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

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**FORM 8-K**

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**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): March 11, 2014 (March 5, 2014)**

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**HedgePath Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

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**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)

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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 March 5, 2014, HedgePath Pharmaceuticals, Inc., a Delaware corporation (the “Company”), entered into an Amendment No. 2 (the “Second Amendment”) to that certain Supply and License Agreement, dated September 3, 2014 (as amended, the “Agreement”), with Mayne Pharma International Pty Ltd, a company incorporated in Australia (“Mayne Pharma”). Pursuant to the Agreement, Mayne Pharma has agreed to: (i) supply the Company with its patented formulation of the drug itraconazole, known as SUBATM-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 Second Amendment amends the Agreement as follows:

(i) the date by which the Conditions (as defined below) must be met was extended from February 28, 2014 to March 31, 2014;

(ii) the Company has agreed to use reasonable efforts to progress the conduct of the activities set out in, and in accordance with, the development plan as set forth in the Agreement (the “Development Plan”), and to seek reimbursement of relevant amounts in accordance with the Agreement;

(iii) the Company and Mayne Pharma acknowledged and agreed that warrants may be issued in connection with an Equity Financing (as defined below) and further agreed that in the event that warrants are issued in connection with an Equity Financing, Mayne Pharma will receive a warrant on the same terms as the warrants issued in the Equity Financing for such a number of shares that will ensure that Mayne Pharma will hold at least 30% of the issued and outstanding shares of capital stock of the Company on a fully diluted, fully converted basis following the Equity Financing;

(iv) if the Company does not (i) submit a complete Investigational New Drug (“IND”) application to the United States Food and Drug Administration (the “FDA”) for the Product for at least one indication in the Field and commence dosing patients in at least two phase II or phase II/III clinical trials across at least two indications in the Field by March 31, 2015 or (ii) submit an application for a new drug application to the FDA for at least one indication by March 31, 2016, then Mayne Pharma may, by notice to Frank E. O'Donnell, Jr. M.D., the Company's Executive Chairman, and Nicholas J. Virca, the Company's President and Chief Executive Officer, require each of them to resign from the Company, in which case each of Hedgepath LLC, Mr. Virca and Dr. O'Donnell will forfeit all of their respective unvested Company options, and Mayne Pharma will have the right to purchase all issued and outstanding shares of the Company's capital stock held by Mr. Virca and Dr. O'Donnell at market price, and neither Mr. Virca nor Dr. O'Donnell will be entitled to receive any severance or similar payments from the Company;

(v) in the event that Dr. O'Donnell or Mr. Virca are removed or resign from the Company's board of directors, any replacement appointees will need to obtain unanimous approval from the remaining board members; and

(vi) Mayne Pharma waived its right to require the Company to obtain a written estimate from a contract research organization relating to the timing and completion of phase II trials on the use of the Product in the Field and waived its right to reasonably expect that the Product would launch by a date agreed upon the Company and Mayne.

Mayne Pharma may terminate the Agreement, as amended, if certain conditions (the “Conditions”) are not met by March 31, 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 shares of the Company’s Series A Preferred Stock, representing, on an as fully converted, fully diluted basis, at least 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 Second Amendment is attached to this Current Report as Exhibit 10.1. All descriptions of the Second Amendment herein are qualified in their entirety to the text of Exhibit 10.1 hereto, which is incorporated herein by reference. The Original 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. A First Amendment to the Agreement is attached as Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on December 23, 2013 (the “December 8-K”). All descriptions of such First Amendment herein are qualified in their entirety to the text of Exhibit 10.1 attached to the December 8-K, which is incorporated 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 Amendment No. 2 to Supply and License Agreement, dated March 5 2014, 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 (including whether the Conditions will be met), (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.

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**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: March 11, 2014

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca

Name: Nicholas J. Virca

Title: President and CEO

March 6, 2014

Mr. Nick Virca  
President and CEO, HedgePath Pharmaceuticals, Inc.  
[nvirca@hedgepathpharma.com](mailto:nvirca@hedgepathpharma.com)

Dear Nick:

#### Amendment No. 2 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., as amended (**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. 2**) takes effect from the date the same is mutually executed by the parties (**Date of Amendment No. 2**), 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. 2 shall govern.

##### 2. Definitions and interpretation

- a. Except to the extent expressly provided otherwise in this Amendment No. 2, terms and expressions defined in the Agreement have the same meaning in this Amendment No. 2, and references to clauses are references to clauses in the Agreement.
- b. The parties agree to extend the **Condition Date** to 31 March 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

The parties acknowledge that HPPI has not yet sought reimbursement of any third party expenses under section 3 of Amendment No 1. HPPI agrees to use reasonable efforts to progress the conduct of the activities set out in, and in accordance with, the Development Plan, promptly after the Date of Amendment No.2 and to seek reimbursement of relevant amounts from Mayne Pharma in accordance with section 3 of Amendment No 1 and subject to sections 4 and 5 of Amendment No 1.



**Mayne Pharma International Pty Ltd**  
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[maynepharma.com](http://maynepharma.com)

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1538 Main North Road, Salisbury South, SA 5106 Australia  
PO Box 700, Salisbury, SA 5108 Australia

#### **4. Equity raising**

Mayne Pharma acknowledges that warrants may be issued in connection with the equity raising in item 1.2 of Schedule 2, provided that:

- a.** Mayne Pharma is issued warrants on equivalent terms; and
- b.** if Mayne Pharma elects to exercise such warrants, Mayne Pharma is able to maintain a holding of at least 30% of the issued and outstanding shares of capital stock on an as fully converted, fully diluted basis following the equity raising in item 1.2 of Schedule 2 (including as a result of any dilution which may result because of the stock reserved pursuant to any other issued warrants and the EIP as set out in Schedule 8).

#### **5. Agreements on Transfers and Holding of Equity**

The parties agree to amend Condition in item 1.3 of Schedule 2 of the Agreement so that, in addition to what is already contemplated:

- a.** Frank E. O'Donnell is also a party to the required agreement;
- b.** if Frank E. O'Donnell or Jr or Nicholas J. Virca proposed to divest of any rights in HPPI (including by sale of any capital stock, options or warrants), Mayne Pharma will have a first right of refusal to acquire such rights; and
- c.** if HPPI does not:
  - i.** submit a complete Investigational New Drug (IND) application to the FDA for the Product for at least one indication in the Field and commence dosing patients in at least two phase II or phase II/III clinical trials across at least two indications in the Field by March 31, 2015; or
  - ii.** submit an application for a new NDA to the FDA for at least one indication by March 31, 2016,

then Mayne Pharma may, by notice with immediate effect, require the resignation of each or both of Frank E. O'Donnell, Jr and Nicholas J. Virca from HPPI's board of directors, in which case:

- iii.** each of Hedgepath LLC, Frank E. O'Donnell, Jr or Nicholas J. Virca forfeit all unvested warrants and options in HPPI; and
- iv.** Mayne Pharma has the option to acquire from any of Frank E. O'Donnell, Jr or Nicholas J. Virca all of his capital stock in HPPI at the open market price at that time; and

- v. no severance or other ex gratia payments shall be due to Frank E. O'Donnell, Jnr or Nicholas J. Virca.

**6. Board positions**

Any replacement to Frank E. O'Donnell, Jnr or Nicholas J. Virca to the board of HPPI must be appointed with the unanimous approval of all remaining board members.

**7. Development program**

Mayne Pharma waives its right to require satisfaction of the Condition referred to in item 1.6 of Schedule 2.

**8. Stamp duty**

HPPI shall be responsible for and pay any stamp duty assessed or charged in respect of this Amendment No. 2.

**9. Confirmation of the Agreement**

Subject only to this Amendment No. 2, the parties confirm the terms and conditions of the Agreement in all other respects.

**10. Representations of the parties**

Each party represents and warrants, with effect the Date of Amendment No. 2, 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).

**11. Counterparts**

This Amendment No. 2 may be executed in counterparts, including electronic counterparts. All executed counterparts constitute one document. Delivery of an executed signature page of this Amendment No. 2 by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.



You deserve tomorrow.

Please indicate your agreement with the above by countersigning this Amendment No. 2 below.

Sincerely

/s/ Scott Richards  
Scott Richards  
CEO, Mayne Pharma International Pty Ltd  
scott.richards@maynepharma.com

Date: March 6, 2014

Accepted and agreed by

HedgePath Pharmaceuticals, Inc.

/s/ Nicholas J. Virca

Nicholas J. Virca  
President and CEO

Date:

[Signature Page to Amendment No. 2 to Supply and License Agreement]