
**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 September 30, 2015

**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

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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 November 4, 2015, there were 245,353,270 shares of company common stock issued and outstanding.

HedgePath Pharmaceuticals, Inc.
Quarterly Report on Form 10-Q

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HEDGE PATH PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
AS OF SEPTEMBER 30, 2015 AND DECEMBER 31, 2014
(Unaudited)

	<u>September 30, 2015</u>	<u>December 31, 2014</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,243,272	\$ 365,161
Prepaid expenses and other current assets	56,611	97,817
Total current assets	1,299,883	462,978
Other long-term assets	250,000	—
Total assets	<u>\$ 1,549,883</u>	<u>\$ 462,978</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 442,088	\$ 324,966
Other liabilities	98,318	75,933
Total current liabilities	540,406	400,899
Total liabilities	540,406	400,899
Commitments and contingencies (note 7)	—	—
Stockholders' equity:		
Common stock, \$0.0001 par value; 340,000,000 shares authorized; 245,353,270 and 211,419,937 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	24,535	21,142
Additional paid-in capital	36,124,286	32,263,890
Accumulated deficit	(35,139,344)	(32,222,953)
Total stockholders' equity	1,009,477	62,079
Total liabilities and stockholders' equity	<u>\$ 1,549,883</u>	<u>\$ 462,978</u>

See notes to unaudited condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2015 AND 2014
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Revenues:	\$ —	\$ —	\$ —	\$ —
Total Revenues:	—	—	—	—
Expenses:				
Research and development expenses	601,664	166,963	1,214,969	2,122,770
General and administrative	600,397	571,127	1,701,422	917,914
Total Expenses:	1,202,061	738,090	2,916,391	3,040,684
Loss from operations	(1,202,061)	(738,090)	(2,916,391)	(3,040,684)
Interest expense	—	(1,979)	—	(36,531)
Net loss	\$ (1,202,061)	\$ (740,069)	\$ (2,916,391)	\$ (3,077,215)
Basic and diluted net loss per share	\$ —	\$ (0.01)	\$ (0.01)	\$ (0.05)
Weighted average common stock shares outstanding	245,353,270	130,115,236	228,324,455	56,949,513

See notes to unaudited condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances, January 1, 2015	211,419,937	\$21,142	\$32,263,890	\$ (32,222,953)	\$ 62,079
Sale of common stock and common stock warrants to related party	33,333,333	3,333	2,496,667	—	2,500,000
Common shares issued for payment of trade payables	600,000	60	89,940	—	90,000
Stock-based compensation	—	—	1,273,789	—	1,273,789
Net loss	—	—	—	(2,916,391)	(2,916,391)
Balances, September 30, 2015	<u>245,353,270</u>	<u>\$24,535</u>	<u>\$36,124,286</u>	<u>\$ (35,139,344)</u>	<u>\$ 1,009,477</u>

See notes to unaudited condensed financial statements

HEDGE PATH PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014
(Unaudited)

	Nine months Ended September 30,	
	2015	2014
Operating activities:		
Net loss	\$ (2,916,391)	\$ (3,077,215)
Adjustments to reconcile net loss to net cash flows from operating activities:		
In-process research and development purchased with the issuance of preferred stock and common stock warrants	—	1,909,860
Non-cash interest expense	—	24,666
Stock based compensation	1,273,789	333,882
Changes in assets and liabilities:		
Prepaid expense, other current assets, and other assets	(208,794)	(37,240)
Accounts payable and other current liabilities	229,507	61,307
Net cash used in operating activities	<u>(1,621,889)</u>	<u>(784,740)</u>
Financing activities:		
Proceeds from related party advances	—	273,638
Proceeds from sale of common stock and common stock warrants and collection of stock subscription receivable, related party	2,500,000	950,000
Payment on notes payable	—	(63,250)
Net cash flows from financing activities	<u>2,500,000</u>	<u>1,160,388</u>
Net change in cash and cash equivalents	878,111	375,648
Cash and cash equivalents at beginning of period	365,161	217
Cash and cash equivalents at end of period	<u>\$ 1,243,272</u>	<u>\$ 375,865</u>
Supplemental disclosure of non-cash financing activity:		
Issuance of stock in debt forgiveness transaction	\$ —	\$ 189,768
Issuance of warrants in debt forgiveness transaction	\$ —	\$ 450,000
Issuance of common stock for common stock subscription receivable	\$ —	\$ 1,250,000
Issuance of common stock in payment of trade payables	\$ 90,000	\$ —

See notes to unaudited condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014
(Unaudited)

1. Corporate overview:

Overview

The accompanying condensed financial statements (unaudited) 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 September 30, 2015, 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, 2014, which are included in the Company’s 2014 Annual Report on Form 10-K, filed with the SEC on February 13, 2015 (the “2014 Annual Report”). The accompanying condensed balance sheet at December 31, 2014 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 nine month periods ended September 30, 2015 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 2014 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 and Background

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’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 has begun dosing its Phase II(b) clinical trial. The Company’s proposed therapy is based upon the use of SUBA-Itraconazole™, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole. 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 (“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 has applied for patents to cover the Company’s inventions.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014
(Unaudited)

1. Corporate overview (continued):

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 our 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.

On May 15, 2015, the Company and Mayne Pharma, along with Nicholas J. Virca, the Company’s President and Chief Executive Officer (“Virca”), Frank O’Donnell, Jr., M.D., the Company’s Executive Chairman (“O’Donnell”) and Hedgepath, LLC, a Florida limited liability company and substantial stockholder of the Company which is controlled by Black Robe Capital LLC, of which O’Donnell is the manager (“HPLLC”), consummated a series of related transactions in connection with a \$2.5 million equity financing for the Company from Mayne Pharma and to remedy certain breaches by the Company related to the agreements previously consummated by the Company, Mayne Pharma, HPLLC, Virca and O’Donnell on June 24, 2014.

On September 2, 2015, the Company entered into a sublicense agreement with Mayne Pharma. Pursuant to the Agreement, Mayne Pharma sublicensed to the Company the exclusive U.S. rights to two additional patents regarding the use of Itraconazole for treatment of cancer, namely US patent No 8,980,930 entitled “Angiogenesis Inhibitors”, issued on March 17, 2015, and US patent No 8,653,083 entitled “Hedgehog Pathway Antagonists to Treat Disease”, issued on February 28, 2014. Mayne Pharma is the sublicensee of the patents from Accelas Holdings, a British Virgin Islands company, who in turn is the licensee from The Johns Hopkins University, the owner of the patents. The patents relate to the use of itraconazole as a treatment for cancer and age-related macular degeneration. The Company paid a license fee of \$75,000 to Mayne Pharma upon entering into the sublicense agreement, which is included in research and development expenses in the accompanying 2015 condensed statement of operations.

2. Liquidity and management’s plans:

The Company had cash and cash equivalents of approximately \$1.2 million as of September 30, 2015 which should fund current anticipated operations into the first quarter of next year, but requires significant additional financing for its research and development, commercialization and distribution efforts, and its working capital. The Company intends to finance these activities primarily through:

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

However, there is a material risk that none of these plans will be implemented and that the Company will be unable to obtain additional financing on commercially reasonable terms, if at all. If adequate funds are not available, 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 in 2015 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

As a result, there is substantial doubt about the Company’s ability to continue as a going concern. The Company’s current independent registered public accounting firm has included a paragraph emphasizing this going concern uncertainty in their audit report on the 2014 financial statements dated February 13, 2015. The condensed financial statements included herein do

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014
(Unaudited)

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

not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

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 up to \$250,000 for substantially all depository accounts. As of September 30, 2015, the Company had approximately \$0.7 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 as well as 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.

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 this standard on its financial statements upon commencement of revenue generating activities.

4. Other long-term assets:

Other long-term assets consist of a \$250,000 deposit with our independent contract research organization. The deposit is fully refundable at the conclusion of our clinical trial which targets basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014
(Unaudited)

5. Other liabilities:

At September 30, 2015, other liabilities include approximately \$61,000 of accrued legal expenses (of which \$52,500 are related to 2013 reorganization and required to be settled in stock upon completion of at least a \$5 million stock offering), \$12,000 of accrued payroll expenses, and \$25,000 of research and development expenses.

6. Stockholders' Equity:

Securities Purchase Agreement

On May 15, 2015, the Company and Mayne Pharma entered into a Securities Purchase Agreement (the "Purchase Agreement") pursuant to which, in consideration of Mayne Pharma's investment of \$2.5 million in the Company, the Company issued (i) 33,333,333 shares of Common Stock and (ii) a warrant to purchase 33,333,333 shares of Common Stock (the "Warrant") for an aggregate purchase price of \$2,500,000, or \$0.075 per share. The transaction contemplated by the Purchase Agreement formally closed on May 18, 2015. The Warrant is immediately exercisable, subject to certain restrictions, at an exercise price of \$0.075 per share and expires on May 15, 2020.

Employee Stock Plans

Total stock-based compensation for the nine months ended September 30, 2015 was approximately \$1.3 million and is related to certain Restricted Stock Units ("RSUs") granted in 2014 and 2015 in connection with the Company's 2014 Equity Incentive Plan. The expense is classified as research and development expense and general and administrative expense in the accompanying condensed 2015 statement of operations. There was approximately \$2.0 million in unamortized stock-based compensation relating to the RSUs at September 30, 2015, which is expected to be recognized over the next 35 months. On August 14, 2015, 1.6 million RSUs were granted to various Board members and the Company Secretary and shall vest upon the earlier to occur of (i) September 5, 2017 or (ii) the approval by the FDA of a New Drug Application ("NDA") for any Company product candidate with a cancer indication utilizing the Company's licensed SUBA-itraconazole technology. The grant date fair value related to these RSUs totaled approximately \$0.2 million and will be recognized over the vesting period through September 2017.

An additional 750,000 RSUs were granted on August 14, 2015 to various employees and contractors of the Company and shall vest over three years through August 14, 2018. The grant date fair value related to these RSUs totaled approximately \$0.1 million and will be recognized over the vesting period through August 2018. The fair value of the 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.

7. Legal Proceedings:

Chien Connecticut Case

In October 2012, Andrew Chien ("Chien"), an alleged shareholder of our predecessor, CBI, filed suit in Connecticut state court (later removed to the United States District Court for the District of Connecticut (the "CT District Court")) against CBI, Dr. Richard J. Freer (a director and officer of CBI) ("Freer"), and the law firm LeClairRyan.

On November 4, 2014, the CT District Court dismissed the case and the matter was closed by the CT District Court. On December 1, 2014, Chien filed various motions including a Motion to Reargue. In response, the Company filed a consolidated opposition to Chien's various pleadings, including to the Motion to Reargue. In June 2015, the CT District Court denied all motions including Chien's Motion to Reargue.

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 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 September 30, 2015 compared to the three months ended September 30, 2014***

Research and Development Expenses. We recognized approximately \$0.6 million in research and development expenses during the three months ended September 30, 2015 compared to approximately \$0.2 million for the three months ended September 30, 2014. The increase of approximately \$0.4 million is due primarily to the expenses relating to our clinical trial targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome which commenced during the three months ended September 30, 2015.

General and Administrative Expenses. We recognized approximately \$0.6 million in general and administrative expenses during the three months ended September 30, 2015 and 2014. General and administrative expenses consist of compensation and related costs for corporate administrative staff, facility expenditures, professional fees and consulting.

Interest Expense. We recognized a nominal amount of interest expense during the three months ended September 30, 2014 related to former employee notes. There was no such expense during the three months ended September 30, 2015 as all notes were paid in full in 2014.

For the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Research and Development Expenses. We recognized approximately \$1.2 million and \$2.1 million in research and development expenses during the nine months ended September 30, 2015 and 2014, respectively. Research and development expenses for the current period include contract research organization expenses related to our clinical trial targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome, salaries and consulting expenses related to clinical and regulatory activities, legal expenses relating to patents, and stock-based compensation. The decrease in research and development expenses for the prior period is primarily due to approximately \$1.9 million in purchased in-process research and development in 2014 related to our supply and license agreement with Mayne Pharma which is offset by current year expense of approximately \$0.6 million related to our clinical trial targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome as well as approximately \$0.1 million in license fees related to the sub-license agreement with Mayne Pharma and an increase of approximately \$0.3 million in non-cash stock-based compensation relating to restricted stock units issued during the nine months ended September 30, 2014 and 2015.

General and Administrative Expenses. We recognized approximately \$1.7 million and \$0.9 million in general and administrative expenses during the nine months ended September 30, 2015 and 2014, respectively. General and administrative expenses consist of compensation and related costs for corporate administrative staff, facility expenditures, professional fees and consulting. The increase is primarily a result of an increase in non-cash stock-based compensation relating to restricted stock units issued during the nine months ended September 30, 2015.

Interest Expense. We recognized approximately \$0.04 million in interest expense during the nine months ended September 30, 2014 related to former employee notes. There was no such expense during the nine months ended September 30, 2015 as all notes were paid in full in 2014.

Liquidity and Capital Resources

We had approximately \$1.2 million cash on hand at September 30, 2015, which we believe will fund our current anticipated operations into the first quarter of next year. We will require additional financing in order to progress our business plan. It is highly unlikely that any funds required during the next twelve months or thereafter can be generated from our operations. Moreover, there can be no assurances given that additional funds will be available from external sources, such as debt or equity financing or other potential sources on commercially acceptable terms, or at all.

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

- securing proceeds from public and private financings and, potentially, other strategic transactions;
- partnering 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
- seeking government or private foundation grants which would be awarded to us to further develop our current and future anti-cancer therapies.

However, there is a material 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 in 2015 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

As a result of the foregoing circumstances, there is substantial doubt about our ability to continue as a going concern. The Company's current independent registered public accounting firm has included a paragraph emphasizing this going concern uncertainty in their audit report on the 2014 financial statements dated February 13, 2015. The financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

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 nine months of fiscal 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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, 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 2014 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

Chien Connecticut Case

In October 2012, Andrew Chien (“Chien”), an alleged shareholder of the Company when it operated as CBI, filed suit in Connecticut state court (later removed to the United States District Court for the District of Connecticut (the “CT District Court”)) against CBI, Dr. Richard J. Freer (a director and officer of CBI) (“Freer”), and the law firm LeClairRyan.

On November 4, 2014, the CT District Court dismissed the case and the matter was closed by the CT District Court. On December 1, 2014, Chien filed various motions including a Motion to Reargue. In response, we filed a consolidated opposition to Chien’s various pleadings, including to the Motion to Reargue. In June 2015, the CT District Court denied all motions including Chien’s Motion to Reargue.

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.

None.

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
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: November 4, 2015

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

Date: November 4, 2015

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: November 4, 2015

/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: November 4, 2015

/s/ Garrison J. Hasara

Garrison J. Hasara
Chief Financial Officer and Treasurer

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 September 30, 2015, 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
November 4, 2015

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 September 30, 2015, 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
November 4, 2015