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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 10, 2013 (September 3, 2013)

HedgePath Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-13467
(Commission
File Number)

30-0793665
(IRS Employer
Identification No.)

324 South Hyde Park Avenue, Suite 350
Tampa, FL 33606
(813) 864-2559

(Address, including Zip Code and Telephone Number, including Area Code, of Principal Executive Offices)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-
-

Item 1.01. Entry into a Material Definitive Agreement.

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

The Supply and License Agreement is attached to this Current Report as Exhibit 10.1. All descriptions of the Supply and License Agreement herein are qualified in their entirety to the text of Exhibit 10.1 hereto, which is incorporated herein by reference.

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

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

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

Although the Supply and License Agreement is effectively immediately, it remains subject to early termination by Mayne Pharma if certain conditions (the “Conditions”) are not met by December 16, 2013. Such Conditions include: (i) the Company shall have raised \$5 million in an equity financing (or such lesser amount as may be agreed to by Mayne Pharma) (the “Equity Financing”); (ii) a representative of Mayne Pharma shall have been appointed to the Company’s board of directors, and Mayne Pharma and the Company shall have entered into an agreement granting Mayne Pharma certain board appointment rights; (iii) Mayne Pharma shall, pursuant to customary definitive documentation to be negotiated by the parties, acquire from the Company, as part of the consideration under the Supply and License Agreement,

170,000.74 shares of the Company's Series A Preferred Stock, par value \$0.0001 per share (the "Series A Preferred Stock"), representing, on an as fully converted, fully diluted basis, 45% of the issued and outstanding shares of capital stock of the Company (prior to the Equity Financing and the anticipated adoption by the Company of an equity incentive plan); (iv) Hedgepath, LLC (an affiliate of the Company who currently has the right to receive shares of Series A Preferred Stock) ("Hedgepath"), Nicholas J. Virca (the Company's President and Chief Executive Officer) ("Virca") and Mayne Pharma shall have entered into an agreement providing for certain restrictions on transfers and ownership of Company equity; (v) the Company and Mayne Pharma shall have entered into an agreement granting Mayne Pharma and accredited investors introduced to the Company by Mayne Pharma certain participation rights in future Company equity financings; (vi) the Company shall have (a) received a written estimate from a credible contract research organization reasonably acceptable to Mayne Pharma relating to the Company's proposed clinical trials and (b) provided reasonable assurances to Mayne Pharma that the Product will be available for commercial launch by a specified date; and (vii) Virca and Frank E. O'Donnell, Jr., the Company's Executive Chairman, shall have entered into customary agreements regarding their positions with the Company.

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

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

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year

On September 9, 2013, the Company, in accordance with Section 151(g) of the Delaware General Corporation Law, filed an Amended and Restated Certificate of Designation of Series A Preferred Stock (the "Amended Certificate of Designation").

The Amended Certificate of Designation was filed prior to the formal issuance of shares of Series A Preferred Stock to clarify (but not alter or modify) the voting rights and conversion rights of the holders of Series A Preferred Stock and to correct a typographical error in the numerical calculation of how the Series A Preferred Stock will be adjusted following reverse stock split or consolidation of the Company's common stock.

The Amended Certificate of Designation is attached to this Current Report as Exhibit 3.1. All descriptions of the Amended Certificate of Designation herein are qualified in their entirety to the text of Exhibit 3.1 hereto, which is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

In connection with the License Agreement described in Item 1.01 of this Current Report, the Company issued a press release on September 10, 2013. This press release is attached to this Current Report as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

Set forth below is a list of Exhibits included as part of this Current Report.

- 3.1 Amended and Restated Certificate of Designation of Series A Convertible Preferred Stock.
- *10.1 Supply and License Agreement, dated September 3, 2013, by and among the Company and Mayne Pharma.
- 99.1 Press Release, dated September 10, 2013.

* **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.**

Cautionary Note on Forward-Looking Statements

This Current Report and any related statements of representatives and partners of the Company contain, or may contain, among other things, certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company’s plans, objectives, projections, expectations and intentions and other statements identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” or similar expressions. These statements are based upon the current beliefs and expectations of the Company’s management and are subject to significant risks and uncertainties, including those detailed in the Company’s filings with the Securities and Exchange Commission. Actual results (including, without limitation, the results (i) stemming from the Company’s commercial partnership with Mayne Pharma, (ii) of regulatory review of SUBA-Itraconazole and derivative products of such or (iii) sales results for derivative products of SUBA-Itraconazole to the Company) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company’s control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 10, 2013

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca

Name: Nicholas J. Virca

Title: President and CEO

**AMENDED AND RESTATED
CERTIFICATE OF DESIGNATION
OF
SERIES A CONVERTIBLE PREFERRED STOCK
OF
HEDGEPATH PHARMACEUTICALS, INC.**

**Pursuant to Section 151(g) of the
Delaware General Corporation Law**

Pursuant to Section 151(g) of the General Corporation Law of the State of Delaware (the “**DGCL**”), the undersigned officer of HedgePath Pharmaceuticals, Inc., a corporation organized and existing under the DGCL (the “**Corporation**”), in accordance with the provisions of Section 103 thereof, **DOES HEREBY CERTIFY**:

1. That by unanimous written consent to action of the Board of Directors of the Corporation (the “**Board of Directors**”) adopted on August 3, 2013, and by a Certificate of Designation of Series A Convertible Preferred Stock of the Corporation (the “**Series A Preferred Stock**”) filed in the office of the Secretary of State of the State of Delaware on August 13, 2013, the Corporation authorized the creation of a series of 500,000 shares of Series A Preferred Stock and established the designation, number of shares, powers, preferences, rights, qualifications, limitations and restrictions thereof.

2. That no shares of said Series A Preferred Stock have been issued.

3. That pursuant to the authority conferred upon the Board of Directors by the Corporation’s Certificate of Incorporation (the “**Certificate of Incorporation**”) and Section 151(g) of the DGCL, on September 9, 2013, the Board of Directors adopted the following resolution by unanimous written consent to action amending and restating, in its entirety and effective on the date this Amended and Restated Certificate of Designations of the Series A Preferred Stock is filed in the office of the Secretary of State of the State of Delaware, the provisions of the Certificate of Designations of Series A Preferred Stock:

RESOLVED, that pursuant to the authority granted to and vested in the Board of Directors of the Corporation in accordance with the provisions of the Certificate of Incorporation and Section 151(g) of the General Corporation Law of the State of Delaware, the designation, number of shares, powers, preferences, rights, qualifications, limitations and restrictions of the Corporation’s Series A Convertible Preferred Stock, par value \$0.0001 per share (in addition to any provisions set forth in the Certificate of Incorporation which are applicable to the preferred stock of the Corporation of all classes and series) is hereby amended and restated in their entirety as follows:

SERIES A CONVERTIBLE PREFERRED STOCK

SECTION 1. DEFINITIONS. For the purposes hereof, the following capitalized terms shall have the following meanings, with other capitalized terms being defined elsewhere herein:

“**Business Day**” means any day except Saturday, Sunday, any day which shall be 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.

“**Common Stock**” means the Corporation’s common stock, par value \$0.0001 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed into.

“**Conversion Shares**” means, collectively, the shares of Common Stock issuable upon conversion of the shares of Series A Preferred Stock in accordance with the terms hereof.

“**DGCL**” means the Delaware General Corporation Law.

“**Effective Date**” means August 13, 2013.

“**Holder**” means any holder of Series A Preferred Stock.

“**Person**” means any individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“**Securities Act**” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

SECTION 2. DESIGNATION, AMOUNT AND PAR VALUE; ASSIGNMENT

(a) The series of preferred stock designated by this Certificate shall be designated as the Corporation’s “Series A Convertible Preferred Stock” (the **Series A Preferred Stock**) and the number of shares so designated shall be 500,000. Each share of Series A Preferred Stock shall have a par value of \$0.0001 per share.

(b) The Corporation shall register shares of the Series A Preferred Stock, upon records to be maintained by the Corporation for that purpose (the **Series A Preferred Stock Register**), in the name of the Holders thereof from time to time. The Corporation may deem and treat the registered Holder of shares of Series A Preferred Stock as the absolute owner thereof for the purpose of any conversion thereof and for all other purposes. The Corporation shall register the transfer of any shares of Series A Preferred Stock in the Series A Preferred Stock Register, upon surrender of the certificates evidencing such shares to be transferred, duly endorsed by the Holder thereof, to the Corporation at its principal place of business or such other office of the Corporation as may be designated by the Corporation. Upon any such registration or transfer, a new certificate evidencing the shares of Series A Preferred Stock so transferred shall be issued to the transferee and a new certificate evidencing the remaining portion of the shares not so transferred, if any, shall be issued to the transferring Holder, in each case, within three (3) Business Days. The provisions of this Certificate are intended to be for the benefit of all Holders from time to time and shall be enforceable by any such Holder.

SECTION 3. DIVIDENDS. Holders shall be entitled to receive, and the Corporation shall pay, dividends on shares of the Series A Preferred Stock equal (on an as-if-converted-to-Common-Stock basis) to and in the same form as dividends (other than dividends in the form of Common Stock) actually paid on shares of the Common Stock when, as and if such dividends (other than dividends in the form of Common Stock) are paid on shares of the Common Stock.

SECTION 4. VOTING RIGHTS. Each issued and outstanding share of Series A Preferred Stock shall be entitled at all times to the number of votes equal to the number of shares of Common Stock into which each such share of Series A Preferred Stock is convertible, or would be convertible were the restrictions on conversion set forth in Section 6(a) hereof not in force at the time such vote is taken (as

adjusted from time to time pursuant to Section 6 hereof), at each meeting of stockholders of the Corporation (or pursuant to any action by written consent) with respect to any and all matters presented to the stockholders of the Corporation for their action or consideration. Except as provided by law, or by the provisions establishing any other series of Preferred Stock, holders of Series A Preferred Stock shall vote together with the holders of Common Stock as a single class.

SECTION 5. RANK; LIQUIDATION.

(a) The Series A Preferred Stock shall rank: (i) senior to all of the Common Stock; (ii) senior to any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms junior to any Series A Preferred Stock ("**Junior Securities**"); (iii) on parity with any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms on parity with the Series A Preferred Stock ("**Parity Securities**"); and (iv) junior to any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms senior to any Series A Preferred Stock ("**Senior Securities**"), in each case, as to dividends, distributions of assets upon liquidation, dissolution or winding up of the Corporation, whether voluntarily or involuntarily. The foregoing shall not preclude the Corporation from designating or issuing any Junior Securities, Parity Securities or Senior Securities.

(b) Subject to the prior and superior rights of the holders of any Senior Securities of the Corporation, upon liquidation, dissolution or winding up of the Corporation, whether voluntary or involuntary (each, a "**Liquidation Event**"), each holder of shares of Series A Preferred Stock shall be entitled to receive, in preference to any distributions of any of the assets or surplus funds of the Corporation to the holders of the Common Stock and Junior Securities and pari passu with any distribution to the holders of Parity Securities, an amount equal to \$0.0001 per share of Series A Preferred Stock, plus an additional amount equal to any dividends declared but unpaid on such shares, before any payments shall be made or any assets distributed to holders of any class of Common Stock or Junior Securities. If, upon any such Liquidation Event, the assets of the Corporation shall be insufficient to pay the holders of shares of the Series A Preferred Stock the amount required under the preceding sentence, then all remaining assets of the Corporation shall be distributed ratably to holders of the shares of the Series A Preferred Stock and Parity Securities.

(c) After payment to the holders of shares of the Series A Preferred Stock of the amount required under Section 5(b) and subject to the prior and superior rights of the holders of any Senior Securities of the Corporation, the remaining assets or surplus funds of the Corporation, if any, available for distribution to stockholders shall be distributed ratably among the holders of the Series A Preferred Stock, any other class or series of capital stock that participates with the Common Stock in the distribution of assets upon any Liquidation Event and the Common Stock, with the holders of the Series A Preferred Stock deemed to hold that number of shares of Common Stock into which such shares of Series A Preferred Stock are then convertible, or otherwise would be then convertible were the restrictions on conversion set forth in Section 6(a) hereof not in force at the time of such Liquidation Event.

SECTION 6. CONVERSION.

(a) Conversions at Option of Holder. Following the one (1) year anniversary of the Effective Date, all of the shares of Series A Preferred Stock (the "**Total Series A Shares**") shall be convertible on any Business Day in the aggregate into a number of Conversion Shares that equals ninety percent (90%) of the total issued and outstanding shares of the Common Stock (on a fully converted, fully-diluted basis) of the Corporation as of the Effective Date, after giving effect to a hypothetical issuance of such Conversion Shares (the "**Conversion Rate**") without any additional consideration by the holder to effectuate the conversion, in the manner provided for herein. As of the Effective Date, there are

18,888,971 shares of Common Stock outstanding on a fully-diluted basis; therefore, the Total Series A Shares are convertible into 170,000,739 shares of Common Stock (the “**Total Series A Conversion Shares**”), and each share of Series A Preferred Stock is convertible into its pro rata portion of such the Total Series A Conversion Shares. After the one (1) year anniversary of the Effective Date, each Holder of Series A Preferred Stock may at his or its option, convert from time to time, all or some of his or its shares of Series A Preferred Stock. Except as a result of the adjustments of Section 7 hereof, the Conversion Rate shall not be subject to dilution, modification or any other change, regardless of any action undertaken by the Board of Directors or stockholders of the Corporation.

(b) Mechanics of Conversion.

(i) Generally. Each Holder who converts the Series A Preferred Stock held by such Holder into shares of Common Stock pursuant to this Section 6 shall surrender the certificate or certificates therefor, duly endorsed, at the office of the Corporation, and shall give written notice (a “**Notice of Conversion**”) to the Corporation at such office that such holder elects to convert the same. Such Notice of Conversion, to be given on any Business Day, shall state the number of shares of Series A Preferred Stock being converted and shall contain instructions as to where Conversions Shares should be delivered. Thereupon, the Corporation shall promptly issue and deliver to such Holder a certificate or certificates for the number of shares of Common Stock to which such Holder is entitled (which certificate or certificates shall bear appropriate restrictive legends as may be required by the Securities Act) and shall promptly pay in Common Stock any declared and unpaid dividends on the shares of Series A Preferred Stock being converted. Such conversion shall be deemed to have been made at the close of business on the date of which both certificates representing the shares of Series A Preferred Stock to be converted are surrendered to the Corporation and the Holder has delivered a Notice of Conversion to the Corporation (the “**Conversion Date**”), and the Person entitled to receive the shares of Common Stock issuable upon such conversion shall be treated for all purposes as the record holder of such shares of Common Stock on the Conversion Date.

(ii) Reservation of Shares Issuable Upon Conversion. The Corporation covenants that it will at all times reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of the Series A Preferred Stock, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holders of the Series A Preferred Stock, not less than such aggregate number of shares of the Common Stock as shall be issuable (taking into account the adjustments of Section 7) upon the conversion of the Total Series A Shares. The Corporation covenants that all shares of Common Stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid and nonassessable.

(iii) Fractional Shares. No fractional shares or scrip representing fractional shares of Common Stock shall be issued, or be deemed to be issued for purposes of determining the number of votes held by a Holder of Series A Preferred Stock, upon the conversion of the Series A Preferred Stock. As to any fraction of a share which a Holder would otherwise be entitled to receive upon such conversion, the Corporation shall round up to the next whole share.

(iv) Transfer Taxes. The issuance of certificates for Conversion Shares shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such certificates, provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such certificate upon conversion in a name other than that of the registered Holder(s) of such shares of Series A Preferred Stock and the Corporation shall not be required to issue or deliver such certificates unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid.

(e) Status as Stockholder. Upon each Conversion Date: (i) the shares of Series A Preferred Stock being converted shall be deemed converted into shares of Common Stock and (ii) the Holder's rights as a holder of such converted shares of Series A Preferred Stock shall cease and terminate, excepting only the right to receive certificates for or (if applicable and permitted under the Securities Act) electronic delivery of such shares of Common Stock and to any remedies provided herein or otherwise available at law or in equity to such Holder because of a failure by the Corporation to comply with the terms of this Certificate of Designation. In all cases, the Holder shall retain all of its rights and remedies for the Corporation's failure to convert Series A Preferred Stock.

SECTION 7. CERTAIN ADJUSTMENTS.

(a) Stock Dividends and Stock Splits. If the Corporation, at any time while the Series A Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Corporation upon conversion of shares of Series A Preferred Stock) with respect to the then outstanding shares of Common Stock; (ii) subdivides outstanding shares of Common Stock into a larger number of shares; or (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, then the Total Series A Conversion Shares shall be multiplied by a fraction of which the denominator shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) outstanding immediately before such event and of which the numerator shall be the number of shares of Common Stock outstanding immediately after such event (excluding any treasury shares of the Corporation). Any adjustment made pursuant to this Section 7(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision or combination.

(b) Rights Upon Distribution of Assets. If the Corporation shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) other than cash to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "**Distribution**"), a Holder shall be entitled to receive the dividend or distribution of assets that would have been payable to such Holder pursuant to the Distribution had such Holder converted his or her shares of Series A Preferred Stock (or, if such Holder had partially converted such shares prior to the Distribution, any unconverted portion thereof) immediately prior to such record date.

(c) Fundamental Transaction. If, at any time while the Series A Preferred Stock is outstanding: (i) the Corporation effects any merger or consolidation of the Corporation with or into another Person (other than a merger in which the Corporation is the surviving or continuing entity and its Common Stock is not exchanged for or converted into other securities, cash or property), (ii) the Corporation effects any sale of all or substantially all of its assets in one transaction or a series of related transactions, (iii) any tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which all of the Common Stock is exchanged for or converted into other securities, cash or property, or (iv) the Corporation effects any reclassification of the Common Stock or any compulsory share exchange pursuant (other than as a result of a dividend, subdivision or combination covered by Section 7(a) above) to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (in any such case, a "**Fundamental Transaction**"), then, upon any subsequent conversion of this Series A Preferred Stock, the Holders shall have the right to receive, in lieu of the right to receive Conversion Shares, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of

such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of one share of Common Stock (the “**Alternate Consideration**”). For purposes of any such subsequent conversion, the determination of the Conversion Rate shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Corporation shall adjust the Conversion Rate in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holders shall be given the same choice as to the Alternate Consideration it receives upon any conversion of this Series A Preferred Stock following such Fundamental Transaction. To the extent necessary to effectuate the foregoing provisions, any successor to the Corporation or surviving entity in such Fundamental Transaction shall file a new Certificate of Designation with the same terms and conditions and issue to the Holders new preferred stock consistent with the foregoing provisions and evidencing the Holders’ right to convert such preferred stock into Alternate Consideration. The terms of any agreement to which the Corporation is a party and pursuant to which a Fundamental Transaction is effected shall include terms requiring any such successor or surviving entity to comply with the provisions of this Section 7(b) and ensuring that the Series A Preferred Stock (or any such replacement security) will be similarly adjusted upon any subsequent transaction analogous to a Fundamental Transaction. The Corporation shall cause to be delivered (via overnight courier, facsimile or email) to each Holder who does not have a representative or affiliate of such Holder serving on the Board of Directors of the Corporation, at its last address as it shall appear upon the books and records of the Corporation, written notice of any Fundamental Transaction at least ten (10) calendar days prior to the date on which such Fundamental Transaction is expected to become effective or close.

(d) Calculations. All calculations under this Section 7 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 7, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

SECTION 8. MISCELLANEOUS.

(a) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by email, facsimile, or sent by a nationally recognized overnight courier service, addressed to the Corporation, at 324 South Hyde Park Avenue, Suite 350, Tampa FL 33606, Fax Number: (813) 831-2372, or such other facsimile number or address or email address as the Corporation may specify for such purposes by notice to the Holders delivered in accordance with this Section. Any and all notices or other communications or deliveries to be provided by the Corporation hereunder shall be in writing and delivered personally, by facsimile, or sent by a nationally recognized overnight courier service or email addressed to each Holder at the facsimile number or address of such Holder appearing on the books of the Corporation, or if no such facsimile number or address appears on the books of the Corporation, at the principal place of business of such Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address specified in or pursuant to this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the date immediately following the date of transmission, if such notice or communication is delivered via facsimile or mail at the facsimile number or email address specified in or pursuant to this Section between 5:30 p.m. and 11:59 p.m. (New York City time) on any date, (iii) the second (2nd) Business Day following the date of mailing, if sent by nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

(b) No Impairment. For so long as any shares of Series A Preferred Stock are outstanding, the terms of this Certificate of Designation may not be amended, modified, repealed or waived without the affirmative vote or written consent of the holders of at least seventy-five percent (75%) of the then outstanding shares of Series A Preferred Stock. In addition, except as authorized by the affirmative vote or written consent of the holders of not less than seventy-five percent (75%) of the then outstanding shares of Series A Preferred Stock, the Corporation will not, by amendment of this Certificate of Designation or its Certificate of Incorporation or through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, fail to observe, or avoid or seek to avoid the observance or performance of, any of the terms contained herein, and will at all times in good faith take all actions as may be necessary to carry out of all the provisions hereof and to take all such actions as may be necessary or appropriate in order to protect the rights of the holders of Series A Preferred Stock against any impairment.

(c) Lost or Mutilated Series A Preferred Stock Certificate. If a Holder's Series A Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Series A Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership thereof, reasonably satisfactory to the Corporation and, in each case, customary and reasonable indemnity, if requested. Applicants for a new certificate under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Corporation may prescribe.

(d) Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designation. Any waiver by the Corporation or a Holder must be in writing.

(e) Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

(f) Next Business Day. Whenever any obligation hereunder shall be due on a day other than a Business Day, such obligation shall be made or fulfilled on the next succeeding Business Day.

(g) Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

(h) Status of Converted Series A Preferred Stock. If any shares of Series A Preferred Stock shall be converted or reacquired by the Corporation, such shares shall resume the status of authorized but unissued shares of Preferred Stock and shall no longer be designated as Series A Preferred Stock.

IN WITNESS WHEREOF, the Corporation has caused this Amended and Restated Certificate of Designation to be signed by its duly authorized officer this 9th day of September, 2013.

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca

Name: Nicholas J. Virca

Title: President and Chief Executive Officer

Confidential Treatment Requested by HedgePath Pharmaceuticals, Inc.,
IRS Employer Identification No. 30-0793665
Confidential treatment requested with respect to certain portions hereof denoted with “***”
CONFIDENTIAL TREATMENT REQUESTED

Final
Date: 3 September 2013

Supply and License Agreement
Mayne Pharma International Pty Ltd (Mayne Pharma)
HedgePath Pharmaceuticals, Inc. (HPPI)

Table of contents

Table of contents	2
Details	6
Agreed terms	7
1. Defined terms & interpretation	7
1.1 Defined terms	7
1.2 Interpretation	11
2. Term	11
2.1 Initial Term	11
2.2 Extension	11
3. Licence	12
3.1 Licence to exploit the Product in the Territory	12
3.2 HPPI obligations	12
3.3 Supporting the exclusive licence	12
3.4 Sub licensing the MP Licensed Rights	12
4. Development	13
4.1 Development Plan	13
4.2 JDC	13
4.3 Target Launch Date	14
4.4 Tax considerations	14
4.5 Waiving a Condition	14
4.6 Notice of satisfaction or waiver of a Condition	14
4.7 Agreement can be terminated if the Conditions are not satisfied by the Condition Date	14
4.8 Material development decisions	14
5. Marketing Authorisation	15
5.1 Obtaining and maintaining Marketing Authorisations	15
5.2 Assistance by Mayne Pharma	15
5.3 Failure to obtain Marketing Authorisations	15
6. Manufacture and supply of Product	15
6.1 Forecasts	15
6.2 Orders	15
6.3 Manufacture; Failure to Supply	16
6.4 Backup manufacturer	16
7. Payments	16
7.1 HPPI Payments	16
7.2 Review of Prices	16
7.3 Mayne Pharma Payments	16
7.4 Payment terms	17
7.5 Reimbursement	17

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

17.	Confidentiality	25
17.1	Definition	25
17.2	Restrictions on disclosure and use	26
17.3	Exceptions	26
18.	Intellectual Property Rights	26
18.1	Intellectual Property Rights in the Product as at the Start Date	26
18.2	***	26
18.3	***	26
18.4	***	27
18.5	Development of Intellectual Property Rights and Licence of HPPI Licensed Rights	27
18.6	Notification of infringement	27
18.7	Right to take action	27
19.	Branding	27
19.1	Directions regarding use of the Trade Mark	27
19.2	Samples of marketing materials	27
19.3	Use of the Trade Mark	28
19.4	Goodwill	28
19.5	No right for HPPI to register the Trade Mark	28
20.	Termination	28
20.1	Termination for breach by a party	28
20.2	Termination by Mayne Pharma for cause arising under a related agreement	28
20.3	Notification of insolvency events	29
20.4	Change of control and disposal of assets or business by HPPI	29
20.5	***	29
20.6	Accrued rights and remedies	29
20.7	Sell down or repurchase	29
20.8	Return of Confidential Information	30
21.	Force majeure	30
21.1	Occurrence of Force Majeure Event	30
21.2	Termination	30
22.	Notices and other communications	31
22.1	Service of notices	31
22.2	Effective on receipt	31
23.	Dispute resolution	31
23.1	No court proceeding unless procedure followed	31
23.2	Notice of Dispute	31
23.3	Negotiations	31
23.4	Failure to negotiate settlement	31
23.5	Arbitration	32
23.6	Urgent injunctive or other interlocutory relief	32
24.	GST	32
24.1	Interpretation	32
24.2	Consideration is GST exclusive	32
24.3	Gross up of consideration	32

**Confidential Treatment Requested by HedgePath Pharmaceuticals, Inc.,
IRS Employer Identification No. 30-0793665**

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

24.4	The sale of the Product is intended to be a GST-free export of goods	32
24.5	Reimbursements (net down)	33
24.6	Tax invoices	33
24.7	Adjustments	33
24.8	Similar goods and services taxes or value added taxes	33
25.	Tax	33
25.1	Payments free of taxes; obligations to withhold; payments on account of taxes	33
25.2	Refunds	34
26.	Miscellaneous	34
26.1	Survival of Obligations	34
26.2	Approvals and consents	34
26.3	Announcements	34
26.4	Subcontracting	34
26.5	Assignment	34
26.6	Costs	35
26.7	Relationship	35
26.8	No modification	35
26.9	Non waiver	35
26.10	Entire agreement	35
26.11	Further Action	35
26.12	Severability	35
26.13	Counterparts	35
26.14	Governing law	35
Schedule 1 – Agreement details		36
Schedule 2 – Conditions		37
Schedule 3 – Development Plan		42
Schedule 4 – Product and Product Specification		43
Schedule 5 – Economic details		44
Schedule 6 – Qualification of Backup Manufacturer		47
Schedule 7 – Licence of HPPI Licensed Rights		48
Schedule 8 – EIP		51

Confidential treatment requested with respect to certain portions hereof denoted with “***”

Details

Date **3 September, 2013**

Parties

Name **Mayne Pharma International Pty Ltd**, a company incorporated in Australia
Short form name **Mayne Pharma**
ABN 88 007 870 984
Notice details Level 14/474 Flinders Street, Melbourne, VIC, 3000, Australia
Facsimile: +61 3 8614 7022
Attention: General Counsel

Name **HedgePath Pharmaceuticals, Inc.**, a company incorporated in Delaware, successor in interest by merger to Commonwealth Biotechnologies, Inc, a Virginia corporation
Short form name **HPPI**
Notice details 324 South Hyde Park Avenue #350, Tampa, FL 33606, United States
Facsimile: +1 813-258-6912
Attention: Nicholas Jon Virca, President & CEO

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.

Agreed terms

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.

Alternate Product means any product ***.

API means active pharmaceutical ingredient.

Business Day means:

- (a) for receiving a notice under clause 0, 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 any pharmaceutical product ***.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

Condition Date means 16 December 2013 as that date may be extended:

- (a) by agreement of the parties in writing; or
- (b) by Mayne Pharma in its discretion by notice to HPPI if the Conditions have not been satisfied by the then current Condition Date.

Condition means each of the conditions set out in item 1 of Schedule 2.

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 as set out in Schedule 3, and updated in accordance with clause 4.8(b).

Disclosing Party is defined in clause 17.1.

Dispute is defined in clause 23.2.

Dispute Notice is defined in clause 23.2.

EIP means the 2013 Equity Incentive Plan of HPPI, details of which are set out in Schedule 8.

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.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

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 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.

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.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

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.

Series A Preferred Stock means the Series A Convertible Preferred Stock, par value \$0.0001 per share, of HPPI, the terms of which are memorialized in the Certificate of Designation for the Series A Preferred Stock, the form of which has been provided to Mayne Pharma filed with the Secretary of State of Delaware on August 13, 2013, as the same may be amended, restated or corrected from time to time.

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 defined in clause 4.3 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 trade marks (whether registered or unregistered) notified in writing by Mayne Pharma to HPPI for the purposes of this agreement from time to time.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

1.2 Interpretation

In this agreement, except where the context otherwise requires:

- (a) the singular includes the plural and vice versa, and a gender includes other genders;
- (b) another grammatical form of a defined word or expression has a corresponding meaning;
- (c) a reference to a clause, paragraph, schedule or annexure is to a clause or paragraph of, or schedule or annexure to, this agreement, and a reference to this agreement includes any schedule or annexure;
- (d) a reference to a document or instrument includes the document or instrument as novated, altered, supplemented or replaced from time to time;
- (e) a reference to AUD is to Australian dollars, to USD is to United States dollars, to GBP is to British pounds and to EUR is to euros;
- (f) a reference to time is to Melbourne, Australia time;
- (g) a reference to a party is to a party to this agreement, and includes the party’s executors, administrators, successors and permitted assigns and substitutes;
- (h) a reference to a person includes a natural person, partnership, corporation, limited liability company, trust, association, governmental or local authority or agency or other entity;
- (i) a reference to a statute, ordinance, code or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them;
- (j) the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions;
- (k) a rule of construction does not apply to the disadvantage of a party because the party was responsible for the preparation of this agreement or any part of it;
- (l) if a day on or by which an obligation must be performed or an event must occur is not a Business Day, the obligation must be performed or the event must occur on or by the next Business Day;
- (m) headings are for ease of reference only and do not affect interpretation; and
- (n) clauses 0 and 0 prevail over a Schedule to the extent of any inconsistency.

Term

2.1 Initial Term

This agreement starts on 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.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

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 for **** after the end of the Term; or
 - (ii) sell or distribute the Product to any other party which it knows, or has reasonable grounds for suspecting, will sell or distribute the Product outside the Territory or outside the Field;
 - (iii) import, promote, market, sell or distribute the Product outside the Territory or outside the Field; and
- (c) refer to Mayne Pharma all enquiries, sales leads, prospects and other information HPPI may receive concerning sales and prospective sales of the Product outside the Territory or the Field.

3.3 Supporting the exclusive licence

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

3.4 Sub licensing the MP Licensed Rights

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

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

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

- (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.

Development

4.1 Development Plan

- (a) HPPI will conduct the activities set out in, and in accordance with, the Development Plan at its cost and expense.
- (b) Up until the Target Launch Date, the parties must review the Development Plan through the JDC at least each Quarter, for the following 8 Quarters. The parties will discuss the Development Plan in good faith and (subject to clause 4.8(b)) HPPI may amend such Development Plan, and provide an updated written copy to Mayne Pharma.
- (c) If HPPI fails to update the Development Plan in accordance with clause 4.1(b), the then current Development Plan will continue to apply.
- (d) Mayne Pharma agrees to provide at its expense the relevant *** section of the *** 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;
 - (ii) to review progress against the current Development Plan 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; and
 - (iv) before the Condition Date, to review progress of satisfying Conditions, which JDC will continue until the Target Launch Date.
- (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.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

- (d) 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.
- (e) HPPI is responsible for coordinating the JDC meetings. The site, date and proposed agenda of any meeting of the JDC must be determined by agreement of the members of the JDC. If a member of the JDC is required to travel to attend any meeting of the JDC, HPPI will reimburse the reasonable expenses incurred by that member in respect of that travel.

4.3 Target Launch Date

The parties must procure that the Joint Development Committee (acting by a majority of all representatives) nominates the target for the Actual Launch Date **(Target Launch Date)**, and HPPI must notify Mayne Pharma of the Target Launch Date in writing, by ****.

4.4 Tax considerations

In satisfying any Condition, the parties agree to use reasonable commercial efforts to structure transactions in a tax effective manner.

4.5 Waiving a Condition

Each Condition may only be waived in writing signed by Mayne Pharma.

4.6 Notice of satisfaction or waiver of a Condition

HPPI must give Mayne Pharma notice when a Condition is satisfied.

4.7 Agreement can be terminated if the Conditions are not satisfied by the Condition Date

If all Conditions have not been satisfied by the Condition Date, then unless or until such time as all Conditions are satisfied, Mayne Pharma may terminate this agreement with immediate effect by notice to HPPI, except if there is a genuine dispute regarding the satisfaction of any Condition in which case Mayne Pharma may not terminate this agreement unless or until:

- (a) the parties agree the Condition has not been satisfied; or
- (b) the Condition is deemed not to have been satisfied in accordance with item 2.2 under Schedule 2, whichever is sooner.

4.8 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; 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.

Confidential treatment requested with respect to certain portions hereof denoted with “***”

Marketing Authorisation

5.1 Obtaining and maintaining Marketing Authorisations

HPPI must:

- (a) actively seek, at its cost and expense, and use reasonable commercial efforts to obtain all Marketing Authorisations in its own name;
- (b) pay fees or charges in respect of the application for all Marketing Authorisations, maintenance of all Marketing Authorisations and the making of any variation to all Marketing Authorisations; and
- (c) comply with the requirements of any Relevant Regulatory Authority within the Territory, including in connection with any Marketing Authorisation and all reporting obligations.

5.2 Assistance by Mayne Pharma

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

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

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

- (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.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

- (d) Mayne Pharma agrees to use reasonable commercial efforts:
 - (i) to provide a Delivery Date *** after the delivery date specified in the Order; and
 - (ii) to supply the Order by the Delivery Date.
- (e) No Order amends this agreement unless HPPI expressly states in the Order that it seeks to amend this agreement, and Mayne Pharma agrees in writing to the Order.

6.3 Manufacture; Failure to Supply

- (a) Mayne Pharma will manufacture the Product in accordance with all confirmed Orders received from HPPI.
- (b) In the situation where Mayne Pharma is not able to supply Product, or Mayne Pharma anticipates that it will be unable to supply Product to HPPI in satisfaction of HPPI's Orders or forecasted Orders, Mayne Pharma shall use reasonable commercial efforts:
 - (i) to inform HPPI in a timely manner about such situation and the details causing such situation; and
 - (ii) to provide HPPI with a reasonable estimate of the length and extent of production interruption or other issue affecting Mayne Pharma's satisfaction of HPPI's Product demand.

6.4 Backup manufacturer

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

Payments

7.1 HPPI Payments

HPPI must make the payments set out in, and comply with, Schedule 5.

7.2 Review of Prices

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

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

7.3 Mayne Pharma Payments

- (a) The parties acknowledge that notwithstanding clause 3.3, there is a risk that Mayne Pharma may, directly itself or indirectly through any third party, sell an Alternate Product in the Territory in the Field as a result of off label use (**Off Label Sales**).
- (b) If HPPI becomes aware of any Off Label Sales in any Quarter ***, it must notify Mayne Pharma promptly, and in any event, no later than ***, and provide Mayne Pharma with its evidence of such Off Label Sales.
- (c) Prior to a Marketing Authorisation being obtained by HPPI, any Affiliate or Sub Licensee, within *** after receipt of a notice from HPPI under clause 7.3(b), Mayne Pharma must pay to HPPI a cash royalty of ***% on gross sales up to USD*** and ***% on gross sales over USD *** for the relevant Quarter for the Alternate Product sold through Off Label Sales ***.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

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

7.4 Payment terms

Each party must make payments due under this agreement:

- (a) in the currency specified in Schedule 5 and where necessary, converted:
- (i) in respect of any payment covering a Quarter, at the average daily exchange rate for the applicable Quarter as published by the financial institution specified in Schedule 5; and
 - (ii) otherwise, at the daily exchange rate quoted by the financial institution specified in Schedule 5 on the date of payment;
- (b) to the bank account of the other party listed on the relevant invoice, with the party making payment to bear the costs of any such remittance; and
- (c) in the case of payments due to Mayne Pharma, to Mayne Pharma or its nominee as specified on the relevant invoice.

7.5 Reimbursement

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

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.

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**).

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

- (b) If HPPI gives notice under clause 9.2(a), the parties agree to consult with each other to resolve the issue (during which time Mayne Pharma may conduct its own retention sample testing). If the discrepancy is not resolved within a further *** from the receipt of the notice, the parties agree to appoint (at HPPI's expense) an independent analyst, acceptable to both parties, that will carry out tests on representative samples taken from such shipment, and the results of such tests will be binding on the parties.
- (c) If HPPI does not notify Mayne Pharma in accordance with clause 9.2(a), then HPPI will be deemed to have accepted the Product at the end of the *** period after delivery of the Product.
- (d) If the independent analyst determines that the Defective Product does not conform to the Product Specification and as long as the Product has been transported, handled and stored in accordance with the Marketing Authorisation and all reasonable directions of Mayne Pharma once the Product has left Mayne Pharma's facility, then:
 - (i) Mayne Pharma must, at its expense, replace any such Defective Product and reimburse HPPI for the costs of the independent analyst; and
 - (ii) all quantities of Defective Product must, at Mayne Pharma's election and expense be either:
 - (A) returned to Mayne Pharma at an address notified by Mayne Pharma, and packed and shipped according to instructions provided by Mayne Pharma; or
 - (B) destroyed by HPPI under Mayne Pharma's direction.
- (e) If:
 - (i) the independent analyst determines that the Defective Product does conform to the Product Specification; or
 - (ii) the Product has not been transported, handled and stored in accordance with the Marketing Authorisation and all reasonable directions of Mayne Pharma once the Product has been delivered to HPPI in accordance with this agreement,then HPPI is deemed to have accepted the Product and will reimburse Mayne Pharma for any costs and expenses incurred by Mayne Pharma in attempting to resolve the issue, including the costs of any retention sample testing conducted by Mayne Pharma.

9.3 Sole remedy

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

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.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

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.

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

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

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 ***, 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.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

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.

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.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

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.

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.

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. 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.

Confidential treatment requested with respect to certain portions hereof denoted with “****”

15.3 HPPI warranties

HPPI represents and warrants that:

- (a) as at the Start Date:
 - (i) HPPI is successor by merger to Commonwealth Biotechnologies, Inc, a Virginia corporation;
 - (ii) the Amended Plan of Reorganization of CBI (the **Plan**), dated January 4, 2013, and filed in In re: Commonwealth Biotechnologies, Inc., Case No. 11-30381-KRH, U.S. Bankruptcy Court, E.D. Virginia (the **Case**), has been confirmed pursuant to a final and non-appealable order of the bankruptcy court;
 - (iii) HPPI has delivered a true, correct and complete copy of the Plan with all amendments to Mayne Pharma;
 - (iv) the Effective Date, as defined in the Plan, has occurred and is August 12, 2013 and HPPI has taken all actions reasonable and necessary to formally close the Case;
 - (v) the entire authorized capital stock of HPPI consists of 350,000,000 shares, of which 340,000,000 shares are common stock, par value of \$0.0001 per share (**Common Stock**), and 10,000,000 shares of preferred stock, par value \$0.0001 per share (**Preferred Stock**). Of the Common Stock, 18,888,971 shares are issued and outstanding and no shares are held in treasury. Of the Preferred Stock, 500,000 shares have been designated as Series A Convertible Preferred Stock (**Series A Preferred Stock**), of which, 170,000.74 shares are issued and outstanding and no shares are held in treasury. All of the issued and outstanding shares of capital stock have been duly authorized, are validly issued, fully paid, and non-assessable. All of the issued and outstanding shares of Common Stock are held by the prior owners of CBI. All of the issued and outstanding shares of Series A Preferred Stock are held by Hedgepath, LLC. Other than (X) 32,583,475 shares of Common Stock intended to be reserved for under the EIP when implemented and (Y) HPPI's obligation to issue USD52,500 worth of shares of Common Stock to a service provider to Commonwealth Biotechnologies, Inc. notified to Mayne Pharma before the Start Date as part of the initial equity raising referred in item 1.2 of Schedule 2:
 - (A) there are no outstanding or authorized options, warrants, purchase rights, subscription rights, conversion rights, exchange rights, or other contracts or commitments that could require HPPI to issue, sell, or otherwise cause to become outstanding any of its capital stock; and
 - (B) there are no outstanding or authorized stock appreciation, phantom stock, profit participation, or similar rights with respect to HPPI,
 - (vi) there are no voting trusts, proxies, or other agreements or understandings with respect to the voting of the capital stock of HPPI; and
 - (vii) the table set out in item 3 of Schedule 2 is a capitalization table showing ownership of HPPI as of the date hereof and upon satisfaction of the Conditions;
 - (viii) 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.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

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.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

- (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; and
 - (ii) 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

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

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

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 of 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).

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 ****

Confidential treatment requested with respect to certain portions hereof denoted with “****”

18.4 ****

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 or (ii) jointly developed by HPPI and Mayne Pharma and their respective Affiliates and Personnel (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.

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.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

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

20.1 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) Hedgepath, LLC or Nicholas J. Virca breaches a material provision of the agreement referred to in item 1.3 of Schedule 2, 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 agreement referred to in item 1.5 of Schedule 2, 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.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

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 ***

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 0, 0 and 0 continue to apply), subject to HPPI meeting its contractual obligations after the termination or expiry of this agreement.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

20.8 Return of Confidential Information

At the termination or expiry of this agreement for any reason whatsoever:

- (a) each party will, as soon as practicable, return to the other party all of the other party's Confidential Information (other than Confidential Information comprising part of the HPPI Licensed Rights), whether in permanent or magnetic/computer disk form or any other form provided that each party may:
 - (i) provide one copy of that Confidential Information to its legal advisers, to be held by them solely for the purpose of determining the scope of that party's obligations under this clause; and
 - (ii) retain one copy of such of that Confidential Information that is required by the Relevant Regulatory Authority, to be retained by that party.
- (b) HPPI must, within 3 months 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.

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.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

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.

Dispute resolution

23.1 No court proceeding unless procedure followed

A party must not start arbitration or court proceedings (except proceedings seeking interlocutory relief) unless it has complied with this clause 0.

23.2 Notice of Dispute

A party claiming that a dispute, controversy or claim arising out of or relating to this agreement, or the breach, termination or invalidity of it has arisen (**Dispute**) must give the other party notice of the details of the Dispute (**Dispute Notice**).

23.3 Negotiations

The parties must attempt to resolve any Dispute by negotiations using the following escalation procedure:

- (a) when a Dispute Notice is given, each party's respective representatives must first attempt to resolve the Dispute; and
- (b) if they cannot resolve the Dispute within *** after the Dispute Notice is given, they must refer the Dispute to each party's chief executive officer who must then attempt to resolve it.

23.4 Failure to negotiate settlement

If the parties cannot resolve the Dispute within *** after the Dispute Notice is given (or longer period if the parties to the Dispute agree in writing), the parties must refer the Dispute to arbitration in accordance with clause 23.5.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

23.5 Arbitration

If the parties cannot resolve the Dispute under clause 23.4, the Dispute must be settled by arbitration in accordance with the UNCITRAL Arbitration Rules as at present in force and as may be amended by the rest of this clause. The appointing authority will be Atlanta International Arbitration Society. The place of arbitration will be Atlanta, Georgia. There will only be one arbitrator.

23.6 Urgent injunctive or other interlocutory relief

No party is prevented from applying to a court at any stage for urgent injunctive or other interlocutory relief.

GST

24.1 Interpretation

- (a) Words or expressions used in this clause 0 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 0 prevails over this clause 0 to the extent of any inconsistency.

24.2 Consideration is GST exclusive

Any consideration to be paid or provided to the Supplier for a supply made by it under or in connection with this Agreement, unless specifically described in this Agreement as ‘GST inclusive’, does not include an amount on account of GST.

24.3 Gross up of consideration

- (a) Despite any other provision in this Agreement, if the Supplier makes a taxable supply under or in connection with this Agreement (not being a supply the consideration for which is specifically described in this Agreement as ‘GST inclusive’):
 - (i) the consideration payable or to be provided for that supply under this Agreement but for the application of this clause (**GST exclusive consideration**) is increased by, and the Recipient must also pay to the Supplier, an amount equal to the GST payable on the supply (**GST Amount**); and
 - (ii) the GST Amount must be paid to the Supplier by the Recipient without set off, deduction or requirement for demand, at the same time as the GST exclusive consideration is payable or to be provided.

24.4 The sale of the Product is intended to be a GST-free export of goods

- (a) Mayne Pharma and HPPI acknowledge that the supply of the Product under this Agreement is intended to constitute a GST-free supply of exported goods under item 1 of section 38-185(1) of the GST Act.
- (b) HPPI warrants that in relation to each delivery of the Product, it will 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*’.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

- (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.

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.
- (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;

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

- (ii) promptly pay an amount equal to the amount deducted or withheld as required by law and by the date that Tax is due to be paid to the appropriate governmental or regulatory agency having jurisdiction over HPPI;
- (iii) if requested by Mayne Pharma, within *** of that request, deliver to Mayne Pharma official relevant receipts issued by such Tax authority, if any, received by HPPI or other documentation of HPPI evidencing payment of that amount; and
- (c) pay Mayne Pharma such additional amounts as necessary to ensure Mayne Pharma receives when due a net amount (after deduction or withholding of any Taxes in respect of such additional amounts) equal to the full amount which Mayne Pharma would have received if no deduction or withholding had been made.

25.2 Refunds

Mayne Pharma has no obligation to file or otherwise pursue any refund of Taxes withheld or deducted from funds paid to Mayne Pharma.

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), 0, 0, 18.1, 18.7, 19.3 to 19.5, 20.6 to 20.8, 0, 0, 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 0, 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.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

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, constitutes 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]

Schedule 1 – Agreement details

1. Start Date
3 September 2013
2. Initial Term
Starts on the Start Date and continues until the later of:
 - (a) 10 years from the Target Launch Date;
 - (b) all issued patents of Mayne Pharma or any of its Affiliates referred to in paragraph (a) of the definition of MP Licensed Rights have lapsed or expired.
3. Territory
United States of America, including all of its commonwealths, territories and possessions.

Schedule 2 – Conditions

1. Conditions

1.1 Equity

After the Condition in item 1.2 of this Schedule 2 is satisfied, Mayne Pharma or its nominee shall enter into a stock purchase agreement reasonably acceptable to the parties under which HPPI shall issue to Mayne Pharma 170,000.74 shares of Series A Preferred Stock, representing, on an as fully converted, fully diluted basis, 45% of the issued and outstanding shares of capital stock of HPPI, before any dilution which may have occurred as a result of, and in accordance with, item 1.2 of this Schedule 2, or which may result because of shares reserved pursuant the EIP as set out in Schedule 8. Mayne Pharma will receive and hold its equity pursuant to representations, warranties, covenants and agreements that are commercially standard on such matters, including a confirmation of the capitalization table set out in item 3 of this Schedule 2.

1.2 Equity raising

HPPI obtains at least USD5 million by way of an equity raising, or such lesser amount as agreed by the parties in writing, provided that after such raising Mayne Pharma maintains a holding of at least 30% of the issued and outstanding shares of capital stock on an as fully converted, fully diluted basis, after any dilution which may result because of the shares reserved pursuant to the EIP as set out in Schedule 8. The equity raising can only be effected via the issuance of shares of common stock that rank junior to or pari passu with the Series A Preferred Stock held by Mayne Pharma or its nominee.

1.3 Agreements on Transfers and Holding of Equity

Hedgepath, LLC, Nicholas J. Virca and Mayne Pharma enter into an agreement that:

- (a) contains the following restrictions, to apply until 12 months after the date that Mayne Pharma or its nominee becomes an owner of the shares of Series A Preferred Stock referred to in item 1.1 of this Schedule 2:
 - (i) restricts transfer by each of Hedgepath, LLC and Mayne Pharma of its shares of capital stock in HPPI;
 - (ii) restricts:
 - (A) Mayne Pharma and any of its Affiliates; and
 - (B) Hedgepath, LLC, Nicholas J. Virca, or any of each of its Affiliates,from holding, each in aggregate, more than 49% of the issued and outstanding shares of capital stock in HPPI on a fully converted, fully diluted basis (other than dilution as a result of the exercise of any option or other equity incentive award that is the subject of the restriction in item 1.3(c) of this Schedule 2 for so long as Nicholas J. Virca complies with that restriction);
- (b) after the restrictions referred to in item 1.3(a)(ii) of Schedule 2 end:
 - (i) obliges Mayne Pharma to notify HPPI, if one or more of Mayne Pharma and any of its Affiliates; and
 - (ii) obliges HPPI to notify Mayne Pharma, if one or more of HPPI, Hedgepath, LLC, Nicholas J. Virca, or any of its Affiliates,

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

(as applicable) intend to enter into a transaction under which such entities would hold, each in aggregate, more than 49% of the issued and outstanding shares of capital stock in HPPI on a fully diluted basis;

- (c) restricts the exercise or transfer of any option or other equity incentive award under the EIP by Nicholas J. Virca (other than testamentary transfers or exercises or transfers or exercises by operation of law), until the earlier of: (i) 3 years from the Start Date; or (ii) the acceptance of a new drug application (NDA) for the Product in the Field by the Relevant Regulatory Authority; and
- (d) obliges Hedgepath, LLC to vote its HPPI capital stock in favor of implementing the matters set out in item 1.4 of this Schedule 2.

Hedgepath, LLC must not have transferred any of its shares of capital stock in HPPI, and Nicholas J. Virca must not have exercised or transferred of any option under the EIP, from the Start Date until the agreement referred to in this item of 1.3 of Schedule 2 has been signed.

1.4 Board positions

Within *** from a request by Mayne Pharma which Mayne Pharma must make no later than *** after the Start Date, HPPI will appoint Scott Richards of Mayne Pharma, or another officer, director or senior employee of Mayne Pharma as nominated by Mayne Pharma, (**Initial Mayne Pharma Representative**) as a member of HPPI's board of directors. If at any time the Initial Mayne Pharma Representative is unable or unwilling to serve (it being agreed that if the Initial Mayne Pharma Representative is not an officer, director or senior employee of Mayne Pharma, he or she shall be disqualified from serving on the HPPI board of directors), HPPI must procure that a person nominated by Mayne Pharma (who shall be another officer, director or senior employee of Mayne Pharma) is appointed to the board of directors of HPPI. The board of directors of HPPI shall initially be comprised of 3 persons: Frank E. O'Donnell, Jr., Nicholas J. Virca and Samuel P. Sears, Jr. Mayne Pharma's right to appoint the foregoing person to the HPPI board of directors shall continue until the earlier to occur of: (i) the date that this agreement is terminated or (ii) the date the Mayne Pharma or its Affiliates own less than ten percent (10%) of the outstanding capital stock of HPPI.

1.5 Ongoing obligations relating to Board Positions and participation in subsequent equity raisings

The parties enter into an agreement which provides, after the Condition Date, that:

- (a) if the board of directors of HPPI is expanded to include 7 or more persons, then in response to a request by Mayne Pharma, HPPI must procure that a person nominated by Mayne Pharma (who shall be an officer, director or senior employee of Mayne Pharma) is appointed to the board of directors of HPPI in addition to the Initial Mayne Pharma Representative or any alternate appointed under item 1.4 of Schedule 2 (or two persons in the case that Scott Richards is unable or unwilling to serve), it being agreed that Mayne Pharma's right to appoint the foregoing persons to the HPPI board of directors shall continue until the earlier to occur of: (i) the date that this agreement is terminated or (ii) the date the Mayne Pharma or its Affiliates own less than ten percent (10%) of the outstanding capital stock of HPPI; and

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

- (b) HPPI shall allow Mayne Pharma or its nominee, at Mayne Pharma’s election, a preferential right to participate in any public or private equity raising of HPPI:
 - (i) up to an amount of such raising necessary to maintain Mayne Pharma’s percentage of the outstanding voting capital stock of HPPI, subject to the permitted dilution described in item 1.2 of this Schedule 2 which would have happened before the Condition Date; and
 - (ii) otherwise, to the extent the raising is not fully subscribed by the final deadline for subscription specified in the offering documentation for the raising, subject to, in each case, the restriction referred to in item 1.3(a)(ii) of this Schedule 2;
- (c) HPPI shall provide that, for a period of two (2) years from the date of such agreement, in any private placement equity raising of HPPI, HPPI will afford accredited investors introduced by Mayne Pharma to HPPI a preferential right to participate in such raising, up to 50% of the amount of such raising;
- (d) HPPI shall agree that any equity raising can only be effected via the issuance of shares of common stock that rank junior to or pari passu with the shares of Series A Preferred Stock held by Mayne Pharma or its nominee, except with the prior written consent of Mayne Pharma; and
- (e) without limiting items 1.5(b) to (d) of Schedule 2, HPPI may only issue shares of Series A Preferred Stock with the prior written consent of Mayne Pharma.

Mayne Pharma’s rights as set out in item 1.5(b) to (d) shall continue until the earlier to occur of: (i) the date that this agreement is terminated or (ii) date the Mayne Pharma or its Affiliates own less than ten percent (10%) of the outstanding capital stock of HPPI. The agreement setting out the details of Mayne Pharma’s right of first refusal shall include provisions relating to the time frames around the exercise of such right as well as customary exclusions such as strategic issuances of equity to commercial partners and issuances under the EIP.

1.6 Development program

The following two criteria are satisfied:

- (a) a credible contract research organization (nominated by HPPI and approved by Mayne Pharma, acting reasonably) provides a written estimate for the costs, expenses and time to complete Phase II trials on the use of the Product in the Field (to avoid doubt, for treatment of each of prostate, lung and skin cancer) such that the sum of that estimate and the expenses already incurred by HPPI between the Start Date and the date of the estimate is not more than USD***; and
- (b) HPPI has reasonable prospects that the Actual Launch Date will be before *** including in light of the results of the activities conducted under the Development Plan.

1.7 Employment agreements

- (a) Nicholas J. Virca enters into full time employment agreement with HPPI.
- (b) Frank E. O’Donnell, Jr. M.D. enters into a *** agreement with HPPI.

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

2. Satisfying a condition

2.1 Where a Condition requires an agreement

Where any Condition requires an agreement, that Condition is only satisfied where:

- (a) the agreement is binding, unconditional, effective and in writing; and
- (b) the agreement is on terms acceptable to Mayne Pharma and HPPI (to avoid doubt, even where Mayne Pharma is not a party to the agreement), acting reasonably.

For each agreement referred to in item 1.7 of this Schedule 2 (where Mayne Pharma is not a party to the agreement), HPPI must keep Mayne Pharma informed of the content of that agreement during negotiations and will consult with Mayne Pharma on all key terms.

2.2 Dispute as to whether a Condition has been satisfied

If:

- (a) the parties (and any applicable third party) cannot agree on terms of a particular agreement by the Condition Date; or
- (b) the parties do not agree that a Condition has been satisfied by the Condition Date,

then a party may give notice to the other party requesting referral of the issue to the Chief Executive Officers or equivalent of each party who must seek to resolve the failure to agree. If the parties are unable to agree on terms that are reasonably acceptable or that a Condition has been satisfied within *** after such referral, then the Condition is deemed not to have been satisfied unless one party can show that the other party acted in bad faith in connection with the satisfaction of that Condition.

3. Capitalization table pre-issuance of Series A Preferred Stock to Mayne Pharma and post-issuance

<u>AS OF THE START DATE</u>	<u>Shares</u>	<u>% of Total</u>
Total common shares issued and outstanding	18,888,971	10.0%
Common stock issuable to Hedgepath, LLC upon the conversion of Series A preferred shares	170,000,739	90.0%
Total	188,889,710	100.0%
 <u>AS OF ISSUANCE OF SERIES A PREFERRED SHARES TO MAYNE PHARMA (to avoid doubt, excluding the EIP)</u>	 <u>Shares</u>	 <u>% of Total</u>
Total common shares issued and outstanding	18,888,971	10.0%
Common shares issuable to Mayne Pharma upon conversion of Series A preferred shares	85,000,370	45.0%
Common shares issuable to Hedgepath, LLC upon conversion of Series A preferred shares	85,000,369	45.0%
Total	188,889,710	100.0%

Confidential Treatment Requested by HedgePath Pharmaceuticals, Inc.,
IRS Employer Identification No. 30-0793665

Confidential treatment requested with respect to certain portions hereof denoted with “***”

	<u>Preferred Shares</u>	<u>Common Shares Underlying Preferred</u>	<u>Conversion Multiple - Preferred to Common</u>
<i>Prior to Mayne issuance:</i>			
Hedgepath, LLC	170,000.739	170,000,739	1,000.00
<i>After Mayne issuance:</i>			
Hedgepath, LLC	170,000.739	85,000,369	500.00
Mayne Pharma	<u>170,000.739</u>	<u>85,000,370</u>	<u>500.00</u>
	<u>340,001.478</u>	<u>170,000,739</u>	<u>1,000.00</u>

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

Schedule 3 – Development Plan

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

Schedule 4 – Product and Product Specification

Product: SUBA-itraconazole ****mg 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.

Confidential treatment requested with respect to certain portions hereof denoted with “***”

Schedule 5 – Economic details

1. Floor Price, Minimum Order Quantity and Minimum Annual Volumes

1.1 Floor Price and Minimum Order Quantity

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

1.2 Minimum Annual Volumes

2. Forecast Period

3. Delivery terms

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

4. Minimum shelf life

5. Price

5.1 Product Mayne Pharma provides ***

Mayne Pharma will provide Product 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 free of charge 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.

Confidential treatment requested with respect to certain portions hereof denoted with “***”

5.2 Product for which Mayne Pharma ***

HPPI *** Mayne Pharma for:

- (a) any Product required for the conduct of the activities in the Development Plan and any other activities relating to the research, development or registration activities relating to the Product:
 - (i) above the amount specified in item 5.1 of this Schedule 5; or
 - (ii) ***,
at the Floor Price, and payable by HPPI within *** of the date of Mayne Pharma’s invoice, to be issued on or after shipment of the Product; and
- (b) all other Product, in accordance with this item 5 of this Schedule 5.

5.3 Definitions

In this Schedule 5:

Actual ASP means ***.

Floor Price means the floor price set out in the table above.

Forecast ASP means ***.

Price is calculated under item 5.6 of this Schedule 5.

Total Net Sales means ***

Transfer Price means ***.

Total Units Sold means ***.

5.4 Forecast ASP

At least *** before the start of each ***, the parties will use reasonable commercial efforts to agree on the forecasted Total Net Sales on a per Product basis and the forecasted Total Units Sold for that ***, which will be used to calculate the Forecast ASP.

5.5 Transfer Price

The Transfer Price must be reviewed by the parties, and if necessary, revised at least *** before the start of each ***. The Transfer Price for the Product at the time of invoice is ***

5.6 Price

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

- (a) the Transfer Price, payable by HPPI within *** of the date of Mayne Pharma’s invoice, to be issued on or after shipment of the Product; and
- (b) as adjusted by a reconciliation of the Actual ASP in relation to the Forecast ASP *** as follows:

5.7 Timely accounting for deductions

HPPI must, and must ensure that its Affiliate and any Sub licensee must, promptly process any deduction from Total Net Sales and in any event, process such deductions no later than *** after they are allowed (in the case of discounts, bonuses, commissions and rebates), applied or the Products are rejected or returned.

Confidential treatment requested with respect to certain portions hereof denoted with “***”

5.8 Books of Account

- (a) HPPI will maintain books of account and records with respect to sales and stocks of the Product supplied by Mayne Pharma under this agreement in the Territory by HPPI, its Affiliates and Sub Licensee (including stock records) (**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.

5.9 Reporting requirements

Within *** from the end of each month of each Quarter, HPPI must use reasonable commercial efforts to submit to Mayne Pharma an estimated reconciliation report in reasonable detail.

6. Currency and exchange rate

6.1 Currency

USD

6.2 Financial institution for exchange rate

National Bank of Australia Limited

Confidential treatment requested with respect to certain portions hereof denoted with “*”**

Schedule 6 – Qualification of Backup Manufacturer

Schedule 7 – Licence of HPPI Licensed Rights

1. Licence of HPPI Licensed Rights

1.1 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:

- (a) relates to, or has potential application in connection with, the Product, including any dossier containing technical or clinical information relating to the Product; and
- (b) 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.

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

HPPI must:

- (a) ensure that, in respect of any Intellectual Property Rights comprising the HPPI Licensed Rights owned by it, its Affiliates or any Sub Licensee; and
- (b) use reasonable commercial efforts to ensure that, in respect of any Intellectual Property Rights comprising the HPPI Licensed Rights licensed by it, its Affiliates and any Sub Licensee,

HPPI is free to grant to Mayne Pharma an exclusive, perpetual, irrevocable, royalty free licence to copy and exploit 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.

1.3 Restriction on assignment or sub licence

The licence under item 1.1 of this Schedule 7 may only be assigned or sub licensed in accordance with this agreement or otherwise with the prior written consent of HPPI.

2. Copies of documents, data and other information embodying the HPPI Licensed Rights

Promptly in response to a request by Mayne Pharma at any time during the Term or a reasonable period after the termination or expiry of this agreement, HPPI must provide to Mayne Pharma a copy of any documents, data and other information embodying the HPPI Licensed Rights since the most recent request by Mayne Pharma under this item 2 of Schedule 7.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

3. Intellectual property protection for HPPI Licensed Rights

- (a) HPPI will consult with Mayne Pharma regarding intellectual property protection for such rights outside the Territory.
- (b) In particular, HPPI must give at least *** prior notice before it, or any of its Affiliates:
 - (i) discloses any Confidential Information comprised in the HPPI Licensed Rights to any third party unless subject to equivalent restrictions on use and disclosure as those under clause 18, without any right of further disclosure; and
 - (ii) without limitation, discloses any Confidential Information comprised in the HPPI Licensed Rights to any patent office, including as part of a patent application.
- (c) If HPPI decides not to file, prosecute or maintain patent protection for any invention comprised in the HPPI Licensed Rights in any country outside the Territory, it must promptly give notice to Mayne Pharma (with such notice to be given at least *** before any deadline for decisions relating to such filing, prosecution or maintenance).
- (d) Mayne Pharma may, by notice to HPPI, request that HPPI make a decision in respect of the filing, prosecution or maintenance of patent protection for any invention comprised in the HPPI Licensed Rights in any country outside the Territory, in which case HPPI must respond before any deadline referred to in item 3(c) of this Schedule 7 but in any event no later than *** after the request by Mayne Pharma.
- (e) If HPPI gives notice to Mayne Pharma under item 3(c) or (d) of this Schedule 7 of its intention not to file, prosecute or maintain patent protection of any invention comprised in the HPPI Licensed Rights in any country outside the Territory, Mayne Pharma may decide to take over such filing, prosecution or maintenance at its cost by giving notice to HPPI before the relevant deadline, in which case:
 - (i) HPPI will, or will procure that its Affiliate (as applicable) will, promptly assign to Mayne Pharma or its nominee all rights in respect of the invention (including under any patent application or issued patent); and
 - (ii) from the date of such assignment, HPPI acknowledges that:
 - (A) such rights no longer form part of the HPPI Licensed Rights;
 - (B) Mayne Pharma or its nominee may, in its discretion and at its cost, file, prosecute, maintain, enforce and defend any assigned patent application or issued patent; and
 - (C) any information in respect of the invention that is not public knowledge is deemed to be Confidential Information of Mayne Pharma.

4. Sub licensing and assignment

4.1 Sub licensing

Upon notice to HPPI, Mayne Pharma may grant a sub licence of the HPPI Licensed Rights to a third party without the prior written consent of HPPI under a written agreement that includes obligations on that third party that relate to use and disclosure of Intellectual Property Rights of HPPI and Confidential Information of HPPI at least equivalent to those imposed on Mayne Pharma under this agreement.

Confidential treatment requested with respect to certain portions hereof denoted with “**”**

4.2 Assignment

Despite clause 26.5(b), Mayne Pharma may assign any of its rights or obligations under this Schedule 7 without the prior written consent of HPPI.

Schedule 8 – EIP

The Equity Incentive Plan (**EIP**) will be implemented by HPPI, provided the plan has been approved unanimously by the new HPPI Board of Directors (including the representative of Mayne Pharma).

As at the Start Date, the proposed EIP will initially be comprised of 32,583,475 (subject to adjustments for stock splits approved by the HPPI board of directors, the **Initial EIP Pool**) shares of common stock of HPPI (ranking pari passu with the issued and outstanding common stock of HPPI) to be available in the form of incentive stock options, non-qualified stock options, restricted stock, restricted stock units, performance awards and other customary equity incentives.

Nicholas J. Virca will be awarded 21,722,317 options from the Initial EIP Pool, seventy-five percent (75%) of which (or 16,291,738 options) will vest immediately, and twenty-five percent (25%) of which (or 5,430,579 options) will vest in nearly equal quarterly instalments over 18 months from the grant date. The exercise price and exercise periods of such options shall be customary and reasonably acceptable to both parties.

HPPI represents and agrees that all awards that are included in the Initial EIP Pool (including those already awarded to Nicholas J. Virca) are subject to a restriction on exercise or transfer until the earlier of: (i) 3 years after the Start Date or (ii) acceptance of a new drug application (NDA) for the Product in the Field by the Relevant Regulatory Authority being obtained by HPPI, any Affiliate or Sub Licensee, which restriction may only be changed with the prior written approval of Mayne Pharma. It is acknowledged and agreed however that if the HPPI board of directors votes to approve an increase in the EIP beyond the size of the Initial EIP Pool, such additional shares of common stock and related awards beyond the Initial EIP Pool shall not be subject to the foregoing restrictions on exercise or transfer.

HPPI represents and agrees that Frank E. O'Donnell, Jr. M.D. will not be entitled to participate in the EIP for the first 12 months after the Start Date.

HPPI agrees that:

- (a) there will be no change to the EIP during the period of the lock up referred to in item 1.3(a) of Schedule 2 without the prior written consent of Mayne Pharma;
- (b) except as set out above and without limitation, any change to the EIP during the first 3 years after the Start Date, including for the award of options for, or the issue of, any further shares of capital stock of HPPI beyond those contemplated above, requires approval by the HPPI Board of Directors or a designated committee thereof comprised of independent directors.

Confidential Treatment Requested by HedgePath Pharmaceuticals, Inc.,
IRS Employer Identification No. 30-0793665

Confidential treatment requested with respect to certain portions hereof denoted with “****”

Signing page

EXECUTED as an agreement.

Signed for **Mayne Pharma International Pty Ltd** by an authorised officer in
the presence of

/s/ Stefan Cross
Signature of witness

Stefan Cross
Name of witness (print)

/s/ Scott Richards
Signature of officer

Scott Richards
Name of officer (print)

CEO
Office held

September 3, 2013
Date

Signed for **HedgePath Pharmaceuticals, Inc.** by an authorised officer in the
presence of

/s/ Catherine A. Boyle-Virca
Signature of witness

Catherine A. Boyle-Virca
Name of witness (print)

/s/ Nicholas J. Virca
Signature of officer

Nicholas J. Virca
Name of officer (print)

President and CEO
Office held

September 3, 2013
Date

**HedgePath Pharmaceuticals Enters into
Key Collaboration with Mayne Pharma**

***Acquires Exclusive U.S. Rights for use of
Mayne Pharma's SUBA™ Itraconazole for treatment of cancer***

Mayne Pharma to supply product to HPPI, and companies to jointly pursue clinical development of SUBA Itraconazole for multiple oncology indications

TAMPA, FLORIDA and SAN DIEGO, CALIFORNIA – (September 10, 2013) – HedgePath Pharmaceuticals, Inc. (OTCPink:HPPI) (HPPI) announced today that it has signed an exclusive Supply and License Agreement with Mayne Pharma International Pty Ltd (Mayne Pharma), a wholly owned subsidiary of Mayne Pharma Group Limited, an Australian ASX listed company, whereby HPPI will pursue clinical development of Mayne Pharma's patented formulation of the drug itraconazole, known as SUBA-Itraconazole, for treatment of a variety of cancers with a focus on seeking regulatory approvals and marketing in the United States.

The agreement represents a significant step forward for HPPI in the progression of its business plan of repurposing itraconazole as a potential treatment for cancer. Itraconazole, in other formulations now off-patent, is already approved by the U.S. Food and Drug Administration (FDA) for human use as a treatment for fungal infections.

The agreement provides for the supply to HPPI of specially formulated capsules of SUBA-Itraconazole, manufactured by Mayne Pharma under cGMP (current good manufacturing practice) standards, for use by HPPI in its anticipated clinical trials, and for the future exclusive commercial supply following FDA approvals, if obtained. "SUBA technology" (which stands for "super bioavailability") is designed to improve the bioavailability of orally administered drugs that are poorly soluble. SUBA-Itraconazole is a patented formulation developed by Mayne Pharma, which has improved absorption and significantly reduced variability compared to generic itraconazole. These benefits provide enhancements to patients and prescribers with reduced intra- and inter-patient variability, enabling a more predictable clinical response and a reduction in the active drug quantity to deliver the required therapeutic blood levels.

HPPI and Mayne Pharma will collaborate through a joint development program for SUBA-Itraconazole for multiple oncology indications. Under the agreement, HPPI has been granted exclusive rights to SUBA-Itraconazole for treatment of cancer in the United States, and Mayne Pharma retains rights for use of the drug outside the U.S., including a license from HPPI for current and future developments of anti-cancer therapies using SUBA-Itraconazole.

Under the terms of the agreement, Mayne Pharma has the ability to appoint one person to HPPI's Board of Directors and is preparing to name a senior executive of Mayne Pharma to such position in the near future. Although the Supply and License Agreement is effective immediately, it remains subject to certain conditions being achieved. As part of the achievement of these conditions, Mayne Pharma is expected to acquire an equity stake in HPPI of between 30-45%.

“This is a milestone event for HPPI, and we are very pleased to be collaborating with an innovative developer and manufacturer such as Mayne Pharma” stated Nicholas J. Virca, HPPI’s President and Chief Executive Officer.

“Our clinical strategy is to repurpose itraconazole as a potential treatment for cancer, and we believe that Mayne Pharma’s patented formulation of itraconazole creates the potential to offer cancer patients the benefits of greater bioavailability of the active drug. In short, this agreement is more than just a supply agreement. It jumpstarts our business plan by giving us access to the key technology we need to progress our clinical development programs forward and, if ultimately approved by the FDA, market our anti-cancer therapies in the U.S. with exclusivity. We look forward to what we expect will be a long term and mutually beneficial collaboration with Mayne Pharma” concluded Mr. Virca.

Additional details regarding this agreement and the collaboration between HPPI and Mayne Pharma will be provided in a Current Report on Form 8-K to be filed by the company with the Securities and Exchange Commission.

About SUBA-Itraconazole

SUBA™ technology is proprietary technology that improves the oral bioavailability of poorly soluble drugs. It utilizes a solid dispersion of drug in a polymer to improve the absorption of drugs in the gastrointestinal tract to achieve “super bioavailability” compared to conventional formulations. In testing its use as an anti-fungal medication, clinical trials demonstrated that SUBA Itraconazole had approximately double the bioavailability of the generic formulation and could be taken with or without meals. HPPI plans to administer SUBA-Itraconazole at doses lower than the generic itraconazole formulations previously tested in human cancer trials. This greater bioavailability at lower dosing is intended to improve product performance, while reducing the side-effects associated with the level of doses required for cancer therapy.

About HedgePath Pharmaceuticals

HedgePath Pharmaceuticals, Inc. is a clinical stage biopharmaceutical company that is seeking to repurpose the FDA approved antifungal pharmaceutical itraconazole as a potential treatment for cancer. HPPI is the exclusive licensee of a patented formulation of itraconazole, called SUBA-Itraconazole, which clinical studies have shown to have greater bioavailability than generic itraconazole.

The Hedgehog signaling pathway is a major regulator of cellular processes in vertebrates, including cell differentiation, tissue polarity and cell proliferation. Based on published research, HPPI believes that inhibiting the Hedgehog pathway could delay or possibly prevent the development of certain cancers in humans. Leveraging research undertaken by key investigators in the field, HPPI plans to explore the effectiveness of SUBA-Itraconazole as a cancer inhibitor and to pursue its potential commercialization. HPPI has offices in Tampa, Florida and San Diego, California. For more information, please visit www.hedgepathpharma.com.

About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company that develops and manufactures branded and generic product globally – either directly or through distribution partners, while applying its drug delivery expertise for contract development and manufacturing services. Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialized in numerous products that have been marketed around the world. Mayne Pharma has two drug development and manufacturing facilities based in Salisbury, Australia and Greenville, NC, USA with expertise in formulating complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

Cautionary Note Regarding Forward Looking Statements

This press release and any statements of representatives and partners of HedgePath Pharmaceuticals, Inc. (the “Company”) related thereto contain, or may contain, among other things, certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company’s plans, objectives, projections, expectations and intentions and other statements identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential” or similar expressions. These statements are based upon the current beliefs and expectations of the Company’s management and are subject to significant risks and uncertainties, including those detailed in the Company’s filings with the Securities and Exchange Commission. Actual results (including, without limitation, the outcome of the Company’s collaboration with Mayne and timing for and results of the Company’s clinical trials) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company’s control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Contact: HedgePath Pharmaceuticals, Inc., Nicholas J. Virca, President and CEO, 813-864-2559 nvirca@hedgepathpharma.com

© 2013 HedgePath Pharmaceuticals, Inc. All rights reserved.