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

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**FORM 10-Q**

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(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, 2018

**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

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**HedgePath Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

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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)

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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, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 13, 2018, there were 369,959,064 shares of company common stock issued and outstanding.

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HedgePath Pharmaceuticals, Inc.

Quarterly Report on Form 10-Q

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**HEDGEPATH PHARMACEUTICALS, INC.**  
**CONDENSED BALANCE SHEETS**  
**AS OF SEPTEMBER 30, 2018 AND DECEMBER 31, 2017**  
(Unaudited)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 1,440,826	\$ 344,113
Prepaid expenses	51,441	61,655
Deposit	250,000	250,000
Total current assets	1,742,267	655,768
Other long-term assets	90,315	112,284
Total assets	<u>\$ 1,832,582</u>	<u>\$ 768,052</u>
<b>LIABILITIES, MEZZANINE EQUITY, AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 328,001	\$ 534,956
Dividends payable	49,534	—
Other liabilities	171,545	66,533
Total current liabilities	549,080	601,489
Total liabilities	549,080	601,489
Commitments and contingencies (note 5)	—	—
<b>Mezzanine equity:</b>		
Series B Convertible, Redeemable Preferred Stock, \$0.0001 par value; 7,246,377 shares authorized; 5,797,102 and -0- shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	3,960,866	—
<b>Stockholders' (deficit) equity:</b>		
Series A Preferred Stock, \$0.0001 par value; 500,000 shares authorized; no shares issued and outstanding	—	—
Undesignated Preferred Stock, \$0.0001 par value; 2,253,623 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.0001 par value; 500,000,000 shares authorized; 369,959,064 and 369,599,266 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	36,996	36,960
Additional paid-in capital	48,889,682	48,403,523
Accumulated deficit	(51,604,042)	(48,273,920)
Total stockholders' (deficit) equity	(2,677,364)	166,563
<b>Total liabilities, mezzanine equity, and stockholders' (deficit) equity</b>	<u>\$ 1,832,582</u>	<u>\$ 768,052</u>

See notes to condensed financial statements

**HEDGEPATH PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2018 AND 2017**  
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenues:	\$ —	\$ —	\$ —	\$ —
Expenses:				
Research and development expenses	775,449	433,545	1,978,294	1,692,645
General and administrative	400,076	247,621	1,256,453	2,521,029
Total Expenses:	<u>1,175,525</u>	<u>681,166</u>	<u>3,234,747</u>	<u>4,213,674</u>
Loss from operations	(1,175,525)	(681,166)	(3,234,747)	(4,213,674)
Interest income	3,995	2,086	10,707	16,726
Net loss	\$ (1,171,530)	\$ (679,080)	(3,224,040)	(4,196,948)
Preferred stock dividend	(49,534)	—	(106,082)	—
Net loss applicable to common stockholders	<u>\$ (1,221,064)</u>	<u>\$ (679,080)</u>	<u>(3,330,122)</u>	<u>(4,196,948)</u>
Basic and diluted net loss applicable to common stockholders per share	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>
Weighted average common stock shares outstanding – basic and diluted	<u>369,930,943</u>	<u>369,599,266</u>	<u>369,757,743</u>	<u>365,618,815</u>

See notes to condensed financial statements

**HEDGEPATH PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENT OF STOCKHOLDERS' (DEFICIT) EQUITY AND REDEEMABLE PREFERRED STOCK**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018**  
(Unaudited)

	Mezzanine Equity Preferred Stock—Series B		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount			
<b>Balances, January 1, 2018</b>	—	\$ —	369,599,266	\$36,960	\$48,403,523	\$(48,273,920)	\$ 166,563
Sale of Preferred Stock and Common Stock warrants to related party, net (note 1)	5,797,102	3,960,866	—	—	—	—	—
Issuance of common stock upon warrant exercise	—	—	100,000	10	11,990	—	12,000
Issuance of common stock for payment of dividends on Preferred Stock	—	—	184,798	19	56,529	—	56,548
Stock based compensation	—	—	75,000	7	417,640	—	417,647
Preferred stock dividends	—	—	—	—	—	(106,082)	(106,082)
Net loss	—	—	—	—	—	(3,224,040)	(3,224,040)
<b>Balances, September 30, 2018</b>	<u>5,797,102</u>	<u>\$3,960,866</u>	<u>369,959,064</u>	<u>\$36,996</u>	<u>\$48,889,682</u>	<u>\$(51,604,042)</u>	<u>\$ (2,677,364)</u>

See notes to condensed financial statements

**HEDGEPATH PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**  
(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
<b>Operating activities:</b>		
Net loss	\$(3,224,040)	\$(4,196,948)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	417,647	1,851,933
Changes in assets and liabilities:		
Prepaid expense and other assets	32,183	31,112
Accounts payable and other current liabilities	(101,943)	(55,931)
Net cash used in operating activities	<u>(2,876,153)</u>	<u>(2,369,834)</u>
<b>Financing activities:</b>		
Net settlement in connection with the issuance of shares associated with underlying Restricted Stock Units	—	(3,677,727)
Proceeds from the exercise of common stock warrants	12,000	49,500
Proceeds from the sale of Preferred Stock and Common Stock warrants, related party, net (note 1)	3,960,866	—
Net cash provided by (used in) financing activities	<u>3,972,866</u>	<u>(3,628,227)</u>
Net change in cash and cash equivalents	1,096,713	(5,998,061)
Cash and cash equivalents at beginning of period	344,113	6,885,422
Cash and cash equivalents at end of period	<u>\$ 1,440,826</u>	<u>\$ 887,361</u>
	<u>2018</u>	<u>2017</u>
<b>Non-cash financing activities:</b>		
Issuance of common stock for payment of Preferred Stock dividend	\$ 56,548	\$ —
Fair value of shares withheld with net settlement transaction	\$ —	\$ 3,677,727
Accrued, but unpaid dividends	\$ 49,534	\$ —

See notes to condensed financial statements

**HEDGEPATH PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**  
**(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 September 30, 2018, 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, 2017, which are included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on February 16, 2018 (the “2017 Annual Report”). The accompanying condensed balance sheet as of December 31, 2017 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, 2018 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 Company’s 2017 Annual Report on Form 10-K and our other filings with the SEC.

*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 may also explore acquiring or licensing other innovative therapeutics addressing unmet needs and orphan indications beyond cancer. The Company’s initial product candidate 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’s current focus is on the development of therapies for skin, lung and prostate cancers in the U.S. market, with the first indication targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome) (“BCCNS”), for which the Company commenced an open label, Phase 2(b) clinical trial in the third quarter of 2015. The Company continues to interact with the U.S. Food and Drug Administration (“FDA”) regarding the results of its Phase 2(b) trial in order to gain further guidance regarding the filing of the New Drug Application (“NDA”) for SUBA-Itraconazole for the treatment of BCCNS (“SUBA BCCNS”).

In October 2018, the Company announced the results of its September 25, 2018 meeting with FDA regarding the requirements for filing the NDA. Specifically, FDA instructed the Company to (i) update its efficacy and safety information to include more recent data than its proposed cutoff date of December 2017 in order to provide additional data on the ten remaining patients who were still receiving therapy beyond December 2017, (ii) provide an analysis of basal cell carcinoma tumor burden responses via independent analysis of tumor photographs to confirm results reported by the clinical investigators and (iii) submit an Integrated Safety Summary (“ISS”) that includes data not only from the Company’s clinical trial, but all human trials of SUBA-Itraconazole regardless of strength and indication. The consequence of FDA requiring the completion of the ISS module is that the Company requires more time than previously anticipated to submit the NDA, resulting in a revised anticipated NDA submission date of sometime in the first quarter of 2019. Under the Company’s supply and license agreement, originally dated September 3, 2013, amended and restated on June 24, 2014 and May 15, 2015, and as further amended on November 22, 2016 and January 10, 2018 (collectively, the “SLA”) with Mayne Pharma Ventures Pty Ltd., the Company’s majority stockholder, and its affiliates (“Mayne Pharma”), if the NDA is not accepted for filing by December 31, 2018 (subject to limited extension if the NDA is filed in December), Mayne Pharma may elect to take back the SUBA BCCNS product in the United States (including by way of an exclusive license from the Company of its clinical data) in exchange for a royalty on any future net sales. Additionally, Mayne Pharma will not be obligated to fund the Third Closing (as defined below) of the Financing (as defined below) The Company and Mayne Pharma have commenced discussions on this important matter. See “*Relationship with Mayne Pharma Ventures Pty Ltd. – Amendment to Supply and License Agreement*” and “*Relationship with Mayne Pharma Ventures Pty Ltd. – Series B Preferred Stock Purchase Agreement*” below for more information.

**HEDGEPATH PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**  
**(Unaudited)**

**1. Corporate overview (continued):**

The Company believes that the dosing of oral capsules of SUBA-Itraconazole 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 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 manufacturing partner and majority shareholder Mayne Pharma under 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 majority equity stake in the Company and holds important contractual rights with respect to the Company, such as the right to appoint members to the Company's board of directors, and in particular with respect to SUBA BCCNS, as further explained below.

*Series B Preferred Stock Purchase Agreement*

On January 8, 2018, the Company entered into a definitive securities purchase agreement (the "Purchase Agreement") with Mayne Pharma, pursuant to which Mayne Pharma agreed to purchase from the Company, and the Company agreed to issue to Mayne Pharma (over three closings as described further below, each a "Closing"):

- (i) up to 7,246,377 shares of the Company's newly designated Series B Convertible Preferred Stock (the "Series B Preferred Stock") at \$0.69 per share of Series B Preferred Stock (with each share of Series B Preferred Stock being convertible into three (3) shares of the Common Stock for an effective price per share of Common Stock of \$0.23), for potential gross proceeds of \$5,000,000;
- (ii) Series A warrants (the "Series A Warrants") to purchase up to an aggregate 5,434,783 shares of Common Stock, with a two-year term from the date of issuance and an exercise price per share of \$0.23; and
- (iii) Series B warrants (the "Series B Warrants") to purchase up to an aggregate of 5,434,783 shares of Common Stock, with a five-year term from the date of issuance and an exercise price per share of \$0.275 (the "Series B Warrants", and together with the Series A Warrants, the "Warrants").

The transactions contemplated by the Purchase Agreement are referred to herein as the "Financing." The Financing contemplates three closings (each, a "Closing"), as follows:

- (i) \$2.4 million was funded at an initial closing of the Financing that occurred on January 10, 2018 (the "Initial Closing") resulting in the issuance of 3,478,261 Preferred Shares and a total of 5,217,392 Warrants
- (ii) \$1.6 million was funded on July 5, 2018 resulting in the issuance of 2,318,841 Preferred Shares and a total of 3,478,262 Warrants on July 5, 2018; and
- (iii) \$1.0 million may be funded on or before December 31, 2018 (the "Third Closing") (see below).

The funding of the Third Closing shall be conditioned upon the acceptance of filing by the FDA of the Company's NDA for SUBA BCCNS, provided that such date shall be automatically extended in the event that such NDA is filed with the FDA during December 2018 to a date which is 30 days from the date of such filing. In October 2018, the Company announced that it revised the anticipated NDA submission date to sometime in the first quarter of 2019 which would not meet the condition for the funding of the Third Closing.

In addition, as part of the Financing, the Company and Mayne Pharma agreed to amend the SLA, most notably to eliminate the provision that would have allowed Mayne Pharma to terminate the SLA in the event that the Company had not received an NDA approval for a product covered by the SLA by October 31, 2018.

Under the Purchase Agreement, the Company has agreed to use the proceeds from the Financing solely for purposes of funding the continued development of SUBA BCCNS and for general corporate purposes; provided, however, that the Company may use the proceeds from the Third Closing (in a manner consistent with the SLA) for the development of other SUBA-Itraconazole treatments for cancer and for general operating purposes of the Company. In addition, the Purchase Agreement provides for additional limitations on the use of proceeds from the Financing including, without limitation, that the Company shall not use the proceeds from any Closing for: (i) the satisfaction of any portion of the Company's indebtedness (other than payment of trade payables in the ordinary course of the Company's business and prior practices) or (ii) the redemption of any Common Stock or other Company securities.

**HEDGEPATH PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**  
**(Unaudited)**

**1. Corporate overview – Series B Preferred Stock Purchase Agreement (continued):**

In addition, under the Purchase Agreement, the Company agreed that for the period from the date of the Initial Closing through December 31, 2018 (the “Market Standoff Period”), the Company will not undertake external financing (which shall specifically exclude exercise of existing options and warrants) without the approval of Mayne Pharma, such approval not to be unreasonably withheld, conditioned or delayed, and giving due consideration to the fiduciary duties and business judgment of the Company’s Board of Directors; provided, however, that if, during the Market Standoff Period, any existing warrants or options of the Company are exercised, the proceeds of such exercises may, in the discretion of the Company’s Board of Directors, be used for preliminary work on SUBA-Itraconazole cancer indications other than SUBA BCCNS, in each case in accordance with the SLA.

Under the Purchase Agreement, Mayne Pharma has been afforded certain demand and “piggyback” rights to cause the Company to register the shares of Common Stock underlying the Series B Preferred Stock and the Warrants for public resale; provided, however, that such rights shall only become effective and exercisable from and after the termination of the SLA.

The negotiations with Mayne Pharma and preparation of related transaction documentation associated with Financing and amendment to the SLA was undertaken on behalf of the Company by a special committee of disinterested, independent members of the Company’s Board of Directors.

*Terms of the Series B Preferred Stock*

The Series B Preferred Stock carries the following provisions:

*Price Per Share.* The purchase price for each share of Series B Preferred Stock is \$0.69 (which is equal to three times (3x) the Conversion Price (as defined below)) (the “Per Share Price”). An applicable number of shares of Series B Preferred Stock will be issued at each Closing based on the Per Share Price.

*Dividends.* The shares of Series B Preferred Stock will accrue dividends at a rate of 5% of the Per Share Price per annum per share. Dividends will be paid semi-annually as of June 30 (with a payment date of July 15) and December 31 (with a payment date of January 15) each year. The Company shall have the option in its discretion to pay dividends in cash or shares of Common Stock. If the Company elects to pay dividends in shares of Common Stock, the number of shares to be paid being calculated by dividing (i) the principal value of the dividend to be paid by (ii) the 6-month volume-weighted average price of the Common Stock prior to the measurement date (being December 31st, or June 30th) of the applicable year. On July 15, 2018, the Company made the first semi-annual dividend payment of approximately \$0.06 million by issuing 184,798 shares of Common Stock.

*Voluntary and Mandatory Conversion.* The shares of Series B Preferred Stock will be convertible as provided for below into an aggregate of 21,739,131 shares of Common Stock (assuming all three Closings occur) based on a conversion price per share of \$0.23 (the “Conversion Price”). Each share of Series B Preferred Stock shall be convertible into three (3) shares of Common Stock at any time at the election of Mayne Pharma at a price per share equal to the Conversion Price. The Conversion Price shall be subject to customary stock-based, but not price-based, anti-dilution protection. Each share of Series B Preferred Stock shall automatically convert into three (3) shares of Common Stock based on the Conversion Price upon the approval by the FDA of an NDA for any SUBA-based therapeutic under the SLA (including SUBA BCCNS).

*Liquidation Preference.* In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, Mayne Pharma (with respect to its holdings of Series B Preferred Stock only) will be entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payment will be made to the holders of all other capital stock of the Company (including the Common Stock) an amount per share of Series B Preferred Stock equal to the Per Share Price plus any dividends accrued but unpaid thereon.

*Seniority.* So long as the shares of Series B Preferred Stock are outstanding, the Company shall not, without the prior written approval of from the holders of a majority of the then outstanding shares of Series B Preferred Stock: (i) establish any security nor incur any secured or unsecured indebtedness (other than trade debt in the ordinary course of business) or (ii) establish any security that is pari passu or senior (or reclassify any junior security so as to make it pari passu or senior) in liquidation preference or senior to the Series B Preferred Stock.

*Voting.* With respect to its shares of Series B Preferred Stock, Mayne Pharma shall be entitled to vote together with the holders of Common Stock as a single class the number of votes Mayne Pharma would have if the Series B Preferred Stock were converted into Common Stock.

**HEDGEPATH PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**  
**(Unaudited)**

**1. Corporate Overview – Series B Preferred Stock Purchase Agreement (continued):**

*Redemption.* On or after the five (5) year anniversary of the Initial Closing, Mayne Pharma shall have the right to cause the Company to redeem all (but not less than all) of the outstanding shares of Series B Preferred Stock for a price per share equal to the Per Share Price plus any accrued but unpaid dividends on such shares. As such, the proceeds from the sale of the Series B Preferred Stock have been classified as mezzanine equity on the September 30, 2018 condensed balance sheet.

*Terms of the Warrants*

The Warrants are divided equally between the Series A Warrants and the Series B Warrants (i.e., with each being exercisable for an aggregate of 5,434,783 shares of Common Stock if all Closings occur), which represents fifty percent (50%) warrant coverage on the shares of Common Stock underlying the Series B Preferred Stock. The Warrants have been and will continue to be issued, pro rata in relation to the total investment in the Series B Preferred Stock, at each Closing.

The Warrants are substantially identical in form, except that: (i) the exercise price per share of the Series A Warrants shall be \$0.23 per share and the exercise price per share of the Series B Warrants shall be \$0.275 per share (collectively, the “Warrant Exercise Price”) and (ii) The Series A Warrants shall have a term of two (2) years from the date of issuance and the Series B Warrants shall have term of five (5) years from the date of issuance. The Warrant Exercise Price shall be subject to customary stock-based, but not price-based, anti-dilution protection. The Warrants will not be eligible for “cashless” exercise.

*Amendment to Supply and License Agreement*

In connection with the Initial Closing, on January 10, 2018, the Company and Mayne Pharma entered into an amendment to the SLA to eliminate Mayne Pharma’s right to terminate the SLA if the Company fails to secure NDA approval for a SUBA-Itraconazole-based treatment for cancer by October 31, 2018 and replace such right with provisions that grant to Mayne Pharma a 60-day right (exercisable only on a Target Failure (as defined below)) to elect to assume all responsibility and control for clinical, regulatory and commercial activities for SUBA BCCNS (the “Mayne BCCNS Assumption Right”) by way of an exclusive license from the Company and full access (the “Company BCCNS License”) solely to the Company’s SUBA BCCNS clinical data and the Company’s own itraconazole intellectual property solely for the field of the treatment of Basal Cell Carcinoma Nevus Syndrome.

Mayne Pharma’s election to trigger the Mayne BCCNS Assumption Right shall not terminate the SLA or impact the Company’s ability to pursue other product development opportunities under and in accordance with the terms of the SLA.

The Company BCCNS License includes: (i) a cash royalty to the Company from Mayne Pharma on all net sales of SUBA BCCNS in the United States, (ii) the forfeiture by Mayne Pharma under the Sublicense Agreement (as defined below) of (x) royalties from the Company with respect to SUBA BCCNS sales and (y) a portion of the milestone payments due by the Company to Mayne Pharma under the Sublicense Agreement and (iii) indemnification of the Company by Mayne Pharma for any claims incurred by the Company arising out of Mayne Pharma’s SUBA BCCNS activities following the exercise of the Mayne BCCNS Assumption Right.

The term “Target Failure” means if: (i) the FDA has not accepted for filing the Company’s NDA for SUBA BCCNS by December 31, 2018, provided that such date shall be automatically extended in the event that such NDA is filed with FDA during December 2018 to a date which is 30 days from the date of such filing or (ii) the commercial launch of SUBA BCCNS is not achieved by June 30, 2020. In October 2018, the Company announced that it revised the anticipated NDA submission date to sometime in the first quarter of 2019 which would constitute a Target Failure under the amended SLA.

The SLA Amendment also amends corresponding provisions of that certain Sublicense Agreement, dated August 31, 2015, between Mayne Pharma International Pty Ltd, an affiliate of Mayne Pharma (“Mayne Pharma International”), and the Company, in order to conform to the business terms agreed to in the SLA Amendment.

**2. Liquidity and management’s plans:**

The Company had cash and cash equivalents of approximately \$1.4 million as of September 30, 2018. 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 second quarter of 2019, although this estimation assumes the Company does not build a commercial division, 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.

**HEDGEPATH PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**  
**(Unaudited)**

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

The Company intends to finance additional research and development, commercialization and distribution efforts and its working capital needs primarily through:

- proceeds from public and private financings (including financing from the Company's majority shareholder, Mayne Pharma) and, potentially, from other strategic transactions;
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including, potentially, warrants held by the Company's majority shareholder, Mayne Pharma);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of the Company's 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 candidates; and
- government or private foundation grants or loans which would be awarded to the Company to further develop the Company's current and future anti-cancer therapies.

However, there is a risk that none of these plans will be implemented in a manner necessary to sustain the Company for an extended period of time and that the Company will be unable to obtain additional financing when needed on commercially reasonable terms, if at all. If adequate funds are not available when needed, the Company may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require the Company to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on the Company and its ability to continue as a going concern beyond the second quarter of 2019. A lack of adequate funds could lead to the Company's insolvency and may force the Company to cease operations.

**3. Summary of Significant Accounting Policies:**

*Estimates*

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

*Revenue Recognition*

The Company currently has no ongoing source of revenues. Miscellaneous income 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 September 30, 2018, the Company had approximately \$1.2 million in excess of the amount covered by Federal Deposit Insurance Corporation with one financial institution.

*Mezzanine Equity*

The Company issued Preferred Stock to Mayne Pharma pursuant to the Series B Preferred Stock Purchase Agreement. Based on Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, which requires that conditionally redeemable securities be classified outside of permanent stockholders' equity, the Company is classifying the amount of the proceeds from the sale of these shares as mezzanine equity.

*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.

**HEDGEPATH PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**  
**(Unaudited)**

**3. Summary of Significant Accounting Policies (continued):**

*Stock-Based Compensation*

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

In applying the Black-Scholes options pricing model for options issued in March 2018 (see note 4), the assumptions were as follows: 1) for the options vesting on the grant date – expected price volatility of 113.67%; risk-free interest rate of 2.64%; weighted average expected life of 5 years; and no dividend yield, and 2) for the options vesting on the first anniversary of the grant date – expected price volatility of 116.59%; risk-free interest rate of 2.64%; weighted average expected life of 5.5 years; and no dividend yield. In applying the Black-Scholes options pricing model for options issued in June 2018 (see note 4) which vest on the first anniversary of the grant date, the assumptions were as follows: expected price volatility of 112.6%; risk-free interest rate of 2.81%; weighted average expected life of 5.5 years; and no dividend yield

*Income Taxes*

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. These differences occur primarily in share-based compensation, in-process research and development, and net operating loss carry forward which are offset by a net deferred tax asset valuation allowance due to the Company’s recurring net losses.

*Recent accounting pronouncements:*

In May 2014, the FASB issued Accounting Standards Update (“ASU”)2014-09, “Revenue from Contracts with Customers,” which supersedes the revenue recognition requirements of 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 Company has evaluated the impact of this revised guidance on its financial statements, which was effective January 1, 2018, and determined it had no material impact.

In February 2016, the FASB issued ASU2016-02, “Leases,” which created a new Topic, ASC Topic 842 and established the core principle that a lessee should recognize the assets, representing rights-of-use, and liabilities to make lease payments, that arise from leases. For leases with a term of 12 months or less, a lessee is permitted to make an election under which such assets and liabilities would not be recognized, and lease expense would be recognized generally on a straight-line basis over the lease term. This standard is effective for the Company beginning in 2019, and early application is permitted. The Company has evaluated the potential impact of this guidance and does not believe it will have a material impact on the Company’s financial statements.

In April 2016, the FASB issued ASU2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing.” ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. These ASUs apply to all companies that enter into contracts with customers to transfer goods or services. This ASUs is effective for public entities for interim and annual reporting periods beginning after December 15, 2017. The Company has evaluated the impact of this revised guidance on its financial statements, which was effective January 1, 2018, and determined it had no material impact.

**HEDGEPATH PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**  
**(Unaudited)**

**3. Summary of Significant Accounting Policies** *Recent accounting pronouncements (continued):*

In June 2018, the FASB issued ASU 2018-07, "Compensation – Stock Compensation (Topic 718)." ASU 2018-07 simplifies the accounting for nonemployee share-based payment transactions. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2018. The Company has evaluated the potential impact of this guidance and does not believe that it will have a material impact on the Company's financial statements.

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

**4. Stockholders' Equity:**

*Employee Stock Plans*

On March 13, 2018, as compensation for 2017 service, management was awarded 570,000 stock options pursuant to the Company's 2014 Equity Incentive Plan (the "Plan") with an exercise price of \$0.2722 and Black-Scholes value of \$0.22 per share that vested on the grant date. Independent Board members were awarded a total of 188,000 stock options pursuant to the Plan with an exercise price of \$0.2722 and Black-Scholes value of \$0.22 that also vested on the grant date. 75,000 common shares were issued to the former Secretary of the Company for the prior year's service.

In addition, Board members were awarded approximately 1.1 million stock options pursuant to the Plan with an exercise price of \$0.2722 and Black-Scholes value of \$0.23 that vest on the first anniversary of the grant date. The grant date fair value of common stock options was determined using the Black-Scholes model on the date of issuance and the number of shares expected to vest. The total Black-Scholes value of the March 13, 2018 stock options grants was approximately \$0.4 million.

On June 15, 2018, as compensation for 2018 service, Board members were awarded a total of 912,000 stock options pursuant to the Company's 2014 Equity Incentive Plan (the "Plan") with an exercise price of \$0.33 and Black-Scholes value of \$0.273 per share that vest on the first anniversary of the grant date.

Total stock-based compensation for the nine months ended September 30, 2018 was approximately \$0.4 million and is primarily related to common stock options issued pursuant to the Plan in March and June 2018. The expense is classified as research and development expense and general and administrative expense in the accompanying condensed statements of operations. As of September 30, 2018, there were 3,424,000 outstanding common stock options under the Plan of which 1,408,000 were vested. There was approximately \$0.3 million in unamortized stock-based compensation at September 30, 2018.

*Dividend Payment*

On July 15, 2018, the Company paid a bi-annual dividend payment of approximately \$0.06 million to Mayne Pharma by issuing 184,798 shares of common stock. The number of shares was calculated by dividing the principal value of the dividend owed by the volume-weighted average price of the common stock, as defined, for the dividend period.

**5. Legal Proceedings:**

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

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

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

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

### **Critical Accounting Policies**

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

### **Results of Operations**

#### ***For the three months ended September 30, 2018 compared to the three months ended September 30, 2017***

*Research and Development Expenses.* We recognized approximately \$0.8 million in research and development expenses during the three months ended September 30, 2018 compared to approximately \$0.4 million for the three months ended September 30, 2017. Research and development expenses for both periods primarily include 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 due primarily to an increase in expenses related to regulatory consulting associated with the preparation for an NDA filing.

*General and Administrative Expenses.* We recognized approximately \$0.4 million in general and administrative expenses during the three months ended September 30, 2018 compared to \$0.2 million for the three months ended September 30, 2017. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff and Board members, facility expenditures, professional fees, consulting and taxes. The increase is due primarily to an increase in stock compensation expense associated with stock options issued in March and June of 2018.

*Interest Income.* We recognized interest income of \$3,995 during the three months ended September 30, 2018 compared to \$2,086 for the three months ended September 30, 2017 for interest earned on cash balances in our money market account.

#### ***For the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017***

*Research and Development Expenses.* We recognized approximately \$2.0 million in research and development expenses during the nine months ended September 30, 2018 compared to approximately \$1.7 million for the nine months ended September 30, 2017. Research and development expenses for both periods primarily include 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 due primarily to an increase in expenses related to regulatory consulting associated with the preparation for an NDA filing.

*General and Administrative Expenses.* We recognized approximately \$1.3 million in general and administrative expenses during the nine months ended September 30, 2018 compared to \$2.5 million for the nine months ended September 30, 2017. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff and Board members, facility expenditures, professional fees, consulting and taxes. The decrease is due primarily to a reduction in stock compensation expense of approximately \$1.4 million. A change in control in November 2016 resulted in the revaluation of RSUs increasing the expense which carried forward to the nine months ended September 30, 2017.

*Interest Income.* We recognized interest income of \$10,707 during the nine months ended September 30, 2018 compared to \$16,726 for the nine months ended September 30, 2017 for interest earned on cash balances in our money market account.

### **Liquidity and Capital Resources**

We had approximately \$1.4 million cash on hand at September 30, 2018.

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

- proceeds from public and private financings (including financing from our majority shareholder, Mayne Pharma) and, potentially, other strategic transactions;
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including, potentially, warrants held by our majority shareholder, Mayne Pharma);

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

However, there is a risk that none of these plans will be implemented and that we will be unable to obtain additional financing on commercially reasonable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require us to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on our company, our viability, our financial condition and our results of operations beyond the second quarter of 2019. In addition, a lack of adequate funds could lead to our company's insolvency and may force us to cease operations.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

None.

### **Item 4. Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

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

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

#### *Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the nine months ended September 30, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### *Limitations on the Effectiveness of Internal Controls*

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

### **CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS**

Certain information set forth in this Quarterly Report on Form10-Q, including in Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" (and the "Liquidity and Capital Resources" section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes "forward-looking statements" within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects", "may", "could", "would", "should", "believes", "expects", "anticipates", "estimates", "intends", "plans" or similar expressions. These statements are based upon the current beliefs and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results,

including, without limitation: (i) 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 2017 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.

The Company hereby supplements its risk factor disclosure as set forth in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on February 16, 2018, with the following additional risk factor:

*There is a material risk that Mayne Pharma could in the foreseeable future exercise a right to assume full control of our lead SUBA BCCNS product, which would materially and adversely affect our value as a company and our ability to conduct and finance our operations.*

Under our Supply and License Agreement with Mayne Pharma, as amended, if our NDA for SUBA BCCNS is not accepted for filing by the FDA by December 31, 2018 (subject to limited extension if the NDA is filed in December), Mayne Pharma may elect to assume full control of the SUBA BCCNS product in the United States (including by way of an exclusive license from us of our clinical data) in exchange for a royalty on any future net sales.

In October 2018, we announced the results of our September 25, 2018 meeting with FDA regarding the requirements for filing the SUBA BCCNS NDA. We believe that the time necessary to fulfill the FDA's requirements as articulated to us at the meeting will (absent any alternatives) most likely push the anticipated timing for the SUBA BCCNS NDA into the first quarter of 2019. As a result, there is presently a significant risk that Mayne Pharma will have the right to assume full control of the SUBA BCCNS product in the foreseeable future.

Should this occur, there is a material risk that the overall value of our company will be materially and adversely affected, as we will be left only with a speculative future royalty on net sales of the SUBA BCCNS product (should the product ever be approved by the FDA and should such sales ever occur) as well as uncertain prospects for prosecuting clinical development work for other cancer indications under the Supply and License Agreement with Mayne Pharma. In this instance, our stock price could fall, and our overall business prospects, including our ability to conduct and finance our ongoing operations, would be severely and negatively impacted.

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

None.

### Item 3. Defaults upon Senior Securities.

None.

### Item 4. Mine Safety Disclosures.

Not applicable.

### Item 5. Other Information.

Not applicable.

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**Item 6. Exhibits.**

<b><u>Number</u></b>	<b><u>Description</u></b>
31.1	<a href="#"><u>Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302</u></a>
31.2	<a href="#"><u>Certification of Chief Financial Officer Pursuant To Sarbanes-Oxley Section 302</u></a>
32.1	<a href="#"><u>Certification Pursuant To 18 U.S.C. Section 1350 (*)</u></a>
32.2	<a href="#"><u>Certification Pursuant To 18 U.S.C. Section 1350 (*)</u></a>
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.

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**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 14, 2018

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

Date: November 14, 2018

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 as applicable, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2018

/s/ Nicholas J. Virca

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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 as applicable, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: November 14, 2018

/s/ Garrison J. Hasara

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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 Form10-Q for the period ending September 30, 2018, 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 14, 2018

**HEDGEPATH PHARMACEUTICALS, INC.**

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

In connection with the Quarterly Report of HedgePath Pharmaceuticals, Inc. (the "Company") on Form10-Q for the period ending September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrison J. Hasara, Chief Financial Officer, Treasurer, Chief Compliance Officer, and Secretary of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Garrison J. Hasara  
Garrison J. Hasara  
Chief Financial Officer, Treasurer, Chief Compliance Officer,  
and Secretary  
November 14, 2018