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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

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

For the transition period from_____ to _____

Commission file number 001-13467

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

Delaware	**30-0793665**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
324 S. Hyde Park Avenue Ste. 350 Tampa, FL	**33606**
(Address of principal executive offices)	**(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 September 6, 2013, there were 18,888,971 shares of company common stock issued and outstanding.

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Hedgepath Pharmaceuticals, Inc.

(as successor to Commonwealth Biotechnologies, Inc.)

Quarterly Report on Form 10-Q

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EXPLANATORY NOTE

Subsequent to the period covered by this Report, on August 12, 2013, as the first step in a two-step transaction, Commonwealth Biotechnologies Inc, a Virginia corporation ("CBI"), effected a "short-form" reincorporation merger with HedgePath Pharmaceuticals, Inc. ("HPPI"), a newly created and wholly owned and Delaware subsidiary of CBI, pursuant to which CBI merged with and into HPPI, with HPPI being the surviving entity in the merger and with the effect of CBI becoming reincorporated as a Delaware corporation and changing its corporate name (the "Reincorporation Transaction"). The Company's Certificate of Incorporation authorizes the issuance of up to 350,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

In addition, on August 13, 2013, as the second step in the two-step transaction, HPPI entered into a Contribution Agreement, dated as of August 13, 2013 by and between HPPI and Hedgepath, LLC, a Florida limited liability company, pursuant to which, in exchange for shares of HPPI's newly created Series A Convertible Preferred Stock representing 90% of the fully diluted voting securities of HPPI as of the date of issuance (or 170,000,739 shares of common stock, par value $0.0001 per share, of HPPI on an as converted basis), Hedgepath, LLC contributed and/or assigned to HPPI certain intellectual property and other assets associated with the going-forward business of HPPI (namely, repurposing the approved anti-fungal drug itraconazole as a potential treatment for cancer) (the "Contribution Transaction").

This Report presents the financial statements and related footnotes and disclosures of and for the historic CBI as of June 30, 2013. Since the assets received by HPPI in the Contribution Transaction do not represent a "business" under either Rule 11-01(d) of Regulation S-X or U.S. generally accepted accounting principles, the Contribution Transaction and Reincorporation Transaction are each disclosed herein as a subsequent event and will be accounted for and reported as of the dates of such transactions. See Footnote 8 to the accompanying financial statements for further information.

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
CONDENSED BALANCE SHEETS
AS OF JUNE 30, 2013 AND DECEMBER 31, 2012

	June 30, 2013 (Unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,112	$ 857,702
Other current assets	362	78,733
Total current assets	1,474	936,435
Total assets	$ 1,474	$ 936,435
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 142,014	$ 368,613
Accrued payroll liabilities	62,178	191,340
Other liabilities	6,250	—
Deposits	30,000	—
Due to related party	69,264	—
Total current liabilities	309,706	559,953
Liabilities subject to compromise:		
Priority claims	—	23,450
Accounts payable and other unsecured creditors	—	422,316
Other liabilities	—	63,500
Total liabilities subject to compromise	—	509,266
Total liabilities	309,706	1,069,219
Commitments and contingencies	—	—
Stockholders' deficit:		
Preferred Stock, no par value; 1,000,000 shares authorized, none outstanding	—	—
Common Stock, no par value; 100,000,000 shares authorized; 18,888,971 and 15,560,504 shares issued and outstanding in 2013 and 2012, respectively	—	—
Additional paid-in capital	26,431,815	26,279,815
Accumulated deficit	(26,740,047)	(26,412,599)
Total stockholders' deficit	(308,232)	(132,784)
Total liabilities and stockholders' deficit	$ 1,474	$ 936,435

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
CONDENSED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues:				
Total Revenues:	—	—	—	—
Expenses:				
Chapter 11 expenses	117,324	—	117,324	1,625
General and administrative	286,256	111,424	376,800	214,832
Total Expenses:	403,580	111,424	494,124	216,457
Loss from operations	(403,580)	(111,424)	(494,124)	(216,457)
Interest expense	—	(8,333)	—	(20,833)
Gain on reorganization	166,676	—	166,676	—
Other (expense) income	(30,000)	—	—	7,956
Net loss	$ (266,904)	$ (119,757)	$ (327,448)	$ (229,334)
Basic and diluted loss per share	$ (0.01)	$ (0.01)	$ (0.02)	$ (0.02)
Weighted average common stock shares outstanding	18,376,899	12,660,554	16,976,482	12,660,554

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
CONDENSED STATEMENT OF STOCKHOLDERS' DEFICIT
FOR THE SIX MONTHS ENDED JUNE 30, 2013
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balances, January 1, 2013	15,560,504	$ —	$26,279,815	$(26,412,599)	$ (132,784)
Issuance of restricted stock in lieu of cash payment under the Bankruptcy plan	3,328,467	—	152,000	—	152,000
Net loss	—	—	—	(327,448)	(327,448)
Balances, June 30, 2013	18,888,971	$ —	$26,431,815	$(26,740,047)	$ (308,232)

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
CONDENSED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

	Six months Ended June 30,	
	2013	2012
Operating activities:		
Net loss	$(327,448)	$ (229,334)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Changes in assets and liabilities:		
Other current assets	78,371	2,173
Accounts payable and other current liabilities	(152,836)	54,618
Net cash flows from operating activities before reorganization items	(401,913)	(172,543)
Reorganization items:		
Gain on reorganization	(166,676)	—
Decrease in liabilities subject to compromise	(357,265)	—
Net cash flows from operating activities	(925,854)	(172,543)
Financing activities:		
Proceeds from related party advances	69,264	—
Net cash flows from financing activities	69,264	—
Net change in cash and cash equivalents	(856,590)	(172,543)
Cash and cash equivalents at beginning of period	857,702	1,321,968
Cash and cash equivalents at end of period	$ 1,112	$1,149,425
Supplemental disclosure of non-cash financing activity:		
Stock payments to officers and directors (liabilities subject to compromise) in lieu of cash payments under the Bankruptcy Plan	$ 152,000	$ —

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

1. Basis of presentation:

Overview

The accompanying unaudited condensed financial statements of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company" or "we", "us" or similar terminology) as successor to Commonwealth Biotechnologies, Inc., a Virginia corporation ("CBI"), 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 at June 30, 2013, 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, 2012, which are included in the Company's 2012 Annual Report on Form 10-K, filed with the SEC on May 20, 2013 (the "2012 Annual Report"). The accompanying condensed balance sheet at December 31, 2012 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 CBI's common stock, no par value per share.

The results of operations for the six month period ended June 30, 2013 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 2012 Annual Report as well as the Company's Current Report on Form 8-K, dated August 16, 2013.

The accompanying financial statements have been prepared on a going concern basis which contemplates 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 and 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

CBI was a specialized life sciences outsourcing business that offered cutting-edge expertise and a complete array of Peptide-based discovery chemistry and biology products and services through Mimotopes Pty Limited ("Mimotopes"), a wholly-owned subsidiary of CBI. On January 20, 2011, CBI filed a voluntary petition in the United States Bankruptcy Court for the Eastern District of Virginia (the "Bankruptcy Court") seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code. On April 7, 2011, the Bankruptcy Court approved the private sale of the CBI Mimotopes business unit for a net sales price of $850,000. The sale closed on April 29, 2011. As of June 30, 2013, CBI had no operating units or subsidiaries.

On August 12, 2013, CBI effected a "short-form" reincorporation merger with HedgePath Pharmaceuticals, Inc., ("HPPI"), a newly created and wholly owned Delaware subsidiary of CBI, pursuant to which CBI merged with and into HPPI, with HPPI being the surviving entity in the merger and with the effect of CBI becoming reincorporated as a Delaware corporation and changing its corporate name. Each outstanding share of CBI was converted into one share of HPPI. HPPI's Certificate of Incorporation (and thus the Certificate of Incorporation of the Surviving Company) authorizes the issuance of up to 350,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

On August 13, 2013, the Company entered into a Contribution Agreement, dated as of August 13, 2013 (the "Contribution Agreement"), by and between the Company and Hedgepath, LLC, (a Florida limited liability company), pursuant to which, and subject to the terms and conditions contained therein, in exchange for the right to receive shares of the Company's newly created Series A Convertible Preferred Stock (the "Series A Preferred Stock"), representing 90% of the fully diluted voting securities of the Company as of the date of issuance (or 170,000,739 shares of common stock, par value $0.0001 per share, of the Company (the "HPPI Common Stock") on an as converted basis), Hedgepath, LLC contributed and/or assigned various assets and contract rights to the Company associated with the going forward business of the Company (collectively, the "Assets") as described herein in note 8. The par value was changed from no par value to $0.0001, which par value is customary for newly formed Delaware corporations.

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

1. Basis of presentation (continued):

Pre-Bankruptcy and Emergence from Bankruptcy

On January 20, 2011, CBI filed a voluntary petition in the Bankruptcy Court (the "Chapter 11 case") seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code"). The Chapter 11 case was captioned *In re Commonwealth Biotechnologies, Inc., Case No. 11-30381-KRH.* On January 4, 2013, CBI filed an Amended Plan of Reorganization, dated January 4, 2013 (the "Plan") with the Bankruptcy Court. The Plan was approved by a vote of creditors and CBI stockholders on March 21, 2013. CBI received an auction fee of $30,000 from Hedgepath, LLC, (which fee was a binding, irrevocable offer for the purchase of a portion of CBI's equity interests) in addition to the contribution of Assets. Hedgepath, LLC was the winning bidder for CBI, which is more fully described below in *Post-Bankruptcy Business of HPPI-General.*

On March 29, 2013, the Bankruptcy Court entered an order (the "Confirmation Order") confirming the Plan pursuant to Chapter 11 of the Bankruptcy Code. Under the terms of the Plan, and pursuant to the Contribution Agreement, Hedgepath, LLC contributed and assigned the Assets to HPPI, as the reorganized debtor, in exchange for the right to receive 90% of fully diluted voting equity in HPPI (in the form of the Series A Preferred Stock) on the date of issuance, with the prior stockholders of CBI retaining approximately 10% voting equity in HPPI, represented by 100% the issued and outstanding shares of HPPI Common Stock.

Post-Bankruptcy Business of HPPI - General

As a result of the aforementioned transactions, as of August 13, 2013 the Company is a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer. The Company is currently focused on the development of therapies for a variety of cancers, with initial emphasis on skin, prostate and lung cancers in the U.S. market, based upon the use of the currently marketed anti-fungal drug itraconazole (the "Itra Business Opportunity"). The Company believes that itraconazole could affect the Hedgehog signaling pathway in cells, a major regulator of many fundamental cellular processes, which could, in turn, impact the development and growth of certain cancers.

Itraconazole is approved for and extensively used to treat fungal infections and has an extensive history of safe and effective use in humans. The Company has developed, optioned and is seeking to acquire and/or license, 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.

The Hedgehog Pathway

The Hedgehog signaling pathway is a major regulator of many fundamental cellular processes in vertebrates, including primarily at the embryonic stage of development but also as it relates to stem cell maintenance, cell differentiation, tissue polarity and cell proliferation. Based on published research, the Company believes that inhibiting the Hedgehog pathway could delay or possibly prevent the development of certain cancers in patients. Research has shown that activation of the Hedgehog pathway can lead to the formation of cancerous tumors (a process known as tumorigenesis), such as the most common form of skin cancer known as basal cell carcinoma. A variety of other human cancers, including brain, gastrointestinal, lung, breast and prostate cancers, also demonstrate inappropriate activation of this pathway. Hedgehog signaling from the tumor to the surrounding cell structures has been shown to sometimes promote further tumorigenesis. This pathway has also been shown to regulate proliferation of cancer stem cells and to increase tumor invasiveness.

The Company believes that the targeted inhibition of Hedgehog signaling may be effective in the treatment and prevention of many types of human cancers. The Company also believes that the discovery and synthesis of specific Hedgehog pathway inhibitors may have significant clinical implications regarding the development of novel cancer therapies. Several synthetic Hedgehog antagonists are now being studied, some of which are undergoing clinical evaluation. The orally available compound, GDC-0449 (vismodegib, developed by Genentech, a subsidiary of Roche), is the first Hedgehog inhibitor based-therapy that has been approved for treatment of advanced stages of basal cell carcinoma by the U.S. Food and Drug Administration ("FDA").

Repurposing itraconazole for the treatment of cancer

The Company is currently implementing clinical and regulatory plans to enable the repurposing of itraconazole for the treatment of a variety of cancers. This strategy is intended to significantly reduce the risk and time to potential FDA approvals for marketing in the United States. Initial target applications include therapies for prostate, lung and skin cancers, among others.

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

1. Basis of presentation (continued):

Itraconazole appears to have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of on-going research. These anti-cancer effects have been demonstrated in various animal models and, subsequently in human studies over the last few years, all of which are the basis of our interest in the clinical development of itraconazole for treatment of human cancers.

The Company believes that its development of itraconazole as an anti-cancer therapy may lead to its use as an inhibitor of the Hedgehog pathway, thereby retarding the progression of cancer. In animal models, itraconazole has demonstrated an anti-angiogenic effect (i.e., inhibiting the formation of new blood vessels), which may be important in controlling the proliferation of cancerous cells and tumors in humans based upon its interaction with certain cell-based growth factors. Itraconazole also appears to induce changes related to the mTOR pathway, an important regulator of cell growth, proliferation and survival which, when unregulated, can also lead to cancer.

2. Liquidity and management's plans:

A continued lack of adequate cash resulting from the Company's bankruptcy, the sale of CBI's principal assets, and the resulting inability to generate cash flow from operations or to raise capital from external sources forced the Company to substantially curtail or cease operations and, therefore, had a material adverse effect on its business. As a result, during 2012 and 2013, the Company's business has undergone substantial reductions in relation to size, scale and scope of activities. As of June 30, 2013, the Company has no operating units or subsidiaries.

As a result of the foregoing circumstances, there is substantial doubt about the Company's ability to continue as a going concern. 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 the Company be unable to continue as a going concern.

The Company's previous independent auditors have included a paragraph emphasizing "going concern" uncertainty in their report on the 2012 financial statements. 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 the Company be unable to continue as a going concern.

The Company currently has cash and cash equivalents of $1,100 as of June 30, 2013, and will therefore rely on loans from our insiders and affiliates to fund its operations until the Company is able to raise additional capital. Subsequent to June 30, 2013, working capital advances as of the date of this report from Hedgepath, LLC approximate $62,000, and have been used for officer and employee salaries, legal and professional fees.

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

- 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;
- licensing and joint venture arrangements with third parties, including other pharmaceutical companies where the Company would receive funding based on out-licensing its product to augment their product profile in the treatment of cancers;
- receiving government or private foundation grants which would be awarded to the Company to further develop our current and future anti-cancer therapies; and
- securing proceeds from public and private financings and other strategic transactions. As part of the Plan, the Company will seek an up to $5 million equity financing to provide for its initial working capital. However, no assurances can be given that the Company will be able to raise such funds.

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

3. Summary of Significant Accounting Policies:

Estimates

The preparation of 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 has no operating units or subsidiaries. Consequently, the Company has no ongoing source of revenues. Any 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 maintains cash balances in excess of FDIC insured amounts.

Accounting for Enterprises in Reorganization

Financial Accounting Standards Board (" FASB") Accounting Standards Codification ("ASC") Topic 852—*Reorganizations* ("ASC Topic 852"), which is applicable to companies in Chapter 11, generally does not change the manner in which financial statements are prepared. However, it does require that the financial statements for periods subsequent to the filing of the Chapter 11 petition distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Revenues, expenses, realized gains and losses, and provisions for losses that can be directly associated with the reorganization and restructuring of the business must be reported separately as reorganization items in the statements of operations beginning in the quarter ending March 31, 2011. The balance sheet must distinguish prepetition liabilities subject to compromise from both those prepetition liabilities that are not subject to compromise and from post-petition liabilities. Liabilities that may be affected by a plan of reorganization must be reported at the amounts expected to be allowed by the Bankruptcy Court, even if they may be settled for lesser amounts. In addition, cash flows from reorganization items must be disclosed separately in the statement of cash flows. The Company became subject to ASC Topic 852 effective on January 20, 2011, and has segregated those items as outlined above for all reporting periods after such date. The Company officially emerged from bankruptcy on April 17, 2013, followed by the reincorporation merger, which satisfied the final condition to effectiveness of the Plan as detailed in note 8.

4. Chapter 11 Information:

During the six months ended June 30, 2013, the Company settled all pre-petition claims associated with the bankruptcy in cash and Common Stock. The Company paid approximately $357,265 in cash and $152,000 in Common Stock to settle the claims. The Common Stock was valued using the 30 day average of the Company's stock price. The difference between pre-petition liabilities and the settled amount was recognized as gain on reorganization in the condensed statement of operations as of June 30, 2013.

5. Stockholders' Equity:

Employee Stock Plans

A 2002 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. The Plan makes up to 600,000 shares of Common Stock available for grants of restricted stock awards and stock options in the form of incentive stock options and non-qualified options to employees, directors and consultants of CBI. There were 203,443 options outstanding under the 2002 plan as of June 30, 2013. However, these options were canceled on July 16, 2013, which was 90 days subsequent to the effective date of the emergence from bankruptcy.

A 2007 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. The Plan makes up to 1,000,000 shares of common stock available for grants of restricted stock awards and stock options in the form of incentive stock options and non-qualified options to employees, directors and consultants of CBI. There were 42,000 options outstanding under the 2007 plan as of June 30, 2013. However, these options were canceled on July 16, 2013, which was 90 days subsequent to the effective date of the emergence from bankruptcy.

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

5. Stockholders' Equity (continued):

A 2009 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. The Plan makes up to 1,000,000 shares of Common Stock available for grants of restricted stock awards and stock options in the form of incentive stock options and non-qualified options to employees, directors and consultants of CBI. There are no options outstanding under this plan.

Going forward, incentive awards may be in the form of stock options, restricted stock, restricted stock units and performance and other awards. In the case of incentive stock options, the exercise price will not be less than 100% of the fair market value of shares covered at the time of the grant, or 110% for incentive stock options granted to persons who own more than 10% of the Company's voting stock. Options granted generally vest over a three-year period from the date of grant and are exercisable for ten years, except that the term may not exceed five years for incentive stock options granted to persons who own more than 10% of the Company's outstanding common stock.

Stock-based compensation expense is determined based on the fair value of the stock-based awards and is recognized over the vesting period. No stock-based compensation expense related to employee stock options was recognized for the six month periods ended June 30, 2013 or 2012. As of June 30, 2013 there was no unamortized stock-based compensation cost related to non-vested stock awards. During the six months ended June 30, 2013, no stock options were granted, exercised or forfeited.

Options outstanding and exercisable at June 30, 2013 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.00 – 5.00	207,943	$ 2.50	
$5.01 – 10.00	37,500	$ 5.92	
	245,443		$ —

Warrants

CBI previously granted warrants to purchase shares of Common Stock. On March 20, 2013, the Company filed a motion to cancel all outstanding warrants under the terms of the Bankruptcy Code. This motion was approved and entered by the Bankruptcy Court in April 2013, and was effective immediately upon filing.

Issuance of Restricted Stock

In April 2013, restricted shares were issued to the CBI's CEO, one CBI board member and one former CBI officer for a portion of their approved claims. The number of shares issued were valued using an average of the 30 day closing price of Common Stock and are as follows:

	Number of Shares	Market Value
CEO	2,846,715	$ 130,000
Board Member	372,263	17,000
Former Officer	109,489	5,000
	3,328,467	$ 152,000

6. Related party transactions:

Due to the financial condition of the Company, a portion of certain salaries have been accrued and unpaid totaling approximately $62,178 at June 30, 2013.

As part of the short-form reincorporation merger with HPPI, certain expenses have been incurred for officer salary, travel and patent expense. These expenses, totaling $69,264, were paid by Hedgepath, LLC on behalf of the newly formed HPPI and are included in due to related party in the accompanying condensed balance sheet as of June 30, 2013. This non-interest bearing loan is anticipated to be paid on upon the Company's first capital raise.

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

7. Intellectual Property:

Prior to the asset sale to Bostwick Laboratories ("Bostwick") in December 2011, CBI was primarily focused on fee-for-service offerings. In addition, CBI developed various intellectual properties that had resulted in U.S. and international patents. Most of these were assigned to Bostwick as part of the asset sale. However, the Company retained one dormant patent application in the vaccine development area. This patent, however, has been abandoned and deemed to have no value as of June 30, 2013.

8. Subsequent event:

On August 12, 2013, as the first step in a two-step transaction, CBI effected a "short-form" reincorporation merger with HPPI, a newly created and wholly owned Delaware subsidiary of CBI, pursuant to which CBI merged with and into HPPI, with HPPI being the surviving entity in the merger and with the effect of CBI becoming reincorporated as a Delaware corporation and changing its corporate name.

On August 13, 2013, as the second step in the two-step transaction, the Company entered into the Contribution Agreement, dated as of August 13, 2013, by and between the Company and Hedgepath, LLC pursuant to which, and subject to the terms and conditions contained therein, in exchange for the right to receive shares of the Company's newly created Series A Convertible Preferred Stock, representing 90% of the fully diluted voting securities of the Company as of the date of issuance (or 170,000,739 shares of HPPI Common Stock, on an as converted basis), Hedgepath, LLC contributed and/or assigned the following assets and contract rights (the "Assets") to the Company as described herein.

(i) U.S. Provisional Patent Application 61-813,122, "Prostate-Specific Antigen as Biomarker for Hedgehog Pathway Inhibitor Treatment and Prognostic Monitoring of Prostate Cancer" (previously assigned to Hedgepath, LLC by Francis E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

(ii) U.S. Provisional Patent Application 61-813,823, "Treatment and Prognostic Monitoring of Cancer Using Hedgehog Pathway Inhibitors" (previously assigned to Hedgepath, LLC by Francis E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

(iii) Assignment of Patents, dated November 1, 2012, by Francis E. O'Donnell, Jr. in favor of Hedgepath, LLC;

(iv) Assignment of Patents, dated November 1, 2012, by Nicholas J. Virca in favor of Hedgepath, LLC;

(v) Consulting Agreement, dated and effective as of September 1, 2012, by and between HPPI (the predecessor of Hedgepath, LLC) and Emmanuel Antonarakis, MD ("Antonarakis").

(vi) Confidentiality and Intellectual Property Assignment Agreement, dated and effective September 1, 2012, between Antonarakis and HPPI (the predecessor to Hedgepath, LLC), which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Antonarakis under such agreement.

(vii) Consulting Agreement, effective as of April 11, 2013, by and between Hedgepath, LLC and Arianne Consulting, Inc. ("Arianne"); and

(viii) Confidentiality and Intellectual Property Assignment Agreement, dated and effective April 11, 2013, between Arianne and Hedgepath, LLC , which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Arianne under such agreement.

The Contribution Agreement was entered into to carry out the purposes and intent of the Plan filed by CBI and confirmed by the United States Bankruptcy Court for the Eastern District of Virginia in connection with CBI's voluntary petition before the Bankruptcy Court seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code (Case No. 11-30381-KRH). The Plan was previously approved by CBI's creditors and shareholders and confirmed by the Bankruptcy Court on March 29, 2013.

Hedgepath, LLC is a development stage pharmaceutical company. Since its formation in late 2011, Hedgepath, LLC has sought, among other pharmaceutical business opportunities, to acquire technology rights and to conduct activities related to the development of the currently-marketed drug itraconazole (currently approved as an anti-fungal agent) for the treatment of cancer (the "Itra Business Opportunity"). Hedgepath, LLC has expended approximately $0.1 million acquiring assets and developing the ITRA Business Opportunity including approximately $82,500 on technical and medical consulting and $15,000 on option fees related to intellectual property agreement that has since expired.

HEDGEPATH PHARMACEUTICALS, INC.
(AS SUCCESSOR TO COMMONWEALTH BIOTECHNOLOGIES, INC.)
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012
(Unaudited)

8. Subsequent event (continued):

In accordance with the Plan, and as a result of the transactions contemplated by the Contribution Agreement, from and after August 13, 2013, HPPI will be engaged in the Itra Business Opportunity. The Assets contributed to the Company by Hedgepath, LLC represent the assets and rights heretofore developed or acquired by Hedgepath, LLC related to the Itra Business Opportunity, and by virtue of the Contribution Agreement, the Company acquired all of Hedgepath, LLC's right, title and interest in and to the Assets.

As part of the Contribution Agreement, Hedgepath, LLC, which owned a certain claim against CBI in the amount of $52,500, payable to a third party service provider, contributed such claim to the Company. CBI previously agreed to issue to such service provider a number of restricted shares of its Common Stock, with the number of shares of HPPI Common Stock to be determined based on the valuation of the shares to be issued to purchasers in connection with HPPI's planned $5 million offering of securities as described in the Plan. Such shares of HPPI Common Stock are to be issued to such service provider within five (5) business days of the final determination of such valuation (as memorialized in the final transaction documentation for such offering).

Hedgepath, LLC did not contribute any of its liabilities to the Company in connection with the Contribution Agreement, and retained all of its assets other than those related to the Itra Business Opportunity.

The Company's Certificate of Incorporation authorizes the issuance of up to 350,000,000 shares of HPPI Common Stock and 10,000,000 shares of preferred stock, par value $0.0001 per share. In addition, effective August 13, 2013, Hedgepath, LLC acquired the right to receive as consideration for the Contribution of the Assets, an aggregate of 170,000.739 shares of Series A Preferred Stock, par value $0.0001 per share, representing in the aggregate 90% of the Company's voting equity securities on a fully diluted basis as of such date. The issuance of such securities were pursuant to a transaction exempt from the registration requirements under Section 4(2) and/or Regulation D of the Securities Act of 1933, as amended (the "Securities Act"), inasmuch as Hedgepath, LLC is an accredited investor as defined in Rule 501 of Regulation D promulgated under the Securities Act and is acquiring the securities for investment, for its own account, and not for resale or with a view to distribution thereof in violation of the Securities Act, and the rules and regulations promulgated thereunder.

In conjunction with the execution of the Contribution Agreement, the Company has preliminarily estimated it will expense as in-process research and development cost approximately $1.0 million. The value was calculated by taking 90% of the market capitalization on the date the assets were contributed to reflect the 90% ownership exchanged for the assets contributed by Hedgepath, LLC.

On August 1, 2013, the Company formalized amounts due to a former employee and a former director of CBI by issuing two non-interest promissory notes. The notes total approximately $68,000 and are due the later of five days following the date on which the Company has raised $1 million or November 1, 2013. Upon default, interest will begin accruing at a rate of 18.0%. The amounts are included in accrued payroll liabilities and other liabilities in the accompanying condensed balance sheet as of June 30, 2013.

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 Securities and Exchange Commission (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 the historic activity of Commonwealth Biotechnologies, Inc.

For the three months ended June 30, 2013 compared to the three months ended June 30, 2012

Chapter 11 Expenses. We recognized $117,324 in Chapter 11 expenses during the three months ended June 30, 2013. There was no such expense during the corresponding period in 2012. Chapter 11 expenses consist solely of trustee fees and legal fees relating to the Company's bankruptcy filing.

General and Administrative Expenses. We recognized $286,256 and $111,424 in general and administrative expenses during the three months ended June 30, 2013 and 2012, respectively. General and administrative expenses consist of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes. The increase is primarily a result of accrued officer and employee compensation and accounting fees.

Interest Expense. We recognized $8,333 in interest expense during the three months ended June 30, 2012. There was no such expense during the corresponding period in 2013.

Gain on Reorganization. We recognized $166,676 in gain on reorganization during the three months ended June 30, 2013. There was no such gain during the corresponding period in 2012. Gain on reorganization is associated with the final payments under the Chapter 11 reorganization plan.

Other (expense) income. We recognized ($30,000) in other (expense) income during the three months ended June 30, 2013. There was no such expense during the corresponding period in 2012. The $30,000 expense consists of fees paid by Hedgepath, LLC, the winning bidder at auction for the Company under the terms of the approved Bankruptcy Plan in 2013. The auction fee was a binding, irrevocable offer paid by Hedgepath, LLC, for the purchase of a portion of the Company's equity interests, and has been recorded as a deposit.

For the six months ended June 30, 2013 compared to the six months ended June 30, 2012

Chapter 11 Expenses. We recognized $117,324 and $1,625 in Chapter 11 expenses during the six months ended June 30, 2013 and 2012, respectively. Chapter 11 expenses consist solely of trustee fees and legal fees relating to the Company's bankruptcy filing.

General and Administrative Expenses. We recognized $376,800 and $214,832 in general and administrative expenses during the six months ended June 30, 2013 and 2012, respectively. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes. This increase is primarily a result of accrued officer and employee compensation and accounting fees.

Interest Expense. We recognized $20,833 in interest expense during the six months ended June 30, 2012. There was no such expense during the corresponding period in 2013.

Gain on Reorganization. We recognized $166,676 in gain on reorganization during the six months ended June 30, 2013. There was no such gain during the corresponding period in 2012. Gain on reorganization is associated with the final payments under the Chapter 11 reorganization plan.

Other (expense) income. We recognized $7,956 in other (expense) income during the six months ended June 30, 2012. There was no such income during the corresponding period in 2013. The $7,956 in other income consists of refunds in 2012.

Liquidity and Capital Resources

The Company is currently working to implement its reorganization pursuant to the Plan.

A continued lack of adequate cash resulting from the Company's inability to generate cash flow from operations or to raise capital from external sources following the implementation of its reorganization Plan would force the Company to substantially curtail or cease operations and would, therefore, have a material adverse effect on its business.

There can be no assurance that any funds required during the next twelve months or thereafter can be generated. Nor can there be any assurance that funds will be available from external sources, such as debt or equity financing or other potential sources (including, without limitation, a proposed $5 million stock offering), if they cannot be generated internally.

During the last year, the Company's business has undergone substantial changes in relation to size, scale and scope of activities. The Company has no operating units or subsidiaries.

The Company currently has cash and cash equivalents of $1,100 as of June 30, 2013, and will therefore rely on loans from our insiders and affiliates to fund its operations until the Company is able to raise additional capital. Subsequent to June 30, 3013, working capital advances as of the date of this report from Hedgepath, LLC approximate $62,000, and have been used for officer and employee salaries, legal and professional fees.

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

- 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;
- licensing and joint venture arrangements with third parties, including other pharmaceutical companies where the Company would receive funding based on out-licensing its product to augment their product profile in the treatment of cancers;
- receiving government or private foundation grants which would be awarded to the Company to further develop our current and future anti-cancer therapies; and
- securing proceeds from public and private financings and other strategic transactions. As part of the Plan, the Company will seek an up to $5 million equity financing to provide for its initial working capital. However, no assurances can be given that the Company will be able to raise such funds.

As a result of the foregoing circumstances, there is substantial doubt about the Company's ability to continue as a going concern. 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 the Company be unable to continue as a going concern.

The Company's previous independent auditors have included a paragraph emphasizing "going concern" uncertainty in their report on the 2012 financial statements. 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 the Company 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 to ensure that material information is recorded, processed and summarized timely. However, due to the short-form reincorporation merger with HPPI and changes in management and accounting staff, the current quarterly report was not reported by our management on a timely basis in order to comply with our disclosure obligations under the Exchange Act and the rules and regulations promulgated thereunder.

Changes in Internal Control over Financial Reporting

Further, there were no changes in our internal control over financial reporting during our second fiscal quarter of 2013 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than the change of accounting staff.

Changes in Certifying Officers

Subsequent to our second fiscal quarter of 2013 and in conjunction with the short-form merger between the Company and HPPI, the Company's management and Certifying Officers were replaced, and new officers were installed. The Company does not believe that the change in Certifying Officers will materially affect, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Internal Controls

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

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" (and the "Liquidity and Capital Resources" section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes "forward-looking statements" within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects", "may", "could", "would", "should", "believes", "expects", "anticipates", "estimates", "intends", "plans" or similar expressions. These statements are based upon the current beliefs and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) actual sales results and royalty or milestone payments, if any, (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 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 2012 Annual Report, under "Risk Factors" in our Current Report on Form 8-K dated August 16, 2013 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 1A. Risk Factors.

The Company hereby updates its risk factors as a result of the contribution of the Assets to the Company in August 2013 and the Company's resulting new business of repurposing the approved anti-fungal drug itraconazole as a potential treatment for cancer (i.e., the Itra Business Opportunity).

Risks Related to Our Business

We are a clinical stage pharmaceutical company and are thus subject to the risks associated with new businesses.

We only recently emerged from bankruptcy, and the business opportunity we acquired in connection with our reorganization (the development of itraconazole anti-cancer therapies) is a new business opportunity. As such, we are a clinical stage pharmaceutical company with no history of revenue-generating operations, and our only assets consist of the intellectual property and related assets contributed to us by Hedgepath, LLC on August 13, 2013. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties inherent in a new business, in particular new businesses engaged in the development of pharmaceuticals. We still must establish many important functions necessary to operate a business, including acquiring additional intellectual property rights related to itraconazole , establishing our managerial and administrative structure, continuing product and technology development and implementing financial systems and controls.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in their pre-revenue generating stages, particularly those in the pharmaceutical field. Potential investors should carefully consider the risks and uncertainties that a new company with no operating history will face. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, or that our business plan is sound;
- maintain our anticipated management team;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan;
- determine that the processes and technologies that we have developed are commercially viable; and/or
- attract, enter into or maintain contracts with potentially commercial partners such as licensors of technology and suppliers.

If we cannot execute any one of the foregoing, our business may fail, in which case you would lose the entire amount of your investment in our company.

In addition, as a development stage biopharmaceutical company, we expect to encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be able to reach such point of transaction or make such a transition, which would have a material adverse effect on our company.

Our limited operating history makes it difficult for you to evaluate our business to date and to assess our future viability.

Currently, our sole line of business is the development and marketing of our itraconazole anti-cancer therapies, and we only recently acquired the assets related to this business opportunity on August 13, 2013 as part of our emergence from bankruptcy. Our pre-bankruptcy historic business operations ceased contemporaneously with our becoming subject to bankruptcy proceedings in 2011, and all assets supporting our earlier lines of business have been disposed of. Accordingly, we only recommenced active operations on August 13, 2013, the date we emerged from bankruptcy.

Moreoever, Hedgepath, LLC, from whom we acquired the itraconazole business opportunity as part of our plan of bankruptcy reorganization, was only formed in late 2011 and thus itself has a limited operating history. Our operations are presently limited to organizing and staffing our company, business planning, arranging for the raising of capital, developing our technology, identifying potential commercial partners and planning for clinical trials. We have not yet demonstrated our ability to complete any clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for product commercialization. Consequently, any predictions you make about our future viability or ability to accomplish our business goals may not be as accurate as they could be if we had a longer operating history.

Hedgepath, LLC, our 90% stockholder, has the ability to influence or dictate the outcome of actions requiring stockholder approval.

Hedgepath, LLC (which is controlled by Black Robe Capital LLC, of which Dr. Frank E. O'Donnell, Jr., our Executive Chairman, is the manager) holds voting securities (in the form of Series A Preferred Stock) representing approximately 90% of the voting power of our company. As a result, Hedgepath, LLC has the ability to dictate the outcome of corporate actions of our company requiring stockholder approval. In addition, in connection with CBI's emergence from bankruptcy and pursuant to the Plan, designees of Hedgepath, LLC have become our officers and directors.

The interests of Hedgepath, LLC may not coincide with the interests of our other stockholders, and Hedgepath, LLC could take actions that advance its own interests to the detriment of our other stockholders. Hedgepath, LLC's very high concentration of ownership may also have the effect of delaying or preventing a change in control, entrench our management and the board of directors, impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire or might adversely affect the market price of our securities.

We have no audited or unaudited financial statements related to our new itraconazole anti-cancer business opportunity on which you can make an investment decision.

On August 13, 2013, the date we emerged from bankruptcy, we acquired from Hedgepath, LLC certain intellectual property and other assets relating to the itraconazole anti-cancer therapy business opportunity that we now operate. Since the assets we acquired do not constitute a "business" for accounting or financial reporting purposes, we do not have and are not required to publish stand-alone audited or unaudited financial statements relating to such intellectual property and other assets. As such, you do not have access to audited or unaudited financial or accounting information related to such business opportunity that might be helpful in an evaluation of our business prospects.

We are dependent upon our officers and directors and their loss could adversely affect our ability to operate.

Our operations are dependent upon a relatively small group of individuals and, in particular, our current officers and directors, including most notably Frank E. O'Donnell, Jr. and Nicholas J. Virca. We believe that our ability to effect our business plans depends on the continued service of our officers and directors. Our officers and directors are not presently required to commit any specified amount of time to our affairs and, accordingly, may have conflicts of interest in allocating management time among various business activities, and these conflicts of interest may not be resolved in our favor. We do not presently have an employment agreement with, or key-man insurance on the life of, any of our directors or officers. The unexpected loss of the services of one or more of our directors or officers could have a detrimental effect on us.

The requirements of being a public company may strain our resources and divert management's attention.

Prior to Hedgepath, LLC's contribution of certain assets to us, the Itra Business Opportunity and Assets we acquired had been operated privately. In addition, although our predecessor, CBI, was a company that filed public reports with the SEC, the business of CBI effectively ceased concurrently with its entry into federal bankruptcy proceedings in 2011. As a consequence, our current business has no historical nexus to that of CBI's.

As a public company, we are (and the Itra Business Opportunity we will operate will be) subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (which we refer to herein as the Exchange Act), the Sarbanes-Oxley Act, the Dodd-Frank Act and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities (including activities previously undertaken in a private company context) more difficult, time-consuming or costly and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our ability to implement our business plans. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from business development activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

Our officers, directors, security holders and their respective affiliates may have competitive pecuniary interests that conflict with our interests.

We have not adopted a policy that expressly prohibits our directors, officers, security holders or affiliates from having a direct or indirect pecuniary interest in any investment to be acquired or disposed of by us or in any transaction to which we are a party or have an interest. Furthermore, we do not have a policy that expressly prohibits any such persons from engaging for their own account in business activities of the types conducted by us. Accordingly, such persons or entities may have a conflict between their interests and ours, and those conflicts may not be resolved in our favor.

Risks Related to Our Financial Position and Need For Additional Capital

We currently need and will require substantial additional funding. If we are unable to raise capital, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts and our business could fail.

We currently have cash and cash equivalents of $1,100 as of June 30, 2013, and will therefore rely on loans from our insiders and affiliates to fund our operations until we are able to raise additional capital. This puts us in a position of having to raise funds in the very near future just to operate our business.

Moreover, we expect that we will be required to incur significant expenses in connection with our ongoing activities, particularly as we engage in efforts to develop and ultimately commercialize our itraconazole anti-cancer therapies.

Accordingly, we will need to obtain substantial near and long term additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on commercially acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts, and our business might fail.

In addition, our future capital requirements will be significant and will depend on many factors, including:

- our ability to enter into collaboration agreements and obtain funding and achieve milestones under these agreements;
- the progress and results of our development efforts for itraconazole as a cancer therapy;
- the costs, timing and outcome of clinical trials of our product candidate for one or more types of cancer;
- the costs, timing and outcome of regulatory review of our product candidate for one or more types of cancer;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- competing technological and market developments;
- market acceptance of our product candidate as a treatment for one or more types of cancer;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidate for which we receive marketing approval;
- the revenue, if any, received from commercial sales of any product candidate for which we may receive marketing approval;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

Developing pharmaceutical products, conducting preclinical testing and clinical trials and seeking regulatory approval of such products is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidate, if approved (of which no assurances may be given), may not achieve any level commercial success. Our commercial revenues, if any, will be derived from sales of a product that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We may have difficulty in raising capital and may consume resources faster than expected.

Our company does not generate any revenue from product sales or otherwise, and we therefore have no current source of cash to meet our present and future capital requirements. Although as part of our bankruptcy reorganization, we plan to seek to raise up to $5

million in equity funding, we may not be able to raise these funds, which would leave us without resources to continue operations and force us to resort to stockholder investments or loans, which may not be available to us. We may have difficulty raising needed capital in the near or longer term as a result of, among other factors, the very early stage of our company and our lack of revenues as well as the inherent business risks associated with our company and present and future market conditions. Also, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. Our inability to raise funds could lead to decreases in the price of our common stock and the failure of our business.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Since we will be unable to generate any revenue from actual sales of products sufficient and expect to be in the development stage for the foreseeable future, we will need to seek equity or debt financing to provide the capital required to execute our business plan. We will need significant funding for developing our intellectual property, conducting clinical trials and entering into collaborations with third party partners as well as for working capital requirements and other operating and general corporate purposes.

We do not currently have any financing arrangements in place as a source of funds, and there can be no assurance that we will be able to raise sufficient capital on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be adversely affected to a significant extent.

If we raise additional capital by issuing equity securities, the percentage and/or economic ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock.

Debt financing, if obtained, may involve agreements that include liens on our assets, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, increases in our expenses and requirements that our assets be provided as a security for such debt. Debt financing would also be required to be repaid regardless of our operating results.

If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

Funding from any source may be unavailable to us on acceptable terms, or at all. If we do not have sufficient capital to fund our operations and expenses, our business could fail.

Risks Related to the Clinical Development of Our Product Candidate

We are very early in our development efforts and have only one product candidate. If we are unable to clinically develop and ultimately commercialize itraconazole as an anti-cancer therapy or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have only one product candidate, namely itraconazole for the treatment of cancer. While itraconazole has previously been approved for use as an anti-fungal agent, the use of itraconazole to treat cancer has not been approved and has been subject to limited clinical testing by others. Moreover, we have not engaged in any such testing ourselves, since our operations to date (as undertaken by Hedgepath, LLC) has been limited to developing our own intellectual property and know how, while acquiring the technology and rights of others in order to pursue the clinical development of itraconazole as a cancer therapy.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the development and eventual commercialization of our product candidate. The positive development of our product candidate will depend on several factors, including the following:

- positive commencement and completion of clinical trials;
- successful preparation of regulatory filings and receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidate and protecting our rights in our intellectual property portfolio;
- entering into arrangements with third party manufacturers to produce product needed for clinical testing and, potentially if approvals are obtained, for commercial sale;
- launching commercial sales of our product, if and when approved for one or more indications, whether alone or in collaboration with others;

- acceptance of the product for one or more indications, if and when approved, by patients, the medical community and third party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our product following approval, if any.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to clinically develop and commercialize itraconazole as a cancer therapy, which would materially harm our business.

If we are unable to convince physicians as to the benefits of itraconazole as a cancer therapy, we may incur delays or additional expense in our attempt to establish market acceptance.

Use of itraconazole as a cancer therapy will require physicians to be informed regarding the intended benefits of the product for a new indication. The time and cost of such an educational process may be substantial. Inability to carry out this physician education process may adversely affect market acceptance of itraconazole as a cancer therapy. We may be unable to timely educate physicians in sufficient numbers regarding our intended application of itraconazole to achieve our marketing plans or to achieve product acceptance. Any delay in physician education or acceptance may materially delay or reduce demand for our product candidate. In addition, we may expend significant funds toward physician education before any acceptance or demand for itraconazole as a cancer therapy is created, if at all.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidate.

The risk of failure for product candidates in clinical development is high. It is impossible to predict when our sole product candidate, itraconazole for the treatment of cancer, will prove effective or safe in humans or will receive regulatory approval for any form of cancer or any other indication. Before obtaining marketing approval from regulatory authorities for the sale of itraconazole as a cancer therapy, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, the outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidate, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, which would be time consuming and costly;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of materials necessary to conduct clinical trials of our product candidate may be insufficient or inadequate; and
- our product candidate may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our product candidate beyond those that we currently contemplate, if we are unable to complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidate for one or more indications;
- not obtain marketing approval at all for one or more indications;
- obtain approval for indications or patient populations that are not as broad as intended or desired (particularly, in our case, for different types of cancer);
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidate or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate and may harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidate if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidate, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate, which would cause the value of our company to decline and otherwise materially and adversely affect our company.

If serious adverse or unacceptable side effects are identified during the development of our product candidate, we may need to abandon or limit such development, which would adversely affect our company.

If clinical testing of itraconazole for the treatment of cancer results in undesirable side effects or demonstrates characteristics that are unexpected, we may need to abandon such development or limit such development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. If we are unable to develop itraconazole for the treatment of cancer due to reported adverse effects or characteristics, our business would be severely harmed.

For the foreseeable future, we expect to expend our limited resources to pursue a particular product candidate, leaving us unable to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of clinical and commercial development.

Because we have limited financial and managerial resources, we will focus for the foreseeable future only on the clinical development of itraconazole for the treatment of cancer. As a result, we may forego or be unable to pursue opportunities with other product candidates or for indications other than those we intend to purse that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs related to itraconazole for the treatment of cancer may not yield any commercially viable therapies. Because of this concentration of our efforts, our business will be particularly subject to significant risk of failure of our one current product candidate.

We expect to rely on collaborations with third parties for key aspects of our business. If we are unable to secure or maintain any of these collaborations, or if these collaborations do not achieve their goals, our business would be adversely affected.

We presently have very limited capabilities for drug development and do not yet have any capability for manufacturing, sales, marketing or distribution. Accordingly, we expect to enter into collaborations with other companies that we believe can provide such capabilities. These collaborations may also provide us with important funding for our development programs.

There is a risk that we may not be able to enter into such collaborations on acceptable terms or at all, which would leave us unable to progress our business plan. We will face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of our product candidate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Moreoever, even if we are able to enter into such collaborations, such collaborations may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of our product candidate, might lead to additional responsibilities for us with respect to such product candidate, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators could independently develop or be associated with products that compete directly or indirectly with our product candidate;
- collaborators could have significant discretion in determining the efforts and resources that they will apply to our arrangements with them;
- should our product candidate achieve regulatory approval, a collaborator with marketing and distribution rights to our product candidate may not commit sufficient resources to the marketing and distribution of such product;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to either find alternative collaborators (which we may be unable to do) or raise additional capital to pursue further development or commercialization of the our product candidate on our own.

Our business would be materially or perhaps significantly harmed if any of the foregoing or similar risks comes to pass with respect to our key collaborations

We will contract with third parties for the manufacture of our product candidate for clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing capabilities. We will rely on third parties for the manufacture of our product candidate for clinical testing, as well as for commercial manufacture if our product candidate ultimately receives marketing approval. This reliance on third parties leaves us exposed to the risk that we will not have sufficient quantities of our product candidate or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Moreover, we may be unable to establish any agreements with third party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third party manufacturers, reliance on third party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidate or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidate or products.

In addition, our product candidate and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Also, any performance failure on the part of our manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our manufacturers cannot perform as agreed, we may be required to replace such manufacturers, which would lead to added costs and delays in identifying and qualifying any such replacement.

Risks Related to the Commercialization of Our Product Candidate

Even if itraconazole for the treatment of cancer receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.

Even if itraconazole for the treatment of cancer receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of itraconazole for the treatment of cancer, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

If we are unable to establish sales, marketing and distribution capabilities, we may not be able to commercialize our product candidate if and when it is approved.

We do not have a sales or marketing infrastructure. To achieve any level of commercial success for any product for which we have obtained marketing approval, we will need to establish a sales and marketing organization or outsource sales and marketing functions to third parties.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If approved, factors that may inhibit our efforts to commercialize our product on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may be unable to enter into arrangements with third parties to sell, market and distribute our product candidate or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product effectively. If we do not establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be able to commercialize our product candidate, which would have a material adverse effect on our company.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidate, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of cancer. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs, and we may be unable to effectively compete with these companies for these or other reasons.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals.

Our ability to commercialize any product candidate also will depend in part on the extent to which coverage and adequate reimbursement for our product candidate will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party payors are requiring that drug

companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to commercialize any product candidate for which we obtain marketing approval.

In addition, there may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidate in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot defend ourselves against claims that our product candidate or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- damage to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently do not have product liability insurance coverage, which leaves us exposed to any product-related liabilities that we may incur. We may be unable to obtain insurance on reasonable terms or at all. Insurance coverage is increasingly expensive. In the event that we obtain coverage, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products (particularly itraconazole as an anti-cancer therapy), or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to commercialize our technology and products may be impaired.

Our business plan depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products, and in particular, the rights to develop itraconazole as an anti-cancer therapy. We seek to protect our proprietary position by filing patent applications in the United States related to our novel technologies and product candidate and also expect to license applicable patents from third parties.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances

(particularly in collaboration scenarios), we may not have the right to control (in whole or in part) the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of our product candidate, patents protecting such candidate might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

We expect to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

We expect to enter into licenses with third parties that hold intellectual property, including patent rights, that are important or necessary to the development of itraconazole as an anti-cancer therapy, and it may be necessary for us to use the patented or proprietary technology of third parties to commercialize itraconazole as an anti-cancer therapy, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or else our business could be harmed, possibly materially. If we were not able to obtain such licenses, or were not able to obtain such licenses on commercially reasonable terms, our business could be harmed, possibly substantially.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our business will depend upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our primary product candidate or other products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose rights that are important to our business.

We expect to be party to one or more license or similar agreements that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license, our counterparties may have the right to terminate these agreements, in which case we might not be able to develop, manufacture or market any product that is covered by these agreements (particularly itraconazole as an anti-cancer therapy) or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal and Compliance Matters

If we fail to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidate, and our ability to generate revenue and the viability of our company will be materially impaired.

Our product candidate (itraconazole as an anti-cancer therapy) and the activities associated with its clinical development and commercialization, including matters relating to design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA (including under the Federal Food, Drug and Cosmetic Act) and other regulatory agencies in the United States and by the European Medicines Agency (known as the EMA) and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product candidate will prevent us from commercializing the product candidate. We have not received approval to market itraconazole as an anti-cancer therapy or any other product from regulatory authorities in any jurisdiction and it will likely be years before we are even eligible to receive such approval.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use of our product. In particular, new cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. Even if our product candidate receives marketing approval for one or more indications, of which no assurances may be given, the accompanying labels may limit the approved use of our drug, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States, is very expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of our product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidate, the commercial prospects for our product candidate will be harmed and our ability to generate revenues, and the viability of our company generally, will be materially impaired.

We may also be subject to healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Although we currently do not directly market or promote any products, we may also be subject to several healthcare regulations and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

We will likely seek approval of itraconazole as an anti-cancer therapy under an expedited procedure, which may not be available to us.

It is our intention to seek to avail ourselves of the FDA's 505(b)(2) approval procedure where it is appropriate to do so, particularly for itraconazole as an anti-cancer therapy since itraconazole has previously been approved for another indication. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act permits an applicant to file a NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain preclinical testing or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product.

If this approval pathway is not available to us with respect to our product candidate, the time and cost associated with developing and commercializing such candidate may be prohibitive and our business strategy could be materially and adversely affected.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We may seek "fast track" designation for our product candidate. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe that itraconazole as an anti-cancer therapy may be eligible for this designation, we cannot assure you that the FDA would decide to grant it should we apply for this designation. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

A breakthrough therapy designation by the FDA for our product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidate will receive marketing approval.

We may seek a "breakthrough therapy" designation for our product candidate. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that itraconazole as an anti-cancer therapy meets the criteria for designation as a breakthrough therapy for one or more indications, the FDA may disagree and instead determine not to make such designation. Even if such designation is granted, of which no assurances may be given, the receipt of a breakthrough therapy designation for our product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if itraconazole as an anti-cancer therapy qualifies as a breakthrough therapy for one or more indications, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened, which would deny us the benefits of such designation.

We may seek but be unable to obtain orphan drug exclusivity for our product candidate. If our competitors are able to obtain orphan drug exclusivity for their products that are the same drug as our product candidate, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities may designate drugs for relatively small patient populations as orphan drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which, subject to certain exceptions, precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable market exclusivity period is seven years in the United States.

Obtaining orphan drug exclusivity for itraconazole as an anti-cancer therapy may be important to our commercial strategy. If a competitor obtains orphan drug exclusivity for and approval of a product with the same indication as our itraconazole product before we do, and if the competitor's product is the same drug or a similar medicinal product as ours, we could be excluded from the market. Even if we obtain orphan drug exclusivity for itraconazole as an anti-cancer therapy, we may not be able to maintain it. For example,

if a competitive product that is the same drug or a similar medicinal product as our product candidate is shown to be clinically superior to our product candidate, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. In addition, orphan drug exclusivity will not prevent the approval of a product that is the same drug as our product candidate if the FDA finds that we cannot assure the availability of sufficient quantities of the drug to meet the needs of the persons with the disease or condition for which the drug was designated. If one or more of these events occur, it could have a material adverse effect on our company.

Even if we obtain marketing approval for our product candidate, we could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems.

Even if we obtain marketing approval for itraconazole as an anti-cancer therapy, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, we will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. In addition, even if marketing approval of our product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If our product candidate receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we or any third party partners of ours do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our product, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product, our manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of the product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- the need to utilize warning letters;
- suspension or withdrawal of marketing approvals;
- withdrawal of the product from the market or product recalls;
- refusal by regulatory authorities to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenues;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

We may face similar issues in connection with non-compliance with non-U.S. regulatory requirements.

Risks Related to Our Securities

An active trading market for our common stock may not develop or be sustained.

As we only recently emerged from bankruptcy and are in the early stages of our business plan, an investment in our company will likely require a long-term commitment, with no certainty of return. Although our common stock is listed for quotation on the OTCBB and OTCQB markets, we cannot predict whether an active market for our common stock will ever develop in the future. In the absence of an active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;

- market visibility for shares of our common stock may be limited; and
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock.

The OTCBB and OTCQB markets are relatively unorganized, inter-dealer, over-the-counter markets that provide significantly less liquidity than NASDAQ or the NYSE MKT (formerly known as the NYSE AMEX). In this event, there would be a highly illiquid market for our common stock and you may be unable to dispose of your common stock at desirable prices or at all. Moreover, there is a risk that our common stock could be delisted from the OTCBB and OTCQB, in which case it might be listed on the so called "Pink Sheets", which is even more illiquid than the OTCQB.

The lack of an active market impairs your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We may not maintain qualification for OTC Bulletin Board or OTCQB inclusion, and therefore you may be unable to sell your shares.

Our common stock is eligible for quotation on the OTCBB and OTCQB. However, trading of our common stock could be suspended. If for any reason our common stock does not become eligible or maintain eligibility for quotation on the OTCBB or OTCQB or a public trading market does not develop, purchasers of shares of our common stock may have difficulty selling their shares should they desire to do so. If we are unable to satisfy the requirements for quotation on the OTCBB and OTCQB, any quotation in our common stock could be conducted in the "pink sheets" market. As a result, a purchaser of our common stock may find it more difficult to dispose of, or to obtain accurate quotations as to the price of their shares. This would materially and adversely affect the liquidity of our securities.

Even if a market for our common stock develops, the market price of our common stock may be significantly volatile, which could result in substantial losses for purchasers.

The market price for our common stock may be significantly volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices for securities of biotechnology companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- any delay in or the results of our clinical trials;
- the announcements of clinical trial data, and the investment community's perception of and reaction to those data;
- the results of clinical trials conducted by others on products that would compete with our product candidate;
- any delay or failure to receive approval from the FDA and other regulatory agencies or bodies;
- our inability to commercially launch our product or market and generate sales of our product;
- failure of our product, even if approved for marketing, to achieve any level of commercial success;
- our failure to obtain or maintain patent protection for any of our technologies and product or the issuance of third party patents that cover our technologies or product;
- developments or disputes concerning our product's intellectual property rights;
- our or our competitors' technological innovations;
- general and industry-specific economic conditions that may affect our expenditures;
- changes in market valuations of similar companies;

- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents;
- failure to adequately manufacture our product through third parties for purposes of clinical trials or actual sales;
- future sales of our common stock or other securities;
- period-to-period fluctuations in our financial results; and
- low trading volume of our common stock;

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be significant impact on the market price of our common stock. Additionally, as we approach the announcement of anticipated significant information and as we announce such information, we expect the price of our common stock to be particularly volatile, and negative results would have a substantial negative impact on the price of our common stock.

In some cases, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

Our common stock may be considered a "penny stock," and thereby be subject to additional sale and trading regulations that may make it more difficult to sell.

Our common stock may be considered to be a "penny stock" if it does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our common stock may be a "penny stock" if it meets one or more of the following conditions: (i) the stock trades at a price less than $5 per share; (ii) it is not traded on a "recognized" national exchange; or (iii) is issued by a company (such as ours) that has been in business less than three years with net tangible assets less than $5 million.

The principal result or effect of being designated a "penny stock" is that securities broker-dealers participating in sales of our common stock will be subject to the "penny stock" regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act. For example, Rule 15g-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor's account. Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to: (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

FINRA sales practice requirements may also limit your ability to buy and sell our common stock, which could depress the price of our shares.

FINRA rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares, have an adverse effect on the market for our shares, and thereby depress our share price.

You may face significant restrictions on the resale of your shares due to state "blue sky" laws.

Each state has its own securities laws, often called "blue sky" laws, which (1) limit sales of securities to a state's residents unless the securities are registered in that state or qualify for an exemption from registration, and (2) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or it must be exempt from registration. The applicable broker-dealer must also be registered in that state.

We do not know whether our securities will be registered or exempt from registration under the laws of any state. A determination regarding registration will be made by those broker-dealers, if any, who agree to serve as market makers for our common stock. We have not yet applied to have our securities registered in any state and will not do so until we receive expressions of interest from investors resident in specific states after they have viewed this prospectus. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our common stock to be limited, as you may be unable to resell your shares without the significant expense of state registration or qualification.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company.

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. As we are a start-up company, we are at the very early stages of establishing, and we may be unable to effectively establish such systems. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. 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, have been detected. Failure of our control systems to prevent error or fraud could materially and adversely impact us.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We may be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for our fiscal year ended December 31, 2014. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC.

Anti-takeover provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our Company and may affect the trading price of our common stock.

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders.

In addition, our certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our certificate of incorporation and bylaws:

- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to thwart a takeover attempt;
- provide that vacancies on our board of directors, including newly created directorships, may be filled only by a majority vote of directors then in office;
- provide that special meetings of stockholders may only be called by our Chairman and/or President, our board of directors or a super-majority (66 2/3%) of our stockholders;
- place restrictive requirements (including advance notification of stockholder nominations and proposals) on how special meetings of stockholders may be called by our stockholders;

- do not provide stockholders with the ability to cumulate their votes; and
- provide that only a super-majority of our stockholders (66 2/3%) may amend our bylaws.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in this Report should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

We do not intend to pay dividends on our common stock.

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends for the foreseeable future. Therefore, you should not invest in our common stock in the expectation that you will receive dividends.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

Not applicable

Item 6. Exhibits.

Number	Description
31.1	Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302
31.2	Certification of Chief Financial Officer Pursuant To Sarbanes-Oxley Section 302
32.1	Certification Pursuant To 18 U.S.C. Section 1350 (*)
32.2	Certification Pursuant To 18 U.S.C. Section 1350 (*)

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

SIGNATURES

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

HEDGEPATH PHARMACEUTICALS, INC.

Date: September 6, 2013

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

Date: September 6, 2013

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

Exhibit 31.1

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

I, Nicholas J. Virca, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act 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: September 6, 2013

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

Exhibit 31.2

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

I, Garrison J. Hasara, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act 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: September 6, 2013

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

Exhibit 32.1

HEDGEPATH PHARMACEUTICALS, INC.

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

In connection with the Quarterly Report of HedgePath Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2013, 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
September 6, 2013

Exhibit 32.2

HEDGEPATH PHARMACEUTICALS, INC.

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

In connection with the Quarterly Report of HedgePath Pharmaceuticals, Inc (the "Company") on Form 10-Q for the period ending June 30, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrison J. Hasara, Secretary, 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
Secretary, Treasurer and Chief Financial Officer
September 6, 2013