## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2015

□ 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 (State or other jurisdiction of incorporation or organization)

324 S. Hyde Park Avenue Ste. 350 Tampa, FL (Address of principal executive offices) 30-0793665 (I.R.S. Employer Identification No.)

> 33606 (Zip Code)

Registrant's telephone number (including area code): 813-864-2559

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\boxtimes$  No  $\square$ 

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

Large accelerated filer			Accelerated filer	
Non-accelerated filer	$\Box$ (Do not check if a smaller reporting company)		Smaller reporting company	X
Indicate by check ma	rk whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Ye	es 🗆 N	No 🗵	
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As of August 14, 2015, there were 245,353,270 shares of company common stock issued and outstanding.

## HedgePath Pharmaceuticals, Inc.

## Quarterly Report on Form 10-Q

## TABLE OF CONTENTS

Part I. Fir	nancial Information	Page
Item 1.	Financial Statements (unaudited)	
	Condensed Balance Sheets as of June 30, 2015 and December 31, 2014	1
	Condensed Statements of Operations for the three and six month periods ended June 30, 2015 and 2014	2
	Condensed Statement of Stockholders' Equity for the six months ended June 30, 2015	3
	Condensed Statements of Cash Flows for the six months ended June 30, 2015 and 2014	4
	Notes to Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	10
Item 4.	Controls and Procedures	10
Cautionary	y Note on Forward Looking Statements	11
<u>Part II. O</u>	ther Information	
Item 1	Legal Proceedings	12
Item 1A.	<u>Risk Factors</u>	12
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	12
Item 3	Defaults upon Senior Securities	12
Item 4	Mine Safety Disclosures	12
Item 5	Other Information	12
Item 6.	Exhibits	12
Signatures		S-1

#### HEDGEPATH PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AS OF JUNE 30, 2015 AND DECEMBER 31, 2014 (Unaudited)

	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,893,572	\$ 365,161
Prepaid expenses and other current assets	46,274	97,817
Total current assets	1,939,846	462,978
Other long-term assets	250,000	
Total assets	\$ 2,189,846	\$ 462,978
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 246,470	\$ 324,966
Other liabilities	166,221	75,933
Total current liabilities	412,691	400,899
Total liabilities	412,691	400,899
Commitments and contingencies (note 7)	_	
Stockholders' equity:		
Common stock, \$0.0001 par value; 340,000,000 shares authorized; 245,353,270 and 211,419,937 shares issued and		
outstanding at June 30, 2015 and December 31, 2014, respectively	24,535	21,142
Additional paid-in capital	35,689,903	32,263,890
Accumulated deficit	(33,937,283)	(32,222,953)
Total stockholders' equity	1,777,155	62,079
Total liabilities and stockholders' equity	\$ 2,189,846	<u>\$ 462,978</u>

See notes to condensed financial statements

#### HEDGEPATH PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS FOR THE THREE AND SIX MONTH PERIODS ENDED JUNE 30, 2015 AND 2014 (Unaudited)

	Three Months Ended June 30, Six Months Ended June 30,			nded June 30,
	2015	2014	2015	2014
Revenues:	<u>\$                                    </u>	<u>\$                                    </u>	<u>\$                                    </u>	<u>\$                                    </u>
Total Revenues:				
Expenses:				
Research and development expenses	300,288	1,930,482	613,305	1,955,807
General and administrative	491,368	185,182	1,101,025	346,787
Total Expenses:	791,656	2,115,664	1,714,330	2,302,594
Loss from operations	(791,656)	(2,115,664)	(1,714,330)	(2,302,594)
Interest expense		(24,994)		(34,552)
Net loss	<u>\$ (791,656)</u>	<u>\$ (2,140,658)</u>	<u>\$ (1,714,330)</u>	\$ (2,337,146)
Basic and diluted net loss per share	<u>\$ (0.00</u> )	<u>\$ (0.10</u> )	<u>\$ (0.01</u> )	<u>\$ (0.12</u> )
Weighted average common stock shares outstanding	227,827,263	20,622,065	219,668,924	19,760,306

See notes to condensed financial statements

#### HEDGEPATH PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY FOR THE SIX MONTHS ENDED JUNE 30, 2015 (Unaudited)

	Common	Stock	Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balances, January 1, 2015	211,419,937	\$21,142	\$32,263,890	\$(32,222,953)	\$ 62,079
Sale of common stock and common stock warrants to related party	33,333,333	3,333	2,496,667		2,500,000
Common shares issued for payment of trade payables	600,000	60	89,940		90,000
Stock-based compensation		_	839,406		839,406
Net loss				(1,714,330)	(1,714,330)
Balances, June 30, 2015	245,353,270	\$24,535	\$35,689,903	\$ <u>(33,937,283</u> )	<u>\$ 1,777,155</u>

See notes to condensed financial statements

#### HEDGEPATH PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS FOR THE SIX MONTHS ENDED JUNE 30, 2015 AND 2014 (Unaudited)

	Six montl June	
	2015	2014
Operating activities:		
Net loss	\$ (1,714,330)	\$ (2,337,146)
Adjustments to reconcile net loss to net cash flows from operating activities:		
In-process research and development purchased with the issuance of preferred stock and common stock warrants	_	1,909,860
Non-cash interest expense	—	24,666
Stock based compensation	839,406	_
Changes in assets and liabilities:		
Prepaid expense, other current assets, and other assets	(198,457)	(19,291)
Accounts payable and other current liabilities	101,792	19,282
Net cash used in operating activities	(971,589)	(402,629)
Financing activities:		
Proceeds from related party advances		273,638
Proceeds from sale of common stock and common stock warrants to related party	2,500,000	400,000
Net cash flows from financing activities	2,500,000	673,638
Net change in cash and cash equivalents	1,528,411	271,009
Cash and cash equivalents at beginning of period	365,161	217
Cash and cash equivalents at end of period	<u>\$ 1,893,572</u>	\$ 271,226
Supplemental disclosure of non-cash financing activity:		
Issuance of stock in debt forgiveness transaction	\$ —	\$ 189,768
Issuance of warrants in debt forgiveness transaction	\$ —	\$ 450,000
Issuance of common stock for common stock subscription receivable	\$ —	\$ 1,100,00
Issuance of common stock in payment of trade payables	\$ 90,000	\$ —

See notes to condensed financial statements

#### 1. Corporate overview:

#### Overview

The accompanying unaudited condensed financial statements of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company", "HPPI", "we", "us" or similar terminology), have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows as of June 30, 2015, and for all periods presented, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to the Securities and Exchange Commission ("SEC") rules and regulations. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2014, which are included in the Company's 2014 Annual Report on Form 10-K, filed with the SEC on February 13, 2015 (the "2014 Annual Report"). The accompanying condensed balance sheet at December 31, 2014 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements.

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

The results of operations for the three and six month periods ended June 30, 2015 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this Quarterly Report are strongly encouraged to review the risk factors relating to the Company which are set forth in the 2014 Annual Report and our other filings with the SEC.

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

#### Nature of the Business and Background

The Company is a clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. The Company's preliminary focus is on the development of therapies for skin, lung and prostate cancers in the United States of America ("U.S.") market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome). The Company's proposed therapy is based upon the use of SUBA-Itraconazole<sup>TM</sup>, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole. The Company believes that the dosing of oral capsules of this formulation can affect the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration ("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 has applied for patents to cover the Company's inventions. On July 24,2015, the US Patent and Trademark Office issued a Notice of Allowance with respect to the Company's US patent application, #14/173,588, "Treatment and Prognostic Monitoring of Proliferation Disorders Using Hedgehog Pathway Inhibitors", which was filed on February 5, 2014.

#### Relationship with Mayne Pharma Ventures Pty Ltd.

The Company has exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole Capsules for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner and significant shareholder Mayne Pharma Ventures Pty Ltd. and its affiliates ("Mayne Pharma") under a supply and license agreement, originally dated September 3, 2013 and most recently amended and restated on May 15, 2015 (the "SLA"). Mayne Pharma is an Australian specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes directly or through distribution partners and also provides contract development and manufacturing services. In addition to being the Company's licensor and supply partner, under the SLA and related agreements, Mayne Pharma holds a significant minority equity stake in the Company and holds important rights with respect to the Company, such as the right to appoint a member to the Company's Board of Directors. In addition, the Company expects to obtain a sublicense from Mayne Pharma to rights for certain patents regarding the use of itraconazole as a cancer treatment.

#### 1. Corporate overview (continued):

On May 15, 2015, the Company and Mayne Pharma, along with Nicholas J. Virca, the Company's President and Chief Executive Officer ("Virca"), Frank O'Donnell, Jr., M.D., the Company's Executive Chairman ("O'Donnell") and Hedgepath, LLC, a Florida limited liability company and substantial stockholder of the Company which is controlled by Black Robe Capital LLC, of which O'Donnell is the manager ("HPLLC"), consummated a series of related transactions in connection with a \$2.5 million equity financing for the Company from Mayne Pharma and to remedy certain breaches by the Company related to the agreements previously consummated by the Company, Mayne Pharma, HPLLC, Virca and O'Donnell on June 24, 2014. For more information regarding the equity financing, see note 6.

#### 2. Liquidity and management's plans:

The Company had cash and cash equivalents of approximately \$1.9 million as of June 30, 2015 which should fund current anticipated operations into the first quarter of next year, but requires significant additional financing for its research and development, commercialization and distribution efforts, and its working capital. The Company intends to finance these activities primarily through:

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

However, there is a material risk that none of these plans will be implemented and that the Company will be unable to obtain additional financing on commercially reasonable terms, if at all. If adequate funds are not available, the Company may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require the Company to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on the Company, its viability, its financial condition and its results of operations in 2015 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

As a result, there is substantial doubt about the Company's ability to continue as a going concern. The Company's current independent registered public accounting firm has included a paragraph emphasizing this going concern uncertainty in their audit report on the 2014 financial statements dated February 13, 2015. The condensed financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

#### 3. Summary of Significant Accounting Policies:

Estimates

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

#### Revenue Recognition

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

#### Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts which is up to \$250,000 for substantially all depository accounts. As of June 30, 2015, the Company had approximately \$1.4 million which exceeded these insured limits.

#### 3. Summary of Significant Accounting Policies (continued):

#### Research and Development Expenses

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

#### Stock-Based Compensation

The Company accounts for stock-based awards to employees and non-employees using Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718 – Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by the Company based predominantly on the trading price of the Common Stock. The value of these awards is based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

#### Income Taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. 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 condensed financial statements for the six months ended June 30, 2015 or 2014.

#### Recent accounting pronouncements:

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

#### 4. Other long-term assets:

Other long-term assets consists of a \$250,000 deposit with our independent contract research organization. The deposit is fully refundable at the conclusion of our clinical trial which targets basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome.

#### 5. Other liabilities:

At June 30, 2015 and December 31, 2014 other liabilities include \$52,500 payable to a third party service provider for which the Company has agreed to issue a number of restricted shares of its Common Stock to be determined based on the valuation of the shares to be issued to purchasers in connection with the Company's offering of securities as described in Commonwealth Biotechnology, Inc.'s ("CBI") Amended Plan of Reorganization filed in 2013. Such shares of Common Stock are to be issued to such service provider within five (5) business days of the final determination of such valuation (as memorialized in the final transaction documentation for such offering). Additional other liabilities at June 30, 2015 and December 31, 2014 include approximately \$103,000 and \$23,000 of accrued legal and research and development expenses, respectively.

#### 6. Stockholders' Equity:

#### Securities Purchase Agreement

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

#### Employee Stock Plans

Total stock-based compensation for the six months ended June 30, 2015 was \$839,406 and is related to certain Restricted Stock Units ("RSUs") granted in 2014 in connection with the Company's 2014 Equity Incentive Plan. The expense is classified as research and development expense and general and administrative expense in the accompanying condensed 2015 statement of operations. There was approximately \$2.2 million in unamortized stock-based compensation relating to the RSUs at June 30, 2015, which is expected to be recognized over the next 27 months. The fair value of the RSUs was determined using the quoted market price of the Common Stock on the date of issuance and the number of shares expected to vest.

#### 7. Legal Proceedings:

#### Chien Connecticut Case

In October 2012, Andrew Chien ("Chien"), an alleged shareholder of our predecessor, CBI, filed suit in Connecticut state court (later removed to the United States District Court for the District of Connecticut (the "CT District Court")) against CBI, Dr. Richard J. Freer (a director and officer of CBI) ("Freer"), and the law firm LeClairRyan (the "Chien Connecticut Case").

In October 2012, the CT District Court in the Chien Connecticut Case entered an Order dismissing Chien's claims without prejudice on account of CBI's pending Chapter 11 bankruptcy. Chien filed various motions in response to the CT District Court's decision dismissing the claims asserted against Freer and LeClairRyan, including a motion for reconsideration. On Thursday, May 29, 2014, the presiding judge issued several orders. The CT District Court granted Chien's request that he be allowed to proceed with the fifth and six claims he asserted against CBI in his Complaint, namely (i) a claim for relief entitled "Securities Fraud and Fiduciary Duty Violation against CBI" and (ii) a claim for relief entitled "Fiduciary Duty violation against CBI" (collectively, the "Chien Claims"). A related scheduling order provided that CBI had until June 20, 2014 to answer or otherwise respond to the Complaint. We have retained LeClairRyan to serve as CBI's counsel in the Chien Connecticut Case. On June 20, 2014, LeClairRyan filed on CBI's behalf a motion to dismiss esking a dismissal with prejudice of the Chien Claims. LeClairRyan also filed on CBI's behalf a motion to stay discovery. On August 5, 2014, the CT District Court granted CBI's motion to stay discovery.

On November 4, 2014, the CT District Court dismissed the case and the matter was closed by the CT District Court. On December 1, 2014, Chien filed various motions including a Motion to Reargue. In response, the Company filed a consolidated opposition to Chien's various pleadings, including to the Motion to Reargue. In June 2015, the CT District Court denied all motions including Chien's Motion to Reargue.

#### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the Condensed Financial Statements and Notes thereto included elsewhere in this Quarterly Report. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company's actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Quarterly Report and in the Company's other filings with the SEC. See "Cautionary Note Regarding Forward Looking Statements" below.

As used in this Management's Discussion and Analysis of Financial Condition and Results of Operations, unless otherwise indicated, the terms "the Company", "we", "us", "our" and similar terminology refer to both, as the context requires, the present activity of HPPI and the historic activity of CBI, as the context requires.

#### **Critical Accounting Policies**

See Note 3 of the Notes to Condensed Financial Statements included in Item 1 of this Quarterly Report for a summary of significant accounting policies and information on recently issued accounting pronouncements.

#### **Results of Operations**

#### For the three months ended June 30, 2015 compared to the three months ended June 30, 2014

Research and Development Expenses. We recognized approximately \$0.3 million in research and development expenses during the three months ended June 30, 2015 compared to approximately \$1.9 million for the three months ended June 30, 2014. Research and development expenses for the current period include contract research organization expenses related to our clinical trial, salaries and consulting expenses related to clinical trial design and regulatory activities, legal expenses relating to patents, and stock-based compensation. Research and development expenses for the prior period include approximately \$1.9 million in purchased in-process research and development related to our supply and license agreement with Mayne Pharma, as well as salaries related to clinical trial design and regulatory activities.

General and Administrative Expenses. We recognized approximately \$0.5 million and \$0.2 million in general and administrative expenses during the three months ended June 30, 2015 and 2014, respectively. General and administrative expenses consist of compensation and related costs for corporate administrative staff, facility expenditures, professional fees and consulting. The increase is primarily a result of an increase in stock based compensation relating to restricted stock units issued during the quarter ended September 30, 2014.

Interest Expense. We recognized approximately \$0.02 million in interest expense during the three months ended June 30, 2014 related to former employee notes. There was no such expense during the three months ended June 30, 2015 as all notes were paid in full in 2014.

#### For the six months ended June 30, 2015 compared to the six months ended June 30, 2014

Research and Development Expenses. We recognized approximately \$0.6 million and \$2.0 million in research and development expenses during the six months ended June 30, 2015 and 2014, respectively. Research and development expenses for the current period include contract research organization expenses related to our clinical trial, salaries and consulting expenses related to clinical trial design and regulatory activities, legal expenses relating to patents, and stock-based compensation. Research and development expenses for the prior period include approximately \$1.9 million in purchased in-process research and development related to our supply and license agreement with Mayne Pharma, as well as salaries related to clinical trial design and regulatory activities.

General and Administrative Expenses. We recognized approximately \$1.1 million and \$0.3 million in general and administrative expenses during the six months ended June 30, 2015 and 2014, respectively. General and administrative expenses consist of compensation and related costs for corporate administrative staff, facility expenditures, professional fees and consulting. The increase is primarily a result of an increase in stock based compensation relating to restricted stock units issued during the quarter ended September 30, 2014.

Interest Expense. We recognized approximately \$0.03 million in interest expense during the six months ended June 30, 2014 related to former employee notes. There was no such expense during the six months ended June 30, 2015 as all notes were paid in full in 2014.

#### Liquidity and Capital Resources

We had approximately \$1.9 million cash on hand at June 30, 2015, which we believe will fund our current anticipated operations into the first quarter of next year. We will require additional financing in order to progress our business plan. It is highly



#### **Table of Contents**

unlikely that any funds required during the next twelve months or thereafter can be generated from our operations. Moreover, there can be no assurances given that additional funds will be available from external sources, such as debt or equity financing or other potential sources on commercially acceptable terms, or at all.

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

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

However, there is a material risk that none of these plans will be implemented and that we will be unable to obtain additional financing on commercially reasonable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require us to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on our company, our viability, our financial condition and our results of operations in 2015 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

As a result of the foregoing circumstances, there is substantial doubt about our ability to continue as a going concern. The Company's current independent registered public accounting firm has included a paragraph emphasizing this going concern uncertainty in their audit report on the 2014 financial statements dated February 13, 2015. The financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

None.

#### Item 4. Controls and Procedures

#### Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, the Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer (the "Certifying Officers"), conducted evaluations of our disclosure controls and procedures. As defined under Sections 13a–15(e) and 15d–15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the term "disclosure controls and procedures" means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including the Certifying Officers, to allow timely decisions regarding required disclosures.

Based on this evaluation, the Certifying Officers have concluded that our disclosure controls and procedures were effective.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the first six months of fiscal 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Limitations on the Effectiveness of Internal Controls

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the



#### **Table of Contents**

inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our control have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

#### CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" (and the "Liquidity and Capital Resources" section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes "forward-looking statements" within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects", "may", "could", "would", "should", "believes", "expects", "anticipates", "estimates", "intends", "plans" or similar expressions. These statements are based upon the current beliefs and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) the results of our collaboration with Mayne Pharma, (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA's review and/or approval and potential commercial launch of our products and product candidates and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements are to vary significantly from reporting period. Such factors include, among others, those listed under Item 1A of our 2013 Annual Report and other factors detailed from time to time in our other filings with the SEC. Although management beli

## PART II. OTHER INFORMATION

#### Item 1. Legal Proceedings

#### Chien Connecticut Case

In October 2012, Andrew Chien ("Chien"), an alleged shareholder of the Company when it operated as CBI, filed suit in Connecticut state court (later removed to the United States District Court for the District of Connecticut (the "CT District Court")) against CBI, Dr. Richard J. Freer (a director and officer of CBI) ("Freer"), and the law firm LeClairRyan (the "Chien Connecticut Case").

In October 2012, the CT District Court in the Chien Connecticut Case entered an Order dismissing Chien's claims without prejudice on account of CBI's pending Chapter 11 bankruptcy.

Chien filed various motions in response to the CT District Court's decision dismissing the claims asserted against Freer and LeClairRyan, including a motion for reconsideration. On Thursday, May 29, 2014, the presiding judge issued several orders. The CT District Court granted Chien's request that he be allowed to proceed with the fifth and six claims he asserted against CBI in his Complaint, namely (i) a claim for relief entitled "Securities Fraud and Fiduciary Duty Violation against CBI" and (ii) a claim for relief entitled "Fiduciary Duty Violation against CBI" (collectively, the "Chien Claims"). A related scheduling order provided that CBI had until June 20, 2014 to answer or otherwise respond to the Complaint. HPPI has retained LeClairRyan to serve as CBI's counsel in the Chien Connecticut Case. On June 20, 2014, LeClairRyan filed on CBI's behalf a motion to dismiss seeking a dismissal with prejudice of the Chien Claims. LeClairRyan also filed on CBI's behalf a motion to stay discovery. On August 5, 2014, the CT District Court granted CBI's motion to stay discovery. The parties are now awaiting a final decision on CBI's motion to dismiss.

On November 4, 2014, the CT District Court dismissed the case and the matter was closed by the CT District Court. On December 1, 2014, Chien filed various motions including a Motion to Reargue. In response, we filed a consolidated opposition to Chien's various pleadings, including to the Motion to Reargue. In June 2015, the CT District Court denied all motions including Chien's Motion to Reargue.

#### Item 1A. Risk Factors.

Not required for smaller reporting companies.

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the period of this Quarterly Report, all unregistered sales of our securities were previously disclosed in a Current Report on Form 8-K.

#### Item 3. Defaults upon Senior Securities.

None.

#### Item 4. Mine Safety Disclosures.

Not applicable.

#### Item 5. Other Information.

None.

#### Item 6. Exhibits.

#### Number

4.1 Warrant, dated May 15, 2015 issued to Mayne Pharma Ventures Pty Ltd.

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

Description

10.2 First Amendment to Executive Chairman Agreement, dated May 15, 2015, between the Company and Frank O'Donnell, Jr. M.D.

### **Table of Contents**

First Amendment to Employment Agreement, dated May 15, 2015, between the Company and Nicholas J. Virca Second Amended and Restated Supply and License Agreement, dated May 15, 2015, by and among the Company and Mayne Pharma* Securities Purchase Agreement, dated May 15, 2015, by and between the Company and Mayne Pharma Ventures Pty Ltd.
Securities Purchase Agreement, dated May 15, 2015, by and between the Company and Mayne Pharma Ventures Pty Ltd.
Master Clinical Services Agreement, dated June 15, 2015, by and between the Company and SciQuus, Inc.*
Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302
Certification of Chief Financial Officer Pursuant To Sarbanes-Oxley Section 302
Certification Pursuant To 18 U.S.C. Section 1350 (**)
Certification Pursuant To 18 U.S.C. Section 1350 (**)
XBRL Instance Document
XBRL Taxonomy Extension Schema Document
XBRL Taxonomy Calculation Linkbase Document
XBRL Taxonomy Definition Linkbase Document
XBRL Taxonomy Label Linkbase Document
XBRL Taxonomy Presentation Linkbase Document

\*

Confidential treatment is 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. \*\*

#### SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 14, 2015

Date: August 14, 2015

HEDGEPATH PHARMACEUTICALS, INC.

By: <u>/s/ Nicholas J. Virca</u> Nicholas J. Virca President and Chief Executive Officer (Principal Executive Officer)

By: /s/ Garrison J. Hasara

Garrison J. Hasara, CPA Chief Financial Officer and Treasurer (Principal Financial Officer)

S-1

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT UNDER APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR PURSUANT TO AN APPLICABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, WHICH OPINION SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

Issuance Date: May 15, 2015

#### HEDGEPATH PHARMACEUTICALS, INC. Common Stock Purchase Warrant

THIS CERTIFIES THAT, for value received, Mayne Pharma Ventures Pty Ltd, an Australian company ACN 168 896 357 (the "Holder"), is entitled to subscribe for and purchase, at the Exercise Price (as defined below), from HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company"), shares of the Company's common stock, par value \$0.0001 (the "Common Stock"), at any time prior to the five (5) year anniversary of the issuance date of this Warrant as set forth above (the Warrant Exercise Term").

The Company issues this Warrant in connection with that certain Securities Purchase Agreement by and between the Company and the Holder, dated on or about a date even herewith (the "Agreement"). Capitalized terms used herein and not otherwise defined shall have the definitions ascribed to such terms in the Agreement.

This Warrant is subject to the following terms and conditions:

1. <u>Shares</u>. The Holder has, subject to the terms set forth herein, the right to purchase up to an aggregate of Thirty-Three Million Three Hundred Thirty-Three Thousand Three Hundred Thirty-Three (33,333,333) shares (subject to adjustment as provided herein, "**Shares**" and each a "**Share**") of Common Stock at a per share exercise price of \$0.075 (subject to adjustment as provided herein, the "**Exercise Price**").

#### 2. Exercise of Warrant.

(a) <u>Exercise</u>. This Warrant may be exercised by the Holder at any time prior to the expiration of the Warrant Exercise Term, in whole or in part, by delivering the notice of exercise attached as <u>Exhibit A</u> hereto (the "**Notice of Exercise**"), duly executed by the Holder to the Company at its principal office, or at such other office as the Company may designate, accompanied by payment, in cash by wire transfer of immediately available funds to the order of the Company and to an account designated by the Company (to be delivered prior to delivery of the Shares as provided for in Section 2(b) below), of the amount obtained by multiplying the number of Shares designated in the Notice of Exercise by the Exercise Price (the "**Purchase Price**").

(b) <u>Issuance of Certificates</u>. As soon as practicable (but in no event later than three (3) Business Days) after the valid exercise of this Warrant, in whole or in part, in accordance with Section 2(a) hereof, the Company, at its expense, shall cause to be issued in the name of and delivered to the

Holder: (i) a certificate or certificates for (or, if the Shares are then registered for public resale, by delivery through the facilities of the Depository Trust Company in electronic form of) the number of fully paid and non-assessable Shares to which the Holder shall be entitled upon such exercise and, if applicable, (ii) a new warrant of like tenor to purchase all of the Shares that may be purchased pursuant to the portion, if any, of this Warrant not exercise ad by the Holder. The Holder shall for all purposes hereof be deemed to have become the holder of record of such Shares on the date on which the Notice of Exercise and payment of the Purchase Price in accordance with Section 2(a) hereof were delivered and made, respectively, irrespective of the date of delivery of such certificate or certificates, except that if the date of such delivery, notice and payment is a date when the stock transfer books of the Company are closed, the Holder shall be deemed to have become the holder of record of such Shares on the next succeeding date on which the stock transfer books are open.

(c) <u>Taxes</u>. The issuance of the Shares upon the exercise of this Warrant, and the delivery of certificates or other instruments representing such Shares, shall be made without charge to the Holder for any tax or other charge of whatever nature in respect of such issuance and the Company shall bear any such taxes in respect of such issuance.

#### 3. Adjustment of Exercise Price.

(a) Adjustment for Reclassification, Consolidation, Merger, Sale or Transfer If while this Warrant, or any portion hereof, remains outstanding and unexpired there shall be (i) a reorganization or recapitalization (other than a combination, reclassification, exchange or subdivision of shares otherwise provided for herein), (ii) a merger or consolidation of the Company with or into another corporation or other entity in which the Company shall not be the surviving entity, or a reverse merger in which the Company shall be the surviving entity but the shares of the Company's capital stock outstanding immediately prior to the merger or consolidation are converted by virtue of the merger or consolidation into other property, whether in the form of securities, cash or otherwise, or (iii) a sale or transfer of the Company's properties and assets as, or substantially as, an entirety to any other corporation or other entity in one transaction or a series of related transactions, then, as a part of such reorganization, recapitalization, merger, consolidation, sale or transfer, unless otherwise directed by the Holder, all necessary or appropriate lawful provisions shall be made so that the Holder shall thereafter be entitled to receive upon exercise of this Warrant, during the period specified herein and upon payment of the Exercise Price then in effect, the greatest number of shares of capital stock or other securities or property that a holder of the Shares deliverable upon exercise of this Warrant would have been entitled to receive in such reorganization, recapitalization, merger, consolidation, sale or transfer if this Warrant had been exercised immediately prior to such reorganization, recapitalization, merger, consolidation, sale or transfer, all subject to further adjustment as provided in this Section 3. If the per share consideration payable to the Holder for Shares in connection with any such transaction is in a form other than cash or marketable securities, then the value of such consideration shall be determined in good faith by the Company's Board of Directors. The foregoing provisions of this paragraph shall similarly apply to successive reorganizations, recapitalizations, mergers, consolidations, sales and transfers and to the capital stock or securities of any other corporation or other entity that are at the time receivable upon the exercise of this Warrant. In all events, appropriate adjustment shall be made in the application of the provisions of this Warrant with respect to the rights and interests of the Holder after the transaction, to the end that the provisions of this Warrant shall be applicable after that event, as near as reasonably may be, in relation to any shares or other property deliverable or issuable after such reorganization, recapitalization, merger, consolidation, sale or transfer upon exercise of this Warrant.

(b) Adjustments for Split, Subdivision or Combination of Shares. If while this Warrant, or any portion hereof, remains outstanding and unexpired the Company shall subdivide (by any stock split, stock dividend, recapitalization, reorganization, reclassification or otherwise) the shares of

Common Stock subject to acquisition hereunder, then, after the date of record for effecting such subdivision, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced and the number of shares of Common Stock subject to acquisition upon exercise of this Warrant will be proportionately increased. If the Company at any time combines (by reverse stock split, recapitalization, reorganization, reclassification or otherwise) the shares of Common Stock subject to acquisition hereunder, then, after the record date for effecting such combination, the Exercise Price in effect immediately prior to such combination will be proportionately increased and the number of shares of Common Stock subject to acquisition upon exercise of this Warrant will be proportionately increased and the number of shares of Common Stock subject to acquisition upon exercise of this Warrant will be proportionately increased and the number of shares of Common Stock subject to acquisition upon exercise of this Warrant will be proportionately decreased.

(c) Adjustments for Dividends in Stock or Other Securities or Property. If while this Warrant, or any portion hereof, remains outstanding and unexpired, the holders of any class of securities as to which purchase rights under this Warrant exist at the time shall have received or, on or after the record date fixed for the determination of eligible stockholders, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (other than cash) of the Company by way of dividend, then and in each case, this Warrant shall represent the right to acquire, in addition to the number of shares of such class of security receivable upon exercise of this Warrant, and without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (other than cash) of the Company that such holder would hold on the date of such exercise had it been the holder of record of the class of security receivable upon exercise of this Warrant on the date hereof to and including the date of such exercise, retained such shares and/or all other additional stock available to it as aforesaid during said period, giving effect to all adjustments called for during such period by the provisions of this Section 3.

(d) <u>Notice of Adjustments</u>. Upon any adjustment of the Exercise Price and any increase or decrease in the number of Shares purchasable upon the exercise of this Warrant, then, and in each such case, the Company, within 30 days thereafter, shall give written notice thereof to the Holder at the address of such Holder as shown on the books of the Company, which notice shall state the Exercise Price as adjusted and, if applicable, the increased or decreased number of Shares purchasable upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation of each.

4. <u>Notices</u>. Any notice or other communication required or permitted to be given hereunder shall be in writing and shall be mailed by certified mail, return receipt requested, or delivered by facsimile transmission or by e-mail transmission, or delivered against receipt to the party to whom it is to be given (a) if to the Company, at the address provided to the Holder, or (b) if to the Holder, at the address set forth in the Company's records (or, in either case, to such other address as the party shall have furnished in writing in accordance with the provisions of this Section 4). Any notice or other communication given by certified mail shall be deemed given at the time of receipt thereof.

5. Legends. Each certificate evidencing the Shares issued upon exercise of this Warrant shall be stamped or imprinted with a legend substantially in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS

# EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

6. <u>Removal of Legend</u>. Upon request of a holder of a certificate with the legends required by Section 5 hereof, the Company shall issue to such holder a new certificate therefor free of any transfer legend, if, with such request, the Company shall have received an opinion of counsel satisfactory to the Company in form and substance to the effect that any transfer by such holder of the Shares evidenced by such certificate will not violate the Act or any applicable state securities laws.

7. Fractional Shares. No fractional Shares will be issued in connection with any exercise hereunder. Instead, the Company shall round up, as nearly as practicable to the nearest whole Share, the number of Shares to be issued.

8. <u>Rights of Stockholders</u>. Except as expressly provided in Section 3(c) hereof, the Holder, as such, shall not be entitled to vote or receive dividends or be deemed the holder of any of the Shares or any other securities of the Company that may at any time be issuable on the exercise hereof for any purpose, nor shall anything contained herein be construed to confer upon the Holder, as such, any of the rights of a stockholder of the Company or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of stock, reclassification of stock, change of par value, consolidation, merger, conveyance, or otherwise) or to receive notice of meetings, or otherwise until this Warrant shall have been exercised, in whole or in part, and the Shares purchasable upon such exercise hereof shall have been issued, as provided herein.

9. <u>Transfer</u>. This Warrant and the Shares may be offered for sale, sold, transferred, pledged or assigned without the consent of the Company, provided that any such offer, sale, transfer, pledge or assignment must be undertaken in accordance with Section 6.1 of the Agreement and applicable law, rule and regulation.

#### 10. Miscellaneous.

(a) This Warrant and disputes 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.

(b) In the event of any dispute, claim, question or disagreement arising from or relating to this Warrant or the breach thereof, the parties hereto agree to settle the dispute, claim, question or disagreement by arbitration before a single arbitrator in Atlanta, Georgia, selected by, and such arbitration to be administered by, the American Arbitration Association ("AAA") in accordance with its International 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 disputes between or among them are subject to the alternative dispute resolution procedures of this Section 10(b). Each of the parties hereto agrees that any aspect of alternative dispute resolution not specifically covered in this Warrant 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 dispute, claim, question or disagreement arising from or relating to this Warrant shall be final and binding upon the parties hereto and shall not be subject to further appeal.

(c) The headings in this Warrant are for purposes of reference only, and shall not limit or otherwise affect any of the terms hereof.

(d) The covenants of the respective parties contained herein shall survive the execution and delivery of this Warrant.

(e) The terms of this Warrant shall be binding upon and shall inure to the benefit of any successors or permitted assigns of the Company and of the Holder or holder of the Shares issued or issuable upon the exercise hereof.

(f) This Warrant and the other documents delivered pursuant hereto constitute the full and entire understanding and agreement between the parties with regard to the subject hereof.

(g) The Company shall not, by amendment of its Certificate of Incorporation or Bylaws, or through any other means, directly or indirectly, avoid or seek to avoid the observance or performance of any of the terms of this Warrant and shall at all times in good faith assist in the carrying out of all such terms and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the Holder contained herein against impairment.

(h) Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of any such loss, theft or destruction, upon delivery of an indemnity agreement reasonably satisfactory in form and amount to the Company, or, in the case of any such mutilation, upon surrender and cancellation of such Warrant, the Company, at its expense, will execute and deliver to the Holder, in lieu thereof, a new warrant of like date and tenor.

(i) This Warrant and any provision hereof may be amended, waived or terminated only by an instrument in writing signed by the Company and the Holder.

#### [Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to be signed by its duly authorized officer.

## HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca

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

Signature Page to Mayne Pharma Ventures Pty Ltd 2015 Warrant

## NOTICE OF EXERCISE

TO: HedgePath Pharmaceuticals, Inc. Attention: President

The undersigned hereby elects to purchase shares ('Shares'') of Common Stock of HedgePath Pharmaceuticals, Inc. (the 'Company'') pursuant to the terms of this Warrant, and tenders herewith payment of the purchase price of such Shares in full.

Please issue a certificate or certificates representing said shares in the name of the undersigned or in such other name as is specified below:

Name:	
Address:	

#### The undersigned hereby represents and warrants the following:

(a) He/she/it (i) has such knowledge and experience in financial and business affairs that he/she/it is capable of evaluating the merits and risks involved in purchasing the Shares, (ii) is able to bear the economic risks involved in purchasing the Shares, and (iii) is an "accredited investor," as defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended;

(b) In making the decision to purchase the Shares, he/she/it has relied solely on independent investigations made by him/her/it and has had the opportunity to ask questions of, and receive answers from, the Company concerning the Shares, the financial condition, prospective business and operations of the Company and has otherwise had an opportunity to obtain any additional information, to the extent that the Company possesses such information or could acquire it without unreasonable effort or expense;

(c) His/her/its overall commitment to investments that are not readily marketable is not disproportionate to his/her/its net worth and income, and the purchase of the Shares will not cause such overall commitment to become disproportionate; he/she/it can afford to bear the loss of the purchase price of the Shares;

(d) He/she/it has no present need for liquidity in his/her/its investment in the Shares; and

(e) He/she/it acknowledges that the transaction contemplated in connection with the purchase of the Shares has not been reviewed or approved by the Securities and Exchange Commission or by any administrative agency charged with the administration of the securities laws of any state, and that no such agency has passed on or made any recommendation or endorsement of any of the securities contemplated hereby.

(Signature)

(Date)

## FORM OF ASSIGNMENT

FOR VALUE RECEIVED, hereby sells, assigns and transfers to each assignee set forth below all of the rights of the undersigned under the Warrant (as defined in and evidenced by the attached Warrant) to acquire the number of Shares set opposite the name of such assignee below and in and to the foregoing Warrant with respect to said acquisition rights and the Shares issuable upon exercise of the Warrant:

Name	e of	Assig	nee
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Address

Number of Shares

If the total of the Shares described above are not all of the Shares evidenced by the foregoing Warrant, the undersigned requests that a new warrant evidencing the right to acquire the Shares not so assigned be issued in the name of and delivered to the undersigned.

Dated:

Name of Holder (print):	
(Signature):	
(By:)	
(Title:)	

**EXECUTION VERSION** 

## HEDGEPATH PHARMACEUTICALS, INC.

AMENDED AND RESTATED EQUITY HOLDERS' AGREEMENT

Dated As of May 15, 2015

#### HEDGEPATH PHARMACEUTICALS, INC. AMENDED AND RESTATED EQUITY HOLDERS' AGREEMENT

This AMENDED AND RESTATED EQUITY HOLDERS' AGREEMENT (this "<u>Agreement</u>") is made and entered into as of the 15th day of May, 2015 (the "<u>Effective Date</u>") by and among:

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

(ii) HEDGEPATH LLC, a Florida limited liability company ("HPLLC");

(iii) HEDGEPATH PHARMACEUTICALS, INC., a Delaware corporation ("HPPI");

(iv) FRANK E. O'DONNELL, JR., M.D., a resident of the State of Florida ("FEO"); and

(v) NICHOLAS J. VIRCA, a resident of the State of California ("Virca").

#### RECITALS

WHEREAS, HPPI and Mayne Pharma International Pty. Ltd, an Australian company ACN 007 870 984 and predecessor-in-interest to Mayne Pharma ("MPI"), entered into that certain Supply and License Agreement, dated as of September 3, 2013, as amended, including, without limitation, pursuant to that certain Amendment No. 1 to Supply and License Agreement and that certain Amendment No. 2 to Supply and License Agreement (collectively, the "Original Supply Agreement");

WHEREAS, prior to the Original Effective Date (as defined below), MPI assigned to Mayne Pharma, and Mayne Pharma assumed from MPI, the rights and obligations of MPI under the Original Supply Agreement;

WHEREAS, pursuant to the Original Supply Agreement, Mayne Pharma had the right to terminate the Original Supply Agreement if HPPI did not obtain equity funding of at least Five Million Dollars (\$5,000,000), or lesser amount as agreed to by the parties, on or before May 30, 2014 (the "Termination Right");

WHEREAS, the Original Supply Agreement further provided that HPPI was required to issue to Mayne Pharma certain shares of HPPI's capital stock so that Mayne Pharma would hold no less than thirty percent (30%) of the capital stock of HPPI on a fully diluted basis after the consummation of certain transactions as contemplated therein;

WHEREAS, in consideration for Mayne Pharma not exercising the Termination Right, HPPI agreed to issue to Mayne Pharma, and Mayne Pharma agreed to purchase from HPPI, in a

Private Offering, Two Hundred Fifty-Eight Thousand Three Hundred Sixty-Three and 280/1,000 (258,363.280) shares of HPPI's Series A Convertible Preferred Stock and a warrant to purchase Ten Million Two Hundred Fifty Thousand Five Hundred Sixty-Nine (10,250,569) shares of Common Stock (the "<u>Make-Up Warrant</u>"), pursuant to that certain Securities Purchase Agreement, dated as of June 24, 2014 (the "<u>Mayne Pharma Purchase Agreement</u>");

WHEREAS, in connection with the closing of the transactions contemplated by the Mayne Pharma Purchase Agreement, HPPI and HPLLC entered into that certain HPLLC Stock Purchase Agreement, pursuant to which, among other things, HPLLC purchased from HPPI Twenty Million (20,000,000) shares of Common Stock in exchange the aggregate amount of One Million Five Hundred Thousand and 00/100 Dollars (\$1,500,000.00) (collectively, the "<u>HPLLC Equity Investment</u>");

WHEREAS, HPPI and Mayne Pharma expressly agreed that the HPLLC Equity Investment satisfied the Termination Right;

WHEREAS, in connection with the closing of the transactions contemplated by the Mayne Pharma Purchase Agreement, the parties hereto entered into that certain Equity Holders Agreement (the "Original EHA"), dated as of June 24, 2014 (the 'Original Effective Date"), as extended and amended by that certain letter agreement, dated November 26, 2014;

WHEREAS, on the terms and subject to the conditions set forth in that certain Securities Purchase Agreement, dated on or about an even date herewith, by and between HPPI and Mayne Pharma (the "2015 SPA"), HPPI agrees to issue to Mayne Pharma, in a Private Offering (the "2015 Private Placement"), Thirty-Three Million Three Hundred Thirty-Three Thousand Three Hundred Thirty-Three (33,333,333) shares of Common Stock (the "Shares") and a warrant to purchase Thirty-Three Million Three Hundred Thirty-Three Thousand Three Hundred Thirty-Three (33,333,333) shares of Common Stock (the "2015 Warrant" and, together with the Shares, the "Purchased Securities"), and Mayne Pharma intends to purchase from HPPI the Purchased Securities; and

WHEREAS, in connection with the 2015 Private Placement, and as an inducement for Mayne Pharma to purchase the Purchased Securities, the parties to the Original EHA have agreed to amend and restate the Original EHA as set forth herein.

#### AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals, the agreements and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

#### ARTICLE I. DEFINITIONS AND AMENDMENT OF ORIGINAL EHA

1.1. Definitions. The following definitions shall be applicable to the terms set forth below as used in this Agreement:

(a) "2014 Transaction Documents" shall mean, collectively, the Mayne

Pharma Purchase Agreement, the Make-Up Warrant, the Original EHA, all exhibits, annexes, and schedules hereto and thereto, and any other documents or agreements executed in connection with the transactions contemplated thereunder, and "2014 Transaction Document" shall mean any of the foregoing agreements and instruments individually.

(b) "2015 Private Placement" shall have the meaning ascribed to such term in the recitals to this Agreement.

(c) "2015 SPA" shall have the meaning ascribed to such term in the recitals to this Agreement.

(d) "2015 Transaction Documents" shall mean, collectively, the 2015 SPA, the 2015 Warrant, this Agreement, all exhibits, annexes, and schedules hereto and thereto, and any other documents or agreements executed in connection with the transactions contemplated hereunder or thereunder, and "2015 Transaction Document" shall mean any of the foregoing agreements and instruments individually.

(e) "2015 Warrant" shall have the meaning ascribed to such term in the recitals to this Agreement.

(f) "AAA" shall have the meaning ascribed to such term in Section 10.3 of this Agreement.

(g) "Accredited Investor(s)" shall mean a Person or Persons who are accredited investors as defined in Regulation D promulgated by the Commission under the Securities Act of 1933, as amended from time to time.

(h) "Action" shall have the meaning set forth in the Mayne Pharma Purchase Agreement.

(i) "Affiliate" or "Affiliated" shall mean, with respect to any Person which is an entity, any other Person which directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person, and with respect to any natural Person, such Person's spouse, parents, grandparents, children, grandchildren, siblings and the spouses and children of any of the foregoing. In this definition, "control" means having the power to exercise or control the right to vote attached to fifty percent (50%) or more of the issued voting equity in that party, to appoint one-half or more of the directors to the board or the managers of the party, or to determine substantially the conduct of the party's business activities. Notwithstanding the foregoing, but solely for purposes of this Agreement and not applicable laws, rules and regulations generally, (i) Virca and FEO shall be deemed to be Affiliates of HPLLC and (ii) if Mayne Pharma controls HPPI, (x) Affiliates of HPPI will not include Mayne Pharma nor any Person that would otherwise be an Affiliate of Mayne Pharma as a result of Mayne Pharma's control of HPPI.

(j) "Agreement" shall have the meaning ascribed to such term in the first paragraph of this Agreement.

(k) "Applicable Period" shall have the meaning ascribed to such term in Section 4.4(b) of this Agreement.

(1) "Board" shall mean the board of directors of HPPI.

(m) "Business Day" means:

(i) for receiving a notice under Section 10.1, a day that is not a Saturday, Sunday, public holiday or bank holiday in the place where the notice is received;

(ii) 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; and

(iii) for performing an obligation or exercising a right by any other party to this Agreement and for all other purposes, a day that is not a Saturday, Sunday, bank holiday or public holiday in New York, New York, USA.

(n) "Bylaws" shall mean the Amended and Restated Bylaws of HPPI, adopted effective as of July 18, 2014, as amended from time to time.

(o) "Closing" shall have the meaning ascribed to such term in Section 6.6 of this Agreement.

(p) "Commission" shall mean the United States Securities and Exchange Commission or any other federal agency at the time administering the federal securities

laws.

and

(q) "Common Stock" shall mean HPPI's common stock, par value \$0.0001 per share.

(r) "<u>Confidentiality and Intellectual Property Agreement</u>" means each of those certain Confidentiality and Intellectual Property Agreements executed by and between HPPI and each of FEO and Virca on or about June 24, 2014, or any extension, amendment or renewal thereof.

(s) "Debt Forgiveness Agreement," shall mean that certain Debt Forgiveness Agreement, by and between HPPI and HPLLC, dated as of June 24, 2014.

(t) "Default Notice" shall have the meaning ascribed to such term in Section 7.2(b) of this Agreement.

(u) "Development Plan" shall have the meaning set forth in the Supply and License Agreement.

(v) "Director" or "Directors" shall mean a member or members of the Board.

(w) "<u>Dispute</u>" shall mean any dispute, claim, question, or disagreement between any of the parties hereto arising from, or relating to, the interpretation, performance, or breach of this Agreement or any other Transaction Document; <u>provided</u>, <u>however</u>, that, unless such dispute, claim, question, or disagreement directly or indirectly relates to or effects any party's respective rights and obligations under this Agreement, a "Dispute" shall not include any dispute, claim, question, or disagreement between any of the parties hereto arising from, or relating to, the interpretation, performance, or breach of either: (i) the Virca Employment Agreement, (ii) the FEO Executive Chairman Agreement or (iii) any Confidentiality and Intellectual Property Agreement.

(x) "Effective Date" shall have the meaning ascribed to such term in the first paragraph of this Agreement.

(y) "EIP" shall mean the HPPI 2014 Equity Incentive Plan.

(z) "Equity Security(ies)" shall mean any and all capital stock of HPPI, including without limitation the Common Stock and Preferred Stock.

(aa) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

(bb) "Exercise Date" shall have the meaning ascribed to such term in Section 7.2(d)(iii) of this Agreement.

(cc) "Exercise Price" shall have the meaning ascribed to such term in Section 7.2(d)(ii) of this Agreement.

(dd) "Exercising Party" shall have the meaning ascribed to such term in Section 5.5(f) of this Agreement.

(ee) "FEO" shall have the meaning ascribed to such term in the first paragraph of this Agreement.

(ff) "FEO Executive Chairman Agreement" means that certain Executive Chairman Agreement executed by and between FEO and HPPI, dated as of June 24, 2014, and any extension, amendment or renewal thereof.

(gg) "FEO Indirect Share" means, as of the Original Effective Date, any share of Common Stock personally held of record by HPLLC of which FEO has an indirect beneficial or controlling interest, with respect to HPPI, as a result of his position as (i) manager of HPLLC, (ii) personal holder of record of an interest in HPLLC, or (iii) fiduciary, control Person or beneficial owner of another owner in HPLLC; provided, however, that if HPLLC, or its successors or assigns, distribute or Transfer any portion of such Common Stock to FEO, then such Common Stock that has actually been distributed or Transferred shall cease being a FEO Indirect Share.

5

(hh) "Field" shall have the meaning set forth in the Supply and License Agreement.

(ii) "Follow On Offering" one or more registered or unregistered equity, debt or equity-linked financings, the aggregate net proceeds received by HPPI of which shall be at least Five Million Dollars (\$5,000,000).

(jj) "Fully Diluted" and similar terms shall mean at the time of determination, the total number of shares of Common Stock then issued and outstanding, plus the number of shares of Common Stock issued or issuable upon conversion of any then issued and outstanding Preferred Stock or debt securities or upon the exercise of any outstanding warrants or options, or upon the vesting of any restricted stock units, plus the number of shares of Common Stock then reserved but not used for any employee incentive plan.

(kk) "Fundamental Transaction" means (i) that HPPI shall, directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one (1) or more related transactions, (A) consolidate or merge with or into (whether or not HPPI is the surviving corporation) another Person, (B) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of HPPI to one or more Persons, (C) make, or allow one (1) or more Persons to make, or allow HPPI to be subject to or have its Common Stock be subject to or party to one or more Persons making, a purchase, tender or exchange offer that is accepted by the holders of at least either (x) fifty percent (50%) of the outstanding shares of Common Stock, ( $\nu$ ) fifty percent (50%) of the outstanding shares of Common Stock calculated as if any shares of Common Stock held by all Persons making or party to, or Affiliated with any Persons making or party to, such purchase, tender or exchange offer were not outstanding, or (z) such number of shares of Common Stock such that all Persons making or party to, or Affiliated with any Person making or party to, such purchase, tender or exchange offer, become collectively the beneficial owners (as defined in Rule 13d-3 under the Exchange Act) of at least fifty percent (50%) of the outstanding shares of Common Stock, (D) consummate a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with one (1) or more Persons whereby all such Persons, individually or in the aggregate, acquire, either (x) at least fifty percent (50%) of the outstanding shares of Common Stock,  $\psi$ ) at least fifty percent (50%) of the outstanding shares of Common Stock calculated as if any shares of Common Stock held by all the Persons making or party to, or Affiliated with any Person making or party to, such stock purchase agreement or other business combination were not outstanding, or (z) such number of shares of Common Stock such that the Persons become collectively the beneficial owners (as defined in Rule 13d-3 under the Exchange Act) of at least fifty percent (50%) of the outstanding shares of Common Stock, or (E) reorganize, recapitalize or reclassify its Common Stock such that such modified Common Stock no longer has the residual right to dividends or distributions from HPPI or the residual right to vote on matters given to the holders of Common Stock under Delaware law; (ii) that HPPI shall, directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one or more related transactions, allow any Person individually or Persons in the aggregate to be or become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, whether through acquisition, purchase, assignment, conveyance, tender, tender offer, exchange, reduction in outstanding shares of Common Stock, merger, consolidation, business combination, reorganization, recapitalization, spin-off, scheme of arrangement, reorganization, recapitalization or reclassification or otherwise in any manner whatsoever, of either (A) at least fifty percent (50%) of the aggregate ordinary voting power represented by issued and outstanding Common Stock, (B) at least fifty percent (50%) of the

aggregate ordinary voting power represented by issued and outstanding Common Stock not held by all such Persons as of the date of this Agreement calculated as if any shares of Common Stock held by all such Persons were not outstanding, or (C) a percentage of the aggregate ordinary voting power represented by issued and outstanding shares of Common Stock or other Equity Securities sufficient to allow such Persons to effect a statutory short form merger or other transaction requiring other Stockholders to surrender their shares of Common Stock without approval of the Stockholders; or (iii) that HPPI shall, directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one or more related transactions, the issuance of or the entering into any other instrument or transaction structured in a manner to circumvent, or that circumvents, the intent of this definition in which case this definition shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this definition to the extent necessary to correct this definition or any portion of this definition which may be defective or inconsistent with the intended treatment of such instrument or transaction. The term "Fundamental Transaction" shall specifically exclude, however, any firm commitment, underwritten Public Offering of HPPI's capital stock.

(II) "Governmental Authority" shall have the meaning set forth in the Mayne Pharma Purchase Agreement.

(mm) "HPLLC" shall have the meaning ascribed to such term in the first paragraph of this Agreement.

(nn) "HPLLC At Risk Shares" shall mean the 6,000,000 shares of Common Stock held by HPLLC; provided, however, that such number of HPLLC At Risk Shares shall be adjusted for any stock splits, stock dividends, recapitalizations, reorganizations, reclassifications or similar events.

(oo) "HPLLC Director" shall mean, initially, FEO, and subsequently any other Director who is nominated by HPLLC or is otherwise a director, officer, manager or direct or indirect owner of LLC.

(pp) "HPLLC Equity Investment" shall have the meaning ascribed to such term in the recitals to this Agreement.

(qq) "HPLLC Group" shall have the meaning ascribed to such term in Section 4.1 of this Agreement.

(rr) "HPLLC Stock Purchase Agreement" shall mean that certain Stock Purchase Agreement, dated June 24, 2014, by and among HPPI and HPLLC.

(ss) "HPPI" shall have the meaning ascribed to such term in the first paragraph of this Agreement.

(tt) "Independent Director" shall be a Director that satisfies the independence standards established pursuant to Rule 5605(a)(2) of the Listing Rules of NASDAQ Stock Market LLC; provided, however, that, in addition to the provisions of the aforementioned Rule 5605(a)(2), no (i) Mayne Pharma Director, nor any individual holder of five percent (5%) or more of the voting equity of Mayne Pharma Group Ltd (or any individual Affiliate of any such

holder that is an entity), nor any officer, director, or employee of, or consultant (which has been paid by Mayne Pharma or its Affiliates more than \$50,000 in the thirty six (36) month period prior to the applicable evaluation date) to, Mayne Pharma or its Affiliates (including, without limitation, Mayne Pharma Group Ltd or its Affiliates), nor (ii) any HPLLC Director or any member, manager, equity holder or employee of, or consultant to HPLLC shall qualify as an Independent Director.

(uu) "Independent Board Requirement" shall mean the obligations of the parties as set forth in Section 5.5(a) of this Agreement

(vv) "Initial EIP" shall have the meaning ascribed to such term in Section 4.9(a) of this Agreement.

(ww) "Investor" means Mayne Pharma and any of its successors and assigns, including, without limitation, any subsequent holder of Equity Securities held by Mayne Pharma as of the Effective Date.

(xx) "Lien" shall have the meaning set forth in the Mayne Pharma Purchase Agreement.

- (yy) "Lock-Up Holder(s)" shall have the meaning ascribed to such term in Section 2.1 of this Agreement.
- (zz) "Lock-Up Period" shall have the meaning ascribed to such term in Section 2.1 of this Agreement.
- (aaa) "Make-Up Warrant" shall have the meaning ascribed to such term in the recitals to this Agreement.
- (bbb) "Mayne Pharma" shall have the meaning ascribed to such term in the first paragraph of this Agreement.
- (ccc) "Mayne Pharma Director(s)" shall have the meaning ascribed to such term in Section 5.3 of this Agreement.
- (ddd) "Mayne Pharma Group" shall have the meaning ascribed to such term in Section 4.1 of this Agreement.
- (eee) "Mayne Pharma Purchase Agreement" shall have the meaning ascribed to such term in the recitals to this Agreement.
- (fff) "MPI" shall have the meaning ascribed to such term in the recitals to this Agreement.

(ggg) "<u>New Board</u>" shall mean a Board comprised of a majority of Directors nominated, designated, elected or appointed by Mayne Pharma through the exercise of any of Mayne Pharma's rights to remove or replace Directors under <u>Sections 5.5(b)</u> or (c) hereof.

(hhh) "New Securities" shall have the meaning ascribed to such term in Section 4.3 of this Agreement.

(iii) "Notice" shall have the meaning ascribed to such term in Section 4.4(a) of this Agreement.

(jjj) "Notice of Exercise" shall have the meaning ascribed to such term in Section 7.2(d)(iii) of this Agreement.

(kkk) "Original Effective Date" shall have the meaning ascribed to such term in the recitals to this Agreement.

(III) "Original EHA" shall have the meaning ascribed to such term in the recitals to this Agreement.

(mmm) "Original Supply Agreement" shall have the meaning ascribed to such term in the recitals to this Agreement.

(nnn) "Other Dispute Resolution Provision" shall have the meaning ascribed to such term in Section 10.3(a) of this Agreement.

(000) "<u>Performance Goal</u>" shall mean, on or before the Performance Goal Date, HPPI either (i) closing a Follow On Offering or (ii) entering into a license, development, commercialization or similar agreement relating to the Product; <u>provided</u> that HPPI receives a net upfront payment of at least Five Million Dollars (\$5,000,000); <u>provided</u>, <u>further</u>, that any such agreement pursuant to this clause (ii) shall be subject to the approval of Mayne Pharma.

(ppp) "Performance Goal Date" shall mean May 31, 2016.

(qqq) "Person" shall mean any individual, firm, corporation, limited liability company, partnership, trust, joint venture, Governmental Authority or other entity, and shall include any successor (by merger or otherwise) of such entity.

(rrr) "Preferred Stock" shall mean HPPI's Preferred Stock, par value \$0.0001 per share.

(sss) "Price Per Share" shall have the meaning ascribed to such term in Section 6.4 of this Agreement.

(ttt) "Prime Rate" shall mean the prime rate of interest as published on the date for which the prime rate is to be determined in the *Wall Street Journal*, and generally defined therein as "the base rate on corporate loans posted by at least 70% of the nation's 10 largest banks." If the *Wall Street Journal* is not published on a date for which the prime rate must be determined, the prime rate shall be the prime rate published in the *Wall Street Journal* on the nearest preceding date on which the *Wall Street Journal* was published, and if the *Wall Street Journal* ceases publication, then the prime rate as reported in a financial paper or journal generally accepted in the financial industry as determinative, as of the nearest preceding date.

(uuu) "Private Offering" shall mean any offering of securities of HPPI other than a Public Offering.

(vvv) "Product" shall have the meaning set forth in the Supply and License Agreement.

(www) "Pro Rata Share" shall have the meaning ascribed to such term in Section 4.1 of this Agreement.

(xxx) "Public Offering" shall mean a public offering of the shares of securities of HPPI pursuant to an effective registration statement with the Commission.

(yyy) "Purchase Right" shall have the meaning ascribed to such term in Section 7.2(d) of this Agreement.

(zzz) "Purchase Right Shares" shall be an equivalent number and class of Equity Securities as the HPLLC At Risk Shares forfeited by HPLLC pursuant to Section 7.2(b), adjusted for any stock splits, stock dividends, recapitalizations, recganizations, reclassifications or otherwise.

(aaaa) "Purchase Right Term" shall have the meaning ascribed to such term in Section 7.2(d)(i) of this Agreement.

(bbbb) "Purchased Securities" shall have the meaning ascribed to such term in the recitals to this Agreement.

(cccc) "Relevant Regulatory Authority" shall have the meaning set forth in the Supply and License Agreement.

(dddd) "Selling Stockholder" shall have the meaning ascribed to such term in Section 6.1 of this Agreement.

(eeee) "Shares" shall have the meaning ascribed to such term in the recitals to this Agreement.

(ffff) "Stock Grant Plan" shall mean any current or future stock option, stock incentive or similar plan or agreement, including without limitation the EIP and the

Initial EIP.

(gggg) "Stockholder(s)" shall mean the holders of Equity Securities of HPPI.

(hhhh) "Supply and License Agreement" shall mean that certain Second Amended and Restated Supply and License Agreement, dated on or about an even date herewith, as subsequently amended and/or restated, by and between Mayne Pharma and HPPI.

(iiii) "Termination Right" shall have the meaning ascribed to such term in the recitals to this Agreement.

(jjjj) "Transaction Documents" shall mean, collectively, the 2014 Transaction Documents and the 2015 Transaction Documents, and "Transaction Documents" shall mean any of the 2014 Transaction Documents and 2015 Transaction Documents individually.

(kkkk) "<u>Transfer</u>", "<u>Transferred</u>" or "<u>Transferring</u>" shall mean any sale, gift, assignment, exchange, conveyance, bequeathment, transfer, liquidation, pledge, encumbrance, disposition or alienation of any shares of Equity Securities or rights related thereto, or any securities convertible into or exercisable or exchangeable for Equity Securities.

(llll) "Virca" shall have the meaning ascribed to such term in the first paragraph of this Agreement.

(mmmm) "Virca Employment Agreement" shall mean that certain Employment Agreement executed by and between Virca and HPPI as of June 24, 2014, and any extension, amendment or renewal thereof.

(nnnn) "Voting Rights Termination Date" shall mean 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 and its Affiliates cease to own ten percent (10%) or more of the issued and outstanding Equity Securities.

1.2. Additional Definitions. In addition to the foregoing, capitalized terms used in this Agreement and not otherwise defined in this Article I shall have the meanings so given to such terms herein.

1.3. <u>Amendment and Replacement of the Original EHA</u>. The parties hereby agree that this Agreement, upon full execution hereof by all of the parties, shall amend, restate and replace the Original EHA in its entirety from and after the Effective Date.

#### ARTICLE II. LOCK-UP

2.1. Mayne and HPLLC (each a "Lock-Up Holder" and, collectively, the "Lock-Up Holders") agree that, during the period beginning on and including the Original Effective Date through and including the date that is the first anniversary of the Original Effective Date (the "Lock-Up Period"), each of them will not, directly or indirectly:

(a) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise Transfer of any shares of the Equity Securities or any securities convertible into or exercisable or exchangeable in Equity Securities, whether now owned or hereafter acquired by the Lock-Up Holders or with respect to which the Lock-Up Holders has or hereafter acquires the power of disposition, or

(b) enter into any swap or other agreement, arrangement or transaction that Transfers to another, in whole or in part, directly or indirectly, any of the economic consequence of ownership of any Equity Securities or any securities convertible into or exercisable or exchangeable for any Equity Securities,

(c) whether any transaction described in clause (a) or (b) above is to be settled by delivery of Equity Securities, other securities, in cash or otherwise, or publicly announce any intention to do any of the foregoing.

2.2. Notwithstanding the provisions set forth in <u>Section 2.1</u>, the Lock-Up Holders may, without the prior written consent of the other parties, Transfer any Equity Securities or any securities convertible into or exchangeable or exercisable for Equity Securities to an Affiliate of such Lock-Up Holder if such Transfer is not for value; <u>provided</u>, <u>however</u>, that in the case of any Transfer described above, it shall be a condition to the Transfer that (a) the transfere executes and delivers to the parties hereto not later than one (1) Business Day prior to such Transfer, a written agreement, in substantially the form of this Agreement and otherwise satisfactory in form and substance to the parties hereto, (b) in the case of a Transfer pursuant to this clause, no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of Equity Securities or any securities convertible into or exercisable or exchangeable for Equity Securities shall be required to be made during the Lock-Up Period (as the same may be extended as described above) and (c) no voluntary filing with the Commission or other public report, filing or announcement shall be made in respect of such Transfer during this Lock-Up Period.

## ARTICLE III. OWNERSHIP CAP

3.1. <u>Ownership Cap</u>. Each of HPLLC, Mayne Pharma, FEO and Virca agrees that during the Lock-Up Period, it or he, together with its or his respective Affiliates, shall not own shares of Equity Securities which would result in it or him owning more than forty-nine and one-half percent (49.5%) of the Common Stock on a Fully Diluted basis other than Mayne Pharma as a result of the 2015 Private Placement and the 2015 Warrant.

## 3.2. <u>Remedy</u>.

(a) In the event of a breach of <u>Section 3.1</u> which results from the involuntary action of such breaching party, such breaching party shall, within ten (10) Business Days, Transfer, with or without consideration or compensation therefor, that certain number of shares of Equity Securities for consideration to accomplish compliance with <u>Section 3.1</u>.

(b) In the event of a breach of <u>Section 3.1</u> which results from the voluntary action of such breaching party or from the noncompliance of the breaching party with <u>Section 3.2(a)</u>, such breaching party shall automatically, and without further action, forfeit and Transfer to HPPI, without consideration or compensation therefor, that certain number of shares of Equity Securities to accomplish compliance with <u>Section 3.1</u>.

(c) Such breaching party agrees to execute any documentation necessary to accomplish the foregoing and to provide such further assurances for the performance thereof. Such breaching party shall also tender the necessary certificates evidencing such Equity Securities duly endorsed to HPPI to accomplish such remedy.

<sup>12</sup> 

#### ARTICLE IV. PREEMPTIVE RIGHTS AND RESTRICTIONS

4.1. <u>First Right of Mayne Pharma and HPLLC</u>. Each of Mayne Pharma and its Affiliates (collectively the "<u>Mayne Pharma Group</u>") and HPLLC and its Affiliates (collectively the "<u>HPLLC Group</u>") shall have the right of first refusal to purchase its Pro Rata Share (as defined below) of all (or any part) of any New Securities (as defined below) that HPPI may from time to time issue after the Effective Date. Each of Mayne Pharma Group's or HPLLC Group's "<u>Pro Rata Share</u>" for purposes of this <u>Section 4.1</u> is equal to the ratio of (a) the number of shares of Common Stock on a Fully Diluted basis which the Mayne Pharma Group or the HPLLC Group, as applicable, is deemed to hold immediately prior to the issuance of such New Securities to (b) the total number of shares of outstanding Common Stock on a Fully Diluted basis immediately prior to the issuance of the New Securities.

4.2. <u>Preference to Certain Accredited Investors</u>. For a period from the Effective Date until the second anniversary of the Effective Date, and solely with respect to Private Offerings made during that period, Mayne Pharma shall have the right to introduce Accredited Investors to HPPI, and HPPI shall accept the subscriptions of such Accredited Investors instead of the subscriptions of other investors until such Accredited Investors introduced by Mayne Pharma have purchased fifty percent (50%) of the Equity Securities being sold pursuant to such Private Offering. At least fifteen (15) Business Days before first circulating offering material for such Private Offering, provide HPPI the name and contact information of Accredited Investors that Mayne Pharma desires to introduce to an investment opportunity in HPPI. HPPI agrees that upon Mayne Pharma providing HPPI the name and contact information of any such Accredited Investor, HPPI will promptly send such Accredited Investor all offering material, shall answer all inquiries of such Accredited Investor and make a senior management executive available to discuss HPPI with such Accredited Investor. Mayne Pharma agrees that it shall not be due or paid any commission or fee in connection with the introduction of such Accredited Investor.

4.3. <u>New Securities</u>. "<u>New Securities</u>" shall mean any Common Stock or Preferred Stock, whether now authorized or not, whether issued pursuant to a Public Offering or Private Offering, and options, warrants, restricted stock units or other rights to purchase or acquire such Common Stock or Preferred Stock, and securities of any type whatsoever that are, or may become, convertible or exchangeable into such Common Stock or Preferred Stock; <u>provided</u>, <u>however</u>, that the term "New Securities" does not include:

(a) any securities or Equity Securities granted, issued or issuable pursuant to any Stock Grant Plan approved by (i) the Board and (ii) Stockholders who hold Equity Securities entitling such Stockholders to voting rights; provided, however, that any such securities or Equity Securities, as the case may be, have been granted or issued under a Stock Grant Plan approved in compliance with Section 4.9(b) hereof;

(b) any shares of the Common Stock issued pursuant to (i) the HPLLC Stock Purchase Agreement, (ii) the Debt Forgiveness Agreement or (iii) any warrants issued to HPLLC in connection with the Debt Forgiveness Agreement;

(c) any securities issued pursuant to (i) the Mayne Pharma Purchase Agreement, (ii) the conversion of any preferred stock issued to Mayne Pharma in connection with the Mayne Pharma Purchase Agreement, (iii) any warrants issued to the Mayne Pharma in connection with the Mayne Pharma Purchase Agreement, (iv) the 2015 SPA or (v) the 2015 Warrant;

(d) any shares of the Common Stock or Preferred Stock issued in connection with any stock split or stock dividend or similar event; or

(e) any securities issued (i) in connection with the establishment of credit facilities, (ii) pursuant to the acquisition of another Person by HPPI's consolidation, merger, purchase of all or substantially all of the assets, or other reorganization in which HPPI acquires, in a single transaction or series of related transactions, all or substantially all of the assets of such other Person or at least fifty-one percent (51%) or more of the voting power of such other Person or at least fifty-one percent (51%) or more of the equity ownership of such other Person or (iii) pursuant to acquisitions or strategic transactions, provided that any such issuance shall only be to a Person (or to the equity holders of such Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of HPPI and shall provide to HPPI significant additional benefits in addition to the investment of funds, but shall not include (except as set forth above) a transaction in which HPPI is issuing securities for the purpose of raising capital or to a Person whose primary business is investing in securities; provided, however, that the applicable transaction set forth in (i) through (iii) herein has been unanimously approved by the disinterested members of the Board.

#### 4.4. Procedures.

(a) In the event that HPPI proposes to undertake an issuance of New Securities, it shall give each of Mayne Pharma and HPLLC written notice of its intention to issue New Securities ("Notice"), describing the type of New Securities, whether the offering is private or public, and the price and the general terms upon which HPPI proposes to issue such New Securities.

(b) Each of Mayne Pharma and HPLLC shall have fifteen (15) days from the date of mailing of any such Notice (the "<u>Applicable Period</u>") to agree in writing that Mayne Pharma and/or members of the Mayne Pharma Group or HPLLC and/or members of the HPLLC Group, as applicable, shall purchase all or a portion of its Pro Rata Share of the New Securities for the price and upon the general terms specified in the Notice by giving written notice to HPPI and stating therein the quantity of New Securities to be purchased, and HPPI shall so sell such New Securities to the Mayne Pharma Group and to the HPLLC Group.

(c) With respect to the issuance of shares of New Securities for which either Mayne Pharma or HPLLC has not exercised its right pursuant to this<u>Section 4.4</u> within the Applicable Period, HPPI shall have one hundred twenty (120) days after the Applicable Period to contract to sell such New Securities at a price and upon general terms not more favorable to the purchasers thereof than specified in the original Notice. Except with respect to the sale of additional New Securities to Mayne Pharma or HPLLC set forth in <u>Section 4.4(d)</u>, if HPPI has not contracted to sell such New Securities within such one hundred twenty (120) day period, HPPI shall not thereafter issue or sell any New Securities without again first offering such New Securities to Mayne Pharma and HPLLC pursuant to this <u>Section 4.4</u>.

(d) If the Mayne Pharma Group has exercised its right to purchase its full Pro Rata Share of New Securities, HPPI shall, within two (2) Business Days of the end of said one hundred twenty (120) day period, give Mayne Pharma written notice of the number of shares of New Securities for which subscriptions have not been received and accepted, or that the offering was fully subscribed. The Mayne Pharma Group shall thereupon have the additional right to purchase up to that number of New Securities for which subscriptions have not been received and accepted; provided, however, during the Lock-Up Period, any purchase of New Securities by the Mayne Pharma Group purchased under Section 4.1 through Section 4.4 shall be made subject to Section 3.1.

4.5. <u>Restrictions on Creating and Issuing New Securities</u>. HPPI shall not, without first obtaining the written consent of Mayne Pharma create, issue, or authorize the creation or issuance of, any Equity Security that is senior to the Common Stock or any security convertible into such security.

4.6. <u>Termination</u>. The rights and obligations in <u>Section 4.1</u> through <u>Section 4.5</u> shall terminate upon the earlier to occur of: (a) with respect to the Mayne Pharma Group, the date that the Mayne Pharma Group collectively owns less than ten percent (10%) of the Common Stock on a Fully Diluted basis; or (b) with respect to the HPLLC Group, the date that the HPLLC Group collectively owns less than ten percent (10%) of the Common Stock on a Fully Diluted basis.

4.7. <u>Restrictions on Virca</u>. Virca agrees that with respect to any option, warrant, restricted stock unit or other right to acquire Equity Securities which he holds or may hereafter hold, (a) such option, warrant, restricted stock unit or other right shall not be transferrable by Virca, except upon his death or operation of law, and Virca shall not Transfer the same, and (b) Virca shall not become vested, either in whole or in part, in such option, warrant, restricted stock unit or other right to acquire Equity Securities until the earlier to occur of (i) September 3, 2016, (ii) the receipt of written notice of acceptance for the filing of a new drug application by HPPI for the Product in the Field by the Relevant Regulatory Authority, or (iii) to the extent provided in the applicable award agreement, upon his death or disability. Virca acknowledges and agrees that any option, warrant, restricted stock unit or other right to acquire Equity Securities issued to him by HPPI shall carry a legend describing the restriction herein.

4.8. <u>Restrictions on FEO</u>. HPPI and FEO each agree that HPPI shall not make, and FEO shall not receive, any grant, award or compensation under the EIP, or other grant, award or issuance of any Equity Security, until after the Performance Goal Date.

## 4.9. Stock Grant Plans; Equity Incentive Plan.

(a) The parties acknowledge that the Board has heretofore approved the EIP, which initially authorized the issuance of up to 32,583,475 shares of Common Stock (the "Initial EIP"), and the terms and conditions thereof, and that the Initial EIP was heretofore submitted to and approved by the Stockholders who have voting rights.

(b) For so long as either HPLLC or Mayne Pharma owns more than forty percent (40%) of the outstanding Common Stock on a Fully Diluted basis, without the approval of either, or both as the case may be, Mayne Pharma and HPLLC (which approval in either case may be withheld or delayed in the sole discretion of Mayne Pharma and HPLLC, respectively), HPPI shall not: (i) increase the number of shares authorized under the EIP beyond the Initial EIP, (ii) amend, modify or supplement the terms and conditions of the EIP or the Initial EIP, (iii) approve, adopt or authorize any Stock Grant Plan, or (iv) issue, grant or award any securities or Equity Securities pursuant to the Initial EIP and the EIP which, when taken together with any other securities or Equity Securities issued, granted or awarded pursuant to the Initial EIP and the EIP after the Effective Date, would result in (including, without limitation, upon the full exercise of any such securities) the issuance, grant or award of more than Five Million (5,000,000) shares of Common Stock in the aggregate.

(c) Each of HPPI, HPLLC, FEO, Virca and Mayne Pharma agrees that all awards that are included in the Initial EIP (including those awarded to Virca) are subject to a restriction on exercise or Transfer until the earlier occur of (i) September 3, 2016, or (ii) the receipt of written notice of acceptance for the filing of a new drug application by HPPI for the Product in the Field by the Relevant Regulatory Authority. Each of HPPI, HPLLC, FEO, Virca and Mayne Pharma acknowledges and agrees, however, that if an increase in the EIP beyond the Initial EIP is approved in accordance with Section 4.9(b), such additional awards beyond the Initial EIP shall not be subject to the foregoing restrictions on exercise or Transfer unless the Board expressly otherwise provides therefor.

#### ARTICLE V. VOTING AGREEMENT, BOARD COMPOSITION AND BOARD MATTERS

5.1. <u>Directors, Number of Directors and Mandatory Voting Requirement.</u> Immediately following the Effective Date, HPPI has five (5) Directors: FEO, Samuel Sears, Jr., Stefan James Cross, Dana Ono and Mark Watson. From and after the Effective Date until the Voting Rights Termination Date, the parties hereto agree that no action shall be taken to increase or decrease the number of Directors except with the unanimous approval of the Board. From and after the Effective Date until the Voting Rights Termination Date, they parties hereto agree that no action shall be taken to increase or decrease the number of Directors except with the unanimous approval of the Board. From and after the Effective Date until the Voting Rights Termination Date, HPLLC, and any transferee thereof permitted hereunder, agrees (and shall cause any Affiliate) to vote any shares of Equity Securities they may own from time to time, in favor of the Mayne Pharma Director(s) (as defined below) at each meeting of Stockholders at which Directors are elected, or execute a written consent of Stockholders in favor of the Mayne Pharma Director(s), in the manner necessary to elect such Mayne Pharma Director(s), with the Mayne Pharma Director(s) being designated by Mayne Pharma, as provided in <u>Section 5.3</u> hereof.

5.2. <u>Vacancies on the Board</u>. If any Mayne Pharma Director ceases to hold such position as a Director for any reason while the mandatory voting requirements provided for in <u>Section 5.1</u> remain in effect, Mayne Pharma shall have the right to designate a replacement Mayne Pharma Director nominee, and at Mayne Pharma's request and option, HPPI shall within five (5) Business Days of receipt of notice of such designation, cause the Board to name and elect such nominee as the new Mayne Pharma Director to fill the vacancy of the seat held by the prior Mayne Pharma Director. If the Board shall not have so named and elected such replacement Mayne Pharma Director nominee within ten (10) Business Days of HPPI's original

receipt of notice of designation from Mayne Pharma, Mayne Pharma shall have the right to circulate a written consent of Stockholders to elect such Mayne Pharma Director, or call (or require the calling of), by written request to HPPI, a special Stockholders meeting to elect such Mayne Pharma Director. HPLLC, and any transferee thereof permitted hereunder, agree (and shall cause any Affiliate) to vote any shares of Equity Securities it may own from time to time to elect the replacement Mayne Pharma Director so nominated, or to sign and return to Mayne Pharma such written consent (within five (5) days of receipt thereof), as the cause may be. In the event that Mayne Pharma takes action as a stockholder of HPPI to enforce its right under this Section 5.2. HPPI agrees to take all actions necessary for the calling of any such special meeting of the Stockholders as soon as practicable after its receipt of such written request from Mayne Pharma, and in any event in accordance with any time limitations set forth in the Bylaws. At any such special meeting of the Stockholders called pursuant to this Section 5.2. Mayne Pharma, in its sole discretion, shall have the right to designate or appoint the chairman of such special meeting.

5.3. <u>Method of Designating Directors</u>. From and after the Original Effective Date, until the Voting Rights Termination Date, Mayne Pharma shall have the right to designate one (1) Director nominee to serve on the Board. If at any time, the number of the Board is increased to serven (7) or more Directors, then for so long as there are serven (7) or more Directors, Mayne Pharma shall have the right to designate an additional Director nominee to serve on the Board, for a total of two (2) Directors (together, the "<u>Mayne Pharma Directors</u>" and individually, each a "<u>Mayne Pharma Director</u>"). Mayne Pharma shall nominate only an individual who is an officer, director or senior employee of Mayne Pharma. Prior to or at any election of Directors, Mayne Pharma shall notify HPPI, HPLLC, and the Director(s) of the individual Mayne Pharma desires to nominate for election.

5.4. <u>Replacement of FEO and Virca</u>. Except as set forth in <u>Section 5.5</u>, until the Voting Rights Termination Date, any replacement or removal of FEO or Virca shall require the unanimous approval of all Directors other than FEO, in the case of his replacement.

#### 5.5. Majority Independent Board.

(a) Each party hereto agrees that it will use its diligent good faith efforts (which efforts shall include, without limitation, not taking any action, as part of a "group" (as defined in Section 13(d) of the Exchange Act) with any other Person or Persons to amend or modify the terms of HPPI's certificate of incorporation and Bylaws, each as amended and/or restated at the applicable time, to circumvent the requirements of this <u>Section 5.5</u>) to ensure that the Board consists of a majority of Independent Directors, regardless of whether any Stockholder may at any time own more than fifty percent (50%) of the outstanding or Fully Diluted Common Stock. This <u>Section 5.5</u> shall automatically terminate and be null and void and of no further force and effect upon the date that a single Stockholder owns ninety percent (90%) or more of the Common Stock. Each party hereto agrees to vote for Directors as follows: (i) if neither Mayne Pharma nor HPLLC own a majority of shares of Common Stock, the parties agree to vote for the Board in its current composition (unless otherwise mutually agreed upon by Mayne Pharma and HPLLC); <u>provided, however</u>, that if while this clause (i) is still in effect any Director) ceases to serve on the Board for any reason, including, without limitation, on account of such Director's death, disability, or resignation, the resulting

<sup>17</sup> 

vacancy on the Board shall be filled by the Board pursuant to the Bylaws, and each of Mayne Pharma and HPLLC agrees to vote its Equity Securities in favor of the election of any such replacement Director at any subsequent meeting of the stockholders until this clause (i) is no longer in effect or until such replacement Director is no longer serving on the Board, whichever occurs first; and (ii) if either Mayne Pharma or HPLLC owns more than fifty percent (50%) of the Common Stock, such party agrees that it will vote for and maintain a Board controlled by Independent Directors.

(b) For the avoidance of doubt, if either Mayne Pharma or HPLLC owns more than fifty percent (50%) of the outstanding Common Stock, then (i) such party may, in its sole discretion but acting in accordance with Section 5.5(f) hereof, remove and replace any Director, including Chairman of the Board, provided that such party maintains a Board controlled by Independent Directors pursuant to Section 5.5(a) of this Agreement and (ii) Section 5.4 of this Agreement shall automatically terminate and be null and void and of no further force and effect. Mayne Pharma agrees that while this Agreement is in effect, it shall not act in concert as part of a "group" (as defined in Section 13(d) of the Exchange Act) with any other Person or Persons to own or control more than fifty percent (50%) of the outstanding Common Stock.

(c) If HPPI does not satisfy the Performance Goal, then for One Hundred Fifty (150) days after the Performance Goal Date, (i) Mayne Pharma shall have the right to appoint a majority of the Directors in its sole discretion (subject to the proviso below in this <u>Section 5.5(c)</u>), and the parties hereto agree to vote any shares of Equity Securities they may own in favor of (x) the removal of any current Directors determined by Mayne Pharma in its sole discretion and/or (y) the election of any replacement Directors nominated or designated by Mayne Pharma, in carrying out Mayne Pharma's rights under this <u>Section 5.5(c)</u>, and (ii) Section 5.4 of this Agreement shall automatically terminate and be null and void and of no further force and effect; provided that, unless or until the Independent Board Requirement has automatically terminated as provided in <u>Section 5.5(c)</u> shall be subject to the Independent Board Requirement.

(d) If, at any time this Agreement is in effect (subject to the proviso below in this<u>Section 5.5(d)</u>), there is a material breach of a Transaction Document by any party other than Mayne Pharma, and such party fails to remedy such breach within thirty (30) days of receipt of notice from Mayne Pharma of such breach, then (i) the Independent Board Requirement shall automatically terminate and be null and void and of no further force and effect, and the parties hereto shall no longer be required to maintain a Board consisting of a majority of Independent Directors, (ii) Mayne Pharma shall have the right to freely vote its Equity Securities in its discretion (in the removal, replacement and election of Directors or otherwise), subject to the terms of HPPI's certificate of incorporation and Bylaws, each as amended and/or restated at the applicable time, and applicable laws, rules and regulations, and (iii) <u>Section 5.4</u> of this Agreement shall automatically terminate and be null and void and of no further force and effect; provided, however, that, notwithstanding anything to the contrary contained herein, the parties hereto acknowledge and agree that (x) the failure by HPPI to achieve the Performance Goal shall not be deemed a "material breach" of a Transaction Document for purposes of this <u>Section 5.5(d)</u> and (y) this <u>Section 5.5(d)</u> shall automatically terminate and be null and void and of no further and effect (A) following the election or appointment of a New Board or (B) upon the date that Mayne Pharma no longer holds at least forty percent (40%) of the outstanding Common Stock.

(e) If, at any time this Agreement in in effect and FEO is serving as Chairman of the Board, FEO is removed as a Director under<u>Section 5.5(b)</u>, (c) or (d) hereof, then Mayne Pharma shall have the right to demand by written notice FEO's resignation as Chairman of the Board, and he shall submit to HPPI, with a copy to Mayne Pharma, such written resignation within three (3) Business Days after his receipt of such notice from Mayne Pharma.

(f) If either Mayne Pharma or HPLLC exercises its right to remove or replace any Director pursuant to Section 5.5(b) hereof (such party so exercising such right shall be referred to herein as the "Exercising Party"), the Exercising Party, acting alone in its sole discretion, shall have the right, upon its execution of a written consent of the stockholders of HPPI, to (i) remove any current Director determined by the Exercising Party in its sole discretion and/or (ii) to elect any replacement Director nominated or designated by the Exercising Party, in its sole discretion, for filling any vacancy on the Board or otherwise. The Exercising Party shall deliver any such written consent to HPPI as soon as practicable after the execution or effectiveness of such written consent. Alternatively, the Exercising Party shall have the right, upon its written request to HPPI, to call (or require the calling of) a special meeting of the Stockholders for the purpose or purposes of considering and voting on (x) the removal of any such current Director determined by the Exercising Party in its sole discretion and/or (y) the election of any such replacement Director nominated or designated by the Exercising Party in its sole discretion and/or (y) the election of any such replacement Director nominated or designated by the Exercising Party in its sole discretion and/or (y) the election of any such replacement Director nominated or designated by the Exercising Party, in its sole discretion, for filling any vacancy on the Board or otherwise. HPPI agrees to take all actions necessary for the calling of any such special meeting of the Stockholders as soon as practicable after its receipt of such written request from the Exercising Party, and in any event in accordance with any time limitations set forth in the Bylaws. At any such special meeting of the Stockholders called pursuant to this <u>Section 5.5(f)</u>, the Exercising Party, in its sole discretion, shall have the right to designate or appoint the chairman of such special meeting.

(g) If Mayne Pharma exercises its right to remove or replace any Director pursuant to Section 5.5(c) hereof, Mayne Pharma shall have the right (i) to deliver to HPLLC a written consent of the Stockholders approving the removal of any current Director determined by Mayne Pharma in its sole discretion and/or the election of any replacement Director nominated or designated by Mayne Pharma, in its sole discretion, for filling any vacancy on the Board or otherwise, or (ii) to call (or require the calling of), upon written request to HPPI, a special meeting of the Stockholders for purposes of removing any such current Director and/or nominating or designating for election any such replacement Director. HPLLC, and any transferees thereof permitted hereunder, agree (and shall cause any of its Affiliates) (x) to sign and deliver to Mayne Pharma such written consent of the Stockholders described in this Section 5.5(g) within five (5) days of receipt thereof or (ii) to vote any shares of Equity Securities it or they may own from time to remove any such current Director and/or neeting. HPPI agrees to take all actions necessary for the calling of any such special meeting of the Stockholders as soon as practicable after its receipt of such written request from Mayne Pharma, and in any event in accordance with any time limitations set forth in the Bylaws. At any such special meeting of the Stockholders called pursuant to this Section 5.5(g). Mayne Pharma, in its sole discretion, shall have the right to designate or appoint the chairman of such special meeting.

(h) To secure the obligations of HPLLC to vote its Equity Securities in accordance with (but solely in connection with the matters set forth in Section 5.5(c) and

Section 5.5(g). HPLLC hereby irrevocably appoints the executive officers of Mayne Pharma, or any of them from time to time, or their designees, as HPLLC's true and lawful proxy and attorney, with the power to act alone and with full power of substitution, to vote or otherwise act with respect to (including, without limitation, by executing any written consent of the Stockholders) all of the Equity Securities held by HPLLC consistent with Section 5.5(c) and Section 5.5(g) and on behalf of HPLLC, at any meeting of the Stockholders (whether annual or special and whether or not an adjourned or postponed meeting) or by written consent of the Stockholders in lieu of any such meeting. The proxy and power granted by HPLLC pursuant to this Section 5.5(c) are coupled with an interest and are given to secure the performance of HPLLC's duties underSection 5.5(c) and Section 5.5(g). Each such proxy and power will be irrevocable for so long as Section 5.5(c) is in effect. To the extent permitted under applicable law, such proxy and power shall be binding on any Person to whom HPLLC may transfer any of its Equity Securities. Such proxy and power, so long as any party hereto is an individual, will survive the death, incompetency and disability of such party or any other individual holder of the Equity Securities and, so long as any party hereto is an entity, will survive the merger or reorganization of such party or any other entity holding any Equity Securities currently held by HPLLC. HPLLC hereby revokes all other proxies and powers of attorney with respect to its Equity Securities that may have heretofree been appointed or granted, and no subsequent proxy or power of attorney shall be given or granted (and if given or granted, shall not be effective) with respect to its Equity Securities prior to the termination of this Agreement.

(i) The parties agree that if any Director (other than FEO) is removed from such position by reason of any provision of this <u>Section 5.5</u>, any Equity Securities previously issued to such Director under a Stock Grant Plan which are subject to vesting shall continue to vest following such Director's removal, and any such vested grants shall remain outstanding until exercised, terminated, sold, transferred and/or disposed of pursuant to their respective terms.

5.6. Legend. From and after the Original Effective Date, all certificates or other instruments representing Equity Securities held by any party hereto shall bear a legend which shall state:

"The securities represented by this certificate are subject to that certain Equity Holders Agreement, dated as of June 24, 2014, as the same may be amended from time to time, pursuant to the terms of which the transfer of such securities is restricted. Such Equity Holders Agreement also provides for various other limitations and obligations, and all of the terms thereof are incorporated by reference herein. A copy of such Equity Holders Agreement has been filed in the registered office of the company where the same may be inspected daily during business hours by any stockholder of record of the company."

5.7. <u>Fundamental Transactions</u>. Before the Board holds any vote, or submits any decision for approval or consent, regarding a Fundamental Transaction (including any Fundamental Transaction involving HPLLC, Mayne Pharma and/or their respective Affiliates), the Board must engage a reputable, qualified financial advisor, the identity of which shall be agreed upon by the Board, to render an opinion to the Board before such vote or decision as to whether such Fundamental Transaction is fair, reasonable and in the best interests of the Stockholders.

5.8. <u>Provision of Financial Statements</u>. The Chief Executive Officer and/or President of HPPI shall deliver, or cause to be delivered, to the Board financial statements no later than the fifth (5th) calendar day of each calendar month, and such financial statements shall present fairly, in all material respects and consistent with past practices, the financial condition of HPPI, including the present amount of operational cash on hand with HPPI.

5.9. <u>Amendments to Certificate of Incorporation or Bylaws</u>. Except for actions taken to effectuate the amendments to HPPI's certificate of incorporation and the Bylaws contemplated by the 2015 SPA, HPLLC hereby covenants and agrees that it will not take any action to (i) alter, amend, change, add to, repeal, impair or diminish, in any way, any provision of HPPI's certificate of incorporation or the Bylaws which reference or pertain to this Agreement or (ii) otherwise make any amendment, or add any provision, to HPPI's certificate of incorporation or the Bylaws that would impair or diminish, in any way, any right of the Investor under this Agreement.

## ARTICLE VI. <u>RIGHT OF FIRST REFUSAL</u>

6.1. <u>Mayne Pharma Right of First Refusal</u>. If either FEO or Virca or any transferees of FEO or Virca permitted under <u>Section 6.2</u> (each, a "<u>Selling Stockholder</u>") desires to Transfer any of the Common Stock held personally of record by him or it, as the case may be, to any Person, he or it shall first make an offer to sell all of such shares that he or it desires to Transfer (but not less than all of such shares) to Mayne Pharma for the purchase price per share and on the terms hereinafter set forth. Such offer shall be in writing and shall specify the nature of the Transfer in which the Selling Stockholder desires to engage, including the name or names of the other party or parties to such proposed transaction and the terms thereof, including the purchase price and payment terms, if any, and shall have attached a written copy of the proposed offer to or from the other party or parties to the proposed transaction. Mayne Pharma may irrevocably accept the offer as to all, but not less than all, of the shares, in writing within twenty (20) days after receipt thereof. Notwithstanding the foregoing, the restrictions set forth in this <u>Section 6.1</u> shall not apply to any Common Stock that is an FEO Indirect Share as long as such Common Stock is an FEO Indirect Share.

6.2. <u>Permitted Transfers</u>. The rights granted to Mayne Pharma pursuant to <u>Section 6.1</u> shall not apply to (a) Transfers as a bona fide gift or gifts for tax or estate planning purposes to the spouse, siblings, parents, children or grandchildren of FEO or Virca, or any trust of which any of the foregoing are beneficiaries (provided that any donee thereof agrees in writing to be bound by the terms of this Agreement), (b) Transfers pursuant to a valid divorce decree or by will or intestate succession upon death (provided that any recipient thereof agrees in writing to be bound by the terms of this Agreement), or (c) Transfers to FEO or Virca pursuant to the exercise of, or vesting in, any stock option, warrant, restricted stock unit, or other right issued pursuant to the EIP or other stock option or incentive plan of HPPI, provided that the Common Stock received upon such exercise or vesting shall remain subject to the rights of Mayne Pharma provided for in this Agreement.

6.3. <u>Purchase by Mayne Pharma</u>. If a Selling Stockholder offers to sell his Common Stock to Mayne Pharma pursuant to <u>Section 6.1</u> above, then each party hereto agrees to vote its shares of Common Stock, including with respect to the Selling Stockholder, the shares that are offered for sale by the Selling Stockholder, at any meeting of the Stockholders in order to approve any corporate action that may be required to be taken by HPPI or its officers or Directors in order to enable Mayne Pharma to purchase any or all of the shares of Common Stock offered by the Selling Stockholder.

6.4. <u>Purchase Price and Terms</u>. The purchase price and terms of payment set forth in any offer by a Selling Stockholder under<u>Section 6.1</u> shall be identical to any offer given or received by such Selling Stockholder to or from a proposed third-party purchaser, except that if the consideration to be paid the Selling Stockholder by such proposed third-party purchaser consists in whole or in part of property (rather than cash), the purchaser(s) hereunder may transfer cash or other property of similar kind and equivalent value to the Selling Stockholder in payment for his shares of Common Stock. If a Selling Stockholder desires to pledge, give or otherwise encumber his shares of Common Stock, or make such other Transfer where the consideration for such Transfer is other than cash, then the purchase price for each share of Common Stock sold to Mayne Pharma pursuant to <u>Section 6.1</u> of this Agreement shall be equal to the average closing price of the Common Stock as reported on the OTC Bulletin Board, OTCQB Marketplace or any exchange on which the Common Stock is then traded for the twenty (20) day trading period ending on the trading date immediately prior to the date of acceptance by Mayne Pharma of the offer set forth in <u>Section 6.1</u> (the "<u>Price Per Share</u>"). The terms of payment of any purchase price determined by reference to the Price Per Share shall be payable twenty-five percent (25%) at the Closing (as defined herein), and then the balance in twelve (12) quarterly installments of equal principal amounts plus accrued interest at a rate of the Prime Rate plus five percent (5%) beginning on the first (1st) day of the calendar quarter immediating following the Closing; <u>provided</u>, <u>however</u>, that Mayne Pharma may, at its sole discretion, prepay any or all amounts due under such payment without penalty therefor.

6.5. Acceptance of Offers. Any offer made pursuant to Section 6.1 may be accepted by Mayne Pharma within the time provided for acceptance of such offer by Mayne Pharma giving written notice of its irrevocable acceptance to the Person making the offer. An offer shall be deemed to be rejected unless written notice of acceptance of the offer has been received by the Person making the offer prior to the expiration of the time for acceptance set forth in Section 6.1 hereof.

6.6. <u>Closing of Purchase</u>. If any of the shares of Common Stock included in the offers made by the Selling Stockholder pursuant to<u>Section 6.1</u> of this Agreement are accepted for purchase, then such shares shall be sold by the Selling Stockholder to Mayne Pharma, accepting such offers. The closing of the purchase shall take place at the principal office of HPPI or at such other place as the parties may agree, not more than thirty (30) days after the date of the notice of the acceptance of an offer made pursuant to <u>Section 6.1</u> hereof (the "<u>Closing</u>"). The purchase price for all shares of Common Stock sold pursuant to <u>Section 6.1</u> hereof shall be paid in accordance with the terms of payment determined as set forth in <u>Section 6.4</u> above. The Selling Stockholder shall represent and warrant to the purchasers that he is conveying to them such shares, with full warranties of title, free and clear of any claims, options, charges, encumbrances or rights of others, except as may be created by this Agreement.

6.7. <u>Release from Restriction</u>. If Mayne Pharma rejects the offer, fails to accept the offer in writing within thirty (30) days after receipt thereof, or elects to purchase some but not all of the shares of Common Stock offered by the Selling Stockholder pursuant to <u>Section 6.1</u>, then for a period of ninety (90) days after said thirty (30) day period, the shares of Common Stock subject to the offer which are not elected for purchase by Mayne Pharma and are desired to be Transferred by the Selling Stockholder may be Transferred only to such described party or parties and on the terms and conditions therein described, but on no more favorable terms, all as described in the offer pursuant to <u>Section 6.1</u>. After said ninety (90) day period, such shares shall remain subject to all terms and conditions of this<u>Article VI</u>. Any third party or parties purchasing shares of Common Stock pursuant to this Agreement shall be required to execute a counterpart of this Agreement. If a Selling Stockholder shall fail to complete such proposed Transfer within ninety (90) days following the expiration of the time provided in this Agreement for acceptance of the final offer made pursuant to <u>Section 6.1</u> above, then such shares of Common Stock shall again be subject to all of the restrictions set forth in <u>Section 6.1</u> and elsewhere in this Agreement.

## ARTICLE VII. PERFORMANCE GOAL

#### 7.1. Performance Goal Generally.

(a) HPPI agrees to use commercially reasonable efforts to implement the Development Plan and commercialize the Product as soon as practicable and consistent with the Supply and License Agreement. The parties agree that HPPI shall satisfy the Performance Goal; provided, however, that satisfying the Performance Goal shall be subject to the terms and conditions provided herein and that HPPI shall grant to Mayne Pharma and HPLLC equivalent registration rights if any such registration rights are granted in connection with the satisfaction of the Performance Goal.

(b) Each of HPLLC and FEO acknowledges and agrees that (i) the Performance Goal is fair, reasonable and attainable and (ii) the remedies to which each is subject, whether in this Agreement or in any other Transaction Document, for the failure by HPPI to satisfy the Performance Goal are fair and reasonable.

#### 7.2. Surrender of Options; Sale and Forfeiture of Equity Securities; Purchase Right of Equity Securities If HPPI fails to satisfy the Performance Goal:

(a) FEO agrees that he shall forfeit all then unvested options, warrants, restricted stock units, or other right to acquire Equity Securities held personally of record. Furthermore, Mayne Pharma shall have the right to purchase by written notice to FEO, delivered within sixty (60) days after such failure, all Equity Securities, vested options, vested warrants, vested restricted stock units and the like held personally of record by FEO or otherwise Transferred by him, at the fair market value as of the date of such resignation or termination. The fair market value of any issued and outstanding Equity Securities held by FEO shall be determined by the Price Per Share, and the fair market value of any vested option or warrant shall equal to (i) the aggregate value of all Equity Securities determined by the Price Per Share which may be purchased pursuant to such option or warrant, less (ii) the aggregate exercise price

to purchase such Equity Securities. Notwithstanding the foregoing, no Common Stock (including any Common Stock held by HPLLC) that is a FEO Indirect Share shall be subject to the provisions of this <u>Section 7.2(a)</u> as long as such Common Stock or is a FEO Indirect Share; and

(b) Mayne Pharma shall have the right, in its sole discretion, to cause HPPI, as full liquidated damages, to declare by written notice to HPLLC and to Mayne Pharma that some or all of the HPLLC At Risk Shares shall be forfeited by HPLLC to HPPI ("Default Notice"). If HPPI makes such election, it shall have waived and released any and all claims it may have for any damages it may have suffered as a result of HPPI failing to satisfy the Performance Goal. HPLLC agrees that upon receipt of such Default Notice electing forfeiture, it shall, without payment or additional consideration, within two (2) Business Days after receipt of such Default Notice deliver to HPPI any and all stock certificates in its possession or control evidencing any of the HPLLC At Risk Shares duly endorsed for Transfer back to HPPI or accompanied by an executed stock power for Transfer back to HPPI. Such HPLLC At Risk Shares shall be transferred back to HPPI free and clear of all Liens or claims of any nature. HPLLC further agrees upon HPPI delivering such Default Notice, HPPI shall be entitled to Transfer, and HPLLC hereby directs HPPI to Transfer, on its stock ledger back to HPPI any and all HPLLC At Risk Shares forfeited to HPPI under this <u>Section 7.2(b)</u> shall be cancelled on the books and records of HPPI. Any election and decision made by HPPI pursuant to this <u>Section 7.2(b)</u> shall be made by the majority approval of the disinterested Directors; <u>provided</u>, <u>however</u>, for purposes of this <u>Section 7.2(b)</u>, FEO shall be deemed to be an interested Director. Notwithstanding the foregoing in this <u>Section 7.2(b)</u>, the provisions of this <u>Section 7.2(b)</u> shall automatically terminate and be null and void and of no further force and effect if prior to the achievement of the Performance Goal, Mayne Pharma has demanded FEO's resignation as Chairman of the Board, and if FEO has in fact tendered his resignation, in each case as provided by <u>Section 5.5(e)</u> hereof.

(c) If FEO or HPLLC, as the case may be, fails to deliver to HPPI or Mayne Pharma, as the case may be, the certificates or other instruments described in this <u>Section 7.2</u>, the officers of HPPI, or any of them, are each hereby appointed as attorney-in-fact for FEO or HPLLC, as the case may be, for the purpose of complying with this <u>Section 7.2</u>, including Transferring any Equity Securities, and delivering any of the aforesaid certificates or other instruments to HPPI or Mayne Pharma, as the case may be, whereupon FEO's rights with respect to the Equity Securities shall cease. Such officers shall incur no liability for such actions described in this <u>Section 7.2(c)</u>. This appointment of the officers as attorney-in-fact is coupled with an interest and such appointment is irrevocable.

(d) HPPI hereby grants Mayne Pharma the following purchase right (the '<u>Purchase Right</u>') to purchase all or any part of the Purchase Right Shares at the Exercise Price (as defined below) per share and during the Purchase Right Term (as defined below).

(i) The "<u>Purchase Right Term</u>" shall be the period beginning on the date HPPI gives the Default Notice and continuing until the sixtieth (60th) day after such date. This Purchase Right may be exercised regardless of whether HPLLC honors its obligation to convey the HPLLC At Risk Shares back to HPPI as set forth in <u>Section 7.2(b)</u> above. If HPLLC does not honor its obligation to convey the HPLLC At Risk

Shares back to HPPI, Mayne Pharma shall nevertheless have the right to purchase, and this Purchase Right shall be for, the Purchase Right Shares predicated upon the HPLLC At Risk Shares which HPLLC should have conveyed back to HPPI, and each of HPPI and Mayne Pharma shall have the right to seek specific performance to require HPLLC to convey the HPLLC At Risk Shares back to HPPI.

(ii) The "Exercise Price" per share of Common Stock shall be equal to the average closing price of the Common Stock as reported on the OTC Bulletin Board, OTCQB Marketplace or any exchange on which the Common Stock is then traded for the twenty (20) day trading period ending on the trading date immediately prior to the date that Mayne Pharma gives the Notice of Exercise (as defined below).

(iii) This Purchase Right may be exercised by Mayne Pharma at any time prior to the expiration of the Purchase Right Term, in whole or in part, by delivering written notice of exercise (the "<u>Notice of Exercise</u>"), duly executed by Mayne Pharma to HPPI at its principal office, accompanied by payment, in cash by wire transfer of immediately available funds to the order of HPPI and to an account designated by HPPI, of the amount obtained by multiplying the number of shares designated in the Notice of Exercise by the Exercise Price. For purposes hereof, "<u>Exercise Date</u>" shall mean the date on which all deliveries required to be made to HPPI upon exercise of this Purchase Right pursuant to this <u>Section 7.2(d)(iii)</u> shall have been made.

(iv) As soon as practicable (but in no event later than three (3) Business Days) after the valid exercise of this Purchase Right, in whole or in part, in accordance with clause (iii) immediately above, HPPI, at its expense, shall cause to be issued in the name of and delivered to Mayne Pharma a certificate or certificates (which shall contain appropriate restrictive legends) for the number of fully paid and non-assessable shares to which Mayne Pharma shall be entitled upon such exercise. Mayne Pharma shall for all purposes hereof be deemed to have become the holder of record of such shares on the Exercise Date irrespective of the date of delivery of such certificates.

(v) The issuance of the shares upon the exercise of this Purchase Right, and the delivery of certificates or other instruments representing such shares, shall be made without charge to Mayne Pharma for any tax or other charge of whatever nature in respect of such issuance and HPPI shall bear any such taxes in respect of such issuance.

7.3. <u>Mayne Pharma Remedy on Default</u> Mayne Pharma shall have the right to terminate the Supply and License Agreement without damages, penalty, or any liability whatsoever to any party hereto within five (5) Business Days after written notice to HPPI or FEO, respectively, if there has not been full compliance by either party with the applicable provisions of <u>Section 7.2</u>. Mayne Pharma's rights under this <u>Section 7.3</u> are in addition to all other rights and remedies available under any agreement, at law or in equity. Mayne Pharma and HPPI agree that the Supply and License Agreement shall be deemed amended to add the provision of this <u>Section 7.3</u>.

7.4. <u>Mayne Pharma Exercise of Rights: Covenant Not to Sue</u> The parties hereto agree that Mayne Pharma may decide in its sole discretion whether and when to exercise any of its rights under this <u>Article VII</u> and that it may exercise such rights for any reason. In consideration of the benefits conferred upon them in connection with this Agreement, HPPI, HPLLC and FEO each covenant and agree that he or it will not sue or otherwise assert any claim against Mayne Pharma or any of its Affiliates as result of Mayne Pharma's exercise of its rights under this <u>Article VII</u> or for any act or omission leading up to, causing, or contributing to the failure to satisfy the Performance Goal, other than acts or omissions constituting fraud or other willful misconduct.

7.5. No Restrictions. No Transfer under this Article VII shall be subject to the provisions of Article III, Article III (except that any Transfer under Section 7.2(b) shall be subject to Article III), Article IV, Article V or Article VI.

#### ARTICLE VIII. TERMINATION

8.1. <u>General</u>. In addition to the specific provisions of this Agreement that terminate at such time as Mayne Pharma Group collectively owns less than ten percent (10%) of the Common Stock on a Fully Diluted basis, this Agreement generally shall terminate:

(a) If HPPI is adjudicated bankrupt, HPPI executes an assignment for benefit of creditors, a receiver is appointed for HPPI or HPPI is voluntarily or involuntarily dissolved; or

(b) HPPI, HPLLC and Mayne Pharma expressly agree in writing to terminate this Agreement.

## ARTICLE IX. <u>REPRESENTATIONS AND WARRANTIES</u>

9.1. Each of the parties represents and warrants to the other parties that each of the following representations and warranties is true and correct with respect to itself as of the Original Effective Date.

(a) It is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. It is neither in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. It is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in a material adverse effect, and no Action has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

26

(b) It has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out

its

obligations hereunder. Its execution, delivery and performance of this Agreement and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary action, and no further approval or authorization is required by it, its governing board, managers or other body or any of its stockholders, members or owners in connection herewith. It has duly executed this Agreement, and this Agreement will constitute a valid and binding obligation enforceable against itself in accordance with its respective terms.

(c) Its execution, delivery and performance of this Agreement does not and will not, and its consummation of the transactions contemplated hereby do not and will not: (i) conflict with or violate any provision of its certificate or articles of incorporation, bylaws or other organizational or charter documents, (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of its properties or assets, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument or other understanding to which it is a party or by which any of its property or asset is bound or affected, or (iii) 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 it is subject (including federal and state securities laws and regulations), or by which any of its property or asset is bound or affected.

## ARTICLE X. MISCELLANEOUS

10.1. <u>Notices</u>. All notices, requests, demands and other communications provided for hereunder shall be in writing and mailed, faxed or delivered to each applicable party at the addresses set forth on <u>Exhibit A</u> hereto or at such other address as to which such party may inform the other parties in writing in compliance with the terms of this <u>Section 10.1</u>. All such notices, requests, demands and other communications shall, when mailed (which mailing must be accomplished by first class mail, postage prepaid; express overnight courier service; or registered mail, return receipt requested) or transmitted by facsimile, be effective three (3) days after deposited in the mails or upon transmission by facsimile, respectively, addressed as aforesaid, unless otherwise provided herein.

10.2. <u>Severability</u>. The provisions of this Agreement are severable and, in the event that any court of competent jurisdiction shall determine that any one or more of the provisions or part of a provision contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision or part of a provision of this Agreement; but this Agreement shall be reformed and construed as if such invalid or illegal or unenforceable provision, or part of a provision, had never been contained herein, and such provisions or part reformed so that it would be valid, legal and enforceable to the maximum extent possible.

10.3. <u>Dispute Resolution</u>. In the event of any Dispute, then each of the parties hereto agrees to settle all Disputes by arbitration before a single arbitrator in Atlanta, Georgia, selected by, and such arbitration to be administered by, the American Arbitration Association ("<u>AAA</u>") in accordance with its International 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 Disputes between or among them are subject to the alternative dispute resolution procedures of this <u>Section 10.3</u>. 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 Dispute determined by the arbitrator shall be final and binding and shall not be subject to further appeal. Each of the parties hereto shall bear its own costs and expenses and an equal share of the arbitrator's fees and administrative fees of arbitration, subject to any award under <u>Section 10.3(b)</u>.

(a) If there is a Dispute within the scope of this <u>Section 10.3</u>, and if any party to this Agreement is a party to another agreement that contains an arbitration, forum selection, or other dispute resolution provision that is different from or inconsistent with this <u>Section 10.3</u> ("<u>Other Dispute Resolution Provision</u>"), then the Dispute shall be governed by this <u>Section 10.3</u> and not by the Other Dispute Resolution Provision notwithstanding whether such other agreement was entered into after the Original Effective Date, except to the extent each of the parties hereto agrees in writing by express reference to this <u>Section 10.3(a)</u>.

(b) In any Dispute, the arbitrator shall award to the prevailing party all of such party's costs (including fees and costs of the arbitrator and AAA) and attorneys' fees incurred in connection therewith. As used herein, "attorneys' fees" shall mean the full and actual costs of any legal services actually rendered in connection with the matters involved, calculated on the basis of the usual fee charged by the attorneys performing such services.

(c) If any party fails to perform a specific act required under this Agreement (including, without limitation, acts required to be performed under<u>Article VII</u> of this Agreement) or under any of the other Transaction Documents, the party for whose benefit the act was to be taken will be irreparably harmed. Accordingly, in any Dispute, the arbitrator shall award specific performance, in addition to any other remedy available at law, in equity, or under the applicable AAA rules.

(d) This Agreement and all Disputes 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.

10.4. <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument, and any of the parties hereto may execute this Agreement by signing any such counterpart. Counterparts may be delivered via facsimile, electronic mail (including pdf), or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

10.5. <u>Amendments, Waivers and Consents</u>. This Agreement may be amended and any provision of this Agreement may be waived with the prior written consent of HPPI, HPLLC and Mayne Pharma; <u>provided</u>, <u>however</u>, no such amendment shall be valid which adversely affects FEO and/or Virca without the additional written consent of FEO and/or Virca, whichever one or both are adversely affected; <u>provided further</u>, notwithstanding anything in this Agreement to the contrary, Mayne Pharma and HPLLC may amend <u>Section 7.1</u> of this Agreement without the

consent of HPPI. No waiver by any party shall be effective unless in writing and no such waiver shall extend to or affect any other obligation not expressly waived. No failure or delay on the part of any party to this Agreement in exercising any right, power or remedy hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy hereunder. The remedies provided in this Agreement are cumulative and not exclusive of any remedies provided by law.

10.6. <u>Binding Effect</u>; Assignment. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors, assigns, heirs and legatees.

10.7. Prior Agreements. This Agreement contains the entire understanding of the parties and there are no further or other agreements or understandings, written or oral, in effect between the parties relating to the subject matter hereof unless expressly referred to herein.

10.8. <u>Conflict with Bylaws</u>. In the event of any conflict between the terms and provisions of this Agreement and the terms and provisions of the Bylaws, the terms and provisions of this Agreement shall control.

10.9. <u>Securities Covered</u>. The provisions of this Agreement shall apply to all Equity Securities, and any securities convertible into or exercisable or exchangeable into such Equity Securities, now owned and hereafter acquired by the parties to this Agreement or any Person later becoming bound by the provisions of this Agreement as provided hereunder and shall include all Equity Securities and any securities convertible into or exercisable or exchangeable into such Equity Securities.

10.10. <u>Potential Investor Liabilities</u>. HPLLC hereby agrees to defend, indemnify, and hold harmless Mayne Pharma, HPPI, each of their Affiliates, and each of their respective representatives from and against any and all third party claims, demands, Actions, suits, and other proceedings, and all resulting losses, damages, liabilities, settlements, judgments, costs, and expenses (including without limitation, attorneys' fees), arising from or in connection with any capital raising by, or on behalf of, HPPI prior to the Original Effective Date, including without limitation, claims by or from any potential investor in such capital raising.

10.11. Time. Time is of the essence of this Agreement.

# (Signature Page Follows)

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Agreement by duly authorized officers as of the date first above written.

# MAYNE PHARMA VENTURES PTY LTD

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

## HEDGEPATH LLC

By:	Black Robe Capital, LLC, its sole manager	-
<i>Dj</i> .	Black Robe Capital, EEC, ho bole manager	

By:	/s/ Frank E. O'Donnell, Jr., M.D.
Name:	Frank E. O'Donnell, Jr., M.D.
Title:	Manager

## HEDGEPATH PHARMACEUTICALS, INC.

 By:
 /s/ Nicholas J. Virca

 Name:
 Nicholas J. Virca

 Title:
 President and Chief Executive Officer

/s/ Frank E. O'Donnell, Jr., M.D. FRANK E. O'DONNELL, JR., M.D.

/s/ Nicholas J. Virca

NICHOLAS J. VIRCA

[Signature Page to Amended and Restated Equity Holders Agreement]

## FIRST AMENDMENT TO EXECUTIVE CHAIRMAN AGREEMENT

THIS FIRST AMENDMENT TO EXECUTIVE CHAIRMAN AGREEMENT (the "Amendment"), is dated as of May 15, 2015, by and between HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and Frank E. O'Donnell, Jr., M.D. (the "Executive Chairman"). The Company and the Executive Chairman are referred to collectively herein as the "Parties."

WHEREAS, the Parties entered into an Executive Chairman Agreement dated as of June 24, 2014 (the 'Agreement'); and

WHEREAS, the Parties desire to amend the Agreement in accordance with Paragraph 9 thereof.

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

1. Amendments. The Parties hereby amend the Agreement as follows:

a. The third recital of the Agreement is hereby deleted in its entirety and replaced with the following:

WHEREAS, the Company, the Executive Chairman, Nicholas J. Virca, HedgePath LLC, and Mayne Pharma Ventures Pty Ltd, an Australian company ACN 168 896 357 ("Mayne Pharma"), are parties to that certain Equity Holders Agreement dated as of June 24, 2014 (as amended or modified from time to time, the "EHA") that, among other things, affects the parties' business relationship and contains certain conditions and limitations on the Executive Chairman's right to purchase a portion of the Company's capital stock.

b. Section 2 of the Agreement is hereby deleted in its entirety and replaced with the following:

2. TERM. The term of this Agreement shall commence as of the Effective Date and shall continue until the date that the Executive Chairman is no longer serving as a member of the Board of Directors (as the same may be renewed in accordance with the Company's governing instruments), or upon his earlier death, incapacity, removal or resignation.

c. Section 7 of the Agreement is hereby deleted in its entirety and replaced with the following:

7. TERMINATION. With or without cause, the Company or the Executive Chairman may terminate this Agreement at any time upon 60 days' written notice,

and the

#### Page 1 of 2

Company shall be obligated to pay to the Executive Chairman the compensation and expenses due up to the date of the termination. Nothing contained herein or omitted herefrom shall prevent the removal of, or the exercise of any right to cause the resignation of, the Executive Chairman as the chairman of the Board of Directors or as a member of the Board of Directors or otherwise, in each case (i) as permitted under the Company's certificate of incorporation, bylaws or its corporate governance, each as amended or modified from time to time, (ii) pursuant to the EHA, or (iii) by applicable law, rule or regulation, including, without limitation, the DGCL.

# 2. Miscellaneous Provisions.

a. Effect of Amendment. Except as modified by this Amendment, the Agreement is in all respects ratified and confirmed and all of the terms, conditions and provisions thereof shall remain in full force and effect. Nothing in this Amendment is intended to amend any language of the Agreement other than as specifically set forth above.

b. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to conflict of law principles thereof.

c. <u>Counterparts.</u> This Amendment may be executed in one or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method, and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

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

Page 2 of 2

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

HedgePath Pharmaceuticals, Inc.

 By:
 Garrison J. Hasara

 Name:
 Garrison J. Hasara

 Title:
 Chief Financial Officer and Treasurer

/s/ Frank E. O'Donnell, Jr., M.D. Frank E. O'Donnell, Jr., M.D.

[Signature Page to First Amendment to FEO Executive Chairman Agreement]

## FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

THIS FIRST AMENDMENT TO EMPLOYMENT AGREEMENT (the "Amendment"), is dated as of May 15, 2015 by and between HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and Nicholas J. Virca (the "Executive"). The Company and the Executive are referred to collectively herein as the "Parties."

WHEREAS, the Parties entered into an Employment Agreement dated as of June 24, 2014 (the"Agreement"); and

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

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

1. Amendment to Paragraph 1. The Parties hereby amend Paragraph 1 of the Agreement by deleting the words "and the EHA" from the second and third sentences thereof.

2. Amendment to Paragraph 2(a). The Parties hereby completely amend and restate Paragraph 2(a) of the Agreement to read as follows:

(a) <u>Responsibilities</u>. The Executive will report to the Company's Board of Directors (the "**Board**"), understanding that he will act in accordance with the instructions of the JDC (as defined in and subject to the rights and powers of the JDC as set forth in that certain Second Amended and Restated Supply and License Agreement dated as of May 15, 2015, as may be subsequently amended and/or restated, by and between the Company and Mayne Pharma Ventures PTY LTD, the same being referred to herein as the "**SLA**") with respect to all clinical and product development activities relating specifically to any product which is the subject of the SLA. Within the limitations established by the Company's certificate of incorporation or bylaws, each as may be amended from time to time, and Delaware General Corporation Law, the Executive shall have each and all of the duties and responsibilities customarily associated with the position of President and Chief Executive Officer and such other or different duties on behalf of the Company as may be assigned from time to time by the Board (or the JDC); *provided, however*, that the Executive will not be responsible for leading any capital raising initiatives on behalf of the Company.

3. <u>Amendment to Paragraph 3(a)</u>. The Parties hereby amend Paragraph 3(a) of the Agreement by deleting in its entirety the clause therein beginning *provided*, *however*," (thus leaving the word "thereof" as the final word of Paragraph 3(a)).

Page 1 of 3

4. <u>Amendment to Paragraph 7(b)</u>. The Parties hereby amend Paragraph 7(b) of the Agreement by deleting in its entirety the following clause therein – "(vi) the Executive's failure to resign from the Company pursuant to Article VIII of the EHA;".

5. Amendment to Paragraph 7(e)(iii). The Parties hereby amend Paragraph 7(e)(iii) of the Agreement by deleting in its entirety the final sentence thereof.

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

7. Interplay Between Paragraph 2 of the Amendment and Paragraph 7(e)(iii) of the Agreement. The Parties agree that the changes to the Executive's duties and responsibilities effectuated by Paragraph 2 of this Amendment do not constitute "Good Reason" under Paragraph 7(e)(iii) of the Agreement.

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

Page 2 of 3

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

HedgePath Pharmaceuticals, Inc.

 By:
 Garrison J. Hasara

 Name:
 Garrison J. Hasara

 Title:
 Chief Financial Officer and Treasurer

/s/ Nicholas J. Virca

Nicholas J. Virca

Page 3 of 3

#### FOIA CONFIDENTIAL TREATMENT REQUEST BY HEDGEPATH PHARMACEUTICALS, INC. IRS EMPLOYER IDENTIFICATION NUMBER 30-0793665

# **\*\*\*CONFIDENTIAL TREATMENT REQUESTED\*\*\***

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

Final

Date: May 15, 2015

Second Amended and Restated Supply and License Agreement

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

Table of c	ontents
Details	
Agreed te	rms
1.	Defined terms & interpretation
1.1 1.2 1.3	Defined terms Interpretation Amendment and Restatement
2.	Term
2.1 2.2 2.3	Initial Term Extension Acknowledgment with respect to continuing obligations
3.	Licence
3.1 3.2 3.3 3.4	Licence to exploit the Product in the Territory HPPI obligations Supporting the exclusive licence Sub licensing the MP Licensed Rights
4.	Development
4.1 4.2 4.3 4.4	Development Plan and Budget JDC Material development decisions Mayne Pharma support
5.	Marketing Authorisation
5.1 5.2 5.3	Obtaining and maintaining Marketing Authorisations Assistance by Mayne Pharma Failure to obtain Marketing Authorisations
6.	Manufacture and supply of Product
6.1 6.2 6.3 6.4	Forecasts Orders Manufacture; Failure to Supply Backup manufacturer
7.	Payments
7.1 7.2 7.3 7.4 7.5	HPPI Payments Review of Prices Mayne Pharma Payments Payment terms Reimbursement
8.	Delivery, risk and title
8.1 8.2 8.3	Delivery Risk Title

Second Amended and Restated Supply and license agreement – Mayne Pharma and HPPI | page 2

9.	Acceptance of Product	19
9.1 9.2 9.3	Certificate of Analysis Defective Product Sole remedy	19 19 20
10.	Complaints	20
10.1 10.2 10.3 10.4	Handling customer complaints Notification of complaints Adverse Drug Events Supplementary agreements	20 20 20 20
11.	Recalls	20
11.1 11.2 11.3 11.4 11.5	Notice of recall Directing that the Product be recalled Administering a recall Cost of the recall Submission to independent analysis	20 21 21 21 21 21
12.	Performance obligations	21
12.1 12.2 12.3 12.4	Business Plan Promotional Material Efforts to maximise sales Minimum Annual Volumes	21 22 22 22
13.	Compliance with laws and regulations	22
13.1 13.2 13.3	HPPI's obligations Mayne Pharma's obligations Anti-corruption	22 23 23
14.	Inspection	23
15.	Representations and warranties	24
15.1 15.2 15.3	Legal capacity and relationships Mayne Pharma warranties HPPI warranties	24 24 24
16.	Liability, indemnity and insurance	25
16.1 16.2 16.3 16.4 16.5 16.6 16.7 16.8	No exclusion or limitation Exclusion and disclaimer of implied obligations Limitation of liability regarding matters other than Non-Excludable Obligations Indemnity HPPI Insurance Mayne Pharma Insurance Maintain insurance Evidence of insurance	25 25 25 25 25 25 26 26 26
17.	Confidentiality	26
17.1 17.2 17.3	Definition Restrictions on disclosure and use Exceptions	26 27 27
18.	Intellectual Property Rights	27
18.1	Intellectual Property Rights in the Product as at the Start Date	27

***	28
Reserved	28
	28 28
Notification of infringement	28
Right to take action	28
Branding	28
Directions regarding use of the Trade Mark	28
	29 29
	29
No right for HPPI to register the Trade Mark	29
Termination	29
Termination for breach by a party	29
	29
	30 30
	30
Accrued rights and remedies	31
Sell down or repurchase	32
Return of Confidential Information	32
Force majeure	32
Occurrence of Force Majeure Event Termination	32 33
Notices and other communications	33
Service of notices	33
Effective on receipt	33
Dispute resolution	33
GST	34
Interpretation	34
	34 34
1	34
Reimbursements (net down)	34
Tax invoices	35
Adjustments	35
	35
	35
Payments free of taxes; obligations to withhold; payments on account of taxes Refunds	35 35
Miscellaneous	36
Survival of Obligations	36
Approvals and consents	36
Announcements Subcontracting	36 36
	Revery         Procession         Subjection of infrigement         Right to take action         Factors         Factors         Suppose action         Suppose action         Factors         Suppose action         Suppose action         Factors         Suppose action         Suppose action

26.6	Costs	36
26.7	Relationship	36
26.8	No modification	36
26.9	Non waiver	36
26.10	Entire agreement	37
26.11	Further Action	37
26.12	Severability	37
26.13	Counterparts	37
26.14	Governing law	37
Schedule	Schedule 1 – Agreement details 3	
Schedule	Schedule 2 – Not used 3	
Schedule	Schedule 3 – Development Plan 40	
Schedule	Schedule 4 – Product and Product Specification 4	
Schedule	Schedule 5 – Economic details	
Schedule 6 – Qualification of Backup Manufacturer		45
Schedule	Schedule 7 – Licence of HPPI Licensed Rights	

Details	
Date	May 15, 2015
Parties	
Name Short form name Notice details	Mayne Pharma Ventures Pty Ltd, an Australian company ACN 168 896 357 Mayne Pharma Level 14, 474 Flinders Street, Melbourne, Vic 3000, Australia Facsimile: +61 3 9614 7022 Attention: General Counsel
Name Short form name Notice details	<ul> <li>HedgePath Pharmaceuticals, Inc., a company incorporated in Delaware, successor in interest by merger to Commonwealth Biotechnologies, Inc, a Virginia corporation</li> <li>HPPI</li> <li>324 South Hyde Park Avenue #350, Tampa, FL 33606, United States</li> <li>Facsimile: +1 813-527-0500</li> <li>Attention: Nicholas Jon Virca, President &amp; CEO</li> </ul>

## Background

- A Mayne Pharma manufactures and has rights in respect of the Product.
- B HPPI develops and commercialises medicinal products.
- C On the terms and conditions set out in this Agreement:
  - (i) Mayne Pharma agrees to supply HPPI with the Product and provide to HPPI a license to certain Intellectual Property Rights; and
  - (ii) the parties agree to participate in the JDC.
- D 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").
- E MPI and HPPI entered into that certain Amendment No. 1 to the Original Agreement, dated on or about December 17, 2013 (Amendment No. 1").
- F MPI and HPPI entered into that certain Amendment No. 2 to the Original Agreement, dated on or about March 6, 2014 (Amendment No. 2").
- G MPI assigned, and Mayne Pharma assumed, the rights and obligations under the Original Agreement as amended by Amendment No. 1 and Amendment No. 2.
- H 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.

- I 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 Agreement, dated on or about June 24, 2014 (**''First Amended and Restated Supply and License Agreement**').
- J 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").
- K 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 amend and replace, 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 herein.

## 1. Defined terms & interpretation

#### 1.1 Defined terms

In this agreement:

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. In this definition, "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 or the managers of the party, or to determine substantially the conduct of the party's business activities. 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 Second Amended and Restated Supply and License Agreement.

Alternate Product means any product \*\*\*.

API means active pharmaceutical ingredient.

**Budget** is defined in clause 4.1(b).

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 Target Launch Date.

Competing Product means \*\*\*.

Confidential Information is defined in clause 17.1.

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, as at the Start Date which shall be provided by HPPI to Mayne Pharma for approval as provided in clause 4.1, and as may be updated in accordance with clause 4.1(a) and 4.3(b).

Disclosing Party is defined in clause 17.1.

Equity Holders Agreement means the amended and restated equity holders agreement dated of even date herewith between Mayne Pharma, HPPI, Hedgepath, LLC, Frank E. O'Donnell, Jr., M.D. and Nicholas J. Virca.

Field means treatment of human patients with cancer via oral administration. The initial three indications included within the Field shall be prostate, lung and skin cancer, which shall be developed in accordance with the Development Plan. It is agreed that HPPI has the exclusive right hereunder to develop the Product for additional indications in the Field; provided, however, that HPPI may not expand the Field to include any other types of cancer or any other medical indication unless agreed to in advance in writing by Mayne Pharma.

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

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

**HP** Patents means each of US patent application 61/813,122 (prostate-specific antigen as biomarker for hedgehog pathway inhibitor treatment and prognostic monitoring of prostate cancer) and US patent application 61/831,823 (Treatment and Prognostic Monitoring of Cancer Using Hedgehog Pathway Inhibitors) in the name of Hedgepath, LLC 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, extensions, or renewals of it, whether or not in the Territory.

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 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.

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 Purchase Agreement is defined in the Equity Holders Agreement.

MP Licensed Rights means all Intellectual Property Rights in the Product existing as at the Start Date and owned by Mayne Pharma or its Affiliates:

- (a) comprising, in respect of patent rights, \*\*\* 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, extensions, or renewals of it, in the Territory; and
- (b) excluding rights in respect of trade and service marks and logos.

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

\*\*\*

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

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), it being acknowledged and agreed 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.

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.

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 in or comprising the Territory, 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.

Target Launch Date is 30 June 2017, as that date may be extended by agreement of the parties in writing.

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;
- 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;
- 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;
- 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 May 15, 2015, each and all 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.

### 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 at least \*\*\* 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.

## 2.3 Acknowledgment with respect to continuing obligations

HPPI acknowledges that Mayne Pharma has no ongoing obligations with respect to the continuing grant of the IP licence other than under clauses 3.3, 4.1(a) and 4.1(g). This does not limit Mayne Pharma's obligations to the supply of Product and its related obligations in the remainder of this Agreement, including under clauses 5.2, 6 to 11 and clause 13.2.

#### 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 under the Development Plan; and
- (b) to import, promote, market, sell and distribute the Product in the Territory,

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 \*\*\* 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) **\$ub 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.

## 4. Development

# 4.1 Development Plan and Budget

- (a) Within \*\*\* of the execution of this Agreement, HPPI will propose to Mayne Pharma, and Mayne Pharma shall approve, an updated Development Plan as recommended by the JDC. Such Development Plan, as finally approved by both parties, shall be included as an updated Schedule 3 hereto and shall be deemed an integrated part of this Agreement.
- (b) Within \*\*\* of the execution of this Agreement, HPPI will propose to Mayne Pharma a budget for HPPI to conduct its activities (\*\*\*) \*\*\* (once approved, the **Budget**). \*\*\*.
- (c) The Budget shall include a detailed listing of (amongst other customary matters for budgets for the clinical development of a pharmaceutical product), including third party service provider costs to be borne by HPPI.
- (d) HPPI and Mayne Pharma will conduct the activities set out in, and in accordance with, the Development Plan and further in accordance with the Budget.
- (e) Up until the Target Launch Date, the parties must review the Development Plan and the Budget through the JDC \*\*\*.
- (f) \*\*\*.
- (g) Mayne Pharma agrees to provide, as part of its services pursuant to clause 4.4 and at its expense, the relevant CMC section of the Product dossier to support pre-IND activities set out in the Development Plan as of the Start Date.

## 4.2 JDC

(a)

- Within \*\*\* from the Start Date, the parties will form 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 consider and make recommendations to HPPI for appropriate intellectual property protection for the outcomes of any research and development;

(iv) to direct the conduct of entire clinical program for the Product,

which JDC will continue until the Target 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. \*\*\*.
- (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 Target Launch Date, but not less than one per month;
  - (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 Material development decisions

HPPI agrees that any material decisions regarding the following are subject to the prior written consent of Mayne Pharma, such consent not to be unreasonably withheld, conditioned or delayed:

- (a) the research, development and registration of the Product by HPPI;
- (b) any material amendments to the Development Plan or the Budget; and
- (c) the seeking of appropriate intellectual property protection for the outcomes of any research and development (including any decision to disclose Confidential Information of HPPI relating to the Product, and any filing, prosecution or maintenance of patent rights), all of which, for the avoidance of doubt, shall be considered Developed Intellectual Property Rights subject to clause 18.5 and Schedule 7.

## 4.4 Mayne Pharma support

- (a) From the date of this Agreement until \*\*\*, Mayne Pharma will provide to HPPI, from time to time, 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 (at HPPI's expense, subject to clause 4.4(b)) 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.

- (b) Mayne Pharma shall obtain HPPI's advance approval (which may be undertaken by email by HPPI's President, Chief Executive Officer or Chief Financial Officer) prior to providing such services on a case by case basis (including, for the avoidance of doubt, services which require, or would with the passage of time require, cash outlays by or material obligations of HPPI). Mayne Pharma shall use reasonable commercial efforts in performing such services, and shall perform such services in accordance with all applicable laws, rules and regulations.
- (c) Mayne Pharma shall provide all such services in accordance with the Development Plan and within the spending guidelines set out in the Budget. The cost of Mayne Pharma's internal personnel and other internal costs and expenses incurred by Mayne Pharma in the provision of such services shall be borne by Mayne Pharma.
- (d) HPPI shall, at its expense, reimburse Mayne Pharma for any third party costs incurred by Mayne Pharma in connection with the provision of such services, subject to Mayne Pharma's compliance with clauses 4.4(b), 4.4(c) and subject to clause 7.5. Where possible, third party costs to be incurred in connection with the provision of such services will be invoiced directly to HPPI.
- (e) For purposes of HPPI's and Mayne Pharma's accounting and reporting, each party shall reasonably cooperate with the other should the other party request any accounting or financial information relating to Mayne Pharma's services under this clause 4.4.

## 5. Marketing Authorisation

## 5.1 Obtaining and maintaining Marketing Authorisations

HPPI must:

- (a) actively seek, in coordination with the JDC and Mayne Pharma and at its own cost and expense (other than for services provided by Mayne Pharma under clause 4.4), 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 Assistance by Mayne Pharma

Mayne Pharma will, at HPPI's cost and expense other than for services provided under clause 4.4:

- (a) assist HPPI in connection with any Marketing Authorisation, including any application for, maintenance of or variation of, any Marketing Authorisation; and
- (b) provide any documents required by HPPI in connection with any Marketing Authorisation.

## 5.3 Failure to obtain Marketing Authorisations

If, notwithstanding HPPI's compliance with clause 5.1, a Marketing Authorisation has not been obtained by HPPI, any Affiliate or Sub Licensee at least \*\*\* before the Target Launch Date, then following consultation with the other party for up to \*\*\*, either party, acting reasonably, may terminate this agreement with immediate effect with notice to the other party.

# OBLIGATIONS RELATING TO SUPPLY OF PRODUCT

6. Manufacture and supply of Product

#### 6.1 Forecasts

- (a) On the \*\*\*, 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:

#### 6.2 Orders

(d)

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

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

#### 7.3 **Mayne Pharma Payments**

- 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 (a) an Alternate Product in the Territory in the Field as a result of off label use (Off Label Sales).
- If HPPI becomes aware of any Off Label Sales in any Quarter \*\*\*, it must notify Mayne Pharma promptly, and in any event, no later than \*\*\*, and (b) provide Mayne Pharma with its evidence of such Off Label Sales.
- Prior to a Marketing Authorisation being obtained by HPPI, any Affiliate or Sub Licensee, within \*\*\* after receipt of a notice from HPPI under clause (c) 7.3(b), Mayne Pharma must pay to HPPI a cash royalty of \*\*\* on gross sales up to USD\*\*\* and \*\*\* on gross sales over USD\*\*\* for the relevant Quarter for the Alternate Product sold through Off Label Sales \*\*\*.
- After a Marketing Authorisation is obtained by HPPI, any Affiliate or Sub Licensee, if Off Label Sales of any Alternate Product exceed \*\*\*, then the (d) 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:

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

#### (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:

 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 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, 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.

## 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 Target 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 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 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 Target Launch Date, HPPI must provide a business plan to Mayne Pharma in connection with the distribution of Product in the Territory outlining the sales and marketing of the Product in the Territory from the Target 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 Target Launch Date, the parties must meet \*\*\* to review HPPI's Business Plan outlining the sales and marketing of the Product in the Territory 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.
- (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 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.
- (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, which licence is capable of sub license to any Affiliate or licensee of Mayne Pharma.

### 12.3 Efforts to maximise sales

From the Target Launch Date:

- (a) until the Minimum Annual Volumes for the Product have been agreed by the parties as provided for in Schedule 5 of this Agreement, HPPI must use best efforts to maximise the sale of the Product in the Territory; and
- (b) after Minimum Annual Volumes have been established as provided for in Schedule 5 of this Agreement, HPPI must use reasonable commercial efforts to maximise the sale of the Product 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.
- (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:
  - 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
  - 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;
  - 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 Patents have been irrevocably assigned to HPPI on a royalty free basis; and

(b) it will use reasonable commercial efforts to maintain all warehousing, sales, personnel and facilities required to perform its obligations under this Agreement.

## 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:

\*\*\*

## 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 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

#### 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 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.

## 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).

## 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 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 \*\*\*

18.3 Reserved

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18.4
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## 18.5 Development of Intellectual Property Rights and Licence of HPPI Licensed Rights

- (a) From and after the Start Date, all Intellectual Property Rights relating to the Product for its use in the Field that are (i) developed by HPPI, its Affiliates or Personnel; (ii) jointly developed by HPPI and Mayne Pharma and their respective Affiliates and Personnel, or (iii) developed by Mayne Pharma and its Affiliates and Personnel in providing the services referred to in clause 4.4 (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.
- (b) All Intellectual Property Rights relating to the Product for its use in the Field that are developed solely by Mayne Pharma, its Affiliates or Personnel from and after the Start Date shall be the sole and exclusive property of Mayne Pharma, but without limiting clause 3.3 of this Agreement.

## 18.6 Notification of infringement

Each party will immediately notify the other party if it becomes aware of potential or actual:

- (a) infringement of the other party's Intellectual Property Rights the subject of this Agreement; or
- (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.

## 18.7 Right to take action

Each party has the sole right at its own expense to take action in respect of any potential or actual infringement of Intellectual Property Rights it owns, regardless of the grant of any rights, exclusive or otherwise, to the other party under this Agreement. In response to a request by a party taking such action, the other party will provide information and assistance in connection with such potential or alleged infringement to the extent it relates to the Intellectual Property Rights which are the subject of this Agreement, and the requesting party will reimburse to the other party all reasonable costs and expenses incurred as a result.

# 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) any of HPPI, Hedgepath, LLC, Frank E. O'Donnell, Jr., M.D. or Nicholas J. Virca 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 or the 2015 SPA, 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 beneficial ownership or 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.

#### 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:
  - 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 no longer applies;
  - (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 to establish (amongst any other matters the parties may agree) a revised Target Launch Date and resulting date by which the applicable Marketing Authorisation must be obtained to reflect any delay caused by the exercise by Mayne Pharma of its election under this clause 20.5. The parties shall use reasonable commercial efforts to approve such revised Development Plan within 30 days of Mayne Pharma's election. The parties shall not be bound by or be held in breach of this Agreement for failure to achieve any Target Launch Date or similar deadlines to the extent caused by the exercise by Mayne Pharma of its election under this clause 20.5; 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:
  - 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 a single arbitrator in Atlanta, Georgia, selected by, and such arbitration to be administered by, the American Arbitration Association ("AAA") in accordance with its International 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 action, question or disagreement arising from or relating to this Agreement shall be covered, without limitation, by the applicable AAA rules and procedures. Each of the parties hereto further agrees that 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
  - 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;
  - 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), 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 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, 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) 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.

[Schedules Follow Beginning on Next Page]

#### - Agreement details

Start Date

3 September 2013

Initial Term

Starts on the Start Date and continues until the later of:

10 years from the Target Launch Date;

all issued patents of Mayne Pharma or any of its Affiliates referred to in paragraph (a) of the definition of MP Licensed Rights have lapsed or expired.

## Territory

United States of America, including all of its commonwealths, territories and possessions.

To be provided and approved in accordance with clause 4.1(a).

Product: SUBA-itraconazole 50mg hard capsules

Hard gelatin capsules, size \*\*\* body and cap printed "\*\*\*" in \*\*\* on the cap. Capsules contain white to off-white powder. The outside of the capsule must be free from powder and the two capsule halves must lock firmly together.

Comprehensive product specifications will be agreed between the parties during the conduct of the activities in the Development Plan and will form part of Marketing Authorisation submission to the Relevant Regulatory Authority.

## Floor Price, Minimum Order Quantity and Minimum Annual Volumes

# Floor Price and Minimum Order Quantity

			Incremental
		Minimum Order	Order Quantity
	Floor Price per	Quantity (MOQ)	(after the MOQ)
Product	unit (USD)	(capsules)	(capsules)
SUBA-itraconazole 50mg hard capsule	***	***	***
Minimum Annual Volumes			
***			

Forecast Period

\*\*\*

Delivery terms

EXW (Incoterms 2010), Salisbury, South Australia, Australia.

Minimum shelf life

\*\*\*

Price

## Product Mayne Pharma provides \*\*\*

Mayne Pharma will provide Product 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 approved by Mayne Pharma, \*\*\* set out in the table below:

Relevant part of the Field for which the	
Product is used	Maximum capsules free of charge
***	***
***	***
***	***

In response to a request by HPPI following a recommendation by the JDC, Mayne Pharma will review and consider changes to the relevant part of the Field for which the Product is used and/or the maximum number of capsules \*\*\* for the purposes of this item 5.1 of this Schedule 5, and may change either or both, acting in its discretion by notice to HPPI.

## Product for which Mayne Pharma is \*\*\*

HPPI \*\*\* Mayne Pharma for:

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

all other Product, in accordance with this item 5 of this Schedule 5.

#### 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 means \*\*\*.

Total Units Sold \*\*\*.

#### 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.

# **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 \*\*\*.

## Price

The Price to be paid by HPPI for the Product in the Territory is:

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

as adjusted by a reconciliation of the Actual ASP in relation to the Forecast ASP \*\*\* as follows:

\*\*\*

#### 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.

## **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) (**Books of Account**).

- (b) Mayne Pharma will have the right to appoint, on reasonable notice, a certified accountant who is independent and from a nationally recognised accounting firm (Accountant) to inspect and examine the Books of Account.
- (c) Mayne Pharma will bear the fees of the 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 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.

## **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.

Currency and exchange rate

Currency

USD

# Financial institution for exchange rate

National Bank of Australia Limited

Definitions

In this Schedule 6:

\*\*\*

## Licence of HPPI Licensed Rights

## Grant of licence

From the Start Date, HPPI grants to Mayne Pharma an exclusive, perpetual, irrevocable, royalty free licence to copy and exploit outside the Territory 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:

relates to, or has potential application in connection with, the Product, including any dossier containing technical or clinical information relating to the Product; and

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:

- (i) \*\*\*; or
- (ii) the termination or expiry of this Agreement,

(HPPI Licensed Rights) including the HP 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(b)(i) and (ii) 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.

## HPPI to ensure it remains free to licence the HPPI Licensed Rights

HPPI must:

ensure that, in respect of any Intellectual Property Rights comprising the HPPI Licensed Rights owned by it, its Affiliates or any Sub Licensee; and

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 outside the Territory such Intellectual Property Rights. Promptly on becoming aware of any restriction on such right to grant such licence, HPPI must notify Mayne Pharma.

## 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.

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.

Intellectual property protection for HPPI Licensed Rights

HPPI will consult with Mayne Pharma regarding intellectual property protection for such rights outside the Territory.

In particular, HPPI must give at least \*\*\* prior notice before it, or any of its Affiliates:

- 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
- without limitation, discloses any Confidential Information comprised in the HPPI Licensed Rights to any patent office, including as part of a patent application.

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).

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.

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:

- 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.

## Sub licensing and assignment

#### 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.

## 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 in the presence of	/s/ Scott Richards Signature of officer
/s/ Kate Rintoul	Scott Richards
Signature of witness	Name of officer (print)
Kate Rintoul	CEO and Director
Name of witness (print)	Office held
	May 15, 2015
	Date
Signed for HedgePath Pharmaceuticals, Inc by an authorised officer in the	
presence of	/s/ Nicholas J. Virca
	Signature of officer
/s/ Catherine A Boyle-Virca	Nicholas J. Virca
Signature of witness	Name of officer (print)
Catherine A Boyle-Virca	President and CEO
Name of witness (print)	Office held
	May 15, 2015
	Date

Second Amended and Restated Supply and license agreement - Mayne Pharma and HPPI | page 48

**EXECUTION VERSION** 

# SECURITIES PURCHASE AGREEMENT

# Dated May 15, 2015

# by and between

# HEDGEPATH PHARMACEUTICALS, INC.

and

MAYNE PHARMA VENTURES PTY LTD

			Page
SALE	AND PURCHASE OF PURCHASED SECURITIES; CLOSING	ARTICLE I	2
	,		
1.1	Sale and Purchase of Purchased Securities		2
1.2	Closing		2
		ARTICLE II	
DEFI	NITIONS		3
2.1	Definitions		3
		ARTICLE III	
DEDD	ESENTATIONS AND WARRANTIES	ARTICLE III	8
			8
3.1	Representations and Warranties of HPPI		8
3.2	Representations and Warranties of Mayne Pharma		19
		ARTICLE IV	
COND	ITIONS TO CLOSING		21
4.1	Conditions to Mayne Pharma's Obligations at the Closing		21
4.2	Conditions to HPPI's Obligations at the Closing		23
COVE	NANTS	ARTICLE V	24
COVE	INAIN I S		24
5.1	Commercially Reasonable Efforts		24
5.2	Certain Notifications Until Closing		24
		ARTICLE VI	
ADDI	FIONAL AGREEMENTS		24
6.1	Transfer Restrictions		24
6.2	Integration		25
6.3	Securities Laws Disclosure; Publicity		25
6.4	Shareholder Rights Plan		26
6.5	Indemnification of Mayne Pharma, Etc		26
6.6	Use of Proceeds		27
6.7	Reservation of Common Stock		27
6.8	Listing of Common Stock		27
6.9 6.10	Certain Transactions and Confidentiality		27 28
6.10	Acknowledgment of Dilution Equity Incentive Plan		28
6.12	Registration Rights		28
6.12	D&O Policy		28
6.14	Certificate of Amendment to Certificate of Incorporation		28

i

# MISCELLANEOUS

- Termination
- 7.1 7.2 Fees and Expenses
- 7.3 Entire Agreement
- Notices 7.4
- 7.5 Amendments; Waivers
- 7.6 Headings
- 7.7 Successors and Assigns
- No Third-Party Beneficiaries Governing Law 7.8
- 7.9
- Arbitration of Claims 7.10
- Survival 7.11
- 7.12 Execution
- 7.13 Severability
- Rescission and Withdrawal Right 7.14
- 7.15 7.16 Replacement of Securities
- Remedies
- 7.17 Payment Set Aside
- 7.18 Saturdays, Sundays, Holidays, etc
- 7.19 Construction
- 7.20 WAIVER OF JURY TRIAL

33

ii

ARTICLE VII

# LIST OF ANNEXES

- ANNEX A: FORM OF WARRANT
- ANNEX B: DISCLOSURE SCHEDULES
- ANNEX C: FORM OF AMENDED AND RESTATED EQUITY HOLDERS AGREEMENT
- ANNEX D: FORM OF SECOND AMENDED SUPPLY AGREEMENT
- ANNEX E: EHA WAIVER
- ANNEX F: SECOND AMENDED AND RESTATED BYLAWS
- ANNEX G: REGISTRATION RIGHTS AGREEMENT
- ANNEX H: CERTIFICATE OF AMENDMENT TO CERTIFICATE OF INCORPORATION

#### SECURITIES PURCHASE AGREEMENT

THIS SECURITIES PURCHASE AGREEMENT (this "<u>Agreement</u>") is made and entered into this 15th day of May, 2015 (the '<u>Signing Date</u>"), by and between MAYNE PHARMA VENTURES PTY LTD, an Australian company ACN 168 896 357 ('<u>Mayne Pharma</u>") and HEDGEPATH PHARMACEUTICALS, INC., a Delaware corporation ("<u>HPPI</u>").

#### **RECITALS:**

A. As of the date hereof, HPPI has Three Hundred Forty Million (340,000,000) authorized shares of Common Stock and Ten Million (10,000,000) authorized shares of Preferred Stock.

B. HPPI and Mayne Pharma International Pty. Ltd, an Australian company ACN 007 870 984 and predecessor-in-interest to Mayne Pharma (<u>MPI</u>"), entered into that certain Supply and License Agreement, dated as of September 3, 2013, as amended, including, without limitation, pursuant to that certain Amendment No. 1 to Supply and License Agreement and that certain Amendment No. 2 to Supply and License Agreement (collectively, the "<u>Original Supply Agreement</u>").

C. MPI later assigned to Mayne Pharma, and Mayne Pharma assumed from MPI, the rights and obligations of MPI under the Original Supply Agreement.

D. Pursuant to the Original Supply Agreement, Mayne Pharma had the right to terminate the Original Supply Agreement if HPPI did not obtain equity funding of at least Five Million Dollars (\$5,000,000), or lesser amount as agreed to by the parties, on or before May 30, 2014 (the "Termination Right").

E. The Original Supply Agreement further provided that HPPI was required to issue to Mayne Pharma certain shares of HPPI's capital stock so that Mayne Pharma would hold no less than thirty percent (30%) of the capital stock of HPPI on a fully diluted basis after the consummation of certain transactions as contemplated therein.

F. In consideration for Mayne Pharma not exercising the Termination Right, HPPI agreed to issue to Mayne Pharma, and Mayne Pharma agreed to purchase from HPPI, in a private placement, Two Hundred Fifty-Eight Thousand Three Hundred Sixty-Three and 280/1,000 (258,363.280) shares of HPPI's Series A Convertible Preferred Stock (the "Preferred Shares") and a warrant to purchase Ten Million Two Hundred Fifty Thousand Five Hundred Sixty-Nine (10,250,569) shares of Common Stock (the <u>Make-Up</u> <u>Warrant</u>"), pursuant to that certain Securities Purchase Agreement, dated as of June 24, 2014 (the <u>2014 Purchase Agreement</u>").

G. The Company granted to Mayne Pharma certain registration rights pursuant to Annex F of the 2014 Purchase Agreement (the 'Original Registration Rights Agreement').

H. In connection with the closing of the transactions contemplated by the 2014 Purchase Agreement, HPPI, Mayne Pharma, HPLLC, Frank E. O'Donnell Jr., M.D. ("FEO"),

and Nicholas J. Virca ("Virca") entered into that certain Equity Holders Agreement, dated as of June 24, 2014, as extended and amended by that certain letter agreement, dated November 26, 2014 (the "Equity Holders Agreement").

I. On August 14, 2014, Mayne Pharma exercised its right to convert all of the Preferred Shares into Eighty-Seven Million Eight Hundred Forty-Three Thousand Eight Hundred Ninety-Seven (87,843,897) shares of Common Stock, and HPLLC exercised its right to convert all of its Preferred Shares into Eighty-Two Million One Hundred Fifty-Six Thousand Eight Hundred Forty-Two (82,156,842) shares of Common Stock.

J. Pursuant to Section 8.1 of the Equity Holders Agreement, Mayne Pharma has the right to demand the resignation of FEO and/or Virca if HPPI failed or fails to satisfy any of the Performance Goals, including, without limitation, (i) by December 31, 2014, the closing of an equity financing, the gross proceeds of which received by HPPI were at least Five Million Dollars (\$5,000,000), and (ii) by January 31, 2015, the commencement of dosing patients in a phase II/III clinical trial for the treatment of Gorlin's Syndrome, both of which Performance Goals HPPI failed to satisfy by the respective dates related thereto.

K. On the terms and subject to the conditions set forth in this Agreement, including, without limitation, Mayne Pharma not exercising its rights to demand the resignation of FEO and/or Virca, as well as the other agreements and covenants of the parties set forth herein and in the agreements and instruments contemplated hereby, HPPI agrees to issue to Mayne Pharma, in a private placement, Thirty-Three Million Three Hundred Thirty-Three Thousand Three Hundred Thirty-Three (33,333,333) shares of Common Stock (the "<u>Shares</u>") and a warrant to purchase Thirty-Three Million Three Hundred Thirty-Three Thousand Three Hundred Thirty-Three (33,333,333) shares of Common Stock, the substantial form of which is attached hereto as <u>Annex A</u> (the "<u>Warrant</u>" and, together with the Shares, the "<u>Purchased Securities</u>"), and Mayne Pharma intends to purchase from HPPI the Purchased Securities.

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, HPPI and Mayne Pharma agree as follows:

#### ARTICLE I SALE AND PURCHASE OF PURCHASED SECURITIES; CLOSING

1.1 Sale and Purchase of Purchased Securities On the terms and subject to the conditions set forth in this Agreement, HPPI agrees to sell to Mayne Pharma, and Mayne Pharma agrees to purchase from HPPI, at the Closing, the Purchased Securities, in consideration for an aggregate purchase price of Two Million Five Hundred Thousand Dollars (\$2,500,000) (the "Purchase Price").

#### 1.2 Closing.

(a) On the terms and subject to the conditions set forth in this Agreement, the closing of the sale and purchase of the Purchased Securities pursuant to  $\underline{Section 1.1}$  hereof (the "<u>Purchase</u>") and the transactions contemplated herein (the "<u>Closing</u>") will take place on the fifth ( $\underline{Sh}$ ) Business Day following the Signing Date or earlier with the agreement of the parties,

provided that all of the conditions set forth in <u>Article IV</u> hereof have been fulfilled or waived. The Closing shall take place at the office of HPPI's Counsel (or remotely via the exchange of electronic documents and signatures), or at such other place as HPPI and Mayne Pharma may mutually agree. The time and date on which the Closing occurs is referred to in this Agreement as the "<u>Closing Date</u>".

(b) Subject to the fulfillment or waiver of the conditions set forth in <u>Section 4.1</u> and <u>Section 4.2</u> hereof, respectively, at the Closing, (i) HPPI will deliver to Mayne Pharma (x) the Shares, as evidenced by one or more certificates dated the Closing Date and bearing appropriate legends as hereinafter provided for, and (y) the Warrant, and (ii) Mayne Pharma will deliver to HPPI the Purchase Price, by wire transfer of immediately available funds to an account designated by HPPI.

#### ARTICLE II DEFINITIONS

2.1 Definitions. For all purposes of this Agreement, the following terms will have the following meanings:

"2014 Purchase Agreement" shall have the meaning ascribed to such term in the Recitals.

"AAA" shall have the meaning ascribed to such term in Section 7.10 hereof.

"Action" means an action, charge, claim, complaint, dispute, suit, arbitration, inquiry, notice of violation, investigation, or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced, threatened, legal, administrative or regulatory.

"Affiliate" or "Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Agreement" shall have the meaning ascribed to such term in this first paragraph of this Agreement.

"Amended Equity Holders Agreement" shall have the meaning ascribed to such term in Section 4.1(g) hereof.

"<u>Amended Supply Agreement</u>" means that certain Amended and Restated Supply and License Agreement, dated as of June 24, 2014, by and between HPPI and Mayne Pharma, as amended, including, without limitation, pursuant to that certain Amendment No. 1 to the Amended and Restated Supply and License Agreement, dated as of September 17, 2014.

"BHCA" shall have the meaning ascribed to such term in Section 3.1(11) hereof.

"Board of Directors" means the board of directors of HPPI.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental Action to close.

"Certificate of Amendment" shall have the meaning ascribed to such term in Section 6.14 hereof.

"Closing" shall have the meaning ascribed to such term in Section 1.2(a) hereof.

"Closing Date" shall have the meaning ascribed to such term in Section 1.2(a) hereof.

"Code" means the Internal Revenue Code of 1986, as amended.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of HPPI, par value \$0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"<u>Common Stock Equivalents</u>" means any securities of HPPI or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

4

"D&O Policy" shall have the meaning ascribed to such term in Section 3.1(p) hereof.

"Disclosure Schedules" shall have the meaning ascribed to such term in Section 3.1 hereof.

"Disqualification Event" shall have the meaning ascribed to such term in Section 3.1(nn) hereof.

"EHA Waiver" shall have the meaning ascribed to such term in Section 4.1(n) hereof.

"EIP" means the HPPI 2014 Equity Incentive Plan.

"Equity Holders Agreement" shall have the meaning ascribed to such term in the Recitals.

"Evaluation Date" shall have the meaning ascribed to such term in Section 3.1(r) hereof.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended.

"FDA" shall have the meaning ascribed to such term in Section 3.1(ii) hereof.

"FDCA" shall have the meaning ascribed to such term in Section 3.1(ii) hereof.

"Federal Reserve" shall have the meaning ascribed to such term in Section 3.1(11) hereof.

"FEO" shall have the meaning ascribed to such term in the Recitals.

"FEO Chairman Agreement" means that certain Executive Chairman Agreement by and between HPPI and FEO, dated as of June 24, 2014.

"GAAP" shall have the meaning ascribed to such term in Section 3.1(h) hereof.

"Governmental Authority(ies)" means any foreign, domestic, federal, territorial, state or local governmental authority, quasi-governmental authority, instrumentality, court, legislative body, government or self-regulatory organization, commission, court, tribunal or organization or any regulatory, administrative or other agency, or any political or other subdivision, department or branch of any of the foregoing.

"HPLLC" means Hedgepath, LLC, a Florida limited liability company.

"HPLLC Warrant" means that certain warrant to purchase an aggregate of Ten Million Two Hundred Fifty Thousand Five Hundred Sixty-Nine (10,250,569) shares of Common Stock, issued to HPLLC on June 24, 2014.

"HPPI" shall have the meaning ascribed to such term in the first paragraph of this Agreement.

"HPPI's Counsel" means Ellenoff Grossman & Schole LLP, with offices located at 1345 Avenue of the Americas, New York, New York 10105-0302.

"Indebtedness" shall have the meaning ascribed to such term in Section 3.1(aa) hereof.

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3.1(o) hereof.

"Issuer Covered Person" shall have the meaning ascribed to such term in Section 3.1(nn) hereof.

"JDC" shall have the meaning ascribed to such term in the Second Amended Supply Agreement.

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Make-Up Warrant" shall have the meaning ascribed to such term in the Recitals.

"<u>Material Adverse Effect</u>" means (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of HPPI and the Subsidiaries, or (iii) a material adverse effect on HPPI's ability to perform in any material respect on a timely basis its obligations under any Transaction Document.

"Mayne Pharma" shall have the meaning ascribed to such term in this first paragraph of this Agreement.

"Mayne Pharma Party(ies)" shall have the meaning ascribed to such term in Section 6.5 hereof.

"Money Laundering Laws" shall have the meaning ascribed to such term in Section 3.1(mm) hereof.

"MPI" shall have the meaning ascribed to such term in the Recitals.

"OFAC" shall have the meaning ascribed to such term in Section 3.1(jj) hereof.

"Original Registration Rights Agreement" shall have the meaning ascribed to such term in the Recitals.

"Original Supply Agreement" shall have the meaning ascribed to such term in the Recitals.

"Performance Goals" shall have the meaning ascribed to such term in the Equity Holders Agreement.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, Governmental Authority or other entity of any kind.

"Pharmaceutical Product" shall have the meaning ascribed to such term in Section 3.1(ii) hereof.

"Preferred Shares" shall have the meaning ascribed to such term in the Recitals.

"Preferred Stock" means the preferred stock of HPPI, par value \$0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Product" shall have the meaning ascribed to such term in the Second Amended Supply Agreement.

"Purchase" shall have the meaning ascribed to such term in Section 1.2(a) hereof.

"Purchase Price" shall have the meaning ascribed to such term in Section 1.1 hereof.

"Purchased Securities" shall have the meaning ascribed to such term in the Recitals.

"Registration Rights Agreement" shall have the meaning ascribed to such term in Section 6.12 hereof.

"Regulatory Permit" shall have the meaning ascribed to such term in Section 3.1(m) hereof.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e) hereof.

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such rule.

"SEC Report(s)" shall have the meaning ascribed to such term in Section 3.1(h) hereof.

"Second Amended Bylaws" shall have the meaning ascribed to such term in Section 4.1(o) hereof.

"Second Amended Supply Agreement" shall have the meaning ascribed to such term in Section 4.1(m) hereof.

"Securities" means the Purchased Securities and the Warrant Shares.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Shares" shall have the meaning ascribed to such term in the Recitals.

"Signing Date" shall have the meaning ascribed to such term in the first paragraph of this Agreement.

"Subsidiary(ies)" means any subsidiary of HPPI as set forth on Schedule 3.1(a) and shall, where applicable, also include any direct or indirect subsidiary of HPPI formed or acquired after the Signing Date.

"Termination Right" shall have the meaning ascribed to such term in the Recitals.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange or the OTC Bulletin Board (or any successors to any of the foregoing).

"Transaction Documents" means this Agreement, the Warrant, the Amended Equity Holders Agreement, all exhibits, annexes, and schedules hereto and thereto, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means Computershare Trust Company, Inc., the current transfer agent of HPPI, with a mailing address of 350 Indiana Street, Suite 800, Golden, Colorado 80401 and a facsimile number of (201) 680-4665, and any successor transfer agent of HPPI.

"Virca" shall have the meaning ascribed to such term in the Recitals.

"Virca Employment Agreement" means that certain Employment Agreement by and between HPPI and Virca, dated as of June 24, 2014.

"Warrant" shall have the meaning ascribed to such term in the Recitals.

"Warrant Shares" means the shares of Common Stock issuable upon exercise, in whole or in part, of the Warrant.

### ARTICLE III <u>REPRESENTATIONS AND WARRANTIES</u>

3.1 <u>Representations and Warranties of HPPI</u>. Except as set forth in the Disclosure Schedules attached hereto as<u>Annex B</u> and deemed a part hereof (<u>'Disclosure</u> <u>Schedules</u>''), and except as disclosed in the SEC Reports, HPPI hereby represents and warrants to Mayne Pharma that each of the following representations and warranties (i) is true and correct as of the Signing Date (except as otherwise indicated) and (ii) will be true and correct as of the Closing Date (except as otherwise indicated).

(a) <u>Subsidiaries</u>. All of the direct and indirect Subsidiaries of HPPI are set forth on <u>Schedule 3.1(a)</u>. HPPI owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary (if any) free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If HPPI has no subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. Each of HPPI and the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither HPPI nor any Subsidiary is in violation or default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of HPPI and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in a Material Adverse Effect, and no Action has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) <u>Authorization, Enforcement</u>. HPPI has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder (which includes the issuance of the Securities). The execution, delivery and performance of each of this Agreement and the other Transaction Documents by HPPI and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary action on the part of HPPI and no further approval or authorization is

required by HPPI, the Board of Directors or HPPI's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which HPPI is a party has been (or upon delivery will have been) duly executed by HPPI, and when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of HPPI enforceable against HPPI in accordance with their respective terms.

(d) <u>No Conflicts</u>. The execution, delivery and performance by HPPI of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of any of the Securities, 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 or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of HPPI or any Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a debt of HPPI or a Subsidiary or other wise) or other understanding to which HPPI or any Subsidiary is a party or by which any property or asset of HPPI or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, 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 or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of HPPI or a Subsidiary is bound or affected.

(e) <u>Filings. Consents and Approvals</u>. HPPI is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any Governmental Authority or other Person in connection with the execution, delivery and performance by HPPI of the Transaction Documents, other than: (i) the filings required pursuant to <u>Section 6.3</u> of this Agreement and (ii) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the "<u>Required Approvals</u>").

#### (f) Issuance of Securities.

(i) The Shares are duly authorized, and, when issued and delivered pursuant to this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens other than restrictions on transfer provided for in the Transaction Documents.

(ii) The Warrant has been duly authorized and, when executed and delivered as contemplated hereby, will constitute a valid and legally binding obligation of HPPI in accordance with its terms, and the Warrant Shares have been duly authorized and reserved for issuance upon exercise of the Warrant and when so issued in accordance with the terms thereof will be validly issued, fully paid and non-assessable, free and clear of all Liens other than restrictions on transfer provided for in the Transaction Documents.

#### (g) Capitalization.

(i) The authorized capital stock of HPPI, as of the Signing Date and effective immediately prior to the Closing, consists of (i) Three Hundred Forty Million (340,000,000) shares of Common Stock, of which (A) Two Hundred Eleven Million Four Hundred Nineteen Thousand Nine Hundred Thirty-Seven (211,419,937) shares are issued and outstanding and (B) no shares are held in treasury, and (ii) Ten Million (10,000,000) shares of Preferred Stock, of which (A) no shares are issued and outstanding and (B) no shares are held in treasury. As of the Signing Date and effective immediately prior to the Closing, no shares of Common Stock or Preferred Stock are reserved for issuance, except for (1) Ten Million Two Hundred Fifty Thousand Five Hundred Sixty-Nine (10,250,569) shares of Common Stock reserved for issuance pursuant to the Make-Up Warrant, and (2) Ten Million Two Hundred Fifty Thousand Five Hundred Sixty-Nine (10,250,569) shares of Common Stock reserved for issuance pursuant to the HPLLC Warrant.

(ii) <u>Schedule 3.1(g)</u> sets forth the capitalization of HPPI immediately prior to the Closing and immediately following the Closing, and, in each case, shall include (A) all issued and outstanding Common Stock, including, with respect to any restricted Common Stock, any vesting schedule and repurchase price; (B) all granted stock options, including any vesting schedule and exercise price; (C) all shares of Common Stock to be reserved for future award grants under the EIP; (D) each series and all shares of issued and outstanding Preferred Stock and shares of Common Stock issuable upon conversion of such shares of Preferred Stock; (E) all granted warrants or other stock purchase rights, if any; and (F) the number of shares of Common Stock owned beneficially, and of record, by Affiliates of HPPI.

(iii) HPPI has not issued any capital stock since its most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. Except as set forth on the Disclosure Schedules, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire any shares of Common Stock or Preferred Stock or any other securities of HPPI, or contracts, commitments, understandings or arrangements by which HPPI or any Subsidiary is or may become bound to issue additional shares of Common Stock any Common Stock Equivalents or any other securities of HPPI. The issuance and sale of any of the Securities will not obligate HPPI is execurities of adjust the exercise, conversion, exchange or reset price under any of such securities. All of the outstanding shares of capital stock of HPPI are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities (or is subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities (or is subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities (or is subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities (or is subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities (or is subject to any preemptive rights, rights of first

(iv) No further approval or authorization of any stockholder, the Board of Directors or any other Person is required for the issuance and sale of any of the Securities. Except for the Equity Holders Agreement, there are no stockholders agreements, voting agreements or other similar agreements with respect to HPPI's capital stock to which HPPI is a party or, to the knowledge of HPPI, between or among any of HPPI's stockholders.

(h) SEC Reports; Financial Statements. HPPI has, since August 12, 2013, filed all reports, schedules, forms, statements and other documents required to be filed by HPPI under the Securities Act and the Exchange Act, including pursuant to Section 13(a), 14(a) or 15(d) thereof (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "SEC Reports" and each an "SEC Report"), on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when they became effective or were filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of HPPI included in the SEC Reports comply in all material respects with upplicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial position of HPPI and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(i) <u>Material Changes: Undisclosed Events, Liabilities or Developments</u>. Since August 12, 2013, except as specifically disclosed in a subsequent SEC Report filed at least three (3) Business Days prior to the Signing Date: (i) there has been no event, liability, fact, circumstance, occurrence or development that, individually or in the aggregate, has had or could reasonably be expected to result in a Material Adverse Effect, (ii) HPPI has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in HPPI's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) HPPI has not altered its method of accounting, (iv) HPPI has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) HPPI has not issued any equity securities to any officer, director or Affiliate. HPPI does not have pending before the Commission any request for confidential treatment of information. No event, liability, fact, circumstance, occurrence or development has occurred or exists, or is reasonably expected to occur or exist, with respect to HPPI or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition, that would be required to be disclosed by HPPI under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

(j) Litigation. Except as described in <u>Schedule 3.1(j)</u>, there is no Action active, pending or, to the knowledge of HPPI, threatened against or affecting HPPI, any Subsidiary or Affiliate of HPPI or any of their respective properties before or by any arbitrator or Governmental Authority which, individually or in the aggregate, (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither HPPI nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of HPPI, there is not pending or contemplated, any investigation by the Commission involving HPPI or any current or former director or officer of HPPI. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by HPPI or any Subsidiary under the Exchange Act or the Securities Act.

(k) Labor Relations. No labor dispute exists or, to the knowledge of HPPI, is imminent with respect to any of the employees of HPPI, which could reasonably be expected to result in a Material Adverse Effect. None of HPPI's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with HPPI or such Subsidiary, and neither HPPI nor any of its Subsidiaries is a party to a collective bargaining agreement, and HPPI and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of HPPI, no executive officer of HPPI or any Subsidiary is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject HPPI or any of its Subsidiaries to any liability with respect to any of the foregoing matters. HPPI and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and hours.

(1) <u>Compliance</u>. Neither HPPI nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by HPPI or any Subsidiary under), nor has HPPI or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree, or order of any arbitrator or Governmental Authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any Governmental Authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters except, in the case of clauses (ii) and (iii) above, where the violation would not reasonably be expected to result in a Material Adverse Effect.

(m) <u>Regulatory Permits</u>. HPPI and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate Governmental Authorities necessary to conduct their respective businesses as described in the SEC Reports (each a "<u>Regulatory Permit</u>"), and neither HPPI nor any Subsidiary has received any notice of Actions relating to the revocation or modification of any Regulatory Permit.

(n) <u>Title to Assets</u>. HPPI and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of HPPI and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by HPPI and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by HPPI and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which HPPI and the Subsidiaries are in compliance.

(o) Intellectual Property. Subject to the conditional use of the Intellectual Property Rights permitted by Mayne Pharma to HPPI pursuant to the Amended Supply Agreement, HPPI and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights (collectively, the "Intellectual Property Rights") as necessary or required for use in connection with their respective businesses. None of, and neither HPPI nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights of HPPI and the Subsidiaries has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither HPPI nor any Subsidiary has received, since August 12, 2013, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights of HPPI or any of the Subsidiaries violate or infringe upon the rights of any Person. To the knowledge of HPPI and subject to the conditional use of the Intellectual Property Rights permitted by Mayne Pharma to HPPI pursuant to the Amended Supply Agreement, all Intellectual Property Rights of HPPI and the Subsidiaries are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights of HPPI and the Subsidiaries have taken commercially reasonable security measures to protect the secrecy, confidentiality and value of all of their Intellectual Property Rights.

(p) <u>Insurance</u>. HPPI and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which HPPI and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage at least equal to Two Million Dollars (\$2,000,000) (the "<u>D&O Policy</u>"). Neither HPPI nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(q) <u>Transactions With Affiliates and Employees</u>. Except as set forth in the SEC Reports, none of the officers, directors or employees of HPPI or any Subsidiary is presently a party to any transaction with HPPI or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of or otherwise requiring payments to or from any officer, director or such employee or any entity in which any officer, director, or any such employee has a substantial interest or is an officer, manager, director, trustee, stockholder, member or partner, other than for: (i) payment of reasonable salary or consulting fees for services rendered, (ii) reimbursement for reasonable expenses incurred on behalf of HPPI and (iii) other employee benefits, including stock option agreements under any stock option plan of HPPI.

(r) Sarbanes-Oxley: Internal Accounting Controls. HPPI and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the Signing Date, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the Signing Date and as of the Closing Date. HPPI and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. HPPI and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for HPPI and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by HPPI in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. HPPI's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of HPPI and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). HPPI presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no

(s) <u>Certain Fees</u>. No brokerage or finder's fees or commissions are or will be payable by HPPI or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. Mayne Pharma shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this <u>Section 3.1(s)</u> that may be due in connection with the transactions contemplated by the Transaction Documents.

(t) <u>Private Placement</u>. Assuming the accuracy of Mayne Pharma's representations and warranties set forth in <u>Section 3.2</u> hereof, no registration under the Securities Act is required for the offer, sale or issuance of any of the Securities, by HPPI to Mayne Pharma as contemplated hereby. The offer, sale and issuance of any of the Securities hereunder, or otherwise, do not contravene the rules and regulations of the Trading Market.

(u) <u>Investment Company</u>, HPPI is not, and is not an Affiliate of, and immediately after the Purchase, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. HPPI shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(v) <u>Registration Rights</u>. Except for the Original Registration Rights Agreement, no Person has any right to cause HPPI to effect the registration under the Securities Act of any securities of HPPI or any Subsidiary.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and HPPI has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has HPPI received any notification that the Commission is contemplating terminating such registration. HPPI has not, since August 12, 2013, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that HPPI is not in compliance with the listing or maintenance requirements of such Trading Market. HPPI is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is cruently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and HPPI is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(x) <u>Application of Takeover Protections</u> HPPI and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under HPPI's amended and restated certificate of incorporation (or similar charter documents) or the laws of the State of Delaware that is or could become applicable to Mayne Pharma as a result of Mayne Pharma and HPPI fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of HPPI's issuance of the Securities and Mayne Pharma's ownership of the Securities.

(y) <u>Disclosure</u>. All of the disclosures furnished by or on behalf of HPPI to Mayne Pharma regarding HPPI and HPPI's Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules, and all of the representations and warranties of HPPI contained herein, are true and correct and do not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The press releases disseminated by HPPI during the twelve months preceding the

date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading. HPPI acknowledges and agrees that Mayne Pharma does not make or has not made any representations or warranties with respect to the transactions contemplated by the Transaction Documents other than those specifically set forth in <u>Section 3.2</u> hereof.

(z) <u>No Integrated Offering</u>. Assuming the accuracy of Mayne Pharma's representations and warranties set forth in<u>Section 3.2</u> hereof, neither HPPI, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Purchased Securities to be integrated with prior offerings by HPPI for purposes of the Securities Act which would require the registration of any such securities under the Securities Act.

(aa) Solvency. Based on the consolidated financial condition of HPPI as of the Closing Date, and after giving effect to HPPI's receipt of the Purchase Price as contemplated hereby: (i) the fair saleable value of HPPI's assets exceeds the amount that will be required to be paid on or in respect of HPPI's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) HPPI's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by HPPI, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of HPPI, together with the proceeds HPPI would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. HPPI has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. Schedule 3.1(aa) sets forth as of the Signing Date all outstanding secured and unsecured Indebtedness of HPPI or any Subsidiary, or for which HPPI or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed in excess of Fifty Thousand and 00/100 Dollars (\$50,000) (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in HPPI's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordina

(bb) <u>Tax Status</u>. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, HPPI and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to

which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations, and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of HPPI or of any Subsidiary know of no basis for any such claim.

(cc) <u>No General Solicitation</u>. Neither HPPI nor any Person acting on behalf of HPPI has offered or sold any of the Securities by any form of general solicitation or general advertising. HPPI has offered the Securities for sale or issuance only to Mayne Pharma.

(dd) <u>Foreign Corrupt Practices</u>. Neither HPPI nor any Subsidiary or, to the knowledge of HPPI or any Subsidiary, any agent or other Person acting on behalf of HPPI or any Subsidiary, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by HPPI or any Subsidiary (or made by any Person acting on its behalf of which HPPI is aware) which is in violation of any law or (iv) violated any provision of the FCPA.

(ee) Accountants. HPPI's accounting firm is set forth on <u>Schedule 3.1(ee)</u> of the Disclosure Schedules. To the knowledge and belief of HPPI, such accounting firm: (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in HPPI's annual report for the fiscal year ending December 31, 2015.

(ff) <u>No Disagreements with Accountants and Lawyers</u>. There are no disagreements of any kind presently existing, or reasonably anticipated by HPPI to arise, between HPPI and the accountants and lawyers formerly or presently employed by HPPI and HPPI is current with respect to any fees owed to its accountants and lawyers which could affect HPPI's ability to perform any of its obligations under any of the Transaction Documents.

(gg) Acknowledgment Regarding Purchase of the Purchased Securities HPPI acknowledges and agrees that Mayne Pharma is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. HPPI further acknowledges that Mayne Pharma is not acting as a financial advisor or fiduciary of HPPI (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by Mayne Pharma or any of its respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to Mayne Pharma's Purchase of the Purchased Securities. HPPI further represents to Mayne Pharma that HPPI's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by HPPI and its representatives.

(hh) <u>Regulation M Compliance</u>. HPPI has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of HPPI to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of HPPI.

(ii) <u>FDA</u>. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration (<u>FDA</u>") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder (<u>"FDCA</u>") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by HPPI or any of its Subsidiaries (each such product, a <u>"Pharmaceutical Product</u>"), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by HPPI in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports. There is no pending, completed or, to HPPI's knowledge, threatened, Action against HPPI or any of its Subsidiaries, and none of HPPI or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other Governmental Authority, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical hold on any clinical investigation by HPPI or any of its Subsidiaries, or (v) otherwise alleges any violation of any laws, rules or regulations by HPPI or any of its Subsidiaries. The properties, business and operations of HPPI have been and are being conduction in all material respects in accordance with all applicable laws, rules and regulations of the FDA. HPPI has not been informed by the FDA will prohibit the marketing, sale, license or use in the

(jj) Office of Foreign Assets Control. Neither HPPI nor any Subsidiary nor, to HPPI's knowledge, any director, officer, agent, employee or Affiliate of HPPI or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC").

(kk) U.S. Real Property Holding Corporation. HPPI is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Code, and HPPI shall so certify upon Mayne Pharma's request.

(II) <u>Bank Holding Company Act</u>. Neither HPPI nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "<u>BHCA</u>") or to regulation by the Board of Governors of the Federal Reserve System (the <u>'Federal Reserve</u>").

Neither HPPI nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities, or twenty-five percent (25%) or more of the total equity, of a bank or any Person that is subject to the BHCA or to regulation by the Federal Reserve. Neither HPPI nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any Person that is subject to the BHCA or to regulation by the Federal Reserve.

(mm) <u>Money Laundering</u>. The operations of HPPI and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "<u>Money Laundering Laws</u>"), and no Action by or before any Governmental Authority or any arbitrator involving HPPI or any of its Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of HPPI or any Subsidiary, threatened.

(nn) <u>No Disqualification Events</u>. With respect to the Securities to be offered and sold hereunder in reliance on Rule 506 under the Securities Act, none of HPPI, any of its predecessors, any Affiliated issuer, any director, executive officer, other officer of HPPI participating in the offering hereunder, any beneficial owner of twenty percent (20%) or more of HPPI's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with HPPI in any capacity at the time of sale (each, an "Issuer Covered Person") is subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) through (viii) under the Securities Act (a "Disqualification Event"), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). HPPI has exercised reasonable care to determine whether any Issuer Covered Person is subject to a Disqualification Event. HPPI has complied, to the extent applicable, with its disclosure obligations under Rule 506(e), and has furnished to Mayne Pharma a copy of any disclosures provided thereunder.

(oo) Other Covered Persons. HPPI is not aware of any Person (other than any Issuer Covered Person) that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with the sale of any of the Securities.

(pp) Notice of Disqualification Events. HPPI will notify Mayne Pharma in writing, prior to the Closing Date of (i) any Disqualification Event relating to any Issuer Covered Person and (ii) any event that would, with the passage of time, become a Disqualification Event relating to any Issuer Covered Person.

Mayne Pharma acknowledges and agrees that the representations contained in <u>Section 3.1</u> hereof shall not modify, amend or affect HPPI's right to rely on Mayne Pharma's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transaction contemplated hereby.

3.2 <u>Representations and Warranties of Mayne Pharma</u>. Mayne Pharma hereby represents and warrants to HPPI that each of the following representations and warranties (i) is true and correct as of the Signing Date (except as otherwise indicated) and (ii) will be true and correct as of the Closing Date (except as otherwise indicated).

(a) <u>Organization; Authority</u>. Mayne Pharma is a corporation duly organized, validly existing and in good standing under the laws of Australia with full right, corporate power, and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution, delivery and performance of the Transaction Documents and performance by Mayne Pharma of the transactions contemplated by the Transaction Document to which it is a party has been duly executed by Mayne Pharma, and when delivered by Mayne Pharma in accordance with the terms hereof, will constitute the valid and legally binding obligation of Mayne Pharma, enforceable against it in accordance with its terms.

(b) <u>Own Account</u> Mayne Pharma understands that the Purchased Securities are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Purchased Securities as principal for its own account and not with a view to or for distributing or reselling the Purchased Securities or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing the Purchased Securities in violation of the Securities law and has no direct or indirect arrangement or understandings with any other Persons to distribute or regarding the distribution of the Purchased Securities in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting Mayne Pharma's right to sell the Purchased Securities in compliance with applicable federal and state securities laws).

(c) <u>Status of Mayne Pharma</u>. At the time Mayne Pharma was offered the Purchased Securities, it was, and as of the Signing Date it is, and on the Closing Date and each date on which it exercises the Warrant or any part thereof, it will be either: (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "<u>qualified institutional buyer</u>" as defined in Rule 144A(a) under the Securities Act.

(d) Experience of Mayne Pharma. Mayne Pharma, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Purchased Securities, and has so evaluated the merits and risks of such investment. Mayne Pharma understands and acknowledges that: (i) an investment in HPPI is subject to substantial risk due to the nature of HPPI's business and (ii) Mayne Pharma is able to bear the economic risk of an investment in the Purchased Securities and, at the present time, is able to afford a complete loss of such investment.

(e) <u>No General Solicitation</u>. Mayne Pharma is not purchasing the Purchased Securities as a result of any advertisement, article, notice or other communication regarding the Purchased Securities published in any newspaper, magazine or similar media or broadcast over television, radio or the internet or presented at any seminar or any other general solicitation or general advertisement.

(f) <u>No Conflicts</u>. The execution, delivery and performance by Mayne Pharma of this Agreement and the other Transaction Documents to which it is a party and the consummation by Mayne Pharma of the transactions contemplated hereby and thereby do not and will not: (i) conflict with or violate any provision of Mayne Pharma's organizational or charter documents or (ii) subject to the Required Approvals, 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 Mayne Pharma or its Affiliates is subject (including federal and state securities laws and regulations), or by which any property or asset of Mayne Pharma or its Affiliates are bound or affected.

(g) <u>Disqualification Events</u>. Neither Mayne Pharma nor any of its shareholders, members, managers, general or limited partners, directors, Affiliates or executive officers, are subject to any Disqualification Event, except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). Mayne Pharma's Purchase of the Purchased Securities will not subject HPPI to any Disqualification Event.

(h) <u>Litigation</u>. There is no Action, pending or, to the knowledge of Mayne Pharma or its Affiliates, threatened against or affecting MPI, Mayne Pharma or any of their Affiliates or any of their respective properties which, individually or in the aggregate, (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Purchased Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect on MPI, Mayne Pharma or its Affiliates.

HPPI acknowledges and agrees that the representations contained in <u>Section 3.2</u> hereof shall not modify, amend or affect Mayne Pharma's right to rely on HPPI's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transaction contemplated hereby.

# ARTICLE IV CONDITIONS TO CLOSING

4.1 <u>Conditions to Mayne Pharma's Obligations at the Closing</u> The obligation of Mayne Pharma to consummate the Closing is subject to the fulfillment (or waiver by Mayne Pharma) at or prior to the Closing of each of the following conditions:

(a) <u>Representations and Warranties</u>. The representations and warranties of HPPI contained in <u>Section 3.1</u> hereof shall be true and correct in all respects as of the Closing (other than representations and warranties that by their terms speak as of another date, which representations and warranties shall be true and correct as of such date).

21

(b) <u>Performance</u>. HPPI shall have performed and complied with all covenants, agreements, obligations, and conditions contained in this Agreement that are required to be performed or complied with by HPPI on or before the Closing.

(c) <u>Material Adverse Effect</u>. Since the Signing Date, no fact, circumstance, event, change, occurrence, condition or development shall have occurred that, individually or in the aggregate, has had or would be reasonably likely to have a Material Adverse Effect.

(d) <u>Compliance Certificate</u>. The Chief Executive Officer and President of HPPI shall have duly executed and delivered to Mayne Pharma a certificate, dated as of the Closing Date, in form and substance satisfactory to Mayne Pharma, certifying to the fulfillment of the conditions set forth in subsections (a), (b), (c), (e) and (f) of this <u>Section 4.1</u>.

(e) <u>Qualifications</u>. All authorizations, approvals, or permits, if any, of any Governmental Authority that are required to be made or obtained by HPPI in connection with the consummation of the transactions contemplated by this Agreement shall have been obtained and effective as of the Closing.

(f) <u>Litigation</u>; <u>Illegality</u>. None of the transactions contemplated hereby shall have been enjoined by any Governmental Authority, no Action challenging the transactions contemplated hereby shall have been threatened or instituted and no investigative or other demand shall have been made by any Governmental Authority, and no law shall have been enacted that prohibits, restrains, or makes illegal the consummation of the transactions contemplated hereby.

(g) <u>Amended and Restated Equity Holders Agreement</u>. HPPI and the other respective parties thereto, other than Mayne Pharma, shall have duly executed and delivered to Mayne Pharma the Amended and Restated Equity Holders Agreement, the substantial form of which is attached hereto as <u>Annex C</u> (the "<u>Amended Equity Holders</u> <u>Agreement</u>").

(h) Legal Opinion. HPPI shall have delivered to Mayne Pharma a legal opinion, from HPPI's Counsel, dated as of the Closing Date, the substantial form of which shall be agreed to by HPPI's Counsel and Mayne Pharma.

(i) <u>Secretary's Certificate</u>. HPPI shall have delivered to Mayne Pharma a certificate executed by the Secretary of HPPI, in form and substance satisfactory to Mayne Pharma, together with (i) a certified copy of HPPI's amended and restated certificate of incorporation in effect at the time of the Closing, (ii) HPPI's bylaws in effect at the time of the Closing, (iii) certified resolutions of the Board of Directors authorizing the Transaction Documents and the transactions contemplated thereby, (iv) certified resolutions of the Board of Directors authorizing the Certificate of Amendment and the Second Amended Bylaws, (v) a good standing certificate with respect to HPPI from the Secretary of State of the State of Delaware, dated a recent date before the Closing, and (vi) a certification as to the incumbency of the current officers of HPPI.

(j) <u>Amendment to Virca Employment Agreement</u>. HPPI and Virca shall have entered into an amendment to the Virca Employment Agreement, in form and substance satisfactory to Mayne Pharma.

(k) <u>Amended and Restated FEO Chairman Agreement</u>. HPPI and FEO shall have entered into an amendment to the FEO Chairman Agreement, in form and substance satisfactory to Mayne Pharma.

(1) Reservation of Shares. HPPI shall have duly authorized and reserved for issuance the Warrant Shares.

(m) Second Amended Supply Agreement. HPPI shall have duly executed and delivered to Mayne Pharma the Second Amended and Restated Supply and License Agreement, the substantial form of which is attached hereto as <u>Annex D</u> (the "Second Amended Supply Agreement").

(n) <u>EHA Waiver</u>. HPPI shall have duly executed and delivered to Mayne Pharma the Waiver concerning certain obligations under the Equity Holders Agreement, the substantial form of which is attached hereto as <u>Annex E</u> (the "<u>EHA Waiver</u>").

(o) Second Amended and Restated Bylaws. The Amended and Restated Bylaws of HPPI (adopted effective as of July 18, 2014) shall have been amended and restated pursuant to the Second Amended and Restated Bylaws, the substantial form of which is attached hereto as <u>Annex F</u> (the "Second Amended Bylaws").

4.2 <u>Conditions to HPPI's Obligations at the Closing</u>. The obligation of HPPI to consummate the Closing is subject to the fulfillment (or waiver by HPPI) at or prior to the Closing of each of the following conditions:

(a) <u>Representations and Warranties</u>. The representations and warranties of Mayne Pharma contained in <u>Section 3.2</u> hereof shall be true and correct in all respects as of the Closing (other than representations and warranties that by their terms speak as of another date, which representations and warranties shall be true and correct as of such date).

(b) <u>Performance</u>. Mayne Pharma shall have performed and complied with all covenants, agreements, obligations, and conditions contained in this Agreement that are required to be performed or complied with by Mayne Pharma on or before the Closing.

(c) <u>Compliance Certificate</u>. An officer of Mayne Pharma shall have duly executed and delivered to HPPI a certificate, dated as of the Closing Date, in form and substance satisfactory to HPPI, certifying to the fulfillment of the conditions set forth in subsections (a), (b) and (d) of this <u>Section 4.2</u>.

(d) <u>Qualifications</u>. All authorizations, approvals, or permits, if any, of any Governmental Authority that are required to be made or obtained by Mayne Pharma in connection with the consummation of the transactions contemplated by this Agreement shall have been obtained and effective as of the Closing.

(e) Amended and Restated Equity Holders Agreement. Mayne Pharma shall have duly executed and delivered to HPPI the Amended Equity Holders Agreement.

(f) Second Amended Supply Agreement. Mayne Pharma shall have duly executed and delivered to HPPI the Second Amended Supply Agreement.

(g) EHA Waiver. Mayne Pharma shall have duly executed and delivered to HPPI the EHA Waiver.

# ARTICLE V COVENANTS

5.1 <u>Commercially Reasonable Efforts</u>. Subject to the terms and conditions of this Agreement, each of the parties will use its commercially reasonable efforts in good faith to take, or cause to be taken, all actions, and to do, or cause to be done, all things necessary, proper or desirable, or advisable under applicable laws, so as to permit consummation of the Purchase as promptly as practicable and otherwise to enable consummation of the transactions contemplated hereby and shall use commercially reasonable efforts to cooperate with the other party to that end.

5.2 <u>Certain Notifications Until Closing</u>. From the Signing Date until the Closing Date, HPPI shall promptly notify Mayne Pharma of (i) any fact, event or circumstance of which HPPI is aware and which would be reasonably likely to cause any representation or warranty of HPPI contained in this Agreement to be untrue or inaccurate in any material respect or to cause any covenant or agreement of HPPI contained in this Agreement not to be complied with or satisfied in any material respect and (ii) any fact, circumstance, event, change, occurrence, condition or development of which HPPI is aware and which, individually or in the aggregate, has had or would be reasonably likely to have a Material Adverse Effect; provided, however, that delivery of any notice pursuant to this <u>Section 5.2</u> shall not limit or affect any rights of or remedies available to Mayne Pharma.

# ARTICLE VI ADDITIONAL AGREEMENTS

#### 6.1 Transfer Restrictions.

(a) Mayne Pharma acknowledges and agrees that the Securities may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of the Securities other than pursuant to an effective registration statement or Rule 144 or to HPPI or to an Affiliate of Mayne Pharma, HPPI may require the transferor thereof to provide to HPPI an opinion of counsel selected by the transferor and reasonably acceptable to HPPI, the form and substance of which opinion shall be reasonably satisfactory to HPPI, to the effect that such transfer does not require registration of the Securities which are transferred by the transferor under the Securities Act. As a condition of any such transfere shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of Mayne Pharma under this Agreement.

(b) Mayne Pharma agrees to the imprinting, so long as is required by this Section 6.1, of a legend on any of the Securities in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR

# PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

(c) Certificates evidencing the Shares and the Warrant Shares shall not be required to contain any legend (including the legend set forth in<u>Section 6.1(b)</u> hereof): (i) while a registration statement covering the resale of such security is effective under the Securities Act or (ii) following or in connection with any sale of the Shares or the Warrant Shares pursuant to Rule 144. HPPI shall cause (at HPPI's cost) its counsel to issue a legal opinion to the Transfer Agent promptly after the occurrence of either of the foregoing if required by the Transfer Agent to effect the removal of the legend hereunder. Certificates for the Shares and the Warrant Shares subject to legend removal hereunder shall upon Mayne Pharma's request be transmitted by the Transfer Agent to Mayne Pharma by crediting the account of Mayne Pharma's prime broker with the Depository Trust Company system as directed by Mayne Pharma.

(d) Mayne Pharma agrees with HPPI that Mayne Pharma will sell the Securities pursuant to either the registration requirements of the Securities Act, including any applicable prospectus delivery requirements, or an exemption therefrom, and that if any of the Securities are sold pursuant to a registration statement, they will be sold in compliance with the plan of distribution set forth therein, and acknowledges that the removal of the restrictive legend from certificates representing the Shares and the Warrant Shares as set forth in this <u>Section 6.1</u> is predicated upon HPPI's reliance upon this understanding.

6.2 Integration. HPPI shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of any of the Securities in a manner that would require the registration under the Securities Act of the sale of any of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

6.3 Securities Laws Disclosure; Publicity. HPPI shall (a) by 9:30 a.m. (New York City time) on the Trading Day immediately following the Signing Date, issue a press release disclosing the material terms of the transactions contemplated hereby, and (b) file a Current Report on Form 8-K, including the Transaction Documents as exhibits thereto, with the Commission within the time required by the Exchange Act. HPPI and Mayne Pharma shall consult with each other in issuing any other press releases with respect to the transactions contemplated hereby, and neither HPPI nor Mayne Pharma shall issue any such press release nor otherwise make any such public statement without the prior consent of HPPI, with respect to any press release of Mayne Pharma, or without the prior consent of Mayne Pharma, with respect to any press release of HPPI, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law or any Trading Market, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication.

6.4 <u>Shareholder Rights Plan</u>. No claim will be made or enforced by HPPI or, with the consent of HPPI, any other Person, that Mayne Pharma is an "acquiring person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by HPPI, or that Mayne Pharma could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving any of the Securities under the Transaction Documents or under any other agreement between HPPI and Mayne Pharma.

6.5 Indemnification of Mayne Pharma, Etc. Subject to the provisions of this Section 6.5, HPPI will indemnify and hold Mayne Pharma and Mayne Pharma's directors, officers, shareholders, members, partners, employees and agents (and any other Person with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act) Mayne Pharma, and the directors, officers, shareholders, agents, members, partners or employees (and any other Person with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling Persons (each, a "Mayne Pharma Party" and collectively, the "Mayne Pharma Parties") harmless from and against any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any Mayne Pharma Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by HPPI in this Agreement or in any other Transaction Document or (b) any Action instituted against the Mayne Pharma Parties in any capacity, or any of them or their respective Affiliates with respect to any of the transactions contemplated by the Transaction Documents (unless such Action is based upon a breach of such Mayne Pharma Party's representations, warranties or covenants under the Transaction Documents or any violations by such Mayne Pharma Party of state or federal securities laws or any conduct by such Mayne Pharma Party which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any Action shall be brought against any Mayne Pharma Party in respect of which indemnity may be sought pursuant to this Agreement, such Mayne Pharma Party shall promptly notify HPPI in writing, and HPPI shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to such Mayne Pharma Party. Any such Mayne Pharma Party shall have the right to employ separate counsel in any such Action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Mayne Pharma Party except to the extent that (i) the employment thereof has been specifically authorized by HPPI in writing, (ii) HPPI has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such Action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of HPPI and the position of such Mayne Pharma Party, in which case HPPI shall be responsible for the reasonable fees and expenses of no more than one such separate counsel of such Mayne Pharma Party. HPPI will not be liable to any Mayne Pharma Party under this Agreement (y) for any settlement by a Mayne Pharma Party effected without HPPI's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Mayne Pharma Party's breach of any of the

representations, warranties, covenants or agreements made by such Mayne Pharma Party in this Agreement or in the other Transaction Documents. The indemnification required by this <u>Section 6.5</u> shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnity agreements contained herein shall be in addition to any cause of Action or similar right of any Mayne Pharma Party against HPPI or others and any liabilities HPPI may be subject to pursuant to law.

6.6 Use of Proceeds. HPPI shall use the net proceeds from the Purchase (a) to conduct the Basal Cell Carcinoma Nevus Syndrome clinical program for the Product, (b) to prepare the appropriate regulatory documents to progress an FDA new drug application for the Product, (c) to develop and progress the intellectual property strategy of HPPI, (d) to conduct any additional clinical programs recommended by the JDC and approved by the Board of Directors, and (e) for working capital purposes, and shall not use such proceeds: (i) for the satisfaction of any portion of the Company's debt (other than payment of trade payables in the ordinary course of the Company's business and prior practices), (ii) for the redemption of any Common Stock or Common Stock Equivalents, (iii) for the settlement of any outstanding litigation, or (iv) in violation of FCPA or OFAC regulations.

6.7 <u>Reservation of Common Stock</u>. From the Closing Date until the date on which the Warrant has been fully exercised, HPPI shall at all times have reserved for issuance, free of Liens, a sufficient number of shares of authorized and unissued Common Stock for the purpose of enabling HPPI to issue all of the Warrant Shares.

6.8 Listing of Common Stock. HPPI agrees, if HPPI applies to have the Common Stock traded on any Trading Market other than its current Trading Market, it will then include in such application all of the Shares and the Warrant Shares, and will take such other action as is necessary to cause all of the Shares and the Warrant Shares to be listed or quoted on such other Trading Market as promptly as possible. For so long as the Common Stock trades or is listed for quotation on a Trading Market, HPPI agrees to use its commercially reasonable efforts to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

6.9 <u>Certain Transactions and Confidentiality</u>. Mayne Pharma covenants that neither it, nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales of any of HPPI's securities during the period commencing with the Signing Date and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in <u>Section 6.3</u> hereof. Mayne Pharma covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by HPPI pursuant to the initial press release as described in <u>Section 6.3</u> hereof. Mayne Pharma covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by HPPI pursuant to the initial press release as described in <u>Section 6.3</u> hereof, Mayne Pharma will maintain the confidentiality of the existence and terms of this transaction and the information included in the Transaction Documents and the Disclosure Schedules. Notwithstanding the foregoing, and notwithstanding anything contained in this Agreement to the contrary, HPPI expressly acknowledges and agrees that (i) Mayne Pharma makes no representation, warranty or covenant hereby that it will not engage in effecting

transactions in any securities of HPPI after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in <u>Section 6.3</u> hereof, (ii) Mayne Pharma shall not be restricted or prohibited from effecting any transactions in any securities of HPPI in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in <u>Section 6.3</u> hereof, and (iii) Mayne Pharma shall have no duty of confidentiality to HPPI or its Subsidiaries after the issuance of the initial press release as described in <u>Section 6.3</u> hereof.

6.10 <u>Acknowledgment of Dilution</u>. HPPI acknowledges that the issuance of the Securities may result in dilution of the outstanding shares of Common Stock, which dilution may be substantial under certain market conditions. HPPI further acknowledges that its obligations under the Transaction Documents, including, without limitation, its obligation to issue the Shares and the Warrant Shares pursuant to the Transaction Documents, are unconditional and absolute and not subject to any right of set off, counterclaim, delay or reduction, regardless of the effect of any such dilution or any claim HPPI may have against Mayne Pharma and regardless of the dilutive effect that such issuance may have on the ownership of the other stockholders of HPPI.

6.11 Equity Incentive Plan. HPPI covenants and agrees that, without the prior written consent of Mayne Pharma, the shares authorized to be issued, granted or purchased under the EIP shall not exceed 32,583,475 shares of Common Stock.

6.12 <u>Registration Rights</u>. HPPI agrees to provide to Mayne Pharma the rights and privileges set forth in the Registration Rights Agreement, more specifically set forth in the form attached hereto as <u>Annex G</u> (the "<u>Registration Rights Agreement</u>"). Each of HPPI and Mayne Pharma agrees to be bound by the Registration Rights Agreement.

6.13 <u>D&O Policy</u>. HPPI agrees that it will review the appropriate amount of insurance coverage under the D&O Policy at least once every six (6) months and promptly increase such amount if approved by the Board.

6.14 Certificate of Amendment to Certificate of Incorporation. No later than thirty (30) days after the Effective Date, HPPI shall have executed and filed, or caused to be executed and filed, the Certificate of Amendment to Certificate of Incorporation of HPPI, the form of which is attached hereto as Annex H (the "Certificate of Amendment").

# ARTICLE VII MISCELLANEOUS

#### 7.1 Termination.

(a) Notwithstanding anything in this Agreement to the contrary, this Agreement and the obligations of the parties hereunder may be terminated on or prior to the Closing as follows:

(i) by HPPI or Mayne Pharma if the Closing shall not have taken place within five (5) Business Days after the Signing Date or by such later date as shall be agreed upon by an appropriate amendment to this Agreement; provided that a party shall not have the

right to terminate under this Section 7.1(a)(i) if the conditions precedent to such party's obligation to close have been fully satisfied and such party has failed or refused to close after being requested in writing to close by the other party; or

#### (ii) by HPPI and Mayne Pharma upon their mutual written consent.

(b) In the event of the termination of this Agreement as provided in Section 7.1(a), this Agreement shall forthwith become void and there shall be no liability on the part of either party hereto, except that nothing herein shall relieve either party from liability for any breach of this Agreement by such party.

7.2 <u>Fees and Expenses</u>. Except as expressly set forth in the Transaction Documents, each party 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. HPPI shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by HPPI and any exercise notice delivered by Mayne Pharma), stamp taxes and other taxes and duties levied in connection with the delivery of any of the Securities to Mayne Pharma.

7.3 Entire Agreement. This Agreement, together with the annexes, exhibits, and schedules hereto, and the other Transaction Documents, together with the annexes, exhibits and schedules thereto, contain the entire understanding of the parties 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.

7.4 <u>Notices</u>. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the date of transmission, if such notice or communication is delivered via facsimile at or prior to 5:30 p.m. (New York City time) on a Business Day, (b) the next Business Day after the date of transmission, if such notice or communication is delivered via facsimile on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Business Day, (c) the second (2<sup>nd</sup>) Business Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. All notices hereunder shall be delivered as set forth below, or pursuant to such other instructions as may be designated in writing by the party to receive such notice.

#### If to Mayne Pharma:

Mayne Pharma Ventures Pty Ltd Level 14, 474 Flinders Street Melbourne, Vic 3000 Australia Attention: General Counsel Telephone: 61 3 8614 7711 Facsimile: 61 3 9614 7022

with a copy (which shall not constitute notice) to its counsel:

Miller & Martin PLLC 1180 West Peachtree Street, N.E., Suite 2100 Atlanta, Georgia 30309 Attention: A. Josef DeLisle, Esq. Facsimile: (404) 962-6338

If to HPPI:

HedgePath Pharmaceuticals, Inc. 324 Hyde Park Avenue #350 Tampa, Florida 33606 Attention: Nicholas Jon Virca Facsimile: (813) 258-6912

with a copy (which shall not constitute notice) to its counsel:

Ellenoff Grossman & Schole LLP 1345 Avenue of the Americas, 11th Floor New York, New York 10105 Attention: Barry I. Grossman, Esq. Facsimile: (212) 370-7889

7.5 <u>Amendments</u>; 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 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 to exercise any right hereunder in any manner impair the exercise of any such right.

7.6 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.

7.7 <u>Successors and Assigns</u>. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. HPPI may not assign this Agreement or any rights or obligations hereunder without the prior written consent of Mayne Pharma. Mayne Pharma may assign any or all of its rights under this Agreement to any Person to whom Mayne Pharma assigns or transfers any of the Securities, provided that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to "Mayne Pharma."

7.8 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, except as otherwise set forth in Section 6.5 hereof.

7.9 Governing Law. Each of the Transaction Documents and any dispute arising thereunder 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.

7.10 <u>Arbitration of Claims</u>. In the event of any Action, question or disagreement arising from or relating to any Transaction Document or the breach thereof, the parties hereto agree to settle such Action, question or disagreement by arbitration before a single arbitrator in Atlanta, Georgia, selected by, and such arbitration to be administered by, the American Arbitration Association (<u>'AAA</u>") in accordance with its International 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 are subject to the alternative dispute resolution procedures of this <u>Section 7.10</u>. 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 and shall not be subject to 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 agreeal.

7.11 Survival. The representations, warranties and covenants contained herein shall survive the Closing and the delivery of the Purchased Securities.

7.12 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 and delivered to each other party, it being understood that the parties 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.

7.13 <u>Severability</u>. 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.

7.14 <u>Rescission and Withdrawal Right</u>. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever Mayne Pharma exercises a right, election, demand or option under a Transaction Document and HPPI does not timely perform its related obligations within the periods therein provided, then Mayne Pharma may rescind or withdraw, in its sole discretion from time to time upon written notice to HPPI, any relevant notice, demand or election in whole or in part without prejudice to its future Actions and rights; provided, however, that in the case of a rescission of an exercise of the Warrant or any part thereof, Mayne Pharma shall be required to return any shares of Common Stock subject to any such rescinded exercise notice concurrently with the return to Mayne Pharma of the aggregate exercise price paid to HPPI for such shares and the restoration of Mayne Pharma's right to acquire such shares pursuant to the Warrant (including, issuance of a replacement warrant certificate evidencing such restored right).

7.15 <u>Replacement of Securities</u>. If any certificate or instrument evidencing any of the Securities is mutilated, lost, stolen or destroyed, HPPI shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to HPPI of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement securities.

7.16 <u>Remedies</u>. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of Mayne Pharma and HPPI will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents 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.

7.17 Payment Set Aside. To the extent that HPPI makes a payment or payments to Mayne Pharma pursuant to any Transaction Document or Mayne Pharma enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to HPPI, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of Action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

7.18 <u>Saturdays</u>, <u>Sundays</u>, <u>Holidays</u>, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

7.19 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the

32

normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement. When a reference is made in this Agreement to "Recitals", "Articles", "Sections" or "Annexes", such reference shall be to a Recital, Article or Section of, or Annex to, this Agreement unless otherwise indicated. The terms defined in the singular have a comparable meaning when used in the plural, and vice versa. References to "herein", "hereof", "hereunder" and the like refer to this Agreement as a whole and not to any particular section or provision, unless the context requires otherwise. All references to "\$" or "dollars" mean the lawful currency of the United States of America. Except as expressly stated in this Agreement, all references to any statute, rule or regulation are to the statute, rule or regulation as a amended, modified, supplemented or replaced from time to time (and, in the case of statutes, include any rules and regulations promulgated under the statute) and to any section of any statute, rule or regulation include any successor to the section.

7.20 <u>WAIVER OF JURY TRIAL</u>. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY EITHER PARTY HERETO AGAINST THE OTHER PARTY HERETO, THE PARTIES HERETO EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

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

> > 33

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

# HEDGEPATH PHARMACEUTICALS, INC.

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

# MAYNE PHARMA VENTURES PTY LTD

By:/s/ Scott A. RichardsName:Scott A. RichardsTitle:Director

Signature Page to Securities Purchase Agreement

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

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



## MASTER CLINICAL SERVICES AGREEMENT

This Master Clinical Services Agreement (this "Agreement") is executed as of 15 June, 2015 and made effective as of 29 September, 2014 ("Effective Date"), by and between SciQuus, Inc., a Delaware corporation, having a place of business at 4250 Executive Square, Suite 450, La Jolla, CA 92037 (hereinafter "SciQuus"), and HedgePath Pharmaceuticals, Inc., a Delaware corporation having a place of business at 324 S. Hyde Park Avenue, Ste. 350 Tampa, Florida 33606 (hereinafter "Sponsor"). Sponsor and SciQuus are sometimes referred to herein individually as a "Party" and together as the "Parties."

- A. Sponsor may conduct one or more studies (each, a "Study") involving one or more of Sponsor's proprietary compounds (each, a "Study Drug"); and
- B. Sponsor wishes to retain the services of SciQuus to provide certain services to Sponsor with respect to one or more Studies, subject to the terms and conditions of this Agreement; and
- C. SciQuus is willing to provide such services to Sponsor in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

## 1. SCOPE OF THE AGREEMENT; SERVICES

#### 1.1. Scope of the Agreement

As a "master" form of contract, this Agreement allows the parties to contract for multiple projects through the issuance of multiple Statements of Work (as discussed in Section 1.2 below), without having to re-negotiate the basic terms and conditions contained herein. This Agreement covers the provision of services by SciQuus and, accordingly, this Agreement represents a vehicle by which Sponsor can efficiently contract with SciQuus and its corporate affiliates for a broad range of services.

## 1.2. Services

The specific details of each project under this Agreement shall be negotiated and specified in writing on terms and in a form acceptable to the parties (each such writing, a "Statement of Work"). Each Statement of Work shall specify the nature of the applicable Study, the Study Drug(s) being tested in

the Study, the protocol under which the Study is to be conducted (as amended from time to time, in accordance with this Agreement, the "Protocol"), the Services to be performed by SciQuus and any deliverables to be provided by SciQuus in connection with such Services (the "Deliverables"), as well as the terms and conditions (including, to the extent applicable, the scope of work, specifications, delivery and performance schedules, budget and payment schedule, and fees) under which SciQuus will perform such Services. Additionally, each Statement of Work shall describe any Sponsor obligations with respect to such Study that are transferred to SciQuus. No Statement of Work shall be binding unless approved in a writing signed by authorized representatives of both SciQuusand Sponsor. Each Statement of Work shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Statement of Work. To the extent any terms or provisions of a Statement of Work conflict with the terms and provisions of this Agreement to a specific matter. All Statement of Works and other exhibits hereto shall be deemed to be incorporated herein by reference. Without limiting the foregoing, SciQuus may also perform any incidental services. Any changes to the scope of an executed Statement of Work shall be negotiated in good faith and approved in a writing signed by authorized representatives of both SciQuus and Sponsor.

## 1.3. Change Orders

Any change in the details of Statement of Work or changes in an agreed starting date for Services) may require changes in the budget and/or timelines, and shall require a written amendment to the Statement of Work (a "Change Order"). Sponsor may initiate a Change Order on notice to SciQuus. Each Change Order shall detail the requested changes to the applicable task, responsibility, duty, budget, timeline or other matter. The Change Order will become effective upon the execution of the Change Order by both Parties, and SciQuus will be given a reasonable period of time within which to implement the changes. Both Parties agree to act in good faith and promptly when considering a Change Order requested by the other Party. Without limiting the foregoing, Sponsor agrees that it will not unreasonably withhold approval of changes in pricing or timelines reasonably requested by SciQuus in connection with a Change Order, even if it involves a fixed price contract, if the proposed changes in budgets or timelines reasonable control of SciQuus or changes in the assumptions upon which the initial budget or timelines are based, including, but not limited to, the assumptions set forth in the budget or timelines. For any Change Order that affects the scope of the regulatory obligations that have been transferred to SciQuus, SciQuus and Sponsor shall execute a corresponding amendment to the Transfer of Obligations Form. Sponsor shall file such amendment where appropriate, or as required by law or regulation.

## 1.4. Deliverables

SciQuus shall perform the Services and provide all Deliverables and related documentation in accordance with this Agreement, the applicable Statement of Work, Current Good Clinical Practice, all applicable laws, regulations and guidelines (including with respect to the conduct of clinical trials and the collection of personal information), all applicable regulatory agency requirements (including any specified by the U.S. Food and Drug Administration ("FDA") or any other domestic or

international governmental or regulatory authority (collectively with FDA, each, an "Agency" and collectively the "Agencies") and Sponsor's instructions. All Deliverables shall be deemed accepted and approved by Sponsor unless Sponsor provides written notice to SciQuus of specific non-performance and a list of what should be corrected and how. SciQuus shall promptly dispute Sponsor's findings of non-conformity or should SciQuus not promptly dispute Sponsor's findings of non-conformity, then, without limitation, SciQuus shall correct any non-conformance, at SciQuus' cost, within thirty (30) days of notice thereof. In the event of a dispute, the Parties shall enter into good faith discussions to resolve the dispute. Should dispute resolution yield confirmation of any such non-conformity, SciQuus shall correct such non-conformance, at SciQuus' cost, within thirty (30) days of the date of such dispute resolution, or, at SciQuus's election, remit to Sponsor the amount actually received by SciQuus for the non-conforming item.

## 1.5. Personnel

SciQuus shall have the right to provide Services hereunder through its affiliates, provided that SciQuus remains fully responsible to Sponsor for the performance of, and acts and omissions of, such affiliates. SciQuus shall check on the performance of all employees (including the Project Manager as defined below), agents, SciQuus selected subcontractors, and affiliates who provide Services hereunder (collectively "Personnel", with any Personnel who are not direct employees of SciQuus being subject to Sponsor's prior written approval prior to providing any Services hereunder). SciQuus shall seek to assign Personnel who are trained, qualified, and experienced in providing the Services, and shall instruct any Personnel assisting with the Services to comply with all applicable laws and regulations and all provisions of this Agreement, including without limitation, by requiring Personnel to sign intellectual property assignment and confidentiality and nondisclosure agreements sufficient to enable SciQuus to comply with this Agreement. SciQuus shall make reasonable efforts to ensure that Personnel do not have any conflict of interest, are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or not procurement programs, are not disqualified from performing specific services, and have not been convicted of a criminal offense related to the provision of healthcare items or services. SciQuus shall provide immediate notice to Sponsor if SciQuus becomes aware that any Personnel is subject to any such circumstance or action, or if it is pending or, to SciQuus' knowledge, threatened.

## 1.6. Project Manager

SciQuus shall appoint one of its employees as the "Project Manager" for each Statement of Work. The Project Manager shall be responsible for interacting with the Sponsor on all aspects of the Services under such Statement of Work through completion of such Services. Such Project Manager shall coordinate with the Sponsor contact named in such Statement of Work for the performance of the Services.

## 1.7. Reports and Assistance

At the cost and expense of Sponsor (i.e., charged to Sponsor in accordance with Section 3), SciQuus shall provide Sponsor with written and/or oral reports as Sponsor may reasonably request, on the status of the Services under this Agreement and Personnel from SciQuus shall attend all meetings as reasonably requested by Sponsor, including meetings with the FDA or other applicable Agency, and will provide Sponsor with all cooperation and assistance reasonably required in connection with informal

presentations and administrative hearings with any Agency as related to the Services. In no event shall SciQuus or any Personnel provide any information relating to the Study or the Study Drug to any Agency without Sponsor's prior written approval except for information that has been previously provided to an Agency with Sponsor's written approval. SciQuus should promptly notify Sponsor of any significant deviation from the Protocol and any serious adverse drug experience (including within any titneframe specified by applicable laws, regulations and guidelines). SciQuus should keep Sponsor informed, on a regular and frequent basis, of the progress of the Study and any relevant information regarding the Study.

## 1.8. Records and Audit Rights

SciQuus shall, and shall cause its Personnel to, preserve its accurate records, accounts, notes, reports and data obtained or generated in the course of providing the Services and its activities hereunder, including all computerized records and files, in a secure area reasonably protected from fire, other natural hazards, theft, and destruction. During the term of this Agreement and for a period of two (2) years thereafter, and upon reasonable advance notice and during normal business hours, SciQuus will permit Sponsor or representatives of Sponsor to examine or audit the work performed hereunder, the books and records directly relating to the Study and the Services, any Costs (as defined below), and the facilities at which the Study and Services are conducted to determine that the Study and Services are being conducted in accordance with this Agreement, that the facilities and personnel are adequate, and to verify amounts charged to Sponsor hereunder. SciQuus shall fully cooperate in any audit conducted hereunder, and shall provide reasonable access to any and all employees, agents and other representatives of SciQuus, including Personnel. SciQuus acknowledges that Sponsor shall also have the right to copy and remove such copies of any Study documents referred to herein at any time. SciQuus shall be entitled, at its own expense, to retain a single copy of the books and records as is reasonably necessary to comply with its regulatory obligations or to demonstrate the satisfaction of its obligations hereunder, all subject to the confidentiality obligations set forth in Section 3.

### 1.9. Inspection Rights

If the FDA or any Agency conducts, or gives notice to SciQuus of its intent to conduct an inspection related to the Study or the Services at SciQuus' facilities, or at any other facilities conducting the Study or providing Services under this Agreement, or takes any other regulatory action related to the Study or the Services, SciQuus shall promptly give Sponsor notice thereof, including all information reasonably required in connection therewith. SciQuus shall cooperate with any Agency and allow them access to all applicable records and data. Sponsor and its representatives shall have the right to be present at any such inspection or other regulatory action. In any event, if any Agency issues a notice of observations or other similar document related to the Study or the Services, SciQuus shall send a copy of such document promptly to Sponsor, along with the draft response to such document before it is sent to the applicable Agency. SciQuus shall provide Sponsor with copies of all information, materials, correspondence and documents that are not required to be disclosed during such an inspection, including financial data and pricing information and other materials, correspondence and documents that are not required to be disclosed during such an inspection, including financial data and pricing information. All of this shall be at Sponsor's expense.

### 1.10. Investigator Payments

If SciQuus will be paying Investigators on behalf of Sponsor, the Parties will agree in the applicable Statement of Work as to a schedule of amounts to be paid to Investigators. Sponsor acknowledges and agrees SciQuus will only pay Investigators from advances or pre-payments received from Sponsor for Investigators' services, and that SciQuus will not make payments to Investigators prior to receipt of sufficient funds from Sponsor. Sponsor acknowledges and agrees that SciQuus will not be responsible for delays in a study or Project to the extent that such delays are caused by Sponsor's failure to make adequate pre-payment for Investigators' services or Investigators' delays. Sponsor further acknowledges and agrees that payments for Investigators' services are pass-through payments to third parties and are separate from payments for SciQuus' Services. SciQuus agrees that it will not withhold Investigator payments except to the extent that it has reasonable questions about the services performed by a particular Investigator.

## 1.11. Patient Enrollment

Although enrollment numbers are good faith estimates, SciQuus shall exercise all reasonable diligent efforts to meet such enrollment estimates.

### 2. COMPENSATION

### 2.1. Fees and Expenses

Sponsor shall pay SciQuus the fees specified in each Statement of Work ("Fees") as SciQuus' sole and complete compensation for all Services, Deliverables, and Intellectual Property rights provided by SciQuus under this Agreement. Except as otherwise stated in this Agreement, no other fees or reimbursements shall be owed by Sponsor under this Agreement.

### 2.2. Invoicing and Payment

Unless a different billing cycle is approved by SciQuus in writing, SciQuus generally will issue its invoices on a monthly basis. The amounts due as stated on SciQuus' statements shall be deemed to be correct, conclusive and binding on Sponsor unless Sponsor notifies SciQuus in writing, within thirty (30) days from the date the particular billing is mailed, that Sponsor disputes such charge. SciQuus' statements are due and payable upon receipt. All unpaid amounts for more than \*\*\* bear interest at the rate of \*\*\* on the unpaid amount. If Sponsor fails to pay SciQuus' statements within \*\*\* of the statement date, SciQuus reserves the right to require an additional deposit in an amount determined by SciQuus or to terminate the term of this Agreement. Payment shall be mailed to:

SciQuus, Inc. 4250 Executive Square, Suite 450 La Jolla, CA 92037

Any changes to the payee information set forth above require written notice signed by SciQuus' chief financial officer.

## 2.3. Currency; Taxes

All payments shall be made in U.S. Dollars and are inclusive of all sales, use, value added, withholding and other taxes and duties.

## 3. CONFIDENTIALITY

## 3.1. Definitions

Sponsor's "Confidential Information" means any and all proprietary and confidential information disclosed to SciQuus or its Personnel by or on behalf of Sponsor, in the conduct of the Study or generated by SciQuus or its Personnel in providing the Services hereunder (and by any clinical sites conducting the Study under an agreement with SciQuus or Personnel), including but not limited to the Study Drug, technical information relating to the Study Drug, the Protocol, research, or communications to and from the FDA or other applicable regulatory authorities or other third parties, including any clinical data or other information received from sites participating in any clinical studies or any data safety monitoring boards. Sponsor's "Confidential Information" also includes Data and Inventions as defined in Section 4.1. SciQuus' "Confidential Information" shall mean, other than Sponsor's Confidential Information, any other proprietary and confidential information disclosed to Sponsor by or on behalf of Personnel regarding SciQuus' business or financial information, SciQuus' business methodologies and processes, SciQuus proposals and pricing, and Personnel information (other than as necessary to make use of Sponsor Confidential Information). Further, any proprietary and confidential information of a third party disclosed, obtained, or observed by Sponsor or its representatives during an audit of SciQuus or an affiliate of SciQuus, or the facilities of either, with the exception of Sponsor's Confidential Information, shall be treated as confidential by Sponsor in accordance with the terms contained herein. In each case, Confidential Information shall not include information of a disclosing party that (i) as evidenced by written documentation, was already known to the receiving Party prior to disclosure by the owning Party; (ii) is in or has entered the public domain through no breach of this Agreement or other wrongful act of the receiving Party; (iii) has been rightly received from a third party who is not under an

## 3.2. Obligations

SciQuus shall use Sponsor Confidential Information only as necessary to perform the Services under this Agreement, and Sponsor shall use SciQuus Confidential Information only as necessary to receive the benefit and make use of the Services. To protect Confidential Information, each Party shall (i) limit dissemination of the other Party's Confidential Information to only those of its personnel having a "need to know"; (ii) advise all personnel who receive such Confidential Information of the confidential nature of such information; (1) obtain agreements from personnel containing confidentiality and nondisclosure obligations at least as strict as those set forth in this Agreement prior to disclosure of such Confidential Information and ensure compliance of such agreements by such personnel; and (iv) hold all of the other Party's Confidential Information in strict confidence and take all action reasonably necessary to protect such Confidential Information from unauthorized use, access, duplication, disclosure, loss or damage.

### 3.3. Compelled Disclosure

If a Party is required to disclose the other Party's Confidential Information by order of any Agency, applicable laws or regulations (including, without limitation, the rules and regulations of the U.S. Securities and Exchange Commission), or judicial or administrative order, such compelled Party shall promptly notify the owning Party so that the owning Party may seek a protective order or other remedy (it being agreed that Sponsor is a U.S. publicly listed and reporting company and as such is required (and shall be permitted without notification to SciQuus or the right of SciQuus to seek any protective or other order) to make legally required public disclosures). In the event that such protective order or other remedy is not obtained, disclosure shall be permitted but shall be limited to only that portion of the Confidential Information which is legally required to be disclosed.

## 3.4. Publicity

SciQuus shall not issue press releases or engage in any interviews or other contacts with the media, including but not limited to newspapers, radio, television, and the Internet (including through any social network sites) related to the Study, the Study Drug, or the Services, without Sponsor's prior written and express approval. The Parties shall not use the name, insignia, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof), without the other Party's prior written and express approval. Notwithstanding the foregoing, each Party may use the name or trade name of the other Party as permitted by this Agreement, or when required by law, rule or regulation as reasonably determined by the Party making the disclosure. SciQuus shall not publish any articles or make any presentations relating to the non-public Study or Services provided to Sponsor hereunder or referring to non-public data, information or materials generated as part of the Study Services without the prior written consent of Sponsor.

## 3.5. Remedy

Each Party agrees and acknowledges that any such violation or threatened violation of Section 3 by such Party may cause irreparable injury to the other Party, and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the other Party shall be entitled to seek injunctive relief against the threatened breach of this Agreement or the continuation of any such breach.

## 4. INTELLECTUAL PROPERTY

### 4.1. Sponsor Data and Inventions

All data, information, reports, analyses, results and other work product (including all Deliverables) generated, derived or prepared by SciQuus or Personnel (or any clinical sites conducting the Study under an agreement with SciQuus or Personnel) as a result of the Services performed under this Agreement, in whole or in part, and whether alone or in conjunction with others (collectively, "Data") shall be the sole and exclusive property of Sponsor, and shall be treated by SciQuus and

Personnel as Sponsor Confidential Information. All discoveries, inventions, improvements, new uses, processes, techniques, and compounds, whether patentable or not, made, conceived or reduced to practice as a direct result of the Services performed under this Agreement whether by SciQuus or Personnel (or clinical sites conducting the Study under an agreement with SciQuus or Personnel), whether in whole or in part, and whether alone or in conjunction with others (collectively referred to hereinafter as "Inventions"), shall also be the sole and exclusive property of Sponsor with full right of ownership, title, and interest thereto and therein. SciQuus shall promptly and fully disclose to Sponsor any Inventions arising under this Agreement. SciQuus agrees that, to the extent permissible under applicable law, all copyrightable works in the Data and Inventions shall constitute "work made for hire" for which Sponsor shall hold the exclusive copyright. SciQuus, on behalf of itself and Personnel, hereby unconditionally assigns, and agrees to assign, to Sponsor, any and all right, title and interest in and to any such Data and Inventions, including, without limitation, all patents, copyrights, and other intellectual property and proprietary rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights by third parties. SciQuus shall, and shall cause Personnel (and any clinical sites conducting the Study under an agreement with SciQuus or Personnel), to (i) fully cooperate with Sponsor and its designees in obtaining and maintaining in Sponsor's name, and at Sponsor's sole cost and expense, any patent or other intellectual property protection as may be available with respect to such Data and Inventions, and (ii) execute all documents reasonably deemed necessary by Sponsor and designees for purposes of procuring and maintaining in Sponsor's name such patent or other intellectual property protection, and all documents necessary for effectuating assignment of Data or Inventions to Sponsor and/or perfecting, recording, or otherwise giving effect to such assignment. SciQuus, on behalf of itself and Personnel (and any clinical sites conducting the Study under an agreement with SciQuus or Personnel) also hereby (x) irrevocably transfers and assigns to Sponsor any and all Moral Rights that SciQuus and Personnel (and any such clinical sites) may have in any Data and Inventions; and (y) forever waives and agrees to never assert against Sponsor, its successors or licensees any and all Moral Rights SciQuus and Personnel (and any such clinical sites) may have in any Data and Inventions, even after expiration or termination of this Agreement. The term "Moral Rights" shall mean any right to claim authorship of Data or an Invention, any right to object to any distortion or other modification of Data or an Invention, and any similar right, existing under the law of any country in the world or under any treaty. SciQuus shall obtain from all Personnel agreements enabling it to carry out SciQuus' obligations under this Section. Notwithstanding the foregoing, Sponsor shall be estopped from asserting its rights in such data and inventions against SciQuus as provided in this Section or otherwise unless and until SciQuus has been paid in full.

## 4.2. SciQuus Property

SciQuus possesses certain inventions, processes, technology, know-how, trade secrets, improvements, other intellectual property and assets, including, without limitation, those related to business or product plans or proposals, marketing strategies, standard operating procedures, composition of matter, research, experimental results, personnel data, financial information and conditions, pricing information, third party customer information, supplier/vendor information, raw materials, data collection and data management processes, laboratory analysis techniques, analytical, biotechnology and clinical methods, procedures and techniques, computer technical expertise and software (including code), in each case which have been developed independently from the Services

and without the benefit of any Confidential Information of Sponsor (collectively, "SciQuus Property"). Sponsor and SciQuus agree that any SciQuus Property or revisions, improvements or enhancements thereto shall be the sole and exclusive property of SciQuus, and Sponsor shall have no rights, title and interest to such SciQuus Property. Notwithstanding the foregoing, nothing herein shall give SciQuus any rights in, and SciQuus Property shall exclude, any Confidential Information of Sponsor, including without limitation any Data, Invention, data or information specific and exclusive to the Study or the Study Drug, even if it is incorporated into a revision, improvement or enhancement to SciQuus Property. Subject to this Agreement, Sponsor is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license to make, have made, modify, and use any SciQuus Property that is incorporated into any Invention or Data to the extent as is reasonably necessary to obtain the benefit of the Invention or Data. Sponsor may freely sublicense and/or transfer the rights granted in the preceding sentence in connection with the development, manufacturing, or commercialization of the Study Drug or other Sponsor products.

## 4.3. No License

Neither anything contained to the contrary herein, nor the delivery of any information to a Party hereto, shall be deemed to grant the other Party any right or license under any patent or patent application or to any know-how, technology or invention of the owning Party who discloses such information other than as expressly set forth herein.

### 5. TERMINATION

## 5.1. Term

This Agreement shall take effect as of the Effective Date, and unless earlier terminated pursuant to Section 5.2, shall terminate upon the completion of the Services.

## 5.2. Termination Process

Either Party may terminate this Agreement for material breach by the other Party thereof, if such breach continues uncured for a period of \*\*\* after written receipt of notice thereof. Sponsor may terminate the Services in whole or in part, with or without cause, effective upon \*\*\* written notice.

### 5.3. Effects of Termination

Upon notice of termination or expiration of this Agreement, SciQuus shall use reasonable efforts to reduce or eliminate further costs and expenses. Sponsor shall pay SciQuus for those Services performed and expenses incurred (including future third party expenses to which SciQuus is irrevocably committed, to the extent reasonably incurred and consistent with the applicable Budget) through the effective date of termination. In no event shall either party be responsible for any lost profits or lost opportunities. SciQuus shall promptly refund any funds or advances received for Services not yet rendered upon the effective date of termination. SciQuus shall assist Sponsor with the orderly transfer of any SciQuus obligations and the Services to Sponsor or its designee as expeditiously as possible, at Sponsor's expense, and render all assistance reasonably requested in

connection therewith. In addition, each Party, in its role as a receiving Party, shall return all Confidential Information of the other Party and all copies thereof in such Party's control or possession, including, to the extent reasonably practicable, purging all electronic copies from any computer systems; provided, however, that each Party may retain a single copy of certain Confidential Information of the other Party as required by law, which copy shall remain subject to the confidentiality obligations contained herein. The election by either Party to terminate this Agreement in accordance with its terms shall not be deemed an election of remedies, and all other remedies provided by this Agreement or available at law or in equity shall survive any termination.

## 5.4. Return of Materials

Upon the termination or expiration of this Agreement and payment in full of SciQuus, SciQuus shall deliver to Sponsor all data and materials provided by or on behalf of Sponsor to SciQuus for the conduct of the Study and the Services. All statistical data, all statistical reports, all data entries, and any other documentation produced as the result of the Study and all Services, including all Deliverables (whether or not complete) shall be delivered to Sponsor as soon as possible after termination unless the Parties agree in writing that SciQuus shall retain certain data and materials as specified in writing for a period of time, in which case such items shall continue to be subject to the confidentiality obligations set forth herein.

## 5.5. Survival

Sections 1.7-1.9, 2-4, 5.3-5.5, and 6-10 shall survive expiration or termination of this Agreement for any reason.

## 5.6. Wind Down

Upon the termination of this Agreement, SciQuus shall cooperate with Sponsor and its designee to provide for an orderly wind-down of the Services provided by SciQuus and Personnel hereunder.

# 6. INDEMNIFICATION

## 6.1. By SciQuus

SciQuus shall indemnify, defend, and hold harmless Sponsor, its affiliates, and their respective officers, directors, employees, and agents ("Sponsor Indemnified Parties") from and against any third party claims, actions, or proceedings ("Claims") against a Sponsor Indemnified Party, to the extent related to or arising from this Agreement and caused by: (i) a SciQuus Indemnified Party's (as defined below) grossly negligent acts or omissions or willful misconduct; (ii) breach of this Agreement by SciQuus; (iii) a SciQuus Indemnified Party's grossly negligent failure to comply with applicable laws, rules and regulations (including without limitation any applicable data privacy laws) and any instructions provided by or on behalf of Sponsor; (iv) any government or regulatory audits of SciQuus or Personnel; or (v) any claim that the Services or SciQuus Property used in the Services infringe the

intellectual property rights of a third party; provided, however, that SciQuus shall not be liable for any Claims to the extent such Claims arise out of any Sponsor provided items or Sponsor Indemnified Party's negligent acts or omissions or willful misconduct or failure to comply with applicable laws, rules or regulations or Sponsor's breach of this Agreement.

# 6.2. By Sponsor

Sponsor shall indemnify, defend, and hold harmless SciQuus, its affiliates, and their respective officers, directors, employees, and agents (collectively, the "SciQuus Indemnified Parties") from and against any Claims against a SciQuus Indemnified Party, to the extent resulting from this Agreement and caused by: (i) a Sponsor Indemnified Party's negligent acts or omissions or willful misconduct, or (ii) breach of this Agreement by Sponsor; (iii) Sponsor's failure to comply with applicable laws, rules or regulations governing its obligations under this Agreement; (iii) bodily injury or death of any research subject participating in the Study, which injury was caused by (a) the Study Drug or other compounds required to be administered under the Protocol; or (b) any procedures required to be performed on a research subject participating in the Study pursuant to the Protocol; or (iv) any claims for patent infringement related to the Study Drug or any compound required to be administered under the Protocol in connection with this Agreement provided, however, that Sponsor is not liable for any Claims to the extent such Claims arise out of SciQuus Indemnified Party's grossly negligent acts or omissions or willful misconduct or failure to comply with applicable laws, rules or regulations or SciQuus breach of the Agreement.

#### 6.3. Conditions of Indemnity

The indemnitee shall give the indemnitor prompt notice of any Claim (including a CODY thereof) as to which it claims a right of indemnification hereunder and shall fully cooperate with the indemnitor and its legal representatives in the investigation, negotiation and/or resolution of any matter that is the subject of the other Party's indemnification. The indemnitor shall have the right to exercise sole control over the defense and settlement of any such Claim, including the sole right to select defense counsel and to direct the defense or settlement of any such Claim; provided that the indemnitor shall not enter into any settlement or admit fault or liability on the indemnitee's behalf without the prior written consent of the indemnitee, which consent shall not be unreasonably withheld, delayed, or conditioned. The indemnitee shall have the right to participate in, but not control, the defense and settlement of a claim and to employ separate legal counsel of its own choice provided, however, that such employment shall be at the indemnite's own expense, unless the indemnitor has failed to assume the defense and employ counsel (in which case the indemnitee shall control the defense and settlement of such claim). The indemnitor shall be relieved of any indemnification obligation hereunder if any Sponsor Indemnified Party or SciQuus Indemnified Party (as applicable) either (i) fails to follow the procedures set forth herein; (ii) negotiates, compromises or settles any Claim without the indemnitor's prior written approval; or (iii) makes any admission or takes any other action with respect to any such Claim that is prejudicial to the defense of such Claim the indemnitor's prior written approval.

### 6.4. Limitation of Liability

EXCEPT FOR LIABILITY ARISING FROM A PARTY'S WILLFUL IMPROPER DISCLOSURE OR SPONSOR'S INFRINGEMENT OF ANOTHER'S INTELLECTUAL PROPERTY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, THE STUDY, OR THE STUDY DRUG (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, BY STATUTE OR OTHERWISE) EXCEPT FOR THE REGARDING INDEMNITY IN SECTION 6.1 OR 6.2, PERSONAL INJURY CLAIMS, NOR TO ANY ACTS OF GROSS NEGLIGENCE OR WILLFUL MISCONDUCT. IT IS INTENDED THAT THIS LIMITATION SHALL APPLY EVEN IF SUCH PARTY HAS BEEN ADVISED OR IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES. NOT WITHSTANDING ANY PROVISION TO THE CONTRARY, SCIQUUS' TOTAL LIABILITY THEREUNDER SHALL NEVER EXCEED THE AMOUNT SCIQUUS ACTUALLY RECEIVES UNDER THIS AGREEMENT. NOTWITHSTANDING ANY PROVISION TO THE CONTRARY, THE LIABILITY OF SCIQUUS SHALL NOT EXCEED THE AMOUNT SCIQUUS ACTUALLY RECEIVES FROM SPONSOR UNDER THIS AGREEMENT.

### 7. INSURANCE

Each Party will maintain, for the duration of this Agreement, appropriate insurance in an amount commercially adequate to cover such Party's obligations, including Sponsor's insurance obligations under its Supply and License Agreement with Mayne Pharma, hereunder and as may be required by applicable laws, and, upon request, each Party will provide to the other Party a certificate of insurance showing that such insurance is in place. Such insurance, if on a claims-made basis, shall be maintained for the duration of the term of this Agreement and for not less than the applicable statute of limitations pertaining to any third party claim. SciQuus shall take all reasonable steps to give Sponsor at least sixty (60) days prior written notice of the cancellation of such insurance.

### 8. NOTICES

Any notices or payments under this agreement shall be in writing and delivered to the Parties at the addresses set forth below, by (i) hand delivery, with notice deemed given upon receipt; (ii) first class certified mail, return receipt requested, with notice deemed given upon receipt; or (iii) a nationally-recognized overnight courier service, with notice deemed given as of the date on the courier's receipt.

If to SciQuus:

SciQuus, Inc. 4250 Executive Square, Suite 450 La Jolla, California 92037 Attention: Kevin de la Torre, CFO Tel: (858) 642-0386

If to Sponsor:

HedgePath Pharmaceuticals, Inc. Address: 324 S. Hyde Park Ave, Suite 350 Tampa, Florida 33606 Attention: Nicholas J. Virca Tel: 813-864-2559

## 9. INDEPENDENT CONTRACTOR

Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

## 10. MISCELLANEOUS

### 10.1. Entire Agreement; Amendment

This Agreement, including the recitals and any Exhibits attached hereto, all of which are incorporated herein by reference, constitutes the entire agreement among the Parties with respect to the subject matter herein and supersedes all prior and contemporaneous agreements, whether written or oral, of the Parties hereto, relating to the subject matter herein. This Agreement may be modified, supplemented or amended only by a writing signed by authorized representatives of the Parties.

## 10.2. Assignment

Neither Party may assign or transfer any of its rights or obligations under this Agreement to any third party without the prior written consent of the other Party. Notwithstanding the foregoing, (i) SciQuus may use subcontractors to the extent permitted in Section 1.4; (ii) Sponsor may freely use subcontractors to perform its obligations under exercise its rights under this Agreement and, in such event, Sponsor shall contract directly with such subcontractor; and (iii) either Party may transfer or assign its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets pertaining to the subject matter of this Agreement whether by sale, merger, operation of law or otherwise. This Agreement shall be binding upon, and shall inure to the benefit of, the Parties, their legal representatives, and permitted successors, and assigns. Any attempted sale, pledge, assignment, or other transfer in violation of this Section shall be void and of no force or effect. Any party subcontracting obligations under this Agreement remains fully responsible to the other party for the performance of, and acts and omissions of, such subcontractors.

## 10.3. Governing Law; Severability

This Agreement and any disputes arising hereunder shall be governed by and construed in accordance with the substantive laws of the State of California, without regard to its conflict of law rules. Exclusive jurisdiction of any disputes arising under or relating to this Agreement will lie in the Federal and state courts located in San Diego, California. All proceedings and documents provided and generated in connection with any disputes hereunder shall be in the English language. If any provision of this Agreement is for any reason found to be unenforceable, the remainder of this Agreement shall continue in full force and effect.

## 10.4. No Waiver

Failure to enforce any rights hereunder, regardless of the length of time such failure continues, shall not constitute a waiver of those or any other rights, unless in a writing signed by an authorized representative of the waiving Party.

# 10.5. Data Privacy

Each Party shall comply with its obligations under any data privacy laws that are applicable to the Study or this Agreement.

## 10.6. Execution in Counterparts

This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or in Portable Document Format (PDF) sent by electronic means. Signatures of authorized signatories of the Parties transmitted by facsimile or sent by electronic means in Portable Document Format shall be deemed to be original signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Agreement.

## 10.7. Force Majeure

To the extent either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder other than a payment obligation by reason of governmental or judicial orders or decrees, riots, insurrection, war, acts of God, or other causes reasonably beyond such Party's control (each a "Disability"), then performance of such act shall be excused for the period and to the extent of such Disability; provided that the Party incurring such Disability shall (i) provide prompt written notice to the other Party of the commencement of such alleged Disability; and (ii) take all reasonable actions to resume performance of the affected acts as soon as possible thereafter. Any timelines affected by a Disability shall be extended for a period equal to that of the Disability.

# 10.8. Foreign Corrupt Practices Act

SciQuus and Personnel shall avoid any conflicts of interest in performing the Services. SciQuus covenants and agrees on behalf of itself and Personnel, to adhere to and comply with all applicable U.S. and non-U.S.

laws, including but not limited to anti-bribery measures such as the U.S. Foreign Corrupt Practices Act (the "FCPA"), and will not give, offer, agree or promise to give, or authorize the giving directly or indirectly through any other person or firm, of any money or thing of value to any employee or official of any government, any employee or official of any public international organization, any political party or official or employee of the same, or any candidate for political office, for the purpose of inducing or rewarding favorable action or the exercise of influence by such official, party or candidate in any governmental matter. Further, SciQuus and Personnel will not give, offer or promise to give, or authorize the giving directly or indirectly through any person or firm, of any money or thing of value to any foreign party or its representative as an inducement or reward for the party or representative doing or forbearing to do any act in relation to the business or affairs of SciQuus, Personnel or Sponsor, or for showing or forbearing to Sponsor. SciQuus further represents and warrants that neither it nor Personnel nor any of their employees, partners, or agents are, or will become during the term of this Agreement officials or employees, or candidates for political office in the government. SciQuus' failure to comply with the provisions of all applicable Laws, including but not limited to the FCPA, may result in immediate termination of this Agreement for cause by Sponsor at its election.

[Signature page follows.]

IN WITNESS WHEREOF the Parties hereto have caused this Agreement to be duly executed as of the date first written above, and effective as of the Effective Date, by their authorized representatives.

# Executed for and on behalf of:

SCIQUUS, INC.

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By:

John C. Gutheil, MD Chief Executive Officer

HEDGEPATH PHARMACEUTICALS, INC.

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By:

Nicholas J. Virca President & CEO

I, Nicholas J. Virca, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 (or persons performing the equivalent functions):

(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: August 14, 2015

/s/ Nicholas J. Virca

Nicholas J. Virca President and Chief Executive Officer I, Garrison J. Hasara, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 (or persons performing the equivalent functions):

(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: August 14, 2015

/s/ Garrison J. Hasara Garrison J. Hasara

Chief Financial Officer and Treasurer

## HEDGEPATH PHARMACEUTICALS, INC.

## CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of HedgePath Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nicholas J. Virca, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report 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 Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Nicholas J. Virca

Nicholas J. Virca President and Chief Executive Officer August 14, 2015

## HEDGEPATH PHARMACEUTICALS, INC.

## CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of HedgePath Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrison J. Hasara, Treasurer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report 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 Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Garrison J. Hasara

Garrison J. Hasara Chief Financial Officer and Treasurer August 14, 2015