UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2019

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to _____

Commission file number 001-13467

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

Delaware	**30-0793665**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4830 W. Kennedy Blvd., Suite 600 Tampa, FL	**33609**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number (including area code): 813-509-2417

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or anon-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	N/A	N/A

As of May 9, 2019 there were 370,446,185 shares of company common stock issued and outstanding.

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HedgePath Pharmaceuticals, Inc.

Quarterly Report on Form 10-Q

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HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
AS OF MARCH 31, 2019 AND DECEMBER 31, 2018

	(Unaudited) March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,130,724	$ 1,108,713
Prepaid expenses	46,152	41,296
Total current assets	1,176,876	1,150,009
Other long-term assets	75,669	82,992
Total assets	$ 1,252,545	$ 1,233,001
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 245,152	$ 384,829
Dividends payable	49,315	99,945
Other liabilities	30,353	215,876
Total current liabilities	324,820	700,650
Deferred revenue, related party	1,500,000	500,000
Total liabilities	1,824,820	1,200,650
Commitments and contingencies (note 5)	—	—
Stockholders' (deficit) equity:		
Series A Preferred Stock, $0.0001 par value; 500,000 shares authorized; no shares issued and outstanding	—	—
Series B Convertible, Redeemable, Preferred Stock, $0.0001 par value; 7,246,377 shares authorized; 5,797,102 shares issued and outstanding at March 31, 2019 and December 31, 2018	3,960,866	3,960,866
Undesignated Preferred Stock, $0.0001 par value; 2,253,623 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized; 370,446,185 and 370,084,064 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	37,045	37,008
Additional paid-in capital	49,246,060	49,015,120
Accumulated deficit	(53,816,246)	(52,980,643)
Total stockholders' (deficit) equity	(572,275)	32,351
Total liabilities and stockholders' (deficit) equity	$ 1,252,545	$ 1,233,001

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenues:	$ —	$ —
Expenses:		
Research and development expenses	196,774	673,970
General and administrative	594,826	500,846
Total Expenses:	791,600	1,174,816
Loss from operations	(791,600)	(1,174,816)
Interest income	5,312	4,222
Net loss	(786,288)	(1,170,594)
Preferred stock dividend	(49,315)	(26,630)
Net loss applicable to common stockholders	$ (835,603)	$ (1,197,224)
Basic and diluted net loss applicable to common stockholders per share	$ (0.00)	$ (0.00)
Weighted average common stock shares outstanding – basic and diluted	370,389,855	369,615,009

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

	Preferred Stock – Series B		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances, January 1, 2019	5,797,102	$3,960,866	370,084,064	$37,008	$49,015,120	$ 52,980,643)	$ 32,351
Issuance of common stock for payment of dividends on Preferred Stock	—	—	362,121	37	99,909	—	99,946
Stock based compensation	—	—	—	—	131,031	—	131,031
Preferred stock dividends						(49,315)	(49,315)
Net loss	—	—	—	—	—	(786,288)	(786,288)
Balances, March 31, 2019	5,797,102	$3,960,866	370,446,185	$37,045	$49,246,060	$(53,816,246)	$ (572,275)

	Preferred Stock – Series B		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances, January 1, 2018	—	$ —	369,599,266	$36,960	$48,403,523	$ 48,273,920)	$ 166,563
Sale of Preferred Stock and Common Stock warrants to related party, net (note 1)	3,478,261	348	—	—	2,360,518	—	2,360,866
Stock based compensation	—	—	75,000	7	208,236	—	208,243
Preferred stock dividends						(26,630)	(26,630)
Net loss	—	—	—	—	—	(1,170,594)	(1,170,594)
Balances, March 31, 2018	3,478,261	$ 348	369,674,266	$36,967	$50,972,277	$(49,471,144)	$ 1,538,448

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (786,288)	$(1,170,594)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	131,031	208,243
Changes in assets and liabilities:		
Prepaid expense and other assets	2,467	17,621
Accounts payable and other current liabilities	(325,199)	(186,957)
Net cash used in operating activities	(977,989)	(1,131,687)
Financing activities:		
Proceeds from the sale of Preferred Stock and Common Stock warrants, related party, net (note 1)	—	2,360,866
Advances of royalties, related party	1,000,000	—
Net cash provided by financing activities	1,000,000	2,360,866
Net change in cash and cash equivalents	22,011	1,229,179
Cash and cash equivalents at beginning of period	1,108,713	344,113
Cash and cash equivalents at end of period	$1,130,724	$ 1,573,292
Non-cash financing activities:		
Issuance of common stock for payment of Preferred Stock dividend	$ 99,946	$ —
Accrued, but unpaid dividends	$ 49,315	$ 26,630

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

1. Corporate overview:

Overview

The accompanying unaudited condensed financial statements of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company", "HPPI", "we", "us" or similar terminology), have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows as of March 31, 2019, and for all periods presented, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to the Securities and Exchange Commission ("SEC") rules and regulations. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2018, which are included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on March 7, 2019 (the "2018 Annual Report"). The accompanying condensed balance sheet as of December 31, 2018 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements.

As used herein, the term "Common Stock" means the Company's common stock, $0.0001 par value per share.

The results of operations for the three-month period ended March 31, 2019 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this Quarterly Report are strongly encouraged to review the risk factors relating to the Company which are set forth in the 2018 Annual Report and our other filings with the SEC.

Nature of the Business and Background

The Company is a pharmaceutical development company that is seeking to discover, develop and ultimately commercialize innovative therapeutics for patients with certain cancers and certain non-cancerous proliferation disorders. The Company has also explored and expects to continue to explore acquiring or licensing other innovative preclinical and clinical stage therapeutics addressing unmet needs and orphan indications beyond cancer. The Company's current primary focus is on the development of therapies initially for prostate and also lung cancers in the U.S. market after licensing its initial indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome ("BCCNS") to the Company's majority stockholder, Mayne Pharma Ventures Pty Ltd ("Mayne Pharma"), in December 2018.

The Company's primary proposed therapy is based upon the use of SUBA-Itraconazole, which is a patented, oral formulation of the currently marketed anti-fungal drug itraconazole. SUBA-Itraconazole is licensed to the Company by Mayne Pharma on an exclusive basis in the United States in the field of certain cancers (including prostate and lung cancer) and certain non-cancerous proliferation disorders pursuant to the Third Amended and Restated Supply and License Agreement between the Company and Mayne Pharma, dated December 17, 2018 (the "Third SLA").

The Company demonstrated in its previous Phase 2(b) trial in BCCNS that the dosing of oral capsules of SUBA-Itraconazole affects the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration ("FDA") for, and has been extensively used to, treat fungal infections and has an extensive history of safe and effective use in humans. The Company has developed, optioned and licensed intellectual property and know-how related to the treatment of cancer patients using itraconazole and certain itraconazole analogues.

Manufacturing and Product Supply and Relationship with Mayne Pharma

The Company does not have any production facilities or manufacturing personnel. The Third SLA provides for the supply to the Company of specially formulated capsules of SUBA-Itraconazole, manufactured by Mayne Pharma under cGMP (current good manufacturing practice) standards, for use by the Company in its clinical trials and for the future commercial supply following FDA approvals, if obtained.

Pursuant to the Third SLA, Mayne Pharma is obligated to supply the Company with its patented formulation of SUBA-Itraconazole in a particular oral dose formulation for the treatment of human patients with certain cancers and non-cancerous proliferation disorders for as long as the Third SLA is in effect. The Company is required to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer in the United States.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

1. Corporate overview (continued):

Overview of December 2018 Transactions with Mayne Pharma

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

- An agreement, by and among the Company, and Mayne Pharma, and Mayne Pharma International, an affiliate of Mayne Pharma (the "Agreement");
- The Third Amended SLA, which amended and restated 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
- Amended and Restated Sublicense Agreement, by and between the Company and Mayne Pharma International, 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 (the "Amended and Restated COD") for the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock"), which amended and restated the terms of the Series B Preferred Stock (originally issued to Mayne Pharma on January 8, 2018) to remove the redemption rights of the Series B Preferred Stock as described below. As of the Effective Date and at March 31, 2019, all 5,797,102 outstanding shares 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 for the treatment of BCCNS (such product candidate "SUBA-Itraconazole BCCNS") in exchange for a royalty on any future net sales of SUBA-Itraconazole BCCNS by Mayne Pharma in the United States if an FDA New Drug Application ("NDA") was not accepted for filing by FDA by December 31, 2018 (subject to limited extension if the NDA were filed in December 2018). 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 three members of the Board who were each disinterested with respect to Mayne Pharma.

December 2018 Agreement with Mayne Pharma

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 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 from 32,583,475 shares to 43,583,475 shares.

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) 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. 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.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

1. Corporate overview (continued):

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 previous 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.

December 2018 – Third Amended and Restated Supply and License Agreement with Mayne Pharma

Pursuant to the Third Amended SLA, as of the Effective Date, Mayne Pharma 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 United States 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 (the "Royalty") on future net sales, if any, of SUBA-Itraconazole product in the BCCNS field in the United States, from which certain royalties owed by the Company to Mayne Pharma for access to certain patents would also be funded.

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

(i) As of the Effective Date, Mayne Pharma shall make an Advance to the Company of $500,000 (the Company received this first Advance on December 18, 2018);

(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 (the Company received this second advance on January 22, 2019);

(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 United States, 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 Series B Preferred Stock held by Mayne Pharma or warrants to third parties ("New Securities") 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 the Company 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 SUBA-Itraconazole 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.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

1. Corporate overview (continued):

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

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. 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.

December 2018 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.

2. Liquidity and management's plans:

The Company had cash and cash equivalents of approximately $1.1 million as of March 31, 2019. Based on the Company's current operational plan and budget (including the receipt of $1.5 million due on or before June 30, 2019 from Mayne Pharma under the Third Amended SLA), the Company expects that it has sufficient cash to manage its business into the third quarter of 2020, although this estimation assumes the Company does not begin any clinical trials, acquire other drug development opportunities or otherwise face unexpected events, costs or contingencies, any of which could affect the Company's cash requirements. Available resources may be consumed more rapidly than anticipated, potentially resulting in the need for additional funding. The Company intends to finance additional research and development, commercialization and distribution efforts and its working capital needs primarily through:

- proceeds from public and private financings (including, most recently, financing from our majority shareholder, Mayne Pharma) and, potentially, from other strategic transactions;
- advances from Mayne Pharma of potential future royalties on the SUBA-Itraconazole BCCNS product available under the Supply and License Agreement;
- royalty revenue from Mayne Pharma from sales of SUBA-Itraconazole BCCNS upon and assuming approval by FDA (after earned royalties have been applied to any advances due under Third Amended SLA);
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including, potentially, warrants held by our majority shareholder, Mayne Pharma);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and
- government or private foundation grants or loans which would be awarded to us to further develop our current and future anti-cancer therapies.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

2. Liquidity and management's plans (continued):

However, there is a risk that none of these plans will be implemented in a manner necessary to sustain the Company for an extended period of time and that the Company will be unable to obtain additional financing when needed on commercially reasonable terms, if at all. If adequate funds are not available when needed, the Company may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require the Company to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on the Company, its viability, its financial condition and its results of operations beyond the third quarter of 2020. In addition, a lack of adequate funds may force the Company to cease operations.

3. Summary of Significant Accounting Policies:

Estimates

The preparation of condensed financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Revenue Recognition

The Company currently has no ongoing source of revenues. Miscellaneous income, including interest, is recognized when earned by the Company. Deferred revenue represents cash received for royalties in advance of being earned. Such payments are reflected as deferred revenue until recognized under the Company's revenue recognition policy. Deferred revenue would be classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date. Deferred revenue will be recognized when the product is sold and the royalty is earned. Since all deferred revenue is related to the SUBA-Itraconazole BCCNS product which is yet to be approved by FDA, the Company has determined that 100% of the advances of the royalty received by Mayne Pharma should be classified as non-current. At March 31, 2019, deferred revenue consisted of $1.5 million of royalties advanced by Mayne Pharma under the Third Amended SLA. There was $0.5 million in deferred revenue at December 31, 2018.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts which is $250,000 for substantially all depository accounts. As of March 31, 2019, the Company had approximately $0.6 million in excess of the amount covered by Federal Deposit Insurance Corporation with one financial institution.

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties who conduct research and development activities on behalf of the Company and purchased in-process research and development.

Stock-Based Compensation

The Company accounts for stock-based awards to employees and non-employees using Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718 – Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of restricted stock units issued are determined by the Company based predominantly on the trading price of the common stock on the date of grant. Fair value of each common stock option is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of a peer group's common stock and other factors estimated over the expected term of the options. The expected term of the options granted is derived using the "simplified method" which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

3. Summary of Significant Accounting Policies (continued):

In applying the Black-Scholes option pricing model for options issued in February 2019 that vest on the first anniversary of the grant date, the assumptions were as follows: expected price volatility of 85.4%; risk-free interest rate of 2.51%; weighted average expected life in years of 6; and no dividend yield. The value of these awards is based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

Income Taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. These differences occur primarily in share-based compensation.

Recent accounting pronouncements:

In February 2016, the FASB issued ASU 2016-02, "Leases," which created a new Topic, ASC Topic 842 and established the core principle that a lessee should recognize the assets, representing rights-of-use, and liabilities to make lease payments, that arise from leases. For leases with a term of 12 months or less, a lessee is permitted to make an election under which such assets and liabilities would not be recognized, and lease expense would be recognized generally on a straight-line basis over the lease term. This standard was effective for the Company beginning in 2019 and was adopted by the Company for the year beginning January 1, 2019. The Company has evaluated the impact of this guidance on its financial statements and has determined that it had no material impact, as the Company has no leasing arrangements with terms greater than 12 months.

Management has considered all recent accounting pronouncements issued, but not effective, and does not believe that they will have a significant impact on the Company's financial statements.

4. Stockholders' Equity:

Employee Stock Plans

On February 3, 2019, Board members were awarded approximately 3.0 million stock options pursuant to the EIP with an exercise price of $0.076 and Black-Scholes value of $0.054 that vest on the first anniversary of the grant date. The grant date fair value of common stock options was determined using the Black-Scholes model on the date of issuance and the number of shares expected to vest. The total Black-Scholes value of the February 3, 2019 stock options grants was approximately $0.2 million.

Total stock-based compensation for the three months ended March 31, 2019 was approximately $0.1 million and is related to common stock options issued pursuant to the EIP in March and June 2018 and in February 2019 as mentioned above. The expense is classified as general and administrative expense in the accompanying condensed statements of operations. As of March 31, 2019, there were 6,384,527 outstanding common stock options under the EIP of which 2,512,000 were vested. There was approximately $0.2 million in unamortized stock-based compensation at March 31, 2019.

5. Legal Proceedings:

The Company is currently not subject to any legal proceedings. However, the Company may from time to time become a party to various legal proceedings arising in the ordinary course of business.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the Condensed Financial Statements and Notes thereto included elsewhere in this Quarterly Report. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company's actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Quarterly Report and in the Company's other filings with the SEC. See "Cautionary Note Regarding Forward Looking Statements" below.

As used in this Management's Discussion and Analysis of Financial Condition and Results of Operations, unless otherwise indicated, the terms "the Company", "we", "us", "our" and similar terminology refer to HedgePath Pharmaceuticals, Inc.

Critical Accounting Policies

See Note 3 of the Notes to Condensed Financial Statements included in Item 1 of this Quarterly Report for a summary of significant accounting policies and information on recently issued accounting pronouncements.

Results of Operations

For the three months ended March 31, 2019 compared to the three months ended March 31, 2018

Research and Development Expenses. We recognized approximately $0.2 million in research and development expenses during the three months ended March 31, 2019 compared to approximately $0.7 million for the three months ended March 31, 2018. Research and development expenses for the three months ended March 31, 2019 primarily included salary expenses and expenses related to preparation for the filing of an Investigational New Drug application for use of SUBA-Itraconazole for prostate cancer. The expenses for the three months ended March 31, 2018 primarily included salary expenses and expenses related to our clinical trial for BCCNS. Other expenses in both periods included legal expenses relating to patents and stock-based compensation. The decrease of $0.5 million is due primarily to a reduction in clinical trial related expenses due to Mayne Pharma assuming control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS in December 2018 and immediately assuming responsibility for all expenses related to exploiting the SUBA-Itraconazole BCCNS product in the BCCNS field in exchange for a 9% quarterly cash royalty and other considerations as discussed in Note 1.

General and Administrative Expenses. We recognized approximately $0.6 million in general and administrative expenses during the three months ended March 31, 2019 compared to $0.5 million for the three months ended March 31, 2018. General and administrative expenses consisted primarily of compensation and related costs for corporate administrative staff and Board members, facility expenditures, professional fees, consulting and taxes. The increase is due primarily to an increase in professional fees including legal fees and investor relations expenses during the quarter ended March 31, 2019.

Interest Income. We recognized interest income of $5,312 during the three months ended March 31, 2019 compared to $4,222 for the three months ended March 31, 2018 for interest earned on cash balances in our money market account.

Liquidity and Capital Resources

We had approximately $1.1 million cash on hand at March 31, 2019. Based on our current operational plan and budget (including the receipt of $1.5 million due on or before June 30, 2019 from Mayne Pharma under the Third Amended SLA), we expect that we will have sufficient cash to manage our business into the third quarter of 2020, although this estimation assumes we do not begin any clinical trials, acquire other drug development opportunities or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements. Available resources may be consumed more rapidly than anticipated, potentially resulting in the need for additional funding.

We intend to seek additional financing for our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- proceeds from public and private financings (including, most recently, financing from our majority shareholder, Mayne Pharma);
- advances from Mayne Pharma of potential future royalties on the SUBA-Itraconazole BCCNS product available under the Supply and License Agreement;
- royalty revenue from Mayne Pharma from sales of SUBA-Itraconazole BCCNS upon approval by FDA (after earned royalties have been applied to any advances due under the Supply and License Agreement)
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including, potentially, warrants held by our majority shareholder, Mayne Pharma);

- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and
- government or private foundation grants or loans which would be awarded to us to further develop our current and future anti-cancer therapies.

However, there is a risk that none of these plans will be implemented and that we will be unable to obtain additional financing on commercially reasonable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require us to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on our company, our viability, our financial condition and our results of operations beyond the third quarter of 2020. In addition, a lack of adequate funds may force us to cease operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

None.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, the Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer (the "Certifying Officers"), conducted evaluations of our disclosure controls and procedures. As defined under Sections 13a–15(e) and 15d–15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the term "disclosure controls and procedures" means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including the Certifying Officers, to allow timely decisions regarding required disclosures.

Based on this evaluation, the Certifying Officers have concluded that our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our first fiscal quarter of 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Internal Controls

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our control have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form10-Q, including in Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" (and the "Liquidity and Capital Resources" section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes "forward-looking statements" within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects", "may", "could", "would", "should", "believes", "expects", "anticipates", "estimates", "intends", "plans" or similar expressions. These statements are based upon the current beliefs and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) our ability to develop and ultimately commercialize therapeutics, (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for beginning, completion, and results of, clinical trials and the FDA's review and/or approval and potential commercial launch of our products and product candidates and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others,

- acceptance of our business model (namely the repurposing of a specialty formulation of the drug itraconazole for the treatment of cancer, and the potential acquisition or license of other pharmaceutical technologies) by investors and potential commercial collaborators;
- our future capital requirements and our ability to satisfy our capital needs;
- our ability to commence and complete required clinical trials of our product candidate and obtain approval from the FDA or other regulatory agencies in different jurisdictions;
- matters associated with the fact that Mayne Pharma is our majority stockholder and key licensor;
- our ability to secure and maintain key development and commercialization partners for our product candidate;
- our ability to obtain, maintain or protect the validity of our owned or licensed patents and other intellectual property;
- our ability to internally develop, acquire or license new inventions and intellectual property;
- our ability to retain key executive members;
- interpretations of current laws and the passages of future laws, rules and regulations applicable to our business; and
- those risk factors listed under Item 1A of our 2018 Annual Report and other factors detailed from time to time in our other filings with the SEC.

Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Report. We undertake no obligation to publically update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors.

Not required for smaller reporting companies.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Number	Description
31.1	Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302
31.2	Certification of Chief Financial Officer Pursuant To Sarbanes-Oxley Section 302
32.1	Certification Pursuant To 18 U.S.C. Section 1350 (*)
32.2	Certification Pursuant To 18 U.S.C. Section 1350 (*)
101.ins	XBRL Instance Document
101.sch	XBRL Taxonomy Extension Schema Document
101.cal	XBRL Taxonomy Calculation Linkbase Document
101.def	XBRL Taxonomy Definition Linkbase Document
101.lab	XBRL Taxonomy Label Linkbase Document
101.pre	XBRL Taxonomy Presentation Linkbase Document

* A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HEDGEPATH PHARMACEUTICALS, INC.

Date: May 9, 2019

By: /s/ Nicholas J. Virca
Nicholas J. Virca
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2019

By: /s/ Garrison J. Hasara
Garrison J. Hasara, CPA
Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Rule 13a-14(a)

I, Nicholas J. Virca, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HedgePath Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries as applicable, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Nicholas J. Virca
Nicholas J. Virca
President and Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Rule 13a-14(a)

I, Garrison J. Hasara, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HedgePath Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries as applicable, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Garrison J. Hasara
Garrison J. Hasara
Chief Financial Officer and Treasurer

Exhibit 32.1

HEDGEPATH PHARMACEUTICALS, INC.

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of HedgePath Pharmaceuticals, Inc. (the "Company") on Form10-Q for the period ending March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nicholas J. Virca, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Nicholas J. Virca
Nicholas J. Virca
President and Chief Executive Officer
May 9, 2019

Exhibit 32.2

HEDGEPATH PHARMACEUTICALS, INC.

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of HedgePath Pharmaceuticals, Inc. (the "Company") on Form10-Q for the period ending March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrison J. Hasara, Chief Financial Officer, Treasurer, Chief Compliance Officer, and Secretary of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Garrison J. Hasara
Garrison J. Hasara
Chief Financial Officer, Treasurer, Chief Compliance Officer,
and Secretary
May 9, 2019