
**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 June 30, 2016

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
(State or other jurisdiction of
incorporation or organization)

30-0793665
(I.R.S. Employer
Identification No.)

324 S. Hyde Park Avenue Ste. 350
Tampa, FL
(Address of principal executive offices)

33606
(Zip Code)

Registrant's telephone number (including area code): 813-864-2559

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>

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

As of August 12, 2016, there were 300,353,270 shares of company common stock issued and outstanding.

[Table of Contents](#)

HedgePath Pharmaceuticals, Inc.

Quarterly Report on Form 10-Q

TABLE OF CONTENTS

	<u>Page</u>
Part I. Financial Information	
Item 1. Condensed Financial Statements (unaudited)	
Condensed Balance Sheets as of June 30, 2016 and December 31, 2015	1
Condensed Statements of Operations for the three and six month periods ended June 30, 2016 and 2015	2
Condensed Statement of Stockholders' Equity for the six months ended June 30, 2016	3
Condensed Statements of Cash Flows for the six months ended June 30, 2016 and 2015	4
Notes to Condensed Financial Statements	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	10
Item 3. Quantitative and Qualitative Disclosures about Market Risk	11
Item 4. Controls and Procedures	11
Cautionary Note on Forward Looking Statements	11
Part II. Other Information	
Item 1. Legal Proceedings	12
Item 1A. Risk Factors	12
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	12
Item 3. Defaults upon Senior Securities	12
Item 4. Mine Safety Disclosures	12
Item 5. Other Information	12
Item 6. Exhibits	12
Signatures	S-1

[Table of Contents](#)

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
AS OF JUNE 30, 2016 AND DECEMBER 31, 2015
(Unaudited)

	<u>June 30, 2016</u>	<u>December 31, 2015</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,615,073	\$ 601,445
Other current assets	50,221	34,414
Total current assets	4,665,294	635,859
Other long term assets	250,000	250,000
Total assets	<u>\$ 4,915,294</u>	<u>\$ 885,859</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 396,047	\$ 383,356
Other liabilities	222,023	78,524
Total current liabilities	618,070	461,880
Total liabilities	<u>618,070</u>	<u>461,880</u>
Commitments and contingencies (Note 6)	—	—
Stockholders' equity:		
Common stock, \$0.0001 par value; 500,000,000 and 340,000,000 shares authorized at June 30, 2016 and December 31, 2015, respectively; 300,353,270 and 245,353,270 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	30,035	24,535
Additional paid-in capital	42,963,198	36,571,982
Accumulated deficit	<u>(38,696,009)</u>	<u>(36,172,538)</u>
Total stockholders' equity	4,297,224	423,979
Total liabilities and stockholders' equity	<u>\$ 4,915,294</u>	<u>\$ 885,859</u>

See notes to condensed financial statements

[Table of Contents](#)

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTH PERIODS ENDED JUNE 30, 2016 AND 2015
(Unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenues:	\$ —	\$ —	\$ —	\$ —
Total Revenues:	—	—	—	—
Expenses:				
Research and development expenses	605,520	300,288	1,188,033	613,305
General and administrative	724,539	491,368	1,336,491	1,101,025
Total Expenses:	1,330,059	791,656	2,524,524	1,714,330
Loss from operations	(1,330,059)	(791,656)	(2,524,524)	(1,714,330)
Interest income	1,053	—	1,053	—
Net loss	<u>\$ (1,329,006)</u>	<u>\$ (791,656)</u>	<u>\$ (2,523,471)</u>	<u>\$ (1,714,330)</u>
Basic and diluted net loss per share	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>
Weighted average common stock shares outstanding	<u>275,941,869</u>	<u>227,827,263</u>	<u>260,647,569</u>	<u>219,668,924</u>

See notes to condensed financial statements

HEDGE PATH PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE SIX MONTHS ENDED JUNE 30, 2016
(Unaudited)

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>			
Balances, January 1, 2016	245,353,270	\$24,535	\$36,571,982	\$ (36,172,538)	\$ 423,979
Proceeds from sale of common stock and common stock warrants, net	27,115,000	2,712	2,662,188	—	2,664,900
Proceeds from sale of common stock and common stock warrants, related party, net	27,885,000	2,788	2,833,636	—	2,836,424
Stock based compensation	—	—	895,392	—	895,392
Net loss	—	—	—	(2,523,471)	(2,523,471)
Balances, June 30, 2016	<u>300,353,270</u>	<u>\$30,035</u>	<u>\$42,963,198</u>	<u>\$ (38,696,009)</u>	<u>\$ 4,297,224</u>

See notes to condensed financial statements

[Table of Contents](#)

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED JUNE 30, 2016 AND 2015
(Unaudited)

	Six months Ended	
	June 30,	
	2016	2015
Operating activities:		
Net loss	\$ (2,523,471)	\$ (1,714,330)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Stock-based compensation	895,392	839,406
Changes in assets and liabilities:		
Prepaid expense and other current assets	(15,807)	(198,457)
Accounts payable and other current liabilities	156,190	101,792
Net cash used in operating activities	(1,487,696)	(971,589)
Financing activities:		
Proceeds from sale of common stock and common stock warrants, net	2,664,900	—
Proceeds from sale of common stock and common stock warrants, related party, net	2,836,424	2,500,000
Net cash flows from financing activities	5,501,324	2,500,000
Net change in cash and cash equivalents	4,013,628	1,528,411
Cash and cash equivalents at beginning of period	601,445	365,161
Cash and cash equivalents at end of period	<u>\$ 4,615,073</u>	<u>\$ 1,893,572</u>
Supplemental disclosure of non-cash financing activity:		
Issuance of common stock in payment of trade payables	<u>\$ —</u>	<u>\$ 90,000</u>

See notes to condensed financial statements

HEDGE PATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTH PERIODS ENDED JUNE 30, 2016 AND 2015
(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 June 30, 2016, 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, 2015, which are included in the Company’s 2015 Annual Report on Form 10-K, filed with the SEC on February 1, 2016 (the “2015 Annual Report”). The accompanying condensed balance sheet as of December 31, 2015 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 and six month periods ended June 30, 2016 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 2015 Annual Report and our other filings with the SEC.

The accompanying financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities of the Company in the normal course of business. If the Company is unable to raise required funding to continue to pursue its business plan, it may have to cease operations. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Nature of the Business

The Company is a clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. The Company may also explore acquiring or licensing other innovative therapeutics addressing unmet needs and orphan indications beyond cancer. The Company’s preliminary focus is on the development of therapies for skin, lung and prostate cancers in the United States of America (“U.S.”) market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome) for which the Company is presently conducting an open label Phase II(b) clinical trial.

The Company’s proposed therapy is based upon the use of SUBA™-Itraconazole, which is a patented, oral formulation of the currently marketed anti-fungal drug Itraconazole to which the Company holds an exclusive U.S. license. The Company believes that the dosing of oral capsules of this formulation can affect 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 (the “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.

Relationship with Mayne Pharma Ventures Pty Ltd.

The Company has exclusive rights in the U.S. to develop and to commercialize SUBA-Itraconazole capsules for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by the Company’s

HEDGE PATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTH PERIODS ENDED JUNE 30, 2016 AND 2015
(Unaudited)

1. Corporate overview (continued):

manufacturing partner and significant shareholder Mayne Pharma Ventures Pty Ltd. and its affiliates (“Mayne Pharma”) under a supply and license agreement, originally dated September 3, 2013 and most recently amended and restated on May 15, 2015 (the “SLA”). Mayne Pharma is an Australian specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes directly or through distribution partners and also provides contract development and manufacturing services. In addition to being the Company’s licensor and supply partner, under the SLA and related agreements, Mayne Pharma holds a significant minority equity stake in the Company and holds important rights with respect to the Company, such as the right to appoint a member to the Company’s Board of Directors.

Recent financing

On May 25, 2016, the Company conducted the final closing (the “Final Closing”) of its previously announced “best efforts/no minimum” private placement offering to accredited investors (the “Offering”) of the Company’s units (each a “Unit”) at a price of \$0.10 per Unit, with each Unit consisting of: (i) one (1) share of the Company’s common stock, par value \$0.0001 per share (“Common Stock”), and (ii) a five-year warrant to purchase one (1) share of Common Stock at an exercise price of \$0.12 per share (each a “Warrant”). No actual Units were issued, and each investor received shares of Common Stock and Warrants only. During the course of the Offering, which began on March 30, 2016, the Company sold all 55,000,000 Units reserved for the Offering for aggregate gross proceeds of \$5,500,000 including the units sold to Mayne Pharma as described below.

The Company has granted the investors certain registration rights requiring the Company, following the Final Closing, to file a registration statement with the Securities and Exchange Commission covering the resale by the investors of the shares of Common Stock issued in the Offering and the shares of Common Stock underlying the Warrants issued in the Offering. The Company is required to use its commercially best efforts to cause the registration statement to be declared effective. The Company filed the registration statement with the Securities and Exchange Commission in June 2016, and it was declared effective on July 22, 2016.

In connection with the Final Closing, and pursuant to an existing right of the Company’s license and manufacturing partner and significant stockholder Mayne Pharma to purchase its pro rata share, on a fully-diluted basis, of new securities issuances of the Company (the “Mayne Right of First Refusal”), the Company entered into a definitive Securities Purchase Agreement (“SPA”) (in substantially the same form as the SPA executed by other investors in the Offering) with Mayne Pharma, and in connection therewith issued an aggregate of 27,885,000 Units to Mayne Pharma, consisting of an aggregate of 27,885,000 shares of Common Stock and a Warrant to purchase up to an aggregate of 27,885,000 shares of Common Stock, for aggregate gross proceeds to the Company of \$2,788,500.

In connection with the Offering, the Company engaged certain FINRA-member agents to help it secure investors for the Offering (the “Finders Arrangements”). Such agents secured investors for an aggregate of \$582,500 for the Offering and received commissions equal to an aggregate of \$46,600 in cash and warrants (in substantially the form of the Warrants) to purchase 466,000 shares of Common Stock. Pursuant to the Mayne Right of First Refusal, the Company issued and sold to Mayne a warrant to purchase 479,236 shares of Common Stock for a purchase price of \$47,924 (the “Mayne Finders Warrant”), which constituted Mayne’s pro rata share, on a fully-diluted basis, of all warrants issued in connection with the Finders Arrangements, inclusive of the Mayne Finders Warrant. For ease of administration, the 479,236 shares of Common Stock underlying the Mayne Finders Warrant were added to the Mayne Offering Warrant, resulting in the issuance to Mayne of a single Warrant to purchase 28,364,236 shares of Common Stock.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTH PERIODS ENDED JUNE 30, 2016 AND 2015
(Unaudited)

2. Liquidity and management's plans:

At June 30, 2016, the Company had cash and cash equivalents of approximately \$4.6 million. Based on the Company's current operational plan and budget, the Company expects that it has sufficient cash to manage its business into approximately the first quarter of 2018, although this estimation assumes the Company does not accelerate the development of the existing product candidate, 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. Additional funding from any source (including equity and debt financings) may be unavailable on favorable terms, if at all.

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 is recognized when earned by the Company.

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 June 30, 2016, the Company had approximately \$4.1 million which exceeded these insured limits.

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 equity securities issued are determined by the Company based predominantly on the trading price of the common stock. 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.

HEDGE PATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTH PERIODS ENDED JUNE 30, 2016 AND 2015
(Unaudited)

3. Summary of Significant Accounting Policies (continued):

Recent accounting pronouncements:

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of Accounting Standards Codification ("ASC") Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard, as updated in 2015, will be effective for the Company in the first quarter of the year ending December 31, 2018 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. The Company will evaluate the impact of adoption of the new standard on its financial statements upon commencement of revenue generating activities.

In August 2014, the Financial Accounting Standards Board issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosure. This ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company is evaluating the impact the guidance will have on its financial statements.

4. Other liabilities

At December 31, 2015, other liabilities included \$52,500 payable to a third party service provider which was required to be settled in stock upon the completion of at least a \$5 million stock offering. That liability was renegotiated and settled in May 2016 with \$25,000 in cash resulting in a gain of \$27,500 which is included as a reduction of general and administrative expenses in the accompanying 2016 condensed statements of operations.

5. Stockholders' Equity:

Employee Stock Plans

Total stock-based compensation for the six months ended June 30, 2016 was approximately \$0.9 million and is related to certain restricted stock units ("RSUs") issued in 2014 and 2015 in connection with the Company's Equity Incentive Plan. The expense is classified as research and development expense and general and administrative expense in the accompanying condensed statements of operations. The grant date fair value of RSUs was determined using the quoted market price of the Common Stock on the date of issuance and the number of shares expected to vest.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTH PERIODS ENDED JUNE 30, 2016 AND 2015
(Unaudited)

5. Stockholders' Equity (continued):

In June 2016, the vesting date for RSUs originally scheduled to vest in September 2016 was extended until March 2017. These RSUs were revalued using the quoted market price of the Company's common stock on the date the vesting was extended. That expense associated with the increase in value will be recognized over the extended vesting period. There was approximately \$2.4 million in unamortized stock-based compensation relating to RSUs at June 30, 2016, which is expected to be recognized over the next 26 months.

As of June 30, 2016, there were 25,891,738 RSUs granted to various members of the Board of Directors, management and other employees. On July 1, 2016, the three independent members of the Board of Directors and the Secretary received a total grant of 650,000 RSUs and 650,000 common stock options with an exercise price of \$0.24 per share.

6. Legal Proceedings:

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

[Table of Contents](#)

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 unaudited 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 both, as the context requires, the present activity of HPPI and the historic activity of CBI, as the context requires.

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 June 30, 2016 compared to the three months ended June 30, 2015

Research and Development Expenses. We recognized approximately \$0.6 million in research and development expenses during the three months ended June 30, 2016 compared to approximately \$0.3 million for the three months ended June 30, 2015. The increase is primarily related to approximately \$0.2 million in research and development expenses related to our clinical trial for Basal Cell Carcinoma Nevus Syndrome for which we commenced dosing patients in September 2015.

General and Administrative Expenses. We recognized approximately \$0.7 million in general and administrative expenses during the three months ended June 30, 2016 and approximately \$0.5 million for the three months ended June 30, 2015. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes. The increase is primarily due to an increase in compensation and consulting expenses of \$0.2 million.

For the six months ended June 30, 2016 compared to the six months ended June 30, 2015

Research and Development Expenses. We recognized approximately \$1.2 million in research and development expenses during the six months ended June 30, 2016 compared to approximately \$0.6 million for the six months ended June 30, 2015. Research and development expenses for the both periods primarily consist of expenses related to our clinical trial for Basal Cell Carcinoma Nevus Syndrome, regulatory activities, legal expenses relating to patents, and stock-based compensation. The increase is primarily related to approximately \$0.5 million in research and development expenses related to our clinical trial for Basal Cell Carcinoma Nevus Syndrome for which we commenced dosing patients in September 2015.

General and Administrative Expenses. We recognized approximately \$1.3 million in general and administrative expenses during the six months ended June 30, 2016 compared to approximately \$1.1 million for the six months ended June 30, 2015. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes. The increase is primarily due to an increase in compensation and consulting expenses of approximately \$0.2 million.

[Table of Contents](#)

Liquidity and Capital Resources

At June 30, 2016, we had cash and cash equivalents of approximately \$4.6 million. Based on our current operational plan and budget, we expect that it has sufficient cash to manage its business into approximately the first quarter of 2018, although this estimation assumes we do not accelerate the development of our existing product candidate, 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. Additional funding from any source (including equity and debt financings) may be unavailable on favorable terms, if at all.

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 the first six months of 2016 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 Form 10-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,

Table of Contents

including, without limitation: (i) the results of our collaboration with Mayne Pharma, (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for completion, and results of, scheduled or additional 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, those listed under Item 1A of our 2015 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.

During the period of this Quarterly Report, all unregistered sales of our securities were previously disclosed in a Current Report on Form 8-K.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

<u>Number</u>	<u>Description</u>
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

Table of Contents

<u>Number</u>	<u>Description</u>
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.

HEDGEPTH PHARMACEUTICALS, INC.

Date: August 12, 2016

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

Date: August 12, 2016

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

**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 Rules 13a-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, 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: August 12, 2016

/s/ Nicholas J. Virca

Nicholas J. Virca
President and Chief Executive Officer

**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 Rules 13a-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, 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: August 12, 2016

/s/ Garrison J. Hasara

Garrison J. Hasara
Chief Financial Officer and Treasurer

HEDGE PATH 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 Form 10-Q for the period ending June 30, 2016, 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

August 12, 2016

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 Form 10-Q for the period ending June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrison J. Hasara, Treasurer and Chief Financial 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/ Garrison J. Hasara

Garrison J. Hasara
Chief Financial Officer and Treasurer

August 12, 2016