# 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): January 24, 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))

**Item 7.01 Regulation FD Disclosure**

As previously reported in a Current Report on Form 8-K filed on December 2, 2016, in November 2016, HedgePath Pharmaceuticals, Inc. (the "Company") submitted a Breakthrough Therapy Designation Request ("BTDR") to the United States Food and Drug Administration ("FDA") for the Company's product candidate, SUBA™-Itraconazole for the treatment of non-metastatic basal cell carcinoma ("BCC") in patients with basal cell carcinoma nevus syndrome ("BCCNS"). On January 19, 2017, the Company received a written communication from the FDA stating that the Company's BTDR cannot be granted at this time due to the FDA's determination that, based on the clinical endpoints for the Company's ongoing, open label Phase II(b) clinical trial of SUBA-Itraconazole for the treatment of BCCNS, the Company is not seeking to treat a life-threatening aspect of BCC associated with BCCNS. The FDA advised that, in lieu of meeting that requirement, the Company may submit a new BTDR at such time as the Company is able to provide further evidence that administration of SUBA-Itraconazole results in delay or avoidance of the need for surgical excision of BCC tumors in BCCNS. The current study endpoint (as previously approved by the FDA) is a 30% or greater reduction in target tumor burden and, to-date only one subject in the Company's current trial has required surgical intervention for a single tumor.

The FDA further advised that, in order to submit a revised BTDR for SUBA-Itraconazole for the treatment of BCCNS, the Company must provide data for at least 24 weeks' duration of confirmed clinical responses for subjects being studied in the Company Phase II(b) trial according to a central independent review committee. As a result of this development, the Company intends to continue its planned recruitment and treatment of patients in the Phase II(b) trial in order to collect further data regarding duration of response for those subjects who have completed 24 weeks or more in the trial. Thirteen such subjects have qualified to date. The Company will continue to evaluate whether a revised BTDR submission is appropriate.

Importantly, these developments are not expected to impact the Company's overall anticipated timing for conclusion of the study (if primary endpoints are met) that would support the filing of a New Drug Application filing with the FDA later this year for potential approval of SUBA-Itraconazole for the treatment of BCCNS.

Separately, in December 2016, the Company entered into an agreement with a leading strategic advisory company, which specializes in the arena of orphan drugs, to provide the Company with additional assistance in the development of its commercial strategy for SUBA-Itraconazole for treatment of BCC in patients with BCCNS. This effort is intended to assist the Company's determination of its pricing and launch strategy for 2018, assuming ultimate FDA approval of SUBA-Itraconazole as a treatment for BCCNS.

**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) of the Company's clinical trial of SUBA-Itraconazole for the treatment of BCCNS and the development of additional product candidates, (ii) of regulatory review of SUBA-Itraconazole and derivative products of such or (iii) sales results for SUBA-Itraconazole, if approved by the FDA) 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: January 24, 2017

HEDGEPATH PHARMACEUTICALS, INC.

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