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): December 17, 2018

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 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 1.01. Entry into a Material Definitive Agreement.

Overview

On December 17, 2018 (the "Effective Date"), HedgePath Pharmaceuticals, Inc. (the "Company") entered into the following related agreements (collectively, the "Transaction Documents"):

1. An agreement, by and among the Company, and Mayne Pharma Ventures Pty Ltd, the Company's majority stockholder ("Mayne Pharma"), and Mayne Pharma International Pty Ltd ("Mayne Pharma International") (the "Agreement");

2. Third Amended and Restated Supply and License Agreement, by and between the Company and Mayne Pharma (the "Third Amended SLA"), which amends and restates the Company's Second Amended and Restated Supply and License Agreement with Mayne Pharma, dated as of May 15, 2015 (as amended immediately prior to the Effective Date, the "Second Amended SLA"); and

3. Amended and Restated Sublicense Agreement, by and between the Company and Mayne Pharma International (the "Amended and Restated Sublicense Agreement"), which amends and restates that certain Sublicense Agreement, dated August 31, 2015, between the Company and Mayne Pharma International, as amended.

In addition, pursuant to the terms of the Agreement, the Company and Mayne Pharma agreed to vote in favor of the adoption of an Amended and Restated Certificate of Designation of Series B Convertible Preferred Stock of the Company (the "Amended and Restated COD"), which amends and restates the Certificate of Designation of Series B Convertible Preferred Stock of the Company, dated January 8, 2018 (as corrected, the "Original COD"), to remove the redemption rights of the Series B Convertible Preferred Stock of the Company as described below. As of the Effective Date, all 5,797,102 outstanding shares of such preferred stock (the "Series B Preferred Stock") are held by Mayne Pharma.

The Transaction Documents resulted from negotiations regarding the existing right of Mayne Pharma under the Second Amended SLA to elect to assume control of the regulatory and clinical development program for SUBA®-Itraconazole (the "Product") for the treatment of basal cell carcinoma nevus syndrome ("SUBA-Itraconazole BCCNS") (a product licensed to the Company for exploitation in the United States (the "Territory") under the Second Amended SLA) after December 31, 2018 in exchange for a royalty on any future net sales if a New Drug Application ("NDA") for SUBA-Itraconazole BCCNS was not accepted for filing by U.S. Food and Drug Administration ("FDA") by December 31, 2018 (subject to limited extension if the NDA were filed in December 2018). As previously announced, based on unforeseen requirements imposed by FDA in September 2018, the Company determined that it would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus the Company commenced negotiations with Mayne Pharma to transfer SUBA-Itraconazole BCCNS in advance of December 31, 2018 on negotiated terms deemed beneficial to the Company.

The Transaction Documents were negotiated and approved on behalf of the Company by a special committee of disinterested, independent members of the Company's Board of Directors (the "Board") which was formed on October 26, 2018 for such purpose. The special Board committee consisted of W. Mark Watson (serving as Chairman), R. Dana Ono and Robert Martin, who are each disinterested with respect to Mayne Pharma.

Agreement

Pursuant to the terms of the Agreement, on the Effective Date, Mayne Pharma (in its capacity as the holder of more than 50% of the outstanding voting securities of the Company) executed and delivered to the Company a written stockholder consent in lieu of a special meeting of the stockholders of the Company (the "Stockholder Consent") which consented to the taking of the following actions:

(a) the adoption of the Amended and Restated COD;

(b) the election of each E. Brendan Magrab, W. Mark Watson, Dr. R. Dana Ono, Stefan J. Cross and Robert D. Martin (each a current member of the Board) to serve on the Board for a one-year term that expires at the next annual meeting of the Company's stockholders or until his earlier death, resignation or removal; and

(c) the approval of an increase in the size of the Company's 2014 Equity Incentive Plan (the "EIP") by 11,000,000 shares of common stock, par value $0.0001 per share (the "Common Stock") from 32,583,475 shares to 43,583,475 shares.

In furtherance of the matters undertaken pursuant to the Stockholder Consent, the Company will prepare and file with the Securities and Exchange Commission a written information statement of the type contemplated by Rule 14c-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), containing the information specified in Schedule 14C under the Exchange Act concerning the actions taken pursuant to the Stockholder Consent (as amended and supplemented, the "Information Statement") and thereafter will promptly mail to the Company's stockholders notice of such action by written consent as required by Section 228(e) of the Delaware General Corporation Law.

In addition, pursuant to the Agreement, for the period beginning on the Effective Date and ending three (3) years from the Effective Date, in the event that the Company asks its stockholders (whether at a meeting of stockholders or pursuant to a written consent of stockholders) to vote on or approve a proposal to effect a reverse split of the Company capital stock for the purpose of uplisting the Common Stock to a U.S. national securities exchange (a "Reverse Stock Split Proposal"), Mayne Pharma (on behalf of itself and its affiliates) has agreed to vote or cause to be voted (in person, by proxy or by action by written consent, as applicable) all shares of the Company's voting capital stock that either Mayne Pharma then owns or over which Mayne Pharma has voting control in favor of the adoption and approval of any such Reverse Stock Split Proposal. The Agreement further provides that the Reverse Stock Split Proposal may take the form of an authorization based on a range of ratios for the reverse stock split, with authority being granted to the Board (or a designated committee thereof) to determine the final ratio of the reverse stock split, provided such range is reasonable in connection with the uplisting of the Common Stock to a U.S. national securities exchange. No assurances are given that the Company will seek an uplisting to a U.S. national securities exchange or implement a reverse stock split of its Common Stock.

Also, pursuant to the Agreement, Mayne Pharma consented and agreed (under the terms of agreements previously executed with the Company) to an increase in the number of shares of Common Stock that the Company may issue under the EIP to 17,624,000 shares from the current limit of 6,624,000 shares, with the agreement and understanding that such increase will be utilized by the Company during the period from the Effective Date through December 31, 2021.

Third Amended and Restated Supply and License Agreement

Pursuant to the Third Amended SLA, as of the Effective Date, Mayne Pharma has assumed control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS and immediately assumed responsibility for all expenses related to exploiting the SUBA-Itraconazole product in the BCCNS field, provided that the Company continues to be responsible for all liabilities related to the product in the United States prior to the Effective Date. The Third Amended SLA will continue in effect on an exclusive basis in the Territory on substantially the same terms as were provided for under the Second Amended SLA, except as described below.

In consideration of the transfer to Mayne Pharma of the SUBA-Itraconazole BCCNS clinical data and regulatory rights, the Company will receive the following consideration:

(a) a 9% quarterly cash royalty on future net sales, if any, of SUBA-Itraconazole product in the BCCNS field in the United States (the "Royalty"), from which certain royalties owed by the Company to Mayne Pharma for access to certain patents would be funded.

(b) Mayne Pharma's agreement to advance funds to the Company in an aggregate amount of up to $5 million (each, an "Advance", and collectively, the "Advances") on the following terms and conditions:

  (i) As of the Effective Date, Mayne Pharma shall make an Advance to the Company of $500,000;

  (ii) Within three (3) business days following the completion of the agreed upon activities associated with transferring the SUBA-Itraconazole BCCNS product to Mayne Pharma, Mayne Pharma must make an Advance to the Company of $1 million;

  (iii) If, and only if, the Company's Phase 2(b) clinical trial data have been provided to Mayne Pharma in all material respects so as to allow Mayne Pharma to assume control of SUBA-Itraconazole BCCNS in the Territory, upon the earlier of June 30, 2019 or the acceptance for filing by FDA of an NDA for the SUBA-Itraconazole BCCNS, Mayne Pharma must make an Advance to the Company of $1,500,000; and

  (iv) If the Company raises aggregate gross proceeds of more than $3 million from the sale of new common stock, preferred stock equity subordinate to the preferred stock held by Mayne Pharma or warrants ("New Securities") to third parties in one or more equity financings by June 30, 2021 (the "Equity Funding Achievement"), the Company may request additional Advances of up to an amount equal to $2 million less the amount of aggregate gross proceeds received by HPPI from Mayne Pharma from the sale of New Securities if Mayne Pharma elects to participate in such equity financings pursuant to contractual pro rata participation rights contained in the Third Amended SLA.

(c) The field covered by the Third Amended SLA was amended to specifically include only the following indications: (i) any prostate cancer, prostatic intraepithelial neoplasia and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia, and (iii) familial adenomatous polyposis, colorectal polyps and Barett's esophagus (the "Field"). The Company's work on these indications will no longer be tied to the achievement of clinical or commercial target dates as they were under the Second Amended SLA.

(d) Mayne Pharma will continue to provide quantities of Product drug and placebo oral capsules without charge for the Company's SUBA-Itraconazole Prostate clinical studies and for future indications as agreed to by the parties.

(e) Pursuant to the Third Amended SLA, unlike under the Second Amended SLA, Mayne Pharma has licensed to the Company the right to use all pre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to the Product anywhere in the world for its activities under the Third Amended SLA.

The Advances are structured as advances against the future Royalty, if any, owed by Mayne Pharma to the Company; provided that if SUBA-Itraconazole-BCCNS is not approved in the U.S. by December 31, 2023, Mayne Pharma may convert such Advances into Common Stock based on a ten percent (10%) discount to the then current market value of the Common Stock. With respect to each Advance made by Mayne Pharma prior to the receipt of FDA approval of an NDA for SUBA-Itraconazole BCCNS, each $0.75 increment of each such Advance will be credited and set off against each $1.00 increment of Royalty owed to the Company, and with respect to each Advance made by Mayne Pharma following the receipt of FDA approval of an NDA for SUBA-Itraconazole BCCNS, each $0.85 increment of each such Advance will be credited and set off against each $1.00 increment of Royalty owed to the Company.

In addition, if, prior to June 30, 2021, the Company has not fulfilled the Equity Funding Achievement, Mayne Pharma shall have the right to satisfy all of its remaining Royalty obligations by making a single lump sum payment to the Company in an amount equal to seventy percent (70%) of the fair market value of the remaining royalties payable to the Company as determined by an independent appraisal process.

Also, for so long as the Third Amended SLA is in effect, the Company must seek the prior written consent of Mayne Pharma before it disposes of the whole or a substantial part of its assets, operations or business, such consent not to be unreasonably withheld, conditioned or delayed. In addition, the Company must notify Mayne Pharma before it undergoes any change in its direct or indirect Control (as defined below). If, acting reasonably, Mayne Pharma considers that such change will have a material, negative impact on its rights under the Third Amended SLA, Mayne Pharma may terminate the Third Amended SLA by giving written notice to the Company; provided, however, that the Company shall not be deemed to have undergone a change in its direct or indirect Control if Mayne Pharma ceases to own more than 50% of the outstanding voting power of the Company solely as a result of (i) the Company's issuance of securities in an equity financing with respect to which Mayne Pharma has preemptive or similar contractual rights to participate on the same terms and conditions as investors in the financing and (ii) Mayne Pharma's election not to participate in such financing on the same terms and conditions as investors in the financing. For purposes of the Third Amended SLA, the term "Control" means having the power to exercise or control the right to vote attached to 50% or more of the issued voting equity in that party, to appoint one half or more of the directors to the board of directors, or the managers as applicable, of the party, or to determine substantially the conduct of the party's business activities.

The Third Amended SLA also gives Mayne Pharma the right to convert the Company's rights licensed from Mayne Pharma under the Third Amended SLA to a non-exclusive license if the FDA has not approved an NDA filed by the Company for the Product in part of the Field within eight (8) years from the Effective Date.

Amended and Restated Sublicense Agreement

The Amended and Restated Sublicense Agreement amends and replaces a similar agreement entered into between the Company and Mayne Pharma International, dated as of May 15, 2015, under which Mayne Pharma International sublicensed to the Company the exclusive U.S. rights to two certain third party patents relating to the use of itraconazole as a treatment for cancer and age-related macular degeneration. The Amended and Restated Sublicense Agreement amends the required payments to Mayne Pharma for certain development-related milestone payments related to SUBA-Itraconazole BCCNS and allows for the termination of the Amended and Restated Sublicense Agreement if the Third Amended SLA expires or is terminated.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

The information regarding the election of the members of the Board set forth in Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

Amended and Restated Certificate of Designation of Series B Convertible Preferred Stock

The Amended and Restated COD restates the Original COD solely to remove Mayne Pharma's right to redeem the Series B Preferred Stock after January 8, 2023. This amendment will allow the Company to fully classify the Series B Preferred Stock as equity on its balance sheet. No other amendments were made to the preferences and rights of the Series B Preferred Stock. The Amended and Restated COD will be filed with the Secretary of State of Delaware 20 calendar days following the mailing of the Information Statement to the Company's stockholders

The foregoing is merely a summary of the Transaction Documents. All descriptions of the Transactions Documents contained herein are qualified in their entirety to the full text of such documents, which will be filed as Exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Item 8.01. Other Information.

On December 17, 2018, the Company issued a press release announcing the execution of the Transaction Documents. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Title
99.1	Press Release, dated December 17, 2018

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 anticipated benefits of the Transaction Documents) 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: December 17, 2018

HEDGEPATH PHARMACEUTICALS, INC.

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

Exhibit 99.1

HedgePath Pharmaceuticals and Mayne Pharma
Enter into Updated Collaboration and Funding Agreements

HPPI to transfer SUBA-Itraconazole BCCNS clinical program to Mayne Pharma in consideration of up to $5 million in new funding from Mayne Pharma and a 9% royalty on future SUBA-Itraconazole BCCNS sales in the U.S.

With new funding, HPPI to move towards IND filing during 2019 and recruitment to initiate human trials for SUBA-Itraconazole Prostate

HPPI also to pursue expansion of product candidate pipeline withnon-SUBA itraconazole analogue technology with University of Connecticut

FOR IMMEDIATE RELEASE — TAMPA, FLORIDA (December 17, 2018)– HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI) announced today that it has entered into a revised Supply and License Agreement (SLA) with its majority stockholder Mayne Pharma Ventures Pty Ltd (Mayne Pharma), an affiliate of Mayne Pharma Group Limited (ASX: MYX).

Under the new SLA, Mayne Pharma will assume control of the regulatory and clinical development program for SUBA®-Itraconazole for the treatment of basal cell carcinoma nevus syndrome (SUBA-Itraconazole BCCNS) in anticipation of conducting a global Phase 3 pivotal clinical trial based on results achieved in the Phase 2(b) trial conducted by HPPI in the U.S. Mayne Pharma will immediately assume responsibility for all future SUBA-Itraconazole BCCNS-related expenses.

In consideration of the transfer to Mayne Pharma of the SUBA-Itraconazole BCCNS clinical data and regulatory rights, HPPI will receive the following consideration:

- a 9% royalty on future net sales of SUBA-Itraconazole BCCNS in the U.S. (subject to deductions for HPPI's continuing access to certain third party patents).
- $3 million of new funding in stages tied to the transfer of SUBA-Itraconazole BCCNS to Mayne Pharma. This funding, which is expected to be completed by mid-2019, will be non-dilutive since it is structured as a discounted advance on the future 9% royalties receivable by HPPI (although if SUBA-Itraconazole BCCNS is not approved in the U.S. by the end of 2023, Mayne Pharma may recapture such discounted advances in the form of common stock of HPPI at the then current market value of HPPI's common stock).
- In addition, if HPPI is able to secure $3 million in new funding from third parties by June 30, 2021, at HPPI's election, Mayne Pharma will make additional royalty advances of up to $2 million on the same terms. This commitment by Mayne Pharma of an additional $2 million in funding may alternatively be satisfied if Mayne Pharma elects to participate in future equity financings of HPPI.
- The SLA will continue in effect, and the exclusive field covered by the SLA has been focused to specifically comprise prostate, lung and certain other non-cancer proliferation disorders. Mayne Pharma will have the right to exploit SUBA-Itraconazole in all other

fields in the U.S., including BCCNS. Importantly, HPPI's continued right to work on these indications will no longer be tied to the achievement of clinical or commercial target dates. HPPI is now working towards the submission of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for SUBA-Itraconazole for the treatment of prostate cancer (SUBA-Itraconazole Prostate), with the goal of having that IND cleared, allowing HPPI to proceed to recruitment for initiating human trials.

- In addition, Mayne Pharma will continue to provide quantities of SUBA-Itraconazole drug and placebo oral capsules for HPPI's SUBA-Itraconazole Prostate clinical study, with an agreed amount to be provided without charge.
- In addition, unlike under the previous SLA, Mayne Pharma has licensed to HPPI the right to use allpre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to the current SUBA-Itraconazole formulation anywhere in the world for HPPI's activities in the U.S. in a specified field under the new SLA.
- In addition, Mayne Pharma has agreed that it will support a reverse stock split of HPPI's common stock should HPPI request this in connection with HPPI's exploration of an uplisting to a senior stock exchange and associated capital raise.
- Finally, Mayne Pharma has agreed to amend the terms of its existing Series B Convertible Preferred Stock to remove Mayne Pharma's future right to require HPPI to redeem such securities, which will allow HPPI to fully classify such preferred stock as equity on its balance sheet.

Additional details of the transaction will be available in a Current Report on Form8-K to be filed by HPPI with the SEC.

This transaction arose out of a right of Mayne Pharma under the previous SLA to assume control of SUBA-Itraconazole BCCNS after December 31, 2018 for a 9% royalty on future net sales of SUBA-Itraconazole BCCNS in the U.S. if a New Drug Application (NDA) for SUBA-Itraconazole BCCNS was not accepted for filing by FDA by December 31, 2018. As previously announced, based on unforeseen requirements imposed by FDA in September 2018, HPPI determined that it would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus HPPI commenced negotiations with Mayne Pharma to transfer SUBA-Itraconazole BCCNS in advance of December 31, 2018 on negotiated terms beneficial to HPPI. During these negotiations, HPPI actively undertook activities aimed at filing the SUBA-Itraconazole BCCNS NDA within the timeframes required under the SLA, but ultimately concluded in its business judgment based on significant regulatory guidance that such a filing, even if it could be accomplished, would imperil the regulatory acceptance and viability of the SUBA-Itraconazole BCCNS asset to the detriment of HPPI's shareholders. HPPI believes that Mayne Pharma's indication that it plans to undertake a Phase 3 study of SUBA-Itraconazole BCCNS validates HPPI's strategic conclusions related to the present transaction with Mayne Pharma.

The transaction was negotiated and approved on behalf of HPPI by a special committee of disinterested, independent members of HPPI's Board of Directors.

Nicholas Virca, HPPI's President and Chief Executive Officer, stated that "It has taken a considerable effort to reach these important agreements with our majority stockholder, Mayne Pharma, and we thank them for working with us to achieve this outcome. We believe, taking into consideration all of the facts and circumstances, that enabling Mayne Pharma to pursue SUBA -Itraconazole BCCNS on advantageous terms to HPPI gives us a fresh start as a research and development company, with $3 million of near term funding and the possibility of an additional $2 million, a less restrictive SLA with Mayne Pharma with no development targets or deadlines, and access to worldwide SUBA-Itraconazole data to support our future business plans."

"Moving forward, our 2019 focus is to seek apre-IND meeting with FDA, with the goal of reaching agreement with FDA on the endpoints for initiating a clinical trial of SUBA-Itraconazole Prostate. We commissioned a market study which included interviews with key opinion leaders to help us target a potential therapy for over 27,000 men who have metastatic castrate resistant prostate cancer who are no longer responding to androgen deprivation therapy (also known as ADT). As with SUBA-Itraconazole BCCNS, we intend to follow the 505(b)(2) regulatory pathway to accelerate our clinical testing program for SUBA-Itraconazole Prostate. Our goal will be to have our IND for SUBA-Itraconazole Prostate cleared by FDA and to begin efforts in recruiting patients for the prostate clinical trial before the end of 2019" continued Mr. Virca.

"Beyond SUBA-Itraconazole, we are planning to work with other compounds for the treatment of cancer in an effort to expand our product candidate pipeline. As announced earlier this year, we hold a world-wide exclusive option from the University of Connecticut regarding its patented chemical analogues of itraconazole to treat cancerous and non-cancerous indications. These next generation formulations of itraconazole appear to have reduced off-target side effects while exhibiting improved pharmacokinetic properties and a reduced concern associated with the use of many other drugs that are contraindicated for patients receiving itraconazole. A preclinical testing program is now underway to assess the effectiveness of the lead compound in treating certain cancers via hedgehog pathway inhibition in a well-established mouse model. If the pre-clinical results prove to be encouraging, we would expect to exercise our option and to begin efforts to outsource manufacturing to produce cGMP product as part of a program to move into human testing in 2020" concluded Mr. Virca.

Scott Richards, Mayne Pharma's Chief Executive Officer, stated "Mayne Pharma remains committed to supporting HPPI and its leadership to pursue the clinical development, registration and commercialization of SUBA-Itraconazole for the treatment of oncology indications in the U.S. The management of HPPI has successfully progressed SUBA-Itraconazole BCCNS through its first major clinical program. We believe out-licensing our SUBA-Itraconazole intellectual property in the U.S. in this focused field through the partnership with HPPI provides Mayne Pharma shareholders with a significant stake in potentially multiple novel cancer programs. We look forward to working with HPPI to further these development programs."

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 development activities described herein) may differ significantly from those set forth or implied in the forward-looking statements (and may further differ from the interim study results previously disclosed by the Company). 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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