
**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 9, 2015 (September 2, 2015)

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))
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Item 1.01. Entry into a Material Definitive Agreement.

On September 2, 2015, HedgePath Pharmaceuticals, Inc. (the “Company”) entered into a Sublicense Agreement (the “Agreement”) with Mayne Pharma International Pty Ltd (“Mayne Pharma”). Pursuant to the Agreement, Mayne Pharma sublicensed to the Company the exclusive U.S. rights to two patents (the “Patents”): US Provisional Application No 60/583,076 entitled “New Angiogenesis Inhibitors”, subsequently filed as PCT/US05/23015 on June 27, 2005, and US patent No 8,653,083 entitled “Hedgehog Pathway Antagonists to Treat Disease”, filed on August 22, 2005, and subsequently filed as PCT/US2006/32952 on August 22, 2006. Mayne Pharma is the sublicensee of the Patents from Accelas Holdings, a British Virgin Islands company, who in turn is the licensee of The John’s Hopkins University, the owner of the Patents. The Patents relate to the use of itraconazole as a treatment for cancer and age-related macular degeneration.

Pursuant to the Agreement: (i) the Company has received an exclusive, non-transferable sublicense to the Patents in the United States; (ii) the Company shall pay an upfront license fee of \$75,000 to Mayne Pharma by October 2, 2015 and (iii) the Company shall be required to pay to Mayne Pharma certain development-related milestone payments, certain annual minimum royalties and a low single digit royalty on net sales of products incorporating the Patent. The Agreement contains other customary terms and conditions.

The Agreement has a term commencing on September 2, 2015 and continuing until the earlier of: (a) the date of expiration of the last to expire Patent; or (b) notice by Mayne Pharma with immediate effect promptly after termination or expiry of its rights to license the Patents. Mayne Pharma and the Company have the right to terminate the Agreement upon the occurrence of certain events, including the bankruptcy of a party or breach of a party’s obligations under the Agreement (subject to a notice and cure period).

The preceding is a summary of the Agreement is qualified in its entirety by reference to the text of the Agreement filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

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

10.1 Sublicense Agreement, entered into effective as of September 2, 2015, by and between Mayne Pharma International Pty Ltd and the Company. (*)

* **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) of the Company's commercial partnership with Mayne Pharma and (ii) clinical trials for and of regulatory review of SUBA-Itraconazole) 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 9, 2015

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca

Name: Nicholas J. Virca

Title: President and CEO

CONFIDENTIAL TREATMENT REQUESTED

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

September 2, 2015

SUBLICENSE AGREEMENT

BETWEEN

MAYNE PHARMA INTERNATIONAL PTY LTD

&

HEDGEPATH PHARMACEUTICALS, INC

SUBLICENSE AGREEMENT

THIS SUBLICENSE AGREEMENT (the “Agreement”) is entered into effective as of the Effective Date by and between MAYNE PHARMA INTERNATIONAL PTY LTD, ABN 88 007 870 984, an Australian body corporate having an address at Level 14, 474 Flinders Street, Melbourne, VIC, 3000, Australia (“**Mayne Pharma**”), and HEDGEPTH PHARMACEUTICALS, INC, a company incorporated in Delaware having an address at 324 South Hyde Park Avenue #350, Tampa, Florida, 33606, United States (“**HPPI**”) with respect to the following:

RECITALS

WHEREAS, valuable inventions entitled “New Angiogenesis Inhibitors” (JHU Ref No C04494; hereinafter referred to as the “**Angiogenesis Patent**”), and “New uses for old drugs: Identification of Hedgehog Pathway Antagonists previously tested in Humans” (JHU Ref No C04820; hereinafter referred to as the “**Hedgehog Patent**”) have heretofore been developed during the course of research conducted by Drs Jun Liu, Curtis Chung, David Sullivan, Schrindar Bhat, Jin Xu and Philip Beachy (all hereinafter “**Inventors**”); and

WHEREAS, THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation having an address at 3400 N. Charles Street, Baltimore, Maryland, 21218-2695 (**JHU**) has acquired through assignment all rights, title and interest, with the exception of certain retained rights by the United States Government, in said valuable inventions; and

WHEREAS, JHU has granted to Accelas Holdings, a BVI corporation having an address at Rm 1228,12/F, One Grand Tower, 639 Nathan Road, Kowloon, Hong Kong (“**Accelas**”) an exclusive license to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions throughout the world under an exclusive license agreement effective on 14 December 2009, as varied by a first amendment effective on 22 May 2012 and a second amendment effective on 23 January 2014 (hereinafter referred to as the “**Head License**”);

WHEREAS, Mayne Pharma obtained from Accelas a sublicense effective August 26, 2015 to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions (hereinafter referred to as the “**Accelas Sublicense**”); and

WHEREAS, HPPI wishes to obtain from Mayne Pharma a sub-sublicense to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions in the United States of America, including all commonwealths, territories and possessions thereof, on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

All references to particular Exhibits, Articles or Paragraphs shall mean the Exhibits to, and Paragraphs and Articles of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

1.1 “AFFILIATED COMPANY” as used herein in either singular or plural shall mean any corporation, company, partnership, joint venture or other entity, which controls, is controlled by or is under common control with HPPI. For purposes of this Paragraph 1.1, control shall mean the direct or indirect ownership of at least fifty- percent (50%).

1.2 “EFFECTIVE DATE” of this License Agreement shall mean the date the last party hereto has executed this Agreement.

1.3 “EXCLUSIVE LICENSE” shall mean a grant by Mayne Pharma to HPPI of its entire right and interest as a licensee in the PATENT RIGHTS subject to rights retained by the United States Government, if any, in accordance with the Bayh-Dole Act of 1980 (established by P.L. 96-517 and amended by P.L. 98-620, codified at 35 USC § 200 et. seq. and implemented according to 37 CFR Part 401), and subject to the retained right of JHU under the Head License to make, have made, provide and use for its and The Johns Hopkins Health Systems’ purposes LICENSED PRODUCT(S) and LICENSED SERVICE(S), including the ability to distribute any biological material disclosed and/or claimed in PATENT RIGHTS for nonprofit academic research use to non-commercial entities as is customary in the scientific community.

1.3A “FIRST COMMERCIAL SALE” shall mean the first day of the calendar quarter that occurs after the first sale for use or consumption by the general public of a LICENSED PRODUCT in the TERRITORY after all required marketing and pricing approvals have been granted by the US Food and Drug Administration (“FDA”).

1.4 “LICENSED FIELD” shall mean (i) for the ANGIOGENESIS PATENT: itraconazole racemic mixture, in all fields of use and all routes of administration under PATENT RIGHTS for oncology and age-related macular degeneration indication except for TOPICAL USE; and (ii) for the HEDGEHOG PATENT: SYSTEMIC USE and OCULAR USE of the racemic mixture of itraconazole for oncology and age-related macular degeneration indication under PATENT RIGHTS. ***

1.5 “LICENSED PRODUCT(S)” as used herein in either singular or plural shall mean any process or method, material, compositions, drug, or other product, the manufacture, use or sale of which would constitute, but for the license granted to HPPI pursuant to this Agreement, an infringement of a claim of PATENT RIGHTS (infringement shall include, but is not limited to, direct, contributory, or inducement to infringe).

1.6 “LICENSED SERVICE(S)” as used herein in either singular or plural shall mean the performance on behalf of a third party of any method or the manufacture of any

product or the use of any product or composition which would constitute, but for the license granted to HPPI pursuant to this Agreement, an infringement of a claim of the PATENT RIGHTS, (infringement shall include, but not be limited to, direct, contributory or inducement to infringe).

1.7 “NET SALES” shall mean ***.

1.8 “NET SERVICE REVENUES” shall mean ***.

1.9 “PATENT RIGHTS” shall mean (i) US Provisional Application No 60/583,076 (JHU Ref No C04494) entitled “New Angiogenesis Inhibitors”, subsequently filed as PCT/US05/23015 on June 27, 2005 (hereinafter referred to as “the ANGIOGENESIS PATENT”); and (ii) US patent No 8,653,083 entitled “Hedgehog Pathway Antagonists to Treat Disease”, filed on August 22, 2005, and subsequently filed as PCT/US2006/32952 on August 22, 2006 (hereinafter referred to as “the HEDGEHOG PATENT”); and (iii) the inventions disclosed and claimed therein, and all continuations, divisions and reissued based thereof, and any patents issuing, granted or registered therefrom. HPPI acknowledges and agrees that PATENT RIGHTS do not include ***.

1.10 “SUBLICENSEE” shall mean any person or entity to which LICENSEE has granted a sublicense with the approval of Mayne Pharma and JHU under Paragraph 2.2 of this Agreement.

1.11 Not used.

1.12 “OCULAR USE” shall mean application to the membranes, cornea or conjunctiva of the eye.

1.13 “SYSTEMIC USE” shall mean internal application throughout the whole body and not confined to a specific localized external area, including ingested or injected formulations of drugs, but excluding intradermal and subcutaneous injected formulations of drugs designed to locally treat external areas of the body and having a predominately local effect.

1.14 “TOPICAL USE” shall mean application to an external area of the body and affecting mostly the area to which it is applied, including intradermal and subcutaneous injection designed to locally treat such external area, including but not limited to the skin, ear and accessible mucous membranes including but not limited to those of the mouth, vagina and anus. TOPICAL USE shall comprise of drug formulations and delivery mechanisms including but not limited to lotions, creams, ointments, gels, powders (talc), patches, nanoparticles, microneedles and solutions (liquids) but shall exclude systemic uses, such as ingested or injected formulations of drugs. For the purpose of this agreement, TOPICAL USE shall specifically exclude OCULAR USE.

1.15 Not used.

1.16 “TERRITORY” shall mean the United States of America, including all commonwealths, territories and possessions thereof.

1.17 “THIRD PARTY” shall mean any entity other than HPPI or any SUBLICENSEE.

ARTICLE 2 LICENSE GRANT

2.1 Grant. Subject to the terms and conditions of this Agreement, Mayne Pharma hereby grants to HPPI an EXCLUSIVE LICENSE to make, have made, use, import, offer for sale and sell the LICENSED PRODUCT(S) and to provide the LICENSED SERVICE(S) in the TERRITORY under the PATENT RIGHTS in the LICENSED FIELD.

2.2 No right of Sublicense. HPPI may not sublicense to others (including any AFFILIATED COMPANY) under this Agreement, except with prior written consent of Mayne Pharma and JHU, which each may withhold or grant subject to conditions, in its discretion.

2.3 Government Rights. The United States Government may have acquired a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the inventions described in PATENT RIGHTS throughout the world. The rights granted herein are additionally subject to: (i) the requirement that any LICENSED PRODUCT(S) produced for use or sale within the United States shall be substantially manufactured in the United States (unless a waiver under 35 USC § 204 or equivalent is granted by the appropriate United States government agency), (ii) the right of the United States government to require JHU, or its licensees, including HPPI, to grant sublicenses to responsible applicants on reasonable terms when necessary to fulfill health or safety needs, and, (iii) other rights acquired by the United States government under the laws and regulations applicable to the grant/contract award under which the inventions were made. HPPI will reimburse to Mayne Pharma all costs and expenses reasonably incurred in connection with an application for a waiver under 35 USC § 204 or equivalent by the appropriate United States government agency, within *** of the receipt of an invoice from Mayne Pharma and reasonable evidence of payment.

ARTICLE 3 FEES, ROYALTIES, PAYMENTS

3.1 License Fee. HPPI shall pay to Mayne Pharma within thirty (30) days of the EFFECTIVE DATE of this Agreement a license fee as set forth in Exhibit A. The license fee is nonrefundable and shall not be credited against royalties or other fees.

3.2 Minimum Annual Royalties. HPPI shall pay to Mayne Pharma minimum annual royalties as set forth in Exhibit A. These minimum annual royalties shall be due within *** after the FIRST COMMERCIAL SALE occurs. Running royalties accrued under Paragraph 3.3 and paid to Mayne Pharma during the *** of the FIRST COMMERCIAL SALE shall be credited against the minimum annual royalties due on that date. Minimum annual royalties cease to be payable on the earlier of (i) the expiry or lapse of all PATENT RIGHTS that have been granted, issued or registered in the TERRITORY; or (ii) there is no longer a marketing authorization in place for sale of a LICENSED PRODUCT in the TERRITORY.

3.3 Running Royalties. HPPI shall pay to Mayne Pharma a running royalty as set forth in Exhibit A, for each LICENSED PRODUCT(S) sold, and for each LICENSED SERVICE(S) provided, by HPPI and any SUBLICENSEE(S), based on NET SALES and NET SERVICE REVENUES for the term of this Agreement. Such payments shall be made quarterly from the FIRST COMMERCIAL SALE occurs.

3.4 Not used.

3.5 Milestone Payments. HPPI shall pay to Mayne Pharma milestone payments upon the occurrence of the triggering events achieved by HPPI or any SUBLICENSEE with respect to a LICENSED PRODUCT as set forth in Exhibit A. HPPI shall provide written notice within *** of achievement of the milestones numbered 1, 2 and 3 in Exhibit A. These milestone payments shall be due within *** following receipt by HPPI of an invoice therefor.

3.6 Patent Reimbursement. In accordance with Paragraph 4.1 below, HPPI will reimburse Mayne Pharma, within *** of the receipt of an invoice from Mayne Pharma and reasonable evidence of payment, for all costs associated with the preparation, filing, maintenance, and prosecution of the PATENT RIGHTS in the TERRITORY incurred by Accelas subsequent to the EFFECTIVE DATE of the Accelas Sublicense (which costs are to be reimbursed by Mayne Pharma to Accelas under the Accelas Sublicense).

3.7 Payment. All payments under this Agreement (including payments under this Article 3 and Paragraph 4.1) shall be payable within *** after HPPI receives an invoice or at any time specified for payment in this Agreement, whichever is the later. Amounts are payable in USD, and where necessary, converted at an average daily exchange rate to buy USD for the applicable calendar quarter to which that payment relates, as published in the Wall Street Journal.

3.8 Payment Information. All check payments from HPPI to Mayne Pharma shall be sent to such address which Mayne Pharma may designate in writing from time to time. Checks are to be made payable to "Mayne Pharma". Wire transfers may be made to the account which Mayne Pharma may designate in writing from time to time. HPPI shall be responsible for any and all costs associated with wire transfers.

3.9 Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the *** following the due date thereof, calculated at the annual rate of the sum of ***, provided however, that in no event shall said annual interest rate exceed the maximum legal interest rate for corporations. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of any party to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to termination of this Agreement as set forth in Paragraph 9.2.

3.10 Withholding tax.

(a) If any payment or deliverable under this Agreement is subject to any tax, duties, levies, charges, fees or other imposts of any kind ("**Taxes**") which HPPI is required at law to withhold, then HPPI will withhold that amount and deduct it from the payments required to be made to Mayne Pharma under this Agreement. HPPI will promptly provide to Mayne Pharma certificates or any other form of documentary evidence issued by any authority regarding the payment of any such Taxes. HPPI will sign all lawful documents as reasonably requested by Mayne Pharma as is necessary to able Mayne Pharma to take advantage of any applicable legal provision or any double taxation treaties that would result in limiting the amount of any such Taxes.

(b) Where any sum due to be paid to Mayne Pharma hereunder is subject to any withholding or similar tax, HPPI shall use its commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable it to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, HPPI shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount paid to Mayne Pharma and secure and send to Mayne Pharma the best available evidence of such payment.

(c) For any period during the term of this Agreement where there is no applicable double taxation agreement or treaty, to the extent that Mayne Pharma, acting reasonably, is not able to obtain the benefit of any amounts withheld or deducted by HPPI under this Agreement, then Mayne Pharma shall give notice of this to HPPI and HPPI must pay Mayne Pharma such additional amounts as necessary to ensure Mayne Pharma receives, when due, a net amount (after deduction or withholding of Taxes in respect of such additional amounts) equal to the full amount which Mayne Pharma would have received if no deduction or withholding had been made.

ARTICLE 4 PATENT PROSECUTION, MAINTENANCE, & INFRINGEMENT

4.1 Prosecution & Maintenance.

4.1.1 Title to all PATENT RIGHTS pursuant to this Agreement shall reside in JHU.

4.1.2 The parties acknowledge that, under the Head License, JHU shall take primary responsibility for the prosecution and maintenance of all PATENT RIGHTS in the TERRITORY. JHU shall have primary responsibility for the PATENT RIGHTS prosecuted and maintained in any jurisdiction in the TERRITORY, and at HPPI's expense, shall file, prosecute and maintain all such patents and patent applications that, subject to the terms and conditions of this Agreement, HPPI has obtained a license hereunder. Notwithstanding the forgoing, JHU shall have full and complete control over all patent prosecution matters in connection therewith under the PATENT RIGHTS in the TERRITORY, provided however, that Mayne Pharma shall

(a) timely provide to HPPI copies of non confidential official actions and written correspondence with the USPTO regarding the PATENT RIGHTS in the TERRITORY, and
(b) consult with HPPI and allow HPPI an opportunity to comment, which comments Mayne Pharma will consider and as appropriate, pass onto JHU.

4.1.3 Provided Mayne Pharma has provided HPPI with at least *** written notice of any filing or response deadline or fee due date, by written notification to Mayne Pharma at least *** of any filing or response deadline, or fee due date (or where Mayne Pharma has not provided sufficient advance notice, such shorter period such that HPPI has at least *** to consider its election), HPPI may elect not to have a patent application filed or not to pay expenses associated with prosecuting or maintaining any patent application or patent comprising the PATENT RIGHTS, provided that HPPI pays for all costs incurred up to receipt of such notification. Failure to provide such notification can be considered to be HPPI's authorization to proceed at HPPI's expense. Upon such notification, on behalf of Mayne Pharma, JHU may file, prosecute, and/or maintain such patent applications or patent at its own expense and for its own benefit and any rights or license granted hereunder held by HPPI or any SUBLICENSEE(S) relating to the PATENT RIGHTS which comprise the subject of such patent applications or patent and/or apply to the TERRITORY, shall terminate.

4.2 Notification. Each party will notify the other promptly in writing when any infringement by another is uncovered or suspected.

4.3 Infringement.

(a) Mayne Pharma shall have the first right to enforce any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY. Subject to Paragraph 4.5A, *** will pay all reasonable costs and expenses (including reasonable attorney fees for litigation and opinion) incurred by *** in connection with such enforcement (**Enforcement Costs**). Before Mayne Pharma commences an action with respect to any infringement of such patents, HPPI acknowledges and agrees that Mayne Pharma shall give careful consideration to the views of JHU and to potential effects on the public interest in making its decision whether or not to sue. HPPI acknowledges and agrees that no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld. This right to sue for infringement shall not be used in an arbitrary or capricious manner. HPPI shall reasonably cooperate in any such litigation at *** expense, including in accordance with Paragraph 4.6. Should HPPI seek the first right to enforce any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY, then it shall notify Mayne Pharma who will seek the consent of JHU (which consent HPPI acknowledges may be withheld or granted subject to conditions by JHU acting in its discretion).

(b) If HPPI elects not to pay Enforcement Costs in respect of a particular infringement in the TERRITORY, then it shall so notify Mayne Pharma in writing within *** of receiving notice that an infringement exists, and Mayne Pharma may, in its sole judgment and at its own expense, take steps to enforce any patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover, for its own account, any damages, awards or settlements resulting therefrom, or may allow JHU to do so.

4.4 Patent Invalidation Suit. Mayne Pharma shall have the first right to defend any declaratory judgment action or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS within LICENSED FIELD in the TERRITORY. Subject to Paragraph 4.5A, *** will pay all reasonable costs and expenses (including reasonable attorney fees for litigation and opinion) incurred by *** in connection with such defense. HPPI acknowledges and agrees that no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld. Should HPPI seek the first right to defend any declaratory judgment action or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS within LICENSED FIELD in the TERRITORY, then it shall notify Mayne Pharma who will seek the consent of JHU (which consent HPPI acknowledges may be withheld or granted subject to conditions by JHU acting in its discretion).

4.5 Recovery. Any recovery by Mayne Pharma under Paragraph 4.3 shall be paid:

(a) first to *** to reimburse its Enforcement Costs; and

(b) following *** recovery of its Enforcement Costs, the Parties shall share equally in the recovery. If the Enforcement Costs exceed the recovery, then *** shall be credited against royalties payable by HPPI to Mayne Pharma hereunder in connection with sales of LICENSED PRODUCT covered in the PATENT RIGHTS which are the subject of the infringement suit in the TERRITORY, provided, however, that any such credit under this Paragraph shall not exceed *** of the royalties otherwise payable to Mayne Pharma with regard to sales in the TERRITORY in any one calendar year, with any excess credit being carried forward to future calendar years.

4.5A Joint litigation committee. Mayne Pharma shall manage the conduct of any enforcement of any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY or defense of any declaration judgment or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS within LICENSED FIELD in the TERRITORY at its sole discretion, subject to:

(a) consulting with HPPI through a joint litigation committee comprising two appointees of each of Mayne Pharma and HPPI, which committee will discuss the management and course of action with respect to such enforcement or defense, including without limitation, the selection of outside counsel, legal strategy, staff, the engagement of any third party consultants, experts or vendors, the advancement of any legal theory or basis for infringement or defense, scope of discovery, deadlines or extensions for discovery, filing of motions, taking of depositions, providing admission or stipulations, schedule for hearings, proceedings before the court, filing of appeals, commencement and conduct of settlement negotiations or any other actions affecting a Party's rights or obligations or entailing the incurring of cost or expense; and

(b) Mayne Pharma obtaining the express consent of HPPI prior to selecting counsel, bringing any suit in HPPI's name, or entering into any settlement, consent judgment or other voluntary final disposition of the suit, such consent not be unreasonably withheld, except that if JHU consents to HPPI enforcing any patent within the PATENT RIGHTS or defending any declaratory judgment action or similar proceeding alleging invalidity of any of the PATENT RIGHTS then HPPI shall manage the conduct of any such enforcement or defense but will consult with Mayne Pharma on the same terms as would have applied under Paragraph 4.5A(a) and obtain the prior written consent of Mayne Pharma prior to the events referred to in Paragraph 4.5A(b), such consent not be unreasonably withheld.

4.6 Conduct of litigation where HPPI is a party. Where it is necessary or desirable for HPPI to be named as a party in any litigation referred to in Paragraph 4.3 or 4.4, HPPI will do all acts and execute such legal papers as are reasonably requested by Mayne Pharma in connection with such litigation. The counsel selected by Mayne Pharma for the litigation (subject to the express consent of HPPI, not to be unreasonably withheld) shall represent both HPPI and Mayne Pharma. Notwithstanding the foregoing, if due to legal conflict, the parties cannot be represented by the same counsel, then each of JHU and Mayne Pharma shall have the right to retain its own separate legal counsel, in which case, the fees of such separate legal counsel shall still be paid by HPPI.

4.7 Listing on the FDA Orange Book. HPPI must use reasonable commercial efforts to list all patents comprised in the PATENT RIGHTS promptly in the FDA Orange Book for the LICENSED PRODUCT.

ARTICLE 5 OBLIGATIONS OF THE PARTIES

5.1 Reports. HPPI shall provide to Mayne Pharma the following written reports according to the following schedules.

(a) HPPI shall provide quarterly Royalty Reports, substantially in the format of Exhibit B and due within *** of *** the FIRST COMMERCIAL SALE occurs. Royalty Reports shall disclose the amount of LICENSED PRODUCT(S) and LICENSED SERVICE(S) sold, the total NET SALES and NET SERVICE REVENUES of such LICENSED PRODUCT(S) and LICENSED SERVICE(S), and the running royalties due to Mayne Pharma as a result of NET SALES and NET SERVICE REVENUES by HPPI or any SUBLICENSEE thereof. Payment of any such royalties due shall accompany such Royalty Reports.

(b) Until HPPI or any SUBLICENSEE has achieved a first commercial sale of a LICENSED PRODUCT or LICENSED SERVICE in the TERRITORY, or received FDA market approval, HPPI shall provide to Mayne Pharma semiannual Diligence Reports, due within *** following the EFFECTIVE DATE of this Agreement. These Diligence Reports shall describe the technical efforts of HPPI or SUBLICENSEE towards meeting its obligations under the terms of this Agreement.

(c) HPPI shall provide to Mayne Pharma Annual Reports within *** following the EFFECTIVE DATE of this Agreement. Annual Reports shall include:

- (i) evidence of insurance as required under Paragraph 10.4, or, a statement of why such insurance is not currently required, and
- (ii) notice of all FDA approvals of any LICENSED PRODUCT(S) or LICENSED SERVICE(S) obtained by HPPI or any SUBLICENSEE, the patent(s) or patent application(s) licensed under this Agreement upon which such product or service is based, and the commercial name of such product or service, or, in the alternative, a statement that no FDA approvals have been obtained.

5.2 Records. HPPI shall make and retain, for a period of *** following the period of each report required by Paragraph 5.1, true and accurate records, files and books of account containing all the data reasonably required for the full computation and verification of sales and other information required in Paragraph 5.1. Such books and records shall be in accordance with generally accepted accounting principles consistently applied. HPPI shall permit the inspection and copying of such records, files and books of account by Mayne Pharma, Accelas or their agents during regular business hours upon *** written notice to HPPI. Such inspection shall not be made more than once each calendar year. All costs of such inspection and copying shall be paid by ***, provided that if any such inspection by Mayne Pharma shall reveal that an error has been made in the amount equal to *** of such payment, such costs shall be borne by ***.

5.3 Best Efforts. HPPI is responsible for the commercialization of the LICENSED PRODUCT(S) and LICENSED SERVICE(S) in the TERRITORY, including the conduct of all development programs, the submission and approval of the marketing authorizations, and payment of all associated fees and expenses, provided that JHU and Mayne Pharma must provide any assistance reasonably requested by HPPI in seeking marketing authorizations (at HPPI's expense). HPPI shall exercise best efforts to develop and to introduce the LICENSED PRODUCT(S) into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgement; thereafter, until the expiration or termination of this Agreement, HPPI shall endeavor to keep LICENSED PRODUCT(S) reasonably available to the public. HPPI shall also exercise reasonable efforts to develop LICENSED PRODUCT(S) suitable for different indications within the LICENSED FIELD, so that the PATENT RIGHTS can be commercialized as broadly and as speedily as good scientific and business judgement would deem possible.

5.4 Patent Acknowledgement. HPPI agrees that all packaging containing individual LICENSED PRODUCT(S) sold by HPPI or any SUBLICENSEE will be marked with the number of the applicable patent(s) licensed hereunder in accordance with patent laws in the TERRITORY.

ARTICLE 6
REPRESENTATIONS

6.1 Duties of the Parties. JHU is not a commercial organization. It is an institute of research and education. Therefore, JHU has no ability to evaluate the commercial potential of any PATENT RIGHTS or LICENSED PRODUCT or other license or rights granted in this Agreement. It is therefore incumbent upon HPPI to evaluate the rights and products in question, to examine the materials and information provided by JHU, and to determine for itself the validity of any PATENT RIGHTS, its freedom to operate, and the value of any LICENSED PRODUCTS or SERVICES or other rights granted.

6.2 PATENT RIGHTS PROVIDED “AS IS” Representations by JHU. JHU has warranted via the Head License that it has good and marketable title to the inventions claimed under PATENT RIGHTS with the exception of certain retained rights of the United States Government, which may apply if any part of the JHU research was funded in whole or in part by the United States Government. JHU does not warrant the validity of any patents or that practice under such patents shall be free of infringement. EXCEPT AS EXPRESSLY SET FORTH IN THIS PARAGRAPH 6.2, EACH OF HPPI AND ANY SUBLICENSEE AGREE THAT THE PATENT RIGHTS ARE PROVIDED “AS IS”, AND THAT EACH OF JHU, ACCELAS AND MAYNE PHARMA MAKE NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE PERFORMANCE OF LICENSED PRODUCT(S) AND LICENSED SERVICE(S) INCLUDING THEIR SAFETY, EFFECTIVENESS, OR COMMERCIAL VIABILITY. EACH OF JHU, ACCELAS AND MAYNE PHARMA DISCLAIM ALL WARRANTIES WITH REGARD TO PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, ALL WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, JHU ADDITIONALLY DISCLAIMS ALL OBLIGATIONS AND LIABILITIES ON THE PART OF JHU AND INVENTORS, AND EACH OF ACCELAS AND MAYNE PHARMA ADDITIONALLY DISCLAIM ALL OBLIGATIONS AND LIABILITIES ON THE PART OF ACCELAS AND MAYNE PHARMA FOR DAMAGES, INCLUDING, BUT NOT LIMITED TO, DIRECT, INDIRECT, SPECIAL, AND CONSEQUENTIAL DAMAGES, ATTORNEYS’ AND EXPERTS’ FEES, AND COURT COSTS (EVEN IF ANY OF JHU, ACCELAS OR MAYNE PHARMA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, FEES OR COSTS), ARISING OUT OF OR IN CONNECTION WITH THE MANUFACTURE, USE, OR SALE OF THE PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT. HPPI AND ANY SUBLICENSEE ASSUME ALL RESPONSIBILITY AND LIABILITY FOR LOSS OR DAMAGE CAUSED BY A PRODUCT AND/OR SERVICE MANUFACTURED, USED, OR SOLD BY HPPI OR ANY SUBLICENSEE WHICH IS A LICENSED PRODUCT(S) OR LICENSED SERVICE(S) AS DEFINED IN THIS AGREEMENT.

6.3 Representations and Covenants of Mayne Pharma.

(a) Mayne Pharma warrants to HPPI that (i) it is entitled to grant HPPI the sublicense of the PATENT RIGHTS on the terms and conditions set out in this Agreement; and

(ii) Exhibit C (with commercial in confidence information redacted) is a true and complete copy of the Accelas Sublicense; and (iii) it has not, and will not during the term of this Agreement, impose in favor of any third party any mortgage, pledge, lien, encumbrance, charge or other security interest over the Sublicense or any PATENT RIGHTS, whether that mortgage, pledge, lien, encumbrance, charge or other security interest has a material, adverse impact on HPPI's rights under this Agreement.

(b) Mayne Pharma covenants to HPPI that it will use reasonable commercial efforts to comply with its obligations under the Accelas Sublicense and will not terminate the Accelas Sublicense without cause except with the prior written consent of HPPI, such consent not to be unreasonably withheld or delayed.

ARTICLE 7 INDEMNIFICATION

7.1 Indemnification. HPPI shall be responsible for injuries or losses to third parties arising from or related to HPPI's own acts or omissions, or caused by arising from HPPI's use or third party use of LICENSED PRODUCT(S) sold by HPPI or any SUBLICENSEE and LICENSED SERVICE(S) performed by HPPI or any SUBLICENSEE, or arising as a consequence of the exercise by HPPI or any SUBLICENSEE(S) of any rights granted in this Agreement. JHU and the Inventors will have no legal liability exposure to third parties if JHU does not license the LICENSED PRODUCT(S) and LICENSED SERVICE(S), and any royalties JHU and the Inventors may receive under the Head License is not adequate compensation for such legal liability exposure. Therefore, JHU requires HPPI to protect JHU and Inventors from such exposure to the same manner and extent to which insurance, if available, would protect JHU and Inventors. Furthermore, JHU and the Inventors will not, under the provisions of the Head License, this Agreement or otherwise, have control over the manner in which HPPI or any SUBLICENSEE(S) or those operating for its account or third parties who purchase LICENSED PRODUCT(S) or LICENSED SERVICE(S) from any of the foregoing entities, develop, manufacture, market or practice the inventions of LICENSED PRODUCT(S) and LICENSED SERVICE(S). Therefore, HPPI and any SUBLICENSEE shall indemnify, defend with counsel reasonably acceptable to JHU, and hold JHU, The Johns Hopkins Health Systems, their present and former trustees, officers, Inventors of PATENT RIGHTS, agents, faculty, employees and students harmless as against any judgments, fees, expenses, or other costs arising from or incidental to any product liability or other lawsuit, claim, demand or other action brought as a consequence of the practice of said inventions by any of the foregoing entities, whether or not JHU or said Inventors, either jointly or severally, is named as a party defendant in any such lawsuit and whether or not JHU or the Inventors are alleged to be negligent or otherwise responsible for any injuries to persons or property. Practice of the inventions covered by LICENSED PRODUCT(S) and LICENSED SERVICE(S), by an agent or any SUBLICENSEE(S) or a third party on behalf of or for the account of HPPI or by a third party who purchases LICENSED PRODUCT(S) and LICENSED SERVICE(S) from HPPI, shall be considered HPPI's practice of said inventions for purposes of this Paragraph. The obligation of HPPI to defend and indemnify as set out in this Paragraph shall survive the termination of this Agreement, shall continue even after assignment of rights and responsibilities to an AFFILIATED COMPANY (but not any other assignment by HPPI in accordance with Paragraph 10.8), and shall not be limited by any other limitation of liability elsewhere in this Agreement.

7.2 Indemnification Procedure. A party intending to claim indemnification under this Agreement (“**Indemnitee**”) shall promptly notify the indemnifying party (“**Indemnitor**”) in writing of any lawsuit, claim, demand or other action, or any judgments, fees, expenses or other costs in respect of which the Indemnitee intends to claim such indemnification. The Indemnitee reasonably shall cooperate with the Indemnitor in the defense of the lawsuit, claim, demand or other action, and the Indemnitor shall have the right to control the defense and/or settlement of the lawsuit, claim, demand or other action; provided, however, that any such settlement shall not require the Indemnitee to admit any liability or pay any amounts without the prior written consent of such Indemnitee. The Indemnitee shall use reasonable efforts to mitigate any fees, expenses or other costs.

ARTICLE 8 CONFIDENTIALITY

8.1 Confidentiality. If necessary, the parties will exchange information in respect of the subject matter of this Agreement, which they consider to be confidential. The recipient of such information agrees to keep it confidential provided such information is marked as confidential at the time it is sent to the recipient, or if it is disclosed orally, summarised in writing and identified as ‘confidential’ within *** after its presentation (provided that a failure to do so shall not detract from the obligations in this Paragraph where it was reasonably apparent that such information was confidential in nature). Without limitation, the recipient agrees to employ all reasonable efforts to maintain the information secret and confidential, such efforts to be no less than the degree of care employed by the recipient to preserve and safeguard its own confidential information. The information shall not be disclosed or revealed to anyone except employees of the recipient who have a need to know the information and who have entered into a secrecy agreement with the recipient under which such employees are required to maintain confidential the proprietary information of the recipient and such employees shall be advised by the recipient of the confidential nature of the information and that the information shall be treated accordingly.

The obligations of this Paragraph 8.1 shall also apply to any SUBLICENSEE(S) provided such information by HPPI. Mayne Pharma’s, HPPI’s, and SUBLICENSEES’ obligations under this Paragraph 8.1 shall extend until *** after the termination of this Agreement.

The obligations of this Paragraph 8.1 shall apply to confidential information exchanged prior to, on or after the EFFECTIVE DATE in connection with this Agreement or the transactions contemplated under it. To avoid doubt, the parties agree that nothing in this Agreement detracts from the restrictions on use and disclosure of confidential information under the Second Amended and Restated Supply and License Agreement, dated May 15, 2015, by and between Mayne Pharma Ventures Pty Ltd., an Affiliated Company of Mayne Pharma, and HPPI.

8.2 Exceptions. The recipient's obligations under Paragraph 8.1 shall not extend to any part of the information:

- or
- (a) that can be demonstrated to have been in the public domain or publicly known and readily available to the trade or the public prior to the date of the disclosure;
 - (b) that can be demonstrated, from written records to have been in the recipient's possession or readily available to the recipient from another source not under obligation of secrecy to the disclosing party prior to the disclosure; or
 - (c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by the recipient; or
 - (d) that is demonstrated from written records to have been developed by or for the receiving party without reference to confidential information disclosed by the disclosing party.
 - (e) that is required to be disclosed by law, government rule or regulation or court or arbitration order, or any applicable stock exchange.

8.3 Right to Publish. JHU may publish manuscripts, abstracts or the like describing the PATENT RIGHTS and inventions contained therein provided confidential information of HPPI as contemplated in Paragraph 8.1, is not included or without first obtaining approval from HPPI to include such confidential information. Otherwise, JHU and the Inventors shall be free to publish manuscripts and abstracts or the like directed to the work done at JHU related to the licensed technology without prior approval.

ARTICLE 9 TERM & TERMINATION

9.1 Term. The term of this Agreement shall commence on the EFFECTIVE DATE and shall continue until the earlier of: (a) the date of expiration of the last to expire patent included within PATENT RIGHTS in the TERRITORY; or (b) notice by Mayne Pharma with immediate effect promptly after termination or expiry of the Head License or Accelas Sublicense in circumstances where Mayne Pharma no longer has the right to obtain an EXCLUSIVE LICENSE to make, have made, use, import, offer for sale and sell the LICENSED PRODUCT(S) and to provide the LICENSED SERVICE(S) in the TERRITORY under the PATENT RIGHTS in the LICENSED FIELD.

9.2 Termination By Either Party. This Agreement may be terminated by either party giving written notice to the other party, with effect immediately (or any later date specified in the notice), in the event that the other party (a) files or has filed against it a petition under the Bankruptcy Act, makes an assignment for the benefit of creditors, has a receiver appointed for it or a substantial part of its assets, otherwise takes advantage of or has any action taken in respect of it under any statute or law designed for relief of debtors, or (having regard to its legal structure and the jurisdiction in which it is incorporated or operates) any event analogous to one of the foregoing events happens to it or (b) fails to perform or otherwise breaches any of its obligations hereunder, if either (i) following the giving of notice by the terminating party of its intent to

terminate and stating the grounds therefor, the party receiving such notice shall not have cured the failure or breach within *** or (ii) that failure to perform or breach is not capable of being cured. In no event, however, shall such notice or intention to terminate be deemed to waive any rights to damages or any other remedy which the party giving notice of breach may have as a consequence of such failure or breach.

9.3 Not used.

9.4 Obligations and Duties upon Termination. If this Agreement is terminated, both parties shall be released from all obligations and duties imposed or assumed hereunder to the extent so terminated, except as expressly provided to the contrary in this Agreement. Upon termination, both parties shall cease any further use of the confidential information disclosed to the receiving party by the other party. Termination of this Agreement, for whatever reason, shall not affect the obligation of either party to make any payments for which it is liable prior to or upon such termination. Termination shall not affect Mayne Pharma's right to recover unpaid royalties, fees, reimbursement for patent expenses, or other forms of financial compensation incurred prior to termination. Upon termination HPPI shall submit a final royalty report to Mayne Pharma and any royalty payments, fees, unreimbursed patent expenses and other financial compensation due Mayne Pharma shall become immediately payable. Furthermore, upon termination of this Agreement, as between Mayne Pharma and HPPI, all rights in and to the licensed technology shall revert immediately to Mayne Pharma at no cost to Mayne Pharma.

ARTICLE 10 MISCELLANEOUS

10.1 Use of Name. HPPI and any SUBLICENSEE shall not use the name of The Johns Hopkins University or The Johns Hopkins Health System or any of its constituent parts, such as the Johns Hopkins Hospital or any contraction thereof or the name of Inventors in any advertising, promotional, sales literature or fundraising documents without prior written consent from an authorized representative of JHU. HPPI and any SUBLICENSEE(S) shall allow at least *** notice of any proposed public disclosure for JHU's review and comment or to provide written consent.

10.2 No Partnership. Nothing in this Agreement shall be construed to create any agency, employment, partnership, joint venture or similar relationship between the parties other than that of a licensor/licensee. Neither party shall have any right or authority whatsoever to incur any liability or obligation (express or implied) or otherwise act in any manner in the name or on the behalf of the other, or to make any promise, warranty or representation binding on the other.

10.3 Notice of Claim. Each party shall give the other or its representative immediate notice of any suit or action filed, or prompt notice of any claim made, against them arising out of the performance of this Agreement or arising out of the practice of the inventions licensed hereunder.

10.4 Product Liability. Prior to initial human testing or first commercial sale of any LICENSED PRODUCT(S) or LICENSED SERVICE(S) in the TERRITORY, HPPI shall establish and maintain product liability or other appropriate insurance coverage in the minimum amount of *** per claim and will annually present evidence to JHU or Mayne Pharma that such coverage is being maintained. Upon JHU's or Mayne Pharma's request, HPPI will furnish it with a Certificate of Insurance of each product liability insurance policy obtained. JHU shall be listed as an additional insured in HPPI's said insurance policies. If such Product Liability insurance is underwritten on a 'claims made' basis, HPPI agrees that any change in underwriters during the term of this Agreement will require the purchase of 'prior acts' coverage to ensure that coverage will be continuous throughout the term of this Agreement.

10.5 Governing Law. For consistency with the Head License which is with JHU (a Maryland corporation) and are governed by the laws of the State of Maryland, and for consistency with the Accelas Sublicense which is governed by the laws of the State of Maryland, this Agreement shall be construed, and legal relations between the parties hereto shall be determined, in accordance with the laws of the State of Maryland applicable to contracts solely executed and wholly to be performed within the State of Maryland without giving effect to the principles of conflicts of laws. EACH PARTY WAIVES ALL RIGHTS TO ANY TRIAL BY JURY IN ALL LITIGATION RELATING TO OR ARISING OUT OF THIS AGREEMENT.

10.5A Resolution of Disputes. A party must not start court proceedings (except proceedings seeking interlocutory relief for the protection of intellectual property or confidential information, or proceedings in relation to debt recovery) for a dispute arising out of this Agreement, including the breach, termination or invalidity of this Agreement, ("**Dispute**") unless it has complied with this Paragraph 10.5A. A party claiming that a Dispute has arisen must notify the other party giving details of the Dispute. When such a notice is given, each party's respective representatives must first attempt to resolve the Dispute and, if they cannot resolve the Dispute within *** after the notice is given, they must refer the Dispute to each party's chief executive officer who must then attempt to resolve it. If the parties cannot resolve the Dispute within six weeks after the notice of the Dispute is given (or longer period if the parties to the Dispute agree in writing), either party may refer the Dispute to arbitration. If either party exercises that right, the Dispute must be settled by arbitration in accordance with the expedited procedure set out in the Singapore International Arbitration Centre Rules for Arbitration, as at present in force and as may be amended by the rest of this Paragraph 10.5A. The place of arbitration will be Singapore. There will only be one arbitrator. The arbitration must be conducted in English. The decision of the arbitrator shall be final and binding and any award rendered thereon may be entered in any court having jurisdiction. The parties hereby waive any and all objections and defenses to such jurisdiction regardless of the nature of such objection or defense.

10.6 Notice. All notices or communication required or permitted to be given by either party hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, to the other party at its respective address set forth below or to such other address as one party shall give notice of to the other from time to time hereunder.

If to Mayne Pharma:

General Counsel
Mayne Pharma International Pty Ltd
14/474 Flinders Street
Melbourne Vic 3000
Australia

If to HPPI:

President and CEO
HedgePath Pharmaceuticals, Inc.
324 South Hyde Park Avenue Suite 350
Tampa, FL 33606, United States
Facsimile: +1 813-527-0500

A notice given in accordance with Paragraph 10.6 takes effect when taken to be received (or at a later time specified in it), and is taken to be received: (i) if hand delivered or sent by reputable international courier, on delivery; (ii) if sent by prepaid post, on the second business day after the date of posting (or on the seventh business day after the date of posting if posted to or from a place outside Australia); or (iii) if sent by facsimile, when the sender's facsimile system generates a message confirming successful transmission of the entire notice unless, within 8 business hours after the transmission, the recipient informs the sender that it has not received the entire notice, but if the delivery, receipt or transmission is not on a business day or is after 5.00pm on a business day, the notice is taken to be received at 9.00am on the next business day.

10.7 Compliance with All Laws. In all activities undertaken pursuant to this Agreement, both Mayne Pharma and HPPI covenant and agree that each will in all material respects comply with such Federal, state and local laws and statutes, as may be in effect at the time of performance and all valid rules, regulations and orders thereof regulating such activities.

10.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein, except for the right to receive any remuneration hereunder, may be assigned or novated by either party, in whole or in part, without the prior written consent of the other party (which consent must not be unreasonably withheld or delayed), except that either party shall be free to assign or novate this Agreement in connection with any sale of substantially all of its assets without the consent of the other and Mayne Pharma shall be free to assign or novate this Agreement to an AFFILIATED COMPANY who is an assignee of Mayne Pharma's rights and obligations under the Accelas Sublicense. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the parties hereto.

10.9 No Waivers; Severability. No waiver of any breach of this Agreement shall constitute a waiver of any other breach of the same or other provision of this Agreement, and no waiver shall be effective unless made in writing. Any provision hereof prohibited by or unenforceable under any applicable law of any jurisdiction shall as to such jurisdiction be deemed ineffective and deleted herefrom without affecting any other provision of this Agreement. It is the desire of the parties hereto that this Agreement be enforced to the maximum extent permitted by law, and should any provision contained herein be held by any governmental agency or court of competent jurisdiction to be void, illegal and unenforceable, the parties shall negotiate in good faith for a substitute term or provision which carries out the original intent of the parties.

10.10 Entire Agreement; Amendment. HPPI and Mayne Pharma acknowledge that they have read this entire Agreement and that this Agreement, including the attached Exhibits constitutes the entire understanding and contract between the parties hereto and supersedes any and all prior or contemporaneous oral or written agreements or communications with respect to the subject matter hereof, all of which agreements and communications are merged herein. It is expressly understood and agreed that (i) there being no expectations to the contrary between the parties hereto, no usage of trade, verbal agreement or another regular practice or method dealing within any industry or between the parties hereto shall be used to modify, interpret, supplement or alter in any manner the express terms of this Agreement; and (ii) this Agreement shall not be modified, amended or in any way altered except by an instrument in writing signed by both of the parties hereto.

10.11 Delays or Omissions. Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any party hereto, shall impair any such right, power or remedy to such party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or in any similar breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

10.12 Force Majeure. If either party fails to fulfill its obligations hereunder (other than an obligation for the payment of money), when such failure is due to an act of God, or other circumstances beyond its reasonable control, including but not limited to fire, flood, civil commotion, riot, war (declared and undeclared), revolution, or embargoes, then said failure shall be excused for the duration of such event and for such a time thereafter as is reasonable to enable the parties to resume performance under this Agreement, provided however, that in no event shall such time extend for a period of more than ***. If a failure to perform continues for more than ***, the other party may terminate this Agreement immediately by giving notice to the affected party.

10.13 Further Assurances. Each party shall, at any time, and from time to time, prior to or after the EFFECTIVE DATE of this Agreement, at reasonable request of the other party, execute and deliver to the other such instruments and documents and shall take such actions as may be required to more effectively carry out the terms of this Agreement.

10.14 Survival. All representations, warranties, covenants and agreements made herein and which by their express terms or by implication are to be performed after the execution and/or termination hereof, or are prospective in nature, shall survive such execution and/or termination, as the case may be. This shall include Paragraph 3.7 (Payment), 3.10 (Withholding tax) 5.2 (Records), and Articles 6, 7, 8, 9.4 and 10, and Paragraphs 4.3 to 4.6 where Mayne Pharma elects to continue with such litigation after execution and/or termination.

10.15 No Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any person, firm, corporation or other entity, other than the parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof, except as expressly set out in this Agreement.

10.16 Headings. Article headings are for convenient reference and not a part of this Agreement. All Exhibits are incorporated herein by this reference.

10.17 Counterparts. This Agreement may be executed in counterparts (including electronic counterparts), each of which shall be deemed an original and all of which when taken together shall be deemed but one instrument. Delivery of an executed signature page of this agreement by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

10.18 Costs. Each party must bear its own costs of preparing and executing this Agreement.

IN WITNESS WHEREOF, this Agreement shall take effect as of the EFFECTIVE DATE when it has been executed below by the duly authorized representatives of the parties.

MAYNE PHARMA INTERNATIONAL PTY LTD

/s/ Scott Richards

Scott Richards
Director

27 August 2015

(Date)

HEDGEPTH PHARMACEUTICALS, INC

/s/ Nicholas J. Virca

Nicholas J. Virca
President and CEO

31 August 2015

(Date)

EXHIBIT A

License fee: USD75,000.

Minimum annual royalty: USD ***, commencing in accordance with Paragraph 3.2.

Royalty: ****% of NET SALES of an itraconazole LICENSED PRODUCT in the LICENSED FIELD and NET SERVICE REVENUES in the LICENSED FIELD in the TERRITORY where a patent comprised in the PATENT RIGHTS is and remains registered at the time the relevant sales revenues and fees are billed.

Where an itraconazole LICENSED PRODUCT has exclusivity in the TERRITORY due solely to the PATENT RIGHTS, a further royalty supplement of ****% of NET SALES and NET SERVICE REVENUES in the TERRITORY except that where Accelas, itself or through any third party, imports, promotes, distributes or sells any product substantially the same as, or similar to, or substitutable for, the LICENSED PRODUCT or providers services substantially the same as, or similar to, the LICENSED SERVICES, in each case in the LICENSED FIELD in the TERRITORY, in which case no royalty supplement applies.

Milestone payments, in each case payable only provided that any claim in the HEDGEHOG PATENT in the TERRITORY directed to administering orally itraconazole remains valid at the time payment falls due:

1. USD *** due on the ***.
2. If ***, USD *** due on the ***.
3. USD *** due on the ***.
4. USD *** on ***.

EXHIBIT B

Royalty Report

EXHIBIT C

Accelas Sublicense

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