
**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): July 10, 2018 (July 6, 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 3.02. Unregistered Sales of Equity Securities.

On July 5, 2018, HedgePath Pharmaceuticals, Inc. (the “**Company**”) closed the second of three tranches of funding (the “**Second Tranche**”) from Mayne Pharma Ventures Pty Ltd (“**Mayne Pharma**”), the Company’s majority shareholder, pursuant to that certain definitive securities purchase agreement, dated January 8, 2018 (the “**Purchase Agreement**”), entered into between the Company and Mayne Pharma, the details of which have been previously reported by the Company on a Current Report on Form 8-K filed with the Securities and Exchange Commission on January 11, 2018 (the “**January 8-K**”). Pursuant to the terms of the Purchase Agreement, the Company issued to Mayne Pharma 2,318,841 shares of Series B Convertible Preferred Stock (the “**Series B Preferred Stock**”), Series A warrants (the “**Series A Warrants**”) to purchase 1,739,131 shares of common stock and Series B warrants (the “**Series B Warrants**,” and together with the Series A Warrants, the “**Warrants**”) to purchase 1,739,131 shares of common stock for gross proceeds of \$1.6 million.

The shares of Series B Preferred Stock are initially convertible into 6,956,523 shares of common stock, subject to customary stock-based, but not price-based, anti-dilution protection. The Series B Preferred Stock may be voluntarily converted into common stock by the holder at any time and will automatically convert into shares of common stock upon the approval by the U.S. Food and Drug Administration of a New Drug Application for any SUBATM-Itraconazole based therapeutic under that certain Second Amended and Restated Supply and License Agreement, as amended, between the Company and Mayne Pharma.

The Warrants are substantially identical in form, except that: (i) the exercise price per share of the Series A Warrants is \$0.23 per share and the exercise price per share of the Series B Warrants is \$0.275 per share (collectively, the “**Warrant Exercise Price**”) and (ii) the Series A Warrants have a term of two (2) years from the date of issuance and the Series B Warrants have term of five (5) years from the date of issuance. The Warrant Exercise Price is subject to customary stock-based, but not price-based, anti-dilution protection. The Warrants will not be eligible for “cashless” exercise.

The securities issued at the second closing have not been registered under the Securities Act of 1933, as amended (the “Securities Act”), and sales were made pursuant to the exemptions from registration provided by Section 4(a)(2) of the Securities Act and/or Rule 506(b) of Regulation D (“Reg. D”) promulgated under the Securities Act because, among other things, Mayne Pharma is an “accredited investor” (as defined under Reg. D) and Mayne Pharma purchased the securities for its own account and not with a view to distributing or reselling the securities in violation of the Securities Act.

For more information regarding the Purchase Agreement and the transactions contemplated thereby and the Series B Preferred Stock and the Warrants, please refer to the January 8-K. The Certificate of Designation of the Series B Preferred Stock (as corrected pursuant to a Certificate of Correction), the Purchase Agreement and the form of Warrants are attached to the January 8-K as Exhibits 3.1, 3.2, 10.1 and 4.1, respectively. All descriptions of such documents are qualified in their entirety to the full text of Exhibits 3.1, 3.2, 10.1, and 4.1 thereto, which are incorporated therein by reference.

Item 8.01. Other Information.

On July 9, 2018, the Company issued a press release announcing the closing of the Second Tranche of financing. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Title</u>
99.1	<u>Press Release, dated July 9, 2018</u>

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: July 10, 2018

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca

Name: Nicholas J. Virca

Title: President and CEO



HedgePath Pharmaceuticals Closes Second Tranche of Mayne Pharma Financing

Additional \$1.6 million in preferred stock and warrant funding to support SUBA BCCNS regulatory program

HPPI to meet with FDA this month to discuss proposed 2018 NDA filing

TAMPA, Fla., July 9, 2018 /PRNewswire/ — HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI), a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer, announced that on July 5, 2018, it closed on a second tranche of funding from its majority stockholder, Mayne Pharma, as part of a securities purchase agreement executed in January 2018.

The \$1.6 million in new funding will support HPPI's ongoing efforts with the U.S. Food and Drug Administration (FDA) toward the anticipated filing of a new drug application (NDA) with the FDA later in 2018 for its SUBA BCCNS clinical and regulatory program.

As with the initial funding tranche that closed in January 2018, HPPI issued shares of Series B preferred stock and warrants to purchase common stock to Mayne Pharma in the current funding. After giving effect to this most recent funding, Mayne Pharma owns 53.6% of HPPI's outstanding common stock and beneficially owns 59.1% of HPPI's voting securities (including shares of common stock, and shares of common stock underlying the Series B preferred stock and all warrants to purchase common stock held by Mayne Pharma).

HPPI will be eligible to receive a third tranche of \$1.0 million on the same terms if its NDA for SUBA BCCNS is accepted by FDA by the end of this year (or in January 2019 if the NDA is filed in December 2018 and accepted within 30 days of filing).

Nicholas J. Virca, HPPI's President and Chief Executive Officer, stated "We are pleased to receive this additional capital, which takes our anticipated cash runway into the second quarter of 2019 and allows us to fully concentrate efforts on our SUBA BCCNS program. By way of update, on June 13, 2018, we filed a briefing package with FDA for our Phase 2(b) trial results in preparation for our face-to-face Type-C Meeting to occur with FDA on July 23, 2018. The July 23rd meeting is intended to provide us with further guidance regarding the regulatory pathway to potential approval of our SUBA-Itraconazole therapy for patients with BCCNS. We intend to provide updates when available through the remainder of the year as we proceed towards our anticipated NDA filing for SUBA BCCNS in 2018."

Readers are cautioned that no assurances can be given that the clinical study referenced herein will be found by FDA to be sufficient for an NDA filing, or if filed, that the NDA will be accepted and later approved by FDA.

About SUBA-Itraconazole

HPPI's lead drug candidate, SUBA-Itraconazole, is a patent-protected formulation of itraconazole, an approved oral antifungal drug that has been in use for over 25 years. HPPI is the exclusive U.S. licensee (through Mayne Pharma, the majority stockholder of HPPI) of SUBA-Itraconazole for the treatment of cancer. Prior to research at Johns Hopkins University, itraconazole was not known to have any target in mammalian cells. Investigators at Johns Hopkins discovered that itraconazole inhibits the hedgehog pathway by binding to a surface receptor in the pathway called Smoothened. Unlike generic itraconazole, that has poor and unpredictable bioavailability, SUBA-Itraconazole can be dosed at half the level of the generic formulation due to its superior bioavailability, which exceeds 90%. As such, HPPI believes that generic itraconazole cannot be substituted for SUBA-Itraconazole.

About BCCNS

HPPI's initial indication is for the orphan disease Basal Cell Carcinoma Nevus Syndrome, known as BCCNS. SUBA-Itraconazole has qualified under the FDA's Orphan Drug Designation Program as a potential therapy for BCCNS.

There is no approved pharmaceutical therapy for this familial cancer syndrome. There are estimated to be 10,000 patients in the U.S. with BCCNS. This is an autosomal dominantly inherited defect in the hedgehog pathway that causes the pathway to be up-regulated, resulting in hundreds or even thousands of basal cell carcinomas developing over the lifetime of the affected patients. In many types of cancers, the hedgehog pathway is basically hijacked by the cancer cells to assist their growth and metastatic spread, but in the case of basal cell carcinomas, whether in this hereditary syndrome or in the much more common, sporadic basal cell carcinomas, the hedgehog pathway has a mutation that makes it the sole driver of the development of BCC tumors. Inhibition of the pathway, then, can inhibit the appearance of new tumors, shrink existing tumors, and even cause some tumors to disappear altogether.

Cautionary Note Regarding Forward Looking Statements

This press release and any statements of representatives and partners of HedgePath Pharmaceuticals, Inc. (the "Company") related thereto contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the actual timing for, or actual results of, the Company's clinical trial described herein, the Company's meeting with FDA or the FDA's review of any trial data or New Drug Application submitted by the Company to FDA as described herein) may differ significantly from those set forth or implied in the forward-looking statements (and may further differ from the Company's previously announced interim study results). These forward-looking statements involve numerous 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.

For more information:

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