
**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): December 23, 2013 (December 17, 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))
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Item 1.01. Entry into a Material Definitive Agreement.

On December 17, 2013, HedgePath Pharmaceuticals, Inc., a Delaware corporation (the “Company”), entered into Amendment No. 1 to Supply and License Agreement (the “Amended Supply and License Agreement”) with Mayne Pharma International Pty Ltd, a company incorporated in Australia (“Mayne Pharma”). The Amended Supply and License Agreement amends that certain Supply and License Agreement, dated September 3, 2013, with Mayne Pharma (the “Agreement”) 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 to clinically develop the Product in the Field and in the Territory.

The Amended Supply and License Agreement amends the Agreement as follows:

(i) the date by which the Conditions (as defined below) must be met was extended from December 16, 2013 to February 28, 2014;

(ii) Mayne Pharma has agreed to reimburse all reasonable third party expenses incurred in the conduct of the activities set out in, and in accordance with, the development plan as set forth in the Agreement (the “Development Plan”), or otherwise related to the Product by the Company from the date of the Amended Supply Agreement through February 28, 2014; provided however that (i) such expenses may not exceed \$100,000, (ii) the Company must receive prior written approval from Mayne Pharma prior to incurring such expenses, and (iii) any third party engaged to provide clinical or other services to the Company must first enter into an agreement with the Company to assign all intellectual property rights developed by or on behalf of it in providing such services to the Company. Furthermore, such reimbursement must be repaid by the Company to Mayne Pharma once the Conditions have been met or waived by Mayne Pharma; and

(iii) if Mayne Pharma terminates the Agreement, then the Company will assign to Mayne Pharma all intellectual property rights created or developed in the conduct of the activities set out in, and in accordance with, the Development Plan or otherwise related to the Product that have been created or developed between the date of the Amended Supply and License Agreement and February, 28 2014. Such assignment will occur whether such rights were created or developed by or on behalf of the Company, its affiliates or any third party providing services to the Company or its affiliates; provided however, that: (i) all rights of the Company in the HP Patents (as defined in the Agreement) and all intellectual property rights of the Company created or developed (either by the Company or jointly with Mayne Pharma) prior to the date of the Amended Supply and License Agreement shall remain the exclusive property of the Company as provided for in the Agreement and (ii) if the Conditions have been waived by Mayne Pharma or satisfied as of or prior to the February 28, 2014, all provisions of the Agreement relating to the ownership of intellectual property rights relating to the Product shall be governed by the original provisions of the Agreement and this provision will be terminated upon the waiver by Mayne Pharma, or satisfaction, of the Conditions.

As provided for in the Agreement, as amended, Mayne Pharma may terminate the Agreement if certain conditions (the “Conditions”) are not met by February 28, 2014. Such Conditions are summarized more fully in the Company’s Current Report on Form 8-K filed on September 10, 2013 (the “September 8-K”) and include conditions relating to a \$5 million equity financing of the Company (or such lesser amount as may be approved by Mayne Pharma, the “Equity Financing”), the appointment of a

representative to the board of directors of the Company, and Mayne Pharma's acquisition of 170,000.74 shares of the Company's 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).

The Amended Supply and License Agreement is attached to this Current Report as Exhibit 10.1. All descriptions of the Amended Supply and License Agreement herein are qualified in their entirety to the text of Exhibit 10.1 hereto, which is incorporated herein by reference. The Agreement is attached as Exhibit 10.1 to the September 8-K. All descriptions of the Agreement herein are qualified in their entirety to the text of Exhibit 10.1 attached to the September 8-K, which is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

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

10.1 Amendment No. 1 to Supply and License Agreement, dated December 17, 2013, between the Company and Mayne Pharma.

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: December 23, 2013

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca

Name: Nicholas J. Virca

Title: President and CEO

Mr. Nick Virca
 President and CEO, HedgePath Pharmaceuticals, Inc.
nvirca@hedgepathpharma.com

Dear Nick:

Amendment No. 1 to Supply and License Agreement

We refer to the supply and license agreement dated, September 3, 2013, between Mayne Pharma International Pty Ltd and HedgePath Pharmaceuticals, Inc. (**Agreement**). For due and valuable consideration, the receipt and sufficiency of which each party acknowledges, and in accordance with clause 26.8 of the Agreement, the parties agree to amend the Agreement, as set out below.

AMENDMENT

1. Commencement of this amendment

This amendment (**Amendment No. 1**) takes effect from the date the same is mutually executed by the parties (**Date of Amendment No. 1**), and is supplementary to and shall be read in conjunction with the Agreement. In the case of any inconsistency between the terms and provisions of the Agreement and the terms and provisions of this Amendment No. 1, the terms of this Amendment No. 1 shall govern.

2. Definitions and interpretation

- a. Except to the extent expressly provided otherwise in this Amendment No. 1, terms and expressions defined in the Agreement have the same meaning in this Amendment No. 1, and references to clauses are references to clauses in the Agreement.
- b. The parties agree to extend the **Condition Date** to 28 February 2014, as that date may be further extended:
 - i. by agreement of the parties in writing; or
 - ii. by Mayne Pharma in its discretion by notice to HPPI if the Conditions have not been satisfied by the then current Condition Date.

3. Initial contribution by Mayne Pharma to third party development expenses

- a. Mayne Pharma agrees, itself or through its nominee, to reimburse all reasonable third party expenses incurred by HPPI:
 - i. in the conduct of the activities set out in, and in accordance with, the Development Plan; or
 - ii. otherwise relating to the Product,



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between the Date of Amendment No 1 and 28 February 2014, up to a maximum of USD100,000, provided that such expenses were incurred with the prior written approval of Mayne Pharma, and subject to clauses 7.5 and 24.5 of the Agreement.

- b. HPPI acknowledges and agrees that before it or any of its Affiliates engages any third party to provide the services referred to in section 3a. of this Amendment No. 1, it must first enter into a written agreement with that third party under which the third party assigns to HPPI or its Affiliate (with effect from the date of creation) all Intellectual Property Rights developed by or on behalf of it in providing such services.

4. Repayment by HPPI if the Conditions are satisfied

If all of the Conditions have been waived by Mayne Pharma or satisfied, HPPI must repay to Mayne Pharma all amounts reimbursed under section 3 of this Amendment No. 1, within 5 Business Days from the date Mayne Pharma or its nominee issues an invoice to HPPI.

5. Transfer of Intellectual Property Rights to Mayne Pharma in certain circumstances

- a. If Mayne Pharma terminates the Agreement under clause 4.7 and Schedule 2 of the Agreement, or for any other valid reason before all of the Conditions have been waived by Mayne Pharma or satisfied, then HPPI will, or will procure that its Affiliates (as applicable) will, promptly assign to Mayne Pharma or its nominee all Intellectual Property Rights:

- i. created or developed in the conduct of the activities set out in, and in accordance with, the Development Plan; or
- ii. otherwise relating to the Product,

and created or developed between the Date of Amendment No. 1 and 28 February 2014, whether such rights were created or developed by or on behalf of HPPI, its Affiliates or any third party providing services to HPPI or its Affiliates; provided, however, it is acknowledged and agreed that: (i) all rights of HPPI in the HP Patents and all Intellectual Property Rights of HPPI created or developed (either by HPPI or jointly with Mayne Pharma) prior to the Date of Amendment No 1 shall remain the exclusive property of HPPI as provided for in clause 18.5 of the Agreement and (ii) if the Conditions have been waived by Mayne Pharma or satisfied as of or prior to the Condition Date, all provisions of the Agreement relating to the ownership of Intellectual Property rights relating to the Product shall be governed by the original provisions of the Agreement, including, without limitation, clause 18.5 of the Agreement, and this paragraph 5 shall be terminated upon the waiver by Mayne Pharma, or satisfaction, of the Conditions.

- b. From the date of such assignment, HPPI acknowledges that:
 - i. such rights no longer form part of the HPPI Licensed Rights;



- ii. Mayne Pharma or its nominee may, in its discretion and at its cost, file, prosecute, maintain, enforce and defend any patent in respect of any assigned invention; and
- iii. any information comprising part of the Intellectual Property Rights that is not public knowledge is deemed to be Confidential Information of Mayne Pharma.

6. Stamp duty

HPPI shall be responsible for and pay any stamp duty assessed or charged in respect of this Amendment No. 1.

7. Confirmation of the Agreement

Subject only to this Amendment No. 1, the parties confirm the terms and conditions of the Agreement in all other respects.

8. Representations of the parties

Each party represents and warrants, with effect the Date of Amendment No. 1, 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 the Agreement (as amended) and perform its obligations under the Agreement (as amended); and
- b. this Agreement (as amended) 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 (as amended).

9. Counterparts

This Amendment No. 1 may be executed in counterparts, including electronic counterparts. All executed counterparts constitute one document. Delivery of an executed signature page of this Amendment No. 1 by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Please indicate your agreement with the above by countersigning this Amendment No. 1 below.

Sincerely

/s/ Mark Cansdale

Mark Cansdale
Director and Secretary, Mayne Pharma International Pty Ltd
mark.cansdale@maynepharma.com

Date: December 16, 2013



You deserve tomorrow.

Accepted and agreed by

HedgePath Pharmaceuticals, Inc.

/s/ Nick Virca

Nick Virca
President and CEO

Date: December 17, 2013

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