreement and consummate the transactions contemplated hereby and (iii) approved the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby;

WHEREAS, in furtherance of the foregoing, HPPI and Mayne Pharma desire to amend and restate the Existing Supply and License Agreement to effect certain amendments thereto, upon the terms and subject to the conditions set forth in a Third Amended and Restated Supply and License Agreement, in the form attached hereto as Exhibit A (the "Third Amended and Restated Supply and License Agreement");

WHEREAS, in furtherance of the foregoing, HPPI and Mayne Pharma International desire to amend and restate the Existing Angiogenesis and Hedgehog Patent Sublicense Agreement to effect certain amendments thereto, upon the terms and subject to the conditions set forth in an Amended and Restated Sublicense Agreement, in the form attached hereto as Exhibit B (the "Amended and Restated Sublicense Agreement");

WHEREAS, in furtherance of the foregoing, HPPI and Mayne Pharma desire to amend and restate the Series B Certificate of Designation to effect certain amendments thereto; and

WHEREAS, as part of the integrated transactions contemplated by the foregoing, HPPI desires for Mayne Pharma to agree, and Mayne Pharma has agreed, to undertake certain actions with respect to HPPI in the manner as set forth herein.

NOW, THEREFORE, in consideration of the promises and agreements of the parties hereto and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, the parties hereto hereby agree as follows:

1. Definitions. In addition to the terms defined elsewhere in this Agreement, the following terms used in this Agreement shall be construed to have the meanings set forth or referenced below:

1.1 "DGCL" means the Delaware General Corporation Law.

1.2 "Equity Holders Agreement" means that certain Amended and Restated Equity Holders Agreement, dated as of May 15, 2015, as amended by Amendment No. 1 to the Amended and Restated Equity Holders Agreement dated December 17, 2015, by and among Mayne Pharma, HPPI and the other parties thereto.

1.3 "Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended.

1.4 "SEC" means the U.S. Securities and Exchange Commission.

1.5 "Transaction Documents" means this Agreement, the Third Amended and Restated Supply and License Agreement, the Amended and Restated Sublicense Agreement and the Restated Series B Certificate of Designation (as defined in Section 4.5 hereof).

2. Third Amended and Restated Supply and License Agreement. Concurrently with the execution and delivery of this Agreement, (a) Mayne Pharma shall deliver to HPPI a duly executed counterpart to the Third Amended and Restated Supply and License Agreement and (b) HPPI shall deliver to Mayne Pharma a duly executed counterpart to the Third Amended and Restated Supply and License Agreement. The effectiveness of the Third Amended and Restated Supply and License Agreement shall not be conditioned on the effectiveness of any other transaction or action contemplated by this Agreement.

3. Amended and Restated Sublicense Agreement. Concurrently with the execution and delivery of this Agreement, (a) Mayne Pharma International shall deliver to HPPI a duly executed counterpart to the Amended and Restated Sublicense Agreement and (b) HPPI shall deliver to Mayne Pharma International a duly executed counterpart to the Amended and Restated Sublicense Agreement. The effectiveness of the Amended and Restated Sublicense Agreement shall not be conditioned on the effectiveness of any other transaction or action contemplated by this Agreement.

4. Restated Series B Certificate of Designation, Election of HPPI Board and Increase in EIP.

4.1 Immediately following the execution and delivery of this Agreement, Mayne Pharma (in its capacity as the holder of more than 50% of the outstanding voting securities of HPPI) shall execute and deliver to HPPI a stockholder consent in lieu of a special meeting of the stockholders of HPPI (the "Stockholder Consent") to vote or cause to be voted all of the shares of common stock, par value $0.0001 per share, of HPPI (the "Common Stock"), and all Series B Preferred Shares held by Mayne Pharma in favor of: (a) the adoption of the Restated Series B Certificate of Designation, (b) the election of each Current Director (as defined in Section 5.2 hereof) to serve on the Board of Directors of HPPI for a one-year term that expires at the next annual meeting of HPPI's stockholders or until his earlier death, resignation or removal and (c) the approval of an increase in the size of HPPI's 2014 Equity Incentive Plan (the "EIP") by 11,000,000 shares of Common Stock from 32,583,475 shares to 43,583,475 shares; provided, however, that neither this Section 4.1 nor Mayne Pharma's execution and delivery of the Stockholder Consent contemplated hereby shall in any way limit, or be construed as any waiver of, any of Mayne Pharma's rights under the Equity Holders Agreement.

4.2 As soon as practicable following HPPI's receipt of the Stockholder Consent contemplated by Section 4.1 of this Agreement, HPPI shall prepare and file with the SEC a written information statement of the type contemplated by Rule 14c-2 of the Exchange Act containing the information specified in Schedule 14C under the Exchange Act concerning the actions taken pursuant to the Stockholder Consent (as amended and supplemented, the "Information Statement") and thereafter shall promptly mail to HPPI's stockholders notice of such action by written consent as required by Section 228(e) of the DGCL. HPPI and Mayne Pharma will cooperate and consult with each other in the preparation of the Information Statement. HPPI agrees that it will not file the Information Statement, or any amendment or supplement thereto, with the SEC without providing Mayne Pharma and its counsel a reasonable opportunity to review and comment thereon (which comments shall be reasonably considered by HPPI).

4.3 HPPI agrees to use its commercially reasonable efforts to ensure that the Information Statement (a) except for information provided to HPPI by Mayne Pharma, will not on the date it is first mailed to the stockholders of HPPI contain any untrue statement of a material fact or omit to state any material fact required to be stated therein in order to make the statements therein, in light of the circumstances under which they are made, not misleading and (b) will comply as to form in all material respects with the applicable requirements of the Exchange Act. If, at any time prior to the date that is twenty (20) days after the Information Statement is first mailed to the stockholders of HPPI, any information relating to HPPI or Mayne Pharma or any of their respective Affiliates, officers or directors should be discovered by HPPI or Mayne Pharma which is required to be set forth in an amendment or supplement to the Information Statement, so that the Information Statement shall not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading, the party hereto that discovers such information shall promptly notify the other parties hereto, and an appropriate amendment or supplement describing such information shall be filed with the SEC and, to the extent required by applicable law, disseminated to the stockholders of HPPI.

4.4 HPPI agrees to (a) notify Mayne Pharma and its counsel, as soon as reasonably practicable, of the receipt of any comments from the SEC with respect to the Information Statement and any request by the SEC for any amendment to the Information Statement or for additional information and (b) provide Mayne Pharma and its counsel with copies of all written correspondence between HPPI and the SEC with respect to the Information Statement. HPPI agrees to use its commercially reasonable efforts to resolve, and each of HPPI and Mayne Pharma agrees to consult and cooperate with the other in resolving, all SEC comments with respect to the Information Statement as promptly as practicable after receipt thereof and to cause the Information Statement in definitive form to be cleared by the SEC and mailed to the stockholders of HPPI as promptly as reasonably practicable following filing with the SEC. HPPI agrees to consult with Mayne Pharma prior to responding to SEC comments with respect to the preliminary Information Statement.

4.5 As soon as twenty (20) calendar days have elapsed since HPPI mailed to its stockholders the Information Statement in definitive form as contemplated by Rule 14c-2 promulgated under the Exchange Act, HPPI shall adopt and file with the Secretary of State of Delaware an Amended and Restated Certificate of Designation of Series B Convertible Preferred Stock, in the form attached hereto as Exhibit C (the "Restated Series B Certificate of Designation").

5. Additional Agreements.

5.1 From the period beginning on the Effective Date and ending three (3) years from the Effective Date, in the event that HPPI asks its stockholders (whether at a meeting of stockholders or pursuant to a written consent of stockholders) to vote on or approve a proposal to effect a reverse split of HPPI's capital stock for the purpose of uplisting the Common Stock to a U.S. national securities exchange (a "Reverse Stock Split Proposal"), the Mayne Pharma Companies (on behalf of themselves and all entities identified as "Reporting Persons" in Mayne Pharma's Schedule 13D/A filed with the U.S. Securities and Exchange Commission on November 5, 2018 (together with the Mayne Pharma Companies and the officers, directors, employees, affiliates, agents or representatives of such entities, the "Mayne Pharma Group") agrees to vote or cause to be voted (in person, by proxy or by action by written consent, as applicable) all shares of HPPI's voting capital stock that either Mayne Pharma Company then owns or over which Mayne Pharma has voting control in favor of the adoption and approval of any such Reverse Stock Split Proposal. It is agreed that the Reverse Stock Split Proposal may take the form of an authorization based on a range of ratios for the reverse stock split, with authority being granted to the HPPI Board of Directors (or a designated committee thereof) to determine the final ratio of the reverse stock split, provided such range is reasonable in connection with the uplisting of the Common Stock to a U.S. national securities exchange.

5.2 Effective upon and subject to the full execution and delivery by the applicable parties of each of this Agreement, the Third Amended and Restated Supply and License Agreement and the Amended and Restated Sublicense Agreement, and in accordance with Section 4.9(b)(iv) of the Equity Holders Agreement, Mayne Pharma hereby consents and agrees to an increase in the number of shares of Common Stock that HPPI may issue under the EIP to 17,624,000 shares from the current limit of 6,624,000 shares, with the agreement and understanding that such increase will be utilized by HPPI during the period from the Effective Date through December 31, 2021.

5.3 Following the execution and delivery of this Agreement, HPPI and Mayne Pharma shall jointly issue a mutually agreeable press release announcing this Agreement and the transactions contemplated hereby (the "Joint Press Release"). Neither HPPI nor any member of the Mayne Pharma Group shall make any public statements inconsistent with the Joint Press Release, except as required by law or the rules of any stock exchange.

6. Representations and Warranties.

6.1 Representations and Warranties of Mayne Pharma. The Mayne Pharma Companies hereby jointly and severally represent and warrant to HPPI as of the date hereof as follows:

(a) Organization; Authorization; Enforceability. Each Mayne Pharma Company is a company duly organized, validly existing and in good standing under the laws of Australia. Each Mayne Pharma Company has the full right, company power, and authority to enter into this Agreement and the other Transaction Documents to which it is a party and to consummate the transactions contemplated hereby and thereby and otherwise to carry out its obligations hereunder and thereunder. With respect to each Mayne Pharma Company, the execution, delivery and performance of this Agreement and the other Transaction Documents to which it is a party and

the performance by each such Mayne Pharma Company of the transactions contemplated by hereby and thereby have been duly authorized by all necessary company action on the part of such Mayne Pharma Company. With respect to each Mayne Pharma Company, each of this Agreement and the other Transaction Documents to which it is a party has been duly executed by such Mayne Pharma Company, and when delivered by such Mayne Pharma Company in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Mayne Pharma Company, enforceable against it in accordance with its terms.

(b) No Conflicts. The execution, delivery and performance by each Mayne Pharma Company of this Agreement and the other Transaction Documents to which it is a party and the consummation by such Mayne Pharma Company of the transactions contemplated hereby and thereby do not and will not: (i) conflict with or violate any provision of such Mayne Pharma Company's organizational or charter documents or (ii) conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any governmental authority to which such Mayne Pharma Company is subject or by which any property or asset of such Mayne Pharma Company is bound or affected.

(c) Litigation. There is no action, pending or, to the knowledge of each Mayne Pharma Company, threatened in writing against such Mayne Pharma Company which, individually or in the aggregate, challenges the legality, validity or enforceability of this Agreement or any of the other Transaction Documents to which it is a party.

6.2 Representations and Warranties of HPPI. HPPI hereby represents and warrants to Mayne Pharma as of the date hereof as follows:

(a) Organization; Authorization; Enforceability. HPPI is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware. HPPI has the requisite corporate power and authority to enter into this Agreement and the other Transaction Documents and to consummate the transactions contemplated hereby and thereby and otherwise to carry out its obligations hereunder and thereunder. The execution, delivery and performance of this Agreement and the other Transaction Documents and the performance by HPPI of the transactions contemplated by hereby and thereby have been duly authorized by all necessary corporate action on the part of HPPI. Each of this Agreement and the other Transaction Documents has been duly executed by HPPI, and when delivered by HPPI in accordance with the terms hereof, will constitute the valid and legally binding obligation of HPPI, enforceable against it in accordance with its terms.

(b) No Conflicts. The execution, delivery and performance by HPPI of this Agreement and the other Transaction Documents to which it is a party and the consummation by HPPI of the transactions contemplated hereby and thereby do not and will not: (i) conflict with or violate any provision of HPPI's certificate of incorporation, bylaws or other organizational or charter documents or (ii) conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any governmental authority to which HPPI is subject or by which any property or asset of HPPI is bound or affected.

(c) Litigation. There is no action, pending or, to the knowledge of HPPI, threatened in writing against HPPI which, individually or in the aggregate, challenges the legality, validity or enforceability of this Agreement or any of the other Transaction Documents.

7. Miscellaneous.

7.1 Fees and Expenses. Except as expressly set forth in the Transaction Documents, each party hereto shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement.

7.2 Entire Agreement. This Agreement, together with the exhibits hereto, and the other Transaction Documents, together with the annexes, exhibits and schedules thereto, contain the entire understanding of the parties hereto with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

7.3 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the duly authorized representatives of HPPI and Mayne Pharma or, in the case of a waiver, by the duly authorized representative of the party hereto against whom enforcement of any such waived provision is sought. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party hereto to exercise any right hereunder in any manner impair the exercise of any such right.

7.4 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

7.5 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their successors and permitted assigns. No party hereto may assign this Agreement or any rights or obligations hereunder without the prior written consent of the other parties hereto.

7.6 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

7.7 Governing Law. This Agreement and any dispute arising hereunder 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 that would result in the application of the laws of another jurisdiction.

7.8 Counterparts; Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party hereto and delivered to each other party hereto, it being understood that the parties hereto need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof. The words "execute," "execution," "signed," "signature," and words of like import in or related to any document to be signed in

connection with this Agreement and the transactions contemplated hereby (other than any stock certificates or the warrants) shall be deemed to include electronic signatures, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature, to the extent and as provided for in any applicable law.

7.9 Severability. If any term, provision, covenant or restriction of this Agreement or any of the Transaction Documents is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

7.10 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each party hereto shall be entitled to specific performance under this Agreement and the transactions contemplated hereby. Each party hereto agrees that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in this Agreement and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

7.11 Dispute Resolution. In the event of any action, question or disagreement arising from or relating to this Agreement, the parties hereto agree to settle such action, question or disagreement by arbitration before three arbitrators in New York, New York, selected by, and such arbitration to be administered by, the American Arbitration Association ("AAA") in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Each of the parties hereto agrees and acknowledges that all actions, questions or disagreements between or among them arising from or relating to this Agreement are subject to the alternative dispute resolution procedures of this Section 7.11. Each of the parties hereto agrees that any aspect of alternative dispute resolution not specifically covered in this Agreement shall be covered, without limitation, by the applicable AAA rules and procedures. Each of the parties hereto further agrees that any determination by the arbitrator regarding any action, question or disagreement arising from or relating to this Agreement shall be final and binding upon the parties hereto and shall not be subject to further appeal.

[Signature page follows]

IN WITNESS WHEREOF, HPPI, Mayne Pharma and Mayne Pharma International have duly executed this Agreement as of the date first written above.

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca
Name: Nicholas J. Virca
Title: President and CEO

MAYNE PHARMA VENTURES PTY LTD

By: /s/ Nick Freeman
Name: Nick Freeman
Title: Authorized Signatory

MAYNE PHARMA INTERNATIONAL PTY LTD

By: /s/ Nick Freeman
Name: Nick Freeman
Title: Authorized Signatory

EXHIBIT A

FORM OF THIRD AMENDED AND RESTATED SUPPLY AND LICENSE AGREEMENT

A-2

EXHIBIT B

FORM OF AMENDED AND RESTATED SUBLICENSE AGREEMENT

EXHIBIT C

FORM OF RESTATED SERIES B CERTIFICATE OF DESIGNATION

C-1

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 March 7, 2019 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, 2018 and 2017, and the related statements of operations, stockholders' equity and cash flows for the years then ended.

/s/ Cherry Bekaert LLP

Tampa, Florida
March 7, 2019

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: March 7, 2019

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

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a)

I, Garrison J. Hasara, hereby certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 7, 2019

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

Exhibit 32.1

CERTIFICATION

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

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

(1) The Annual Report on Form 10-K for the year ended December 31, 2018 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 7, 2019

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

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

Exhibit 32.2

CERTIFICATION

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

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

(1) The Annual Report on Form 10-K for the year ended December 31, 2018 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 7, 2019

/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.