
**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): November 5, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

HedgePath Pharmaceuticals, Inc. (the “Company”) hereby provides the following disclosure in light of the November 5, 2018 filing by Mayne Pharma Ventures Pty Ltd, the Company’s majority stockholder (“Mayne Pharma”), of an amendment to Mayne Pharma’s Schedule 13D (the “Mayne Pharma 13D/A”) and the contents of such amendment, in which Mayne Pharma disclosed certain proposals to the Independent Committee (as defined below).

As previously disclosed by the Company via press release on October 9, 2018: (i) circumstances have arisen that could lead to the anticipated filing of the Company’s New Drug Application (the “NDA”) for the Company’s lead product candidate, SUBA™-Itraconazole as a treatment for Basal Cell Carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (“SUBA BCCNS”), in the first quarter of 2019 rather than by December 31, 2018 and (ii) as previously disclosed, if the NDA is not accepted for filing by the U.S. Food and Drug Administration by December 31, 2018 (subject to limited extension if the NDA is filed in December), Mayne Pharma may, under the current terms of the Supply and License Agreement, as amended and restated to date, between the Company and Mayne Pharma (under which the U.S rights to SUBA BCCNS are exclusively licensed to the Company, the “SLA”), elect to assume full control of the SUBA BCCNS product in the United States (including by way of an exclusive license from the Company of its clinical data) in exchange for a royalty on any future net sales. The Company also disclosed that it is in discussions with Mayne Pharma regarding these important matters.

The Company hereby provides the following update in light of the filing of the Mayne Pharma 13D/A:

1. On October 26, 2018, the Company’s Board of Directors (the “Board”) deemed it necessary in light of the evolution of discussions with Mayne Pharma to form a committee of disinterested directors (the “Independent Committee”) in order to engage in discussions and negotiations regarding Mayne Pharma’s rights to SUBA BCCNS. The Independent Committee consists of W. Mark Watson (serving as Chairman), R. Dana Ono and Robert Martin, who are each disinterested with respect to Mayne Pharma. The Independent Committee has been endowed with the full power of the Board to discuss, negotiate and approve any transactions and related documentation with Mayne Pharma that relate to the SLA (including the SUBA BCCNS product and the Company’s rights thereto), or any contractual or financing matters arising therefrom involving Mayne Pharma, and in connection therewith to fulfill the full Board’s fiduciary obligations to all Company stockholders, including its minority stockholders.
2. It is the Company’s understanding that the 13D/A was filed principally so that Mayne Pharma could be in compliance with applicable U.S. securities laws, rules and regulations. No aspect of any proposal of Mayne Pharma to the Independent Committee as described in the 13D/A (the “Initial 13D/A Proposal”) has been accepted even in concept by the Independent Committee. The Initial 13D/A Proposal was non-binding and the terms thereof were not specifically requested by the Independent Committee. The Independent Committee has been in active discussions with representatives of Mayne Pharma on a variety of related matters, and readers of the 13D/A should not infer from the filing of the 13D/A that the Initial 13D/A Proposal or any aspect thereof has been or will be accepted or approved by the Independent Committee.
3. The Independent Committee is considering all alternatives available to the Company in light of the present circumstances facing the Company with respect to the SUBA BCCNS product.
4. Neither the Company, the Board nor the Independent Committee is committing by making the foregoing disclosures to provide further public updates on the matters described herein, unless required by applicable law, rule or regulation.

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 of the Independent Committee’s discussions and negotiations with Mayne Pharma) 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: November 5, 2018

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca
Name: Nicholas J. Virca
Title: President and CEO