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): October 5, 2017 (October 5, 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 October 5, 2017, Nicholas J. Virca, the President and Chief Executive Officer of HedgePath Pharmaceuticals, Inc. (the "Company"), will be making a presentation at 3:30 pm, Eastern Time, as part of the OTCQX Virtual Investor Conference. Such presentation as well as a replay of Mr. Virca's remarks will be available on the Company's website at http://www.hedgepathpharma.com and a copy of the investor presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Mr. Virca's presentation includes updated interim results of the Company's ongoing, open label Phase 2(b) study of the use of SUBA™-Itraconazole to treat basal cell carcinoma (BCC) in patients with Basal Cell Carcinoma Nevus Syndrome ("BCCNS"), also known as Gorlin Syndrome. The Company reported that recruitment for such trial has been completed, with 38 patients having been dosed with SUBA-Itraconazole, and 10 patients currently in active treatment. The presentation also addresses details of FDA's guidance from its recent Type-C Meeting, and discloses that more than 50% of target lesions across all patients in the trial have responded to treatment with a 30% or greater reduction in tumor size from baseline and that duration of response in those lesions has been greater than one year.

The presentation also discloses that the Company (i) is conducting individual patient data reviews, analyses and follow-up regarding its Phase 2(b) trial results during the fourth quarter of 2017, (ii) plans to lock its database and complete its Clinical Study Report during the first quarter of 2018 and (iii) plans to file a pre-NDA (New Drug Application) Meeting Request with U.S. Food and Drug Administration ("FDA") by the end of the second quarter of 2018.

The presentation also discloses that the Company is conducting key opinion leader studies to better determine its future direction for lung and prostate cancer clinical development programs for SUBA-Itraconazole as an anti-cancer therapy.

The Company notes that while the data disclosed herein appear to be predictive of the desired final study results for the Company's clinical trial described herein, 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 an NDA or (iv) if an NDA is filed, that it will be approved by FDA. Further, by making the disclosures herein contained, the Company is not committing to providing further interim updates prior to the reporting of the final study results.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Investor Presentation.

Cautionary Note on Forward-Looking Statements

This Current Report, the presentation 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 presentation 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: October 5, 2017

HEDGEPATH PHARMACEUTICALS, INC.

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

HedgePath Pharmaceuticals, Inc.

exploring new pathways to cancer therapy

Cautionary Note on Forward-Looking Statements; No Offer of Securities

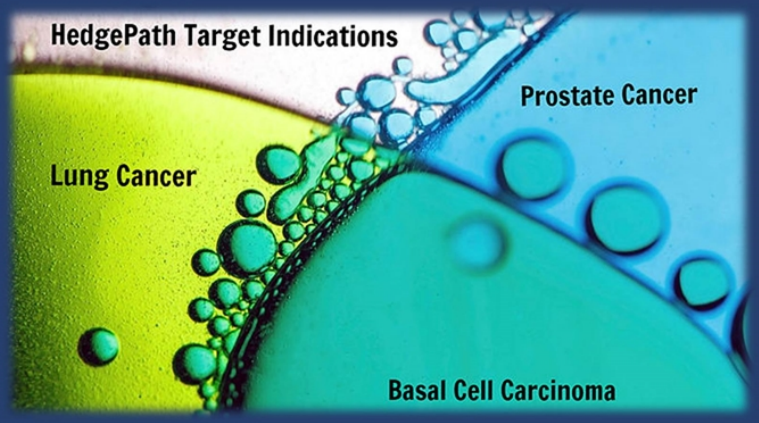
This presentation includes or incorporates by reference statements that constitute "forward-looking statements" within the meaning of the U.S. federal securities laws. These statements relate to future events or to our future performance, and involve significant known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in these forward-looking statements. These statements include, but are not limited to, information or assumptions about our clinical development programs, our expenses, capital and other expenditures, our financing needs and plans, our capital structure, and management's plans, goals and objectives for future operations and growth. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "continue," "or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statement since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could cause actual performance or results to differ materially from those expressed in or suggested by forward-looking statements.

Important factors that could cause such differences include, but are not limited to: (i) risks and uncertainties associated with our research and development activities, including our anticipated clinical trials; (ii) our dependence on Mayne Pharma for the supply of our product candidate and key intellectual property; (iii) our ability to raise capital when needed; (iv) the timing of and our ability to achieve U.S. or international regulatory approvals for our product candidates; (v) our dependence on others to conduct clinical of, and to manufacture and market, our product candidates; (vi) our ability to gain market acceptance for our product candidates; (vii) our ability to maintain or protect the validity of patents and other intellectual property; (viii) our ability to secure registration for our current and future patent applications; and (ix) our ability to attract and retain key personnel.

Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material or even significant respects from those projected in these forward-looking statements. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

This presentation does not constitute an offer or any securities for sale or solicitation of an offer to buy any securities, nor shall there be any sale of the securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction.

HPPI OTCQX – Headquartered in Tampa, Florida



Hedgehog Pathway

- Transmits signals for embryonic development
- Regulates adult stem cells and tissue maintenance

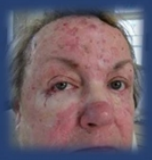
Significant Molecular Pathway in Cancer

- A Validated Cancer Target
- Two FDA approved Hh Inhibitors
- Toxicity is a major issue

Basal Cell Carcinoma (Nevus Syndrome)

Hereditary BCC: BCCNS occurs in Gorlin Syndrome

Autosomal Dominant Inherited Disorder

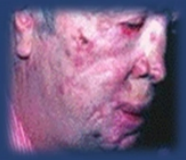


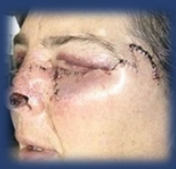
- Gorlin Syndrome is an Orphan Disease : 10,000 Patients in the U.S.
- Genetic abnormality in PTCH Gene: Life-long formation of BCC tumors

Sources: Skin Cancer Foundation 2014, BCCNS LS Network 2015

Unmet Clinical need in Patients with BCCNS

- Standard of care is surgery resulting in facial disfigurement
- Hedgehog signaling must be suppressed on a continual basis to inhibit tumor development and growth
- Need for a chronic low-toxicity therapy to minimize surgical procedures





Unmet Clinical need in Patients with BCCNS

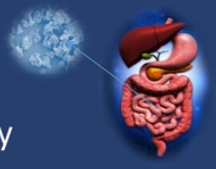
Vismodegib and Sonidegib FDA-Approved

- Limited to Locally Advanced and/or Metastatic BCC
- Response rates (30% to 58% range) in advanced disease
- Serious Side-Effects (Grade 2 – 4) limit even short-term use
- Neither approved for BCCNS – No insurance coverage
- 54% drop out rate – vismodegib clinical testing for BCCNS

SUBA-Itraconazole™ Positioned to Fill Unmet Medical Need

Super Bioavailability (SUBA-Cap)

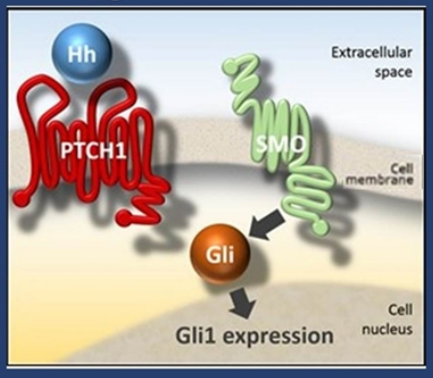
Polymer - drug dispersion technology



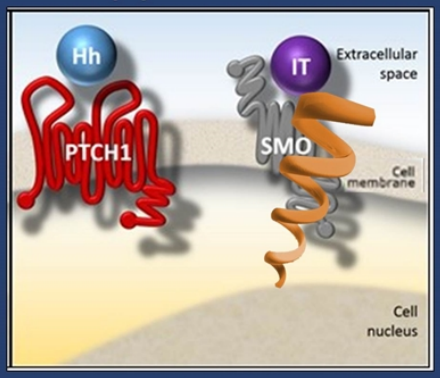
95% bioavailability vs. generic itraconazole at 55%

- More consistent blood levels to improve therapeutic effect
- Oral drug delivery - therapeutic dosing with limited toxicity
- Well suited for chronic use in patients with BCCNS

Targeted Molecular Therapy - Itraconazole



PTCH is mutated in BCCNS and does not inhibit SMO which leads to Gli1 expression (BCC)



Itraconazole binds to SMO and inhibits activation of the Gli1 pathway which causes BCC tumors

BCCNS Clinical Strategy & Development

Phase 2(b) SCORING* Open Label Clinical Trial

First patient dosed in September 2015
Sites in FL, MI, NY, PA and CA
All investigators experienced with BCCNS
Mean of 195 prior BCC excisions per patient
Completed Recruiting
38 patients treated to date
- 10 patients in active treatment
- 10 patients in follow-up
- 18 patients off study

Only one surgery for a BCC target lesion

* SUBA-Cap Objective Response in Gorlins

FDA Guidance from Type C Meeting

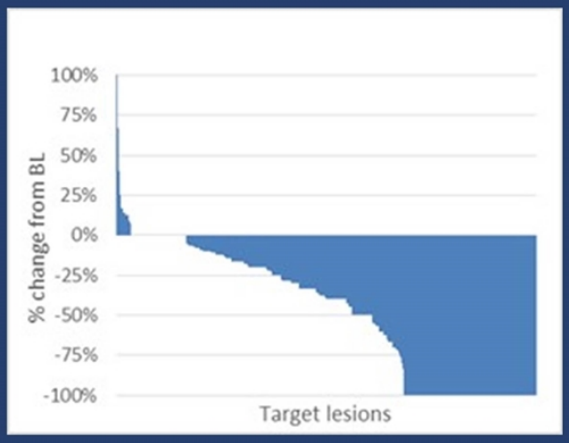
A single-arm open label trial can lead to approval

- If the BCC tumor responses are robust
- If there is a meaningful duration of response
- If tumor responses occur in serious lesions that predict for clinical benefit, such as the delay or elimination of disfiguring surgeries

"FDA agrees that RECIST may not be optimal for BCCNS"

Ph2(b) Results for BCC in BCCNS Patients

Robust Response of Target Lesions to SUBA-Cap Therapy



Target Lesion Response Rates

All Target Lesions	(N=477)	53.7%
Serious TLs	(N=90)	55.6%
Other TLs	(N=387)	53.2%

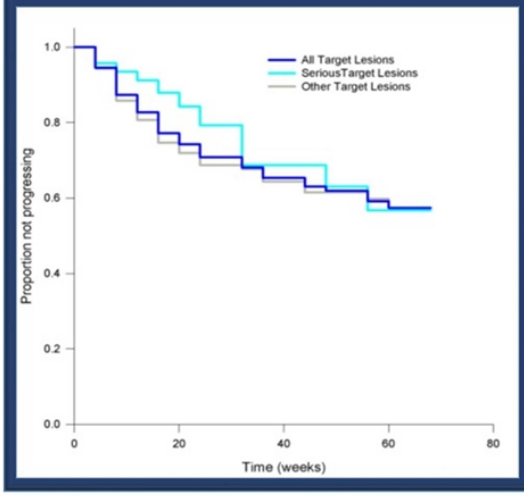
Response defined as ≥ 30% size reduction from baseline

Serious TLs defined as ≥ 6mm on the face or ≥ 20mm elsewhere*

* Bowen, White & Gerwels 2005;
Puig, Berrocal 2015;
EU Dermatology Forum, 2015

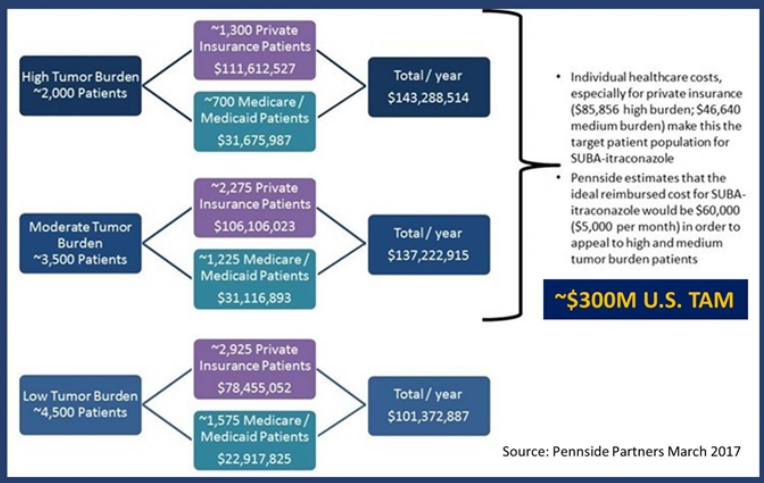
Ph2(b) Results for BCC in BCCNS Patients

Durable Response for 256 Responding Target Lesions with limited side-effects



- Median time on study 38 weeks
- Up to 90 weeks for some patients
- Only 1 Target Lesion Required Surgery
- 11% drop-out due to side-effects
- No hair loss
- No loss of taste
- No severe muscle spasms

Product Positioning – Compete against Surgical Procedures



SUBA-Cap Regulatory Strategy

505(b)(2) Regulatory Pathway – repurposing FDA-approved itraconazole

- Q4 2017 Individual Patient Data Review, Analysis & Follow-up
- Q1 2018 Database Lock and Clinical Study Report
- Q2 2018 Pre-NDA FDA Meeting Request

Orphan Designation for BCCNS:

- FDA recognizes that BCCNS is not a subset of Sporadic BCC
- 7 years market exclusivity post-approval
- 50% tax credit on cost of US clinical trials

Lung Cancer Opportunity

85% of lung cancers are NSCLC (non small cell lung cancer)

SUBA-Itraconazole oral therapy may extend survival in late-stage disease

Target: 58,000 Stage IV Non-Squamous NSCLC patients in the U.S.
Goal: demonstrate efficacy in double-blind placebo controlled clinical trial

Currently conducting Key Opinion Leader study on potential for SUBA-Cap in NSCLC

Phase 2 Physician-Sponsored JHU Trial
Median Survival: improved from 8 months
*to 32 months in Phase II Physician-Sponsored Trial**

* *Journal of Thoracic Oncology,* May 2013 -Johns Hopkins University, Rudin, et. al

Prostate Cancer Opportunity

ADT (androgen deprivation therapy) has no evidence of clinical benefit in men who have castrate-resistant non-metastatic prostate cancer
Itraconazole does not lower testosterone levels causing loss of libido

Target: 190,000 men who have castrate-resistant non-metastatic PC in the U.S.
Goal: Demonstrate efficacy for delaying time to bone metastases in men with NMCRPC in a double-blind placebo controlled trial

Currently conducting Key Opinion Leader study on potential for SUBA-Cap in PC

*90% of men with advanced disease in the Phase II Physician-Sponsored Trial who achieved therapeutic levels of itraconazole had dramatic reductions in PSA progression**

* Johns Hopkins University, Antonarakis, et. al, *The Oncologist*, February 2013

HedgePath Pharmaceuticals, Inc.

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