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): May 30, 2017

HedgePath Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-13467**	**30-0793665**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 Rule12b-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 8.01. Other Information.

On May 30, 2017, HedgePath Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has granted the Company's Type-C Guidance Meeting Request concerning the Company's ongoing, open-label Phase 2(b) clinical trial studying the effect of SUBA-Itraconazole oral capsules in patients with Basal Cell Carcinoma Nevus Syndrome, also known as Gorlin Syndrome. The press release also provided an update on such trial. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release, dated May 30, 2017, Type C Meeting Request grant and update on clinical trial.

Cautionary Note on Forward-Looking Statements

This Current Report, the press release included herein, 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 actual timing for, or actual results of, the Company's clinical trial described herein and in the press release which is an exhibit hereto or the review by the U.S. Food and Drug Administration of any related New Drug Application by 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: May 30, 2017

HEDGEPATH PHARMACEUTICALS, INC.

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

Exhibit 99.1

HedgePath Pharmaceuticals Announces Granting of
Type-C Meeting Request by FDA and Provides Positive Clinical Trial Update

35 subjects with Basal Cell Carcinoma Nevus Syndrome in ongoing Phase 2(b) trial have a median time on study of 32 weeks of dosing with SUBA™-Itraconazole

Third interim analysis shows 97% of patients avoiding surgery with 37% achieving a 30% or greater reduction in target tumor burden and complete disappearance of 28% of target lesions

FOR IMMEDIATE RELEASE — TAMPA, FLORIDA (May 30, 2017)– HedgePath Pharmaceuticals, Inc. (OTCQX:HPPI), a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer, announced the grant of a Type-C Guidance Meeting Request by the U.S. Food and Drug Administration (FDA) concerning further guidance from FDA for HPPI's ongoing, open-label Phase 2(b) clinical trial studying the effect of SUBA-Itraconazole (SUBA-Cap) oral capsules in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS), also known as Gorlin Syndrome.

Included in HPPI's meeting request were summary data for 35 patients enrolled in the trial relating to reduction in target tumor burden, safety and time on study, along with specific questions to FDA regarding further steps necessary for completion of the study and reporting of final data. HPPI noted in its meeting request to FDA that all patients on SUBA-Cap therapy had some degree of measurable target tumor burden decrease with a median time on study of 32 weeks and a dropout rate of only 11%.

As a result of FDA granting HPPI's meeting request, HPPI is required to file a complete background package for its Phase 2(b) trial results to FDA by mid-June 2017, and FDA has indicated its goal is to provide a written response to HPPI with further guidance before the end of July 2017.

Nicholas Virca, President and CEO of HPPI, stated that, "We reported to FDA that 37% of our patients in our Phase 2(b) trial have demonstrated an equal to or greater than 30% reduction in target tumor burden and there has been a complete disappearance of 28% of all target lesions across all subjects. We are testing SUBA-Cap therapy in BCCNS patients with a significant history of BCC surgeries and intend to further note in our background package that, for the 35 patients being dosed in our trial, the mean number of prior BCCs removed by surgery was 195 per patient, yet 97% of our study group have avoided surgery while on SUBA-Cap therapy. We are very pleased with these results and look forward to FDA's feedback as we move towards the conclusion and reporting of the results of this trial."

While these data appear to be predictive of the desired final study results while HPPI seeks further guidance from FDA, readers are cautioned that no assurances can be given that (i) the final study results will match these latest results or (ii) the study when and if completed will achieve its primary and secondary endpoints or (iii) that the study will be found by FDA to be sufficient for the filing of a New Drug Application (NDA) or (iv) if an NDA is filed, that it will be approved by FDA. Further, HPPI is not committing to providing further interim updates prior to the reporting of the final study results.

About BCCNS

BCCNS results from a genetic mutation which causes the Hedgehog pathway (a major regulator of processes in cells) to function improperly, leading to the chronic formation of basal cell tumors, including potentially disfiguring lesions on the face. Industry sources estimate that there are approximately 10,000 patients in the United States with BCCNS, which has qualified SUBA-Itraconazole under the FDA's Orphan Drug Designation Program.

About SUBA-Itraconazole

SUBA-Itraconazole is a patented and proprietary itraconazole formulation that enhances the absorption of itraconazole to improve the bioavailability of orally administered drugs that are poorly soluble. The U.S. rights to SUBA-Itraconazole for the treatment of cancer are exclusively licensed to HPPI by an affiliate of Mayne Pharma Group Limited. SUBA-Itraconazole was developed to improve absorption and significantly reduce variability compared to generic itraconazole. These benefits provide enhancements to patients and prescribers with reduced intra- and inter-patient variability, enabling a more predictable clinical response and a reduction in the active drug quantity to deliver the required therapeutic blood levels.

About HedgePath Pharmaceuticals

HedgePath Pharmaceuticals, Inc. (OTCQX:HPPI) is a clinical stage biopharmaceutical company that is seeking to repurpose the FDA approved antifungal pharmaceutical itraconazole as a potential treatment for cancer. HPPI is the exclusive U.S. licensee of a patented formulation of itraconazole, called SUBA-Itraconazole, which clinical studies have shown to have greater bioavailability than generic itraconazole.

The Hedgehog signaling pathway is a major regulator of cellular processes in vertebrates, including cell differentiation, tissue polarity and cell proliferation. Based on published research, HPPI believes that inhibiting the Hedgehog pathway could delay or possibly prevent the development of certain cancers in humans. Leveraging research undertaken by key investigators in the field, HPPI plans to explore the effectiveness of SUBA-Itraconazole as an anti-cancer agent and to pursue its potential commercialization. HPPI is headquartered in Tampa, Florida. For more information, please visit www.hedgepathpharma.com.

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 or the FDA’s review of any related New Drug Application by the Company) may differ significantly from those set forth or implied in the forward-looking statements (and may further differ from the interim study results described herein). 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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