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

FORM 10-Q

(Mark one)

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

For the Quarterly Period Ended September 30, 2016

Or

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

Commission File Number: 000-55331

INSPYR THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-0438951**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
31200 Via Colinas, Suite 200 Westlake Village, CA	**78258**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(818) 661-6302**

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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a small reporting company) Smaller reporting company ☒

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

As of November 18, 2016, the issuer had 1,397,705 common shares, $0.0001 par value, issued and outstanding.

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ADVISEMENT

We urge you to read this entire Quarterly Report, including the financial statements and related notes included herein as well as our 2015 Annual Report on Form 10-K for the year ended December 31, 2015, which also includes "Risk Factors", filed with the United States Securities and Exchange Commission or SEC on March 30, 2016. As used in this Quarterly Report, unless the context otherwise requires, the words "we," "us," "our," "the Company," "Inspyr Therapeutics" and "registrant" refer to Inspyr Therapeutics, Inc. Also, any reference to "common stock "or "common shares" refers to our $0.0001 par value common stock. The information contained herein is current as of the date of this Quarterly Report (September 30, 2016), unless another date is specified. Also, any reference to "preferred stock" or "preferred shares", when referring to our shares of preferred stock outstanding, refers to our $0.0001 par value Series A 0% Convertible Preferred Stock.

We prepare our interim financial statements in accordance with United States generally accepted accounting principles. Our financials and results of operation for the three and nine-month period ended September 30, 2016 is not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2016. The interim financial statements and other information presented in this Quarterly Report should be read together with the reports, statements and information filed by us with the United States Securities and Exchange Commission or SEC.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report includes "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to our business development plans, clinical trials, regulatory reviews, timing, strategies, expectations, anticipated expense levels, business prospects and positioning with respect to the market for our proposed products, business outlook, technology spending and various other matters (including contingent liabilities and obligations and changes in accounting policies, standards and interpretations) and express our current intentions, beliefs, expectations, strategies or predictions, as well as historical information. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from anticipated results, performance or achievements expressed or implied by such forward-looking statements. When used in this report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan," "intend," "may," "will," "expect," "believe," "could," "anticipate," "estimate," or "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements. Although we believe that the assumptions on which the forward-looking statements contained herein are reasonable, any of those assumptions could prove to be inaccurate given the inherent uncertainties as to the occurrence or nonoccurrence of future events. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict. Our future operating results are dependent upon many factors which are outside our control. You should not place undue reliance on forward-looking statements. Forward-looking statements may not be realized due to a variety of factors, including, without limitation, our ability to:

- attract and build a senior management team;
- manage our business given continuing operating losses and negative cash flows;
- obtain sufficient capital or a strategic business arrangement to fund our operations and expansion plans;
- build the management, human resources and infrastructure necessary to support the growth of our business;
- manage competitive factors and developments beyond our control;
- manage scientific and medical developments which may be beyond our control;
- manage the governmental regulation of our business including state, federal and international laws;
- successfully complete the clinical trials of our proposed drug candidates and gain regulatory approval to market such products;
- maintain and protect our intellectual property;
- obtain patents based on our current and/or future patent applications;
- obtain and maintain other rights to technology required or desirable for the conduct of our business;
- achieve any potential strategic benefits of licensing transactions, collaborations, acquisitions, or in-licensing of new technologies, if any; and
- manage any other factors discussed in the "Risk Factors" section, and elsewhere in this Quarterly Report.

In addition to the foregoing, other factors may influence our future performance including those factors discussed in the "Risk Factors" section of our 2015 Annual Report on Form 10-K. All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. We undertake no obligation to update or revise these forward-looking statements, whether to reflect events or circumstances after the date initially filed, to reflect the occurrence of unanticipated events or otherwise, except to the extent required by federal securities laws. The risks discussed in this report should be considered in evaluating our business and prospects.

PART I
FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INSPYR THERAPEUTICS, INC. (FORMERLY GENSPERA, INC.)
CONDENSED BALANCE SHEETS
(in thousands, except share and per share data)

	September 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 330	$ 2,465
Prepaid expenses	131	114
Total current assets	461	2,579
Office equipment, net of accumulated depreciation of $0 and $27	4	12
Intangible assets, net of accumulated amortization of $140 and $128	72	84
Other assets	3	3
Total assets	$ 540	$ 2,678
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,097	$ 977
Accrued expenses	2,726	2,432
Derivative liability	756	1,177
Total current liabilities	4,579	4,586
Total liabilities	4,579	4,586
Commitments and contingencies		
Stockholders' deficit:		
Convertible preferred stock, par value $.0001 per share; 30,000,000 shares authorized, 1,853 issued and outstanding, respectively	–	–
Common stock, par value $0.0001 per share; 150,000,000 shares authorized, 1,392,079 shares issued and outstanding, respectively	1	1
Additional paid-in capital	43,426	43,356
Accumulated deficit	(47,466)	(45,265)
Total stockholders' deficit	(4,039)	(1,908)
Total liabilities and stockholders' deficit	$ 540	$ 2,678

The accompanying notes are an integral part of these condensed unaudited financial statements.

INSPYR THERAPEUTICS, INC. (FORMERLY GENSPERA, INC.)
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 379	$ 459	$ 1,025	$ 1,885
General and administrative	509	915	1,600	2,864
Total operating expenses	888	1,374	2,625	4,749
Loss from operations	(888)	(1,374)	(2,625)	(4,749)
Gain (loss) on change in fair value of derivative liability	(334)	–	421	–
Interest income (expense), net	1	1	3	–
Loss before provision for income taxes	(1,221)	(1,373)	(2,201)	(4,749)
Provision for income taxes	–	–	–	–
Net loss	$ (1,221)	$ (1,373)	$ (2,201)	$ (4,749)
Net loss per common share, basic and diluted	$ (0.88)	$ (1.12)	$ (1.58)	$ (4.12)
Weighted average shares outstanding	1,392,079	1,228,542	1,392,079	1,152,308

The accompanying notes are an integral part of these condensed unaudited financial statements.

INSPYR THERAPEUTICS, INC. (FORMERLY GENSPERA, INC.)
CONDENSED STATEMENT OF STOCKHOLDERS' DEFICIT
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance, December 31, 2015	1,853	$ –	1,392,079	$ 1	$ 43,356	$ (45,265)	$ (1,908)
Stock-based compensation	–	–	–	–	70	–	70
Net loss	–	–	–	–	–	(2,201)	(2,201)
Balance, September 30, 2016 (unaudited)	1,853	$ –	1,392,079	$ 1	$ 43,426	$ (47,466)	$ (4,039)

The accompanying notes are an integral part of these condensed unaudited financial statements.

INSPYR THERAPEUTICS, INC. (FORMERLY GENSPERA, INC.)
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (2,201)	$ (4,749)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	16	15
Stock-based compensation	70	265
Loss on sale of assets	4	–
Gain on change in fair value of derivative liability	(421)	–
Decrease (increase) in operating assets:		
Prepaid expenses	(17)	70
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	414	779
Cash used in operating activities	(2,135)	(3,620)
Cash flows from investing activities:		
Proceeds from sale of assets	4	
Acquisition of office equipment	(4)	(4)
Cash used in investing activities	–	(4)
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants sold	–	2,514
Cost of common stock and warrants sold	–	(253)
Proceeds from exercise of warrants	–	287
Cash provided by financing activities	–	2,548
Net decrease in cash	(2,135)	(1,076)
Cash and cash equivalents, beginning of period	2,465	2,316
Cash and cash equivalents, end of period	$ 330	$ 1,240

The accompanying notes are an integral part of these condensed unaudited financial statements.

INSPYR THERAPEUTICS, INC. (FORMERLY GENSPERA, INC.)
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

NOTE 1 – BACKGROUND

Inspyr Therapeutics, Inc. ("we", "us", "our company", "our", "Inspyr" or the "Company") was formed under the laws of the State of Delaware in November 2003, and has its principal office in Westlake Village, California. We are an early-stage, pre-revenue, pharmaceutical company focused on the discovery and development of prodrug cancer therapeutics for the treatment of solid tumors, including brain, liver, prostate and other cancers. We plan to develop a series of therapies based on our target-activated prodrug technology platform.

Effective August 1, 2016, pursuant to a certificate of amendment to our amended and restated certificate of incorporation, we changed our corporate name from GenSpera, Inc. to Inspyr Therapeutics, Inc. Effective August 1, 2016, our common stock ceased trading under the symbol "GNSZ" and began trading under the symbol NSPX on August 2, 2016.

Effective November 4, 2016 at 5:00 p.m. Eastern Time, we effected a one (1) for thirty (30) reverse stock split of our common stock. Accordingly, each of our shareholders received one (1) new share of common stock for every thirty (30) shares of common stock such shareholder held immediately prior to the effective time of the reverse split. The reverse stock split affected all of our issued and outstanding shares of common stock as well as the number of shares of common stock underlying stock options, warrants and other exercisable or convertible instruments outstanding at the effective time of the reverse split. The reverse split also has the effect of proportionately increasing the applicable conversion or exercise price of such convertible securities. The shareholders received no fractional shares and instead had every fractional share rounded up to the next whole number.

All references to common stock, share and per share amounts have been retroactively restated to reflect the 1:30 reverse stock split as if it had taken place as of the beginning of the earliest period presented.

Our primary focus at the present time is the clinical development of our lead compound, mipsagargin (formerly referred to as G-202), a novel therapeutic agent with a unique mechanism of action. We have completed a Phase 1a/1b dose escalation, safety, tolerability and dose refinement study of mipsagargin, in which we treated a total of 44 patients, including two patients with hepatocellular carcinoma (HCC), or liver cancer, who experienced prolonged stabilization of disease of up to eleven months after initiation of treatment.

In addition, we have completed an open label single arm Phase II clinical trial of mipsagargin in subjects with liver cancer, in which twenty-five patients were treated. In May 2015, we received a final clinical study report, and consider the results of the study to be positive, with 63% of treated patients having stable disease at two (2) months and a median time to progression of 4.5 months.

In the first quarter of 2014, we entered into a collaborative arrangement to conduct a Phase 2 clinical trial entitled, "G-202-004: An Open-Label, Single-Arm, Phase II Study to Evaluate the Efficacy, Safety and CNS Exposure of G-202 in Patients with Recurrent or Progressive Glioblastoma." In May 2015, we announced that based on preliminary data obtained in the first stage of the trial, we were expanding the trial to a potential 34 patients. In September 2015 we announced interim Phase 2 data from 11 patients with glioblastoma with demonstrated clinical benefit in a subset of patients with high levels of PSMA expression in the primary tumor. As of October 20, 2016, we have treated twenty-six patients in the trial.

During the first quarter of 2016, we initiated a Phase II clinical trial pilot study in patients with prostate cancer entitled, "G-202-005: An Open-Label, Single-Arm, Phase II Study to Evaluate the Safety and Activity of G-202 Administered in the Neoadjuvant Setting Followed by Radical Prostatectomy in Patients with Adenocarcinoma of the Prostate", via a collaborative agreement with a single site in the U.S., in which one patient has been enrolled as of October 20, 2016.

During the second quarter of 2016, we initiated a Phase 2 clinical trial pilot study in patients with clear cell renal cell carcinoma entitled, "G-202-006: An Open-Label, Single-Arm, Phase II Study to Evaluate the Safety and Activity of G-202 in Patients with Clear Cell Renal Cell Carcinoma that Expresses PSMA", via a collaborative agreement with a single site in the U.S. As of October 20, 2016, two patients have been enrolled.

While we believe that the data from the completed trials appear promising, the outcome of our ongoing or future trials may ultimately be unsuccessful.

NOTE 2 – MANAGEMENT'S PLANS TO CONTINUE AS A GOING CONCERN

Basis of Presentation

We have prepared our financial statements on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Certain information and note disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to those rules and regulations, although we believe that the disclosures made are adequate to make the information not misleading. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for fair presentation have been included. We have incurred losses since inception and have an accumulated deficit of $47.5 million as of September 30, 2016. We anticipate incurring additional losses for the foreseeable future until such time, if ever, that we can generate significant sales from our therapeutic product candidates which are currently in development or we enter into cash flow positive business development transactions.

To date, we have generated no sales or revenues, have incurred significant losses and expect to incur significant additional losses as we advance mipsagargin through clinical studies. Consequently, our operations are subject to all the risks inherent in the establishment of a pre-revenue business enterprise as well as those risks associated with a company engaged in the research and development of pharmaceutical compounds.

Our cash and cash equivalents balance at September 30, 2016 was $0.3 million, representing 61% of our total assets. Based on our current expected level of operating expenditures, we expect to be able to fund our operations into the fourth quarter of 2016. We will require additional cash to fund and continue our operations beyond that point. This period could be shortened if there are any unanticipated increases in planned spending on development programs or other unforeseen events. We anticipate raising additional funds through collaborative arrangements, licensing agreements, public or private sales of debt or equity securities, or some combination thereof. There is no assurance that any such arrangement will be entered into or that financing will be available when needed in order to allow us to continue our operations, or if available, on terms favorable or acceptable to us.

In the event financing is not obtained, we may pursue cost cutting measures as well as explore the sale of selected assets to generate additional funds. If we are required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate any of our development programs or clinical trials, these events could have a material adverse effect on: our business, results of operations, and financial condition. These factors raise significant doubt about our ability to continue as a going concern. The financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Our auditors' report issued in connection with our December 31, 2015 financial statements expressed an opinion that our capital resources as of the date of their audit report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Accordingly, our current cash level raises substantial doubt about our ability to continue as a going concern past December 2016. If we do not obtain additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders will lose their entire investment.

NOTE 3 – SUMMARY OF CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying disclosures. Actual results may differ from those estimates.

Research and Development

Research and development costs are charged to expense as incurred. Our research and development expenses consist primarily of expenditures for manufacturing, clinical trials, employee compensation and consulting costs and expenses.

We incurred research and development expenses of approximately $0.4 million and $0.5 million for the three months ended September 30, 2016 and 2015, respectively. We incurred research and development expenses of approximately $1.0 million and $1.9 million for the nine months ended September 30, 2016 and 2015, respectively.

Loss per Share

Basic loss per share is calculated by dividing net loss and net loss attributable to common shareholders by the weighted average number of common shares outstanding for the period. Basic and diluted loss per share are the same, in that any potential common stock equivalents would have the effect of being anti-dilutive in the computation of net loss per share. The following potentially dilutive securities have been excluded from the computations of weighted average shares outstanding as of September 30, 2016 and 2015, as they would be anti-dilutive:

	Nine months ended September 30,	
	2016	**2015**
Shares underlying options outstanding	265,863	297,390
Shares underlying warrants outstanding	1,335,466	867,319
Shares underlying convertible preferred stock outstanding	411,806	—
Shares underlying convertible notes outstanding	—	9,231
	2,013,135	1,173,940

Derivative Liability

The Company has financial instruments that are considered derivatives or contain embedded features subject to derivative accounting. Embedded derivatives are valued separately from the host instrument and are recognized as derivative liabilities in the Company's balance sheet. The Company measures these instruments at their estimated fair value and recognizes changes in their estimated fair value in results of operations during the period of change. Based upon ASC 840-15-25 (EITF Issue 00-19, paragraph 11) the Company has adopted a sequencing approach regarding the application of ASC 815-40 to its outstanding preferred stock.

Pursuant to the sequencing approach, the Company evaluates its contracts based upon earliest issuance date wherein instruments with the earliest issuance date would be settled first. The sequencing policy also considers contingently issuable additional shares, such as those issuable upon a stock split, to have an issuance date to coincide with the event giving rise to the additional shares. Using this sequencing policy, all instruments convertible into common stock, including warrants and the conversion feature of notes payable, issued subsequent to December 25, 2015 are classified as derivative liabilities. The Company values these derivative liabilities using the Black-Scholes option pricing model. The resulting liability is valued at each reporting date and the change in the liability is reflected as change in derivative liability in the statement of operations.

Fair Value of Financial Instruments

Our short-term financial instruments, including cash, accounts payable and other liabilities, consist primarily of instruments with maturities of three months or less when acquired. We believe that the fair values of our current assets and current liabilities approximate their reported carrying amounts.

The derivative liability consists of our convertible preferred stock with anti-dilution provisions, and related warrants. The Company uses the Black-Scholes option pricing model to value its derivative liability which incorporate the Company's stock price, volatility, U.S. risk-free interest rate, dividend rate, and estimated life.

Fair Value Measurements

Valuation Hierarchy - GAAP establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities.
Level 2: Quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.
Level 3: Unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value.

A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The Company has recorded a derivative liability for convertible preferred stock with anti-dilution provisions, and related warrants, as of September 30, 2016. The table below summarizes the fair values of our financial liabilities as of September 30, 2016 (in thousands):

	Fair Value at September 30, 2016	Fair Value Measurement Using		
		Level 1	Level 2	Level 3
Derivative liability	$ 756	$ —	$ —	$ 756

The reconciliation of the derivative liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows (in thousands):

	September 30, 2016
Balance at beginning of year	$ 1,177
Additions to derivative instruments	—
Gain on change in fair value of derivative liability	(421)
Balance at end of year	$ 756

Stock-Based Compensation

We measure the cost of employee services received in exchange for equity awards based on the grant-date fair value of the awards. All awards under our stock-based compensation programs are accounted for at fair value and that cost is recognized over the period during which an employee is required to provide service in exchange for the award (the vesting period).

Compensation expense for options granted to non-employees is determined in accordance with the fair value of the consideration received or the fair value of the equity instruments issued, whichever is a more reliable measurement. Compensation expense for awards granted to non-employees is re-measured on each accounting period.

Determining the appropriate fair value of stock-based compensation requires the input of subjective assumptions, including the expected life of the stock-based compensation grant/award and the volatility of our stock price. We use the Black-Scholes option-pricing model to value our stock option awards which incorporates our stock price, volatility, U.S. risk-free interest rate, dividend rate, and estimated life.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued FASB Accounting Standards Update (ASU) 2016-09, "Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting". The amendments in this update simplify several aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This ASU is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We are currently evaluating the effect that the adoption of this standard will have on our financial statements.

In February 2016, the FASB issued FASB ASU 2016-02, "Leases (Topic 842)". The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. For operating leases, a lessee would be required to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in the statement of financial position. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. The accounting applied by a lessor is largely unchanged from that applied under previous GAAP. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are currently evaluating the effect that the adoption of this ASU will have on our financial statements.

In August 2014, the FASB issued Accounting Standards Update ASU 2014-15 "Presentation of Financial Statements Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". This update provides guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. The amendments contained in this update are effective for public and nonpublic entities for annual periods ending after December 15, 2016. We are currently assessing the impact of the adoption of ASU 2014-15, and we have not yet determined the effect of the standard on our ongoing financial reporting.

There are various other recently issued updates, most of which represented technical corrections to the accounting literature or application to specific industries, and are not expected to have a material impact on the Company's financial position, results of operations or cash flows.

NOTE 4 – SUPPLEMENTAL CASH FLOW INFORMATION

There was no cash paid for interest and income taxes for the nine months ended September 30, 2016 and 2015.

NOTE 5 – ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	September 30, 2016	December 31, 2015
Accrued compensation and benefits	$ 2,438	$ 2,134
Accrued research and development	129	152
Accrued other	159	146
Total accrued expenses	$ 2,726	$ 2,432

NOTE 6 – DERIVATIVE LIABILITY

We account for equity-linked financial instruments, such as our convertible preferred stock, and our common stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the respective agreement. Equity-linked financial instruments are accounted for as derivative liabilities, in accordance with ASC Topic 815 – Derivatives and Hedging, if the instrument allows for cash settlement or provide for modification of the exercise price in the event subsequent sales of our common stock are at a lower price per share than the then-current warrant exercise price. Additionally, financial instruments are classified as derivative liabilities if, as a result of the anti-dilution protection, there is no limit on the number of shares that may be subsequently issued and we conclude there are not adequate authorized shares available to provide for subsequent issuances. We classify derivative liabilities on the balance sheet at fair value, and changes in fair value during the periods presented in the statement of operations, which is revalued at each balance sheet date subsequent to the initial issuance of the stock warrant.

In December 2015, we issued shares of convertible preferred stock which contain anti-dilution protection for subsequent equity sales which occur within 18 months, and related warrants. As a result, the Company assessed its outstanding equity-linked financial instruments and concluded that this series of preferred stock, and related warrants, is subject to derivative accounting. The fair value of these shares is classified as a liability in the financial statements, with the change in fair value during the periods presented recorded in the statement of operations.

During the nine months ended September 30, 2016, we recorded a gain of $0.4 million related to the change in fair value of the derivative liability during the period. For purpose of determining the fair market value of the derivative liability, the Company used the Black Scholes option pricing model. The significant assumptions used in the Black Scholes valuation of the derivative are as follows:

	2016
Volatility	85%
Expected term (years)	10 months
Risk-free interest rate	0.64%
Dividend yield	None

As of September 30, 2016, the derivative liability recognized in the financial statements was approximately $0.8 million.

NOTE 7 – COMMITMENTS AND CONTINGENCIES

On March 16, 2016, Dr. Craig Dionne provided us his notice of termination as the company's Chief Executive Officer and Chief Financial Officer. Dr. Dionne's notice of termination alleges that such termination was for "Good Reason" as a result of a purported material change in his authority, functions, duties and responsibilities as chief executive officer. In the event that termination was for "Good Reason", Dr. Dionne would be entitled to certain severance payments as well as other benefits. His notice of termination, in addition to requesting such severance, also requests the payment of Dr. Dionne's annual and long term bonus for 2014 and 2015. On April 11, 2016, we received a letter from Dr. Dionne demanding approximately $2.3 million as a result of the foregoing.

The Company vigorously disputes that the termination of his employment was for "Good Reason," as that term is defined in his employment agreement and under applicable law. This matter is at the early stages. While no litigation is pending at this time, there can be no assurance that this matter will be resolved in such a manner as to avoid litigation. Accordingly, the Company is unable at this time to predict the outcome of this matter, and any views formed as to the viability of these claims or the costs to the Company which could result from these claims may change from time to time as the matter proceeds through its course.

NOTE 8 – CAPITAL STOCK AND STOCKHOLDER'S EQUITY

Common Stock

In September 2015, our board of directors approved amending our certificate of incorporation to effect a reverse stock split, subject to shareholder approval, at a ratio of not less than one-for-two (1 for 2), and not more than one-for thirty (1 for 30) at the discretion of the board. On November 15, 2015, our shareholders approved the reverse stock split at the discretion of the board. Effective November 4, 2016 at 5:00 p.m. Eastern Time, the Company's board of directors effected a one (1) for thirty (30) reverse stock split.

During the nine months ended September 30, 2016, no warrants were exercised into common shares. During the nine months ended September 30, 2015, 11,239 warrants were exercised into an equivalent number of common shares for which we received approximately $287,000 in proceeds.

NOTE 9 – STOCK OPTIONS

Our 2009 Executive Compensation Plan ("2009 Plan") and our 2007 Equity Compensation Plan ("2007 Plan") each allow for the issuance of up to 6,000,000 shares of common stock, or 12,000,000 in the aggregate. Collectively, the 2009 Plan and 2007 Plan are referred to as "the Plans."

On July 17, 2016, our board of directors adopted the GenSpera, Inc. Inducement Award Stock Option Plan. The plan is to be used in connection with the recruiting and inducement of senior management and employees. We did not seek approval of the plan by our stockholders. Pursuant to the plan, we may grant stock options for up to a total of 9,000,000 shares of common stock to new employees.

Total stock-based compensation expense recognized for stock options issued using the straight-line method in the statement of operations for the nine months ended September 30, 2016 and 2015 was as follows:

	Nine months ended September 30,	
	2016	2015
Research and development	$ 21	$ 28
General and administrative	49	73
	$ 70	$ 101

The following table summarizes stock option activity under the Plans:

	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2015	292,140	$ 48.00		
Granted	121,759	$ 4.50		
Expired	(32,500)	$ 47.10		
Forfeited	(115,536)	$ 52.20		
Outstanding at September 30, 2016	265,863	$ 26.40	5.3	$ —
Exercisable at September 30, 2016	154,384	$ 42.00	2.2	$ —

As of September 30, 2016, there was approximately $199,000 of total unrecognized compensation cost related to non-vested stock options which vest over a weighted-average period of approximately 1.5 years. As of September 30, 2016, there was no unrecognized compensation expense related to performance-based, non-vested employee stock options.

During the nine months ended September 30, 2016, we issued options to purchase 5,300 shares of common stock to non-employee directors under the Plans pursuant to our non-employee director compensation policy. We also issued options to purchase 104,626 shares of common stock to employees. Additionally, we issued options to purchase 11,833 shares of common stock to consultants and advisors. During the nine months ended September 30, 2015, we issued options to purchase 5,300 shares of common stock to non-employee directors, respectively, under the Plans pursuant to our non-employee director compensation policy. Additionally, we issued options to purchase 7,253 shares of common stock to consultants and advisors. The weighted-average fair value of the options granted during 2016 and 2015 was estimated at $2.10 and $9.60 per share, respectively, on the date of grant. During the nine months ended September 30, 2016 and 2015, no options were exercised.

On August 2, 2016, and August 8, 2016, respectively, we entered into employment agreements with Christopher Lowe and Ronald Shazer to serve as our chief executive officer and chief medical officer, respectively. In conjunction with the employment agreement of Christopher Lowe, we issued Mr. Lowe 72,155 common stock purchase options. The options have a term of 7 years, an exercise price of $4.35 per share and (i) 18,039 shares vest monthly over a 12-month period and (ii) the remaining 54,116 shares vest upon achievements of certain milestones and time. In conjunction with the employment agreement of Ronald Shazer, we issued Dr. Shazer 32,470 common stock purchase options. The options have a term of 7 years, an exercise price of $4.50 per share and (i) 8,118 shares vest monthly over a 12-month period and (ii) the remaining 24,352 shares vest upon achievements of certain milestones and time. Both options were granted pursuant to our Inducement Award Stock Option Plan.

The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the grants issued during the nine months ended September 30, 2016 and 2015:

	Nine months ended September 30,	
	2016	**2015**
Volatility	90.9%	58.4%
Expected term (years)	1.9	3.4
Risk-free interest rate	0.76%	1.0%
Dividend yield	0%	0%

NOTE 10 – WARRANTS

In December 2015, in connection with a private placement of our securities, we issued an aggregate of 682,845 common stock purchase warrants, including 649,901 to investors; and 32,944 to placement agents. The warrants were issued with an exercise price of $9.00 per share. The Company assessed these outstanding equity-linked financial instruments and concluded that the warrants are subject to derivative accounting (see Note 6). Transactions involving our equity-classified warrants are summarized as follows:

	Number of shares	**Weighted-average exercise price**	**Weighted-average remaining contractual term (in years)**	**Aggregate intrinsic value (in thousands)**
Outstanding at December 31, 2015	1,409,248	$ 23.70		
Forfeited	(73,782)	$ 96.90		
Outstanding at September 30, 2016	1,335,466	$ 19.80	2.1	$ —
Exercisable at September 30, 2016	1,335,466	$ 19.80	2.1	$ —

During the nine months ended September 30, 2016, no warrants were exercised. During the nine months ended September 30, 2015, 11,239 warrants were exercised into an equivalent number of common shares for which we received approximately $287,000 in proceeds. The following table summarizes outstanding common stock purchase warrants as of September 30, 2016:

	Number of shares	**Weighted-average exercise price**	**Expiration**
Issued to consultants	27,200	$ 40.20	December 2016 through November 2020
Issued pursuant to 2012 financings	9,879	$ 90.00	December 2017
Issued pursuant to 2013 financings	145,874	$ 59.10	December 2017 through August 2018
Issued pursuant to 2014 financings	362,756	$ 24.60	December 2016 through June 2019
Issued pursuant to 2014 financings	789,757	$ 8.70	January 2017 through December 2020
	1,335,466	19.80	

During the nine months ended September 30, 2016, no warrants were issued to consultants. During the nine months ended September 30, 2015, we issued warrants to consultants to purchase 7,500 shares of common stock as compensation for business and advisory services. The common stock purchase warrants have an exercise price of $19.50 per share, are immediately exercisable and expire on the five-year anniversary of the date of issuance. The per share weighted-average fair value of the warrants granted to consultants during 2015 was estimated at $9.00 per share on the date of grant.

Total stock-based compensation expense of approximately $0 and $67,000 was recognized for warrants and included in the statement of operations for the nine months ended September 30, 2016 and 2015, respectively.

The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the grants issued during the nine months ended September 30, 2015:

Volatility	72.7%
Expected term (years)	1.7
Risk-free interest rate	0.6%
Dividend yield	0%

NOTE 11 – SUBSEQUENT EVENTS

On October 1, 2016 we entered into an employment agreement with Michael Elliot to serve as our vice president of clinical operations. In conjunction with the employment agreement, we issued Mr. Elliot 18,039 common stock purchase options. The options have a term of 7 years, an exercise price of $4.20 per share and (i) 4,510 shares vest monthly over a 12-month period and (ii) the remaining 13,529 shares vest upon achievements of certain milestones and time. The options were granted pursuant to our Inducement Award Stock Option Plan.

On October 12, 2016 and October 13, 2016, respectively, in connection with the appointment of Claire M. Thom and Richard E. Buller, M.D. Ph.D to our Board of Directors, we granted each of them 2,500 common stock purchase options. The options vest on the first year anniversary of the grants. The options have a term of 5 years and exercise prices of $3.90 and $4.05 per share, respectively. The options both vest fully on November 1, 2017 provided their continued services to the Company. The options were issued as compensation for Board services to be performed in accordance with Company's amended non-executive Board compensation policy and were granted pursuant to our 2007 Equity Compensation Plan.

Effective November 4, 2016 at 5:00 p.m. Eastern Time, we effected a one (1) for thirty (30) reverse stock split of our common stock. Accordingly, each of our shareholders received one (1) new share of common stock for every thirty (30) shares of common stock such shareholder held immediately prior to the effective time of the reverse split. The reverse stock split affected all of our issued and outstanding shares of common stock as well as the number of shares of common stock underlying stock options, warrants and other exercisable or convertible instruments outstanding at the effective time of the reverse split. The reverse split also has the effect of proportionately increasing the applicable conversion or exercise price of such convertible securities. The shareholders received no fractional shares and instead had every fractional share rounded up to the next whole number.

On November 10, 2016, the Company issued 5,556 common shares to a shareholder pursuant to the conversion of 25.00005 shares of Series A 0% Convertible Preferred Stock at a conversion price of $4.50 per common share.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding our business development plans, capital raising, clinical trials, regulatory reviews, timing, strategies, expectations, anticipated expense levels, business prospects and positioning with respect to the market, business outlook, technology spending and various other matters (including contingent liabilities and obligations and changes in accounting policies, standards and interpretations) and express our current intentions, beliefs, expectations, strategies or predictions. These forward-looking statements are based on several assumptions and currently available information and are subject to several risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements because of various factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements" and elsewhere in this Quarterly Report. The following discussion should be read in conjunction with Part I, Item 1 of this Quarterly Report as well as the financial statements and related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 30, 2016.

Our Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is provided in addition to the accompanying financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows.

Company Overview

Business

We are an early-stage, pre-revenue, pharmaceutical company focused on the development of prodrug cancer therapeutics for the treatment of solid tumors. A prodrug is an inactive precursor of a drug that is converted into its active form only at the site of the tumor. Our technology platform combines a powerful cytotoxin with a patented prodrug delivery system that targets the release of the drug within the tumor. We believe our cancer prodrugs have the potential to provide a targeted therapeutic approach to a broad range of solid tumors with fewer side effects than those related to current chemotherapy treatments. Our lead drug candidate, mipsagargin, has completed an open label single arm Phase 2 clinical trial in patients with advanced hepatocellular carcinoma (HCC) or liver cancer and is currently undergoing open label single arm Phase 2 clinical trials in patients with glioblastoma (brain cancer), prostate cancer and renal cancer.

Our major focus for the next twelve to eighteen months is the (i) development of a clinical protocol for and enrollment into our next clinical trial with single-agent mipsagargin in patients with advanced HCC, (ii) development and completion of a non-clinical study of mipsagargin in combination with Nexavar in liver tumor models (iii) development of a Phase 1b clinical protocol of mipsagargin in combination with Nexavar® in patients with Nexavar naïve HCC in anticipation of positive non-clinical data, (iv) ongoing clinical trials of mipsagargin, (v) development and completion of a non-clinical study of mipsagarin in combination with standard of care agents in orthotopic glioblastoma tumor models, (vi) ongoing business development discussions with potential development partners, and (vii) prioritization of our next prodrug development candidate. Our ability to execute our business plan is dependent on the amount and timing of cash, if any, that we are able to raise. Should we not raise sufficient funds to execute our business plan, our priority is the continuation and completion of our ongoing Phase 2 clinical study in glioblastoma patients and completion of the non-clinical study of mipsagargin in combination with Nexavar.

In January 2015, we presented preliminary results from our Phase 2study of mipsagargin in advanced liver cancer patients, and these data were updated in May 2015 when we received a final clinical study report. We consider the results of the study to be positive, with 42% of evaluable patients demonstrating a reduction in tumor burden, 63% of treated patients having stable disease, and a median time to progression of 4.5 months. Additionally, the trial demonstrated that mipsagargin is effective at destroying the vascularity of solid tumors thereby starving the tumor. These results support our plans to continue the development of mipsagargin for patients with liver cancer, as well as proceed with our clinical development strategy in other indications. We plan to develop subsequent randomized studies to further develop mipsagargin, preferably with a development partner, with a goal of seeking marketing approval from the United States and European regulatory authorities or licensing mipsagargin to a pharmaceutical company. While data from our completed trials appear promising, the outcomes of our ongoing or future trials may ultimately be unsuccessful.

In the first quarter of 2014, we entered into a collaborative arrangement to conduct a Phase 2 clinical trial entitled, "G-202-004: An Open-Label, Single-Arm, Phase II Study to Evaluate the Efficacy, Safety and CNS Exposure of G-202 in Patients with Recurrent or Progressive Glioblastoma." In May 2015, we announced that based on preliminary data obtained in the first stage of the trial, we were expanding the trial to a potential 34 patients. In September 2015 we announced interim Phase 2 data from 11 patients with glioblastoma with demonstrated clinical benefit in a subset of patients with high levels of PSMA expression in the primary tumor. As of October 20, 2016, we have treated twenty-six patients in the trial.

During the second quarter of 2016, we initiated a Phase 2 clinical trial pilot study in patients with prostate cancer entitled, "G-202-005: An Open-Label, Single-Arm, Phase II Study to Evaluate the Safety and Activity of G-202 Administered in the Neoadjuvant Setting Followed by Radical Prostatectomy in Patients with Adenocarcinoma of the Prostate", via a collaborative agreement with a single site in the U.S., in which one patient has been enrolled as of October 20, 2016.

During the second quarter of 2016, we initiated a Phase 2 clinical trial pilot study in patients with clear cell renal cell carcinoma entitled, "G-202-006: An Open-Label, Single-Arm, Phase II Study to Evaluate the Safety and Activity of G-202 in Patients with Clear Cell Renal Cell Carcinoma that Expresses PSMA", via a collaborative agreement with a single site in the U.S. As of October 20, 2016, two patients have been enrolled.

While we believe that the data from our nonclinical and completed clinical studies appear promising, the outcome of our ongoing or future trials may ultimately be unsuccessful.

Recent Developments

- In October 2016, we strengthened our board of directors with the appointment of Dr. Richard Buller and Dr. Clair Thom. Both Dr. Buller and Dr. Thom bring considerable oncology and drug development experience to our board of directors.
- In October 2016, we further enhanced our management team with the appointment of Michael Elliott as Vice President of Clinical Operations.
- Effective August 1, 2016, the Company initiated its corporate reorganization plan by changing its name from GenSpera, Inc. to Inspyr Therapeutics, Inc. and changing its ticker symbol from GNSZ to NSPX.
- On August 2, 2016 and August 8, 2016, respectively, we entered into employment agreements with Christopher Lowe and Ronald Shazer to serve as our chief executive officer and chief medical officer, respectively. At such time, Mr. Lowe also joined the Company's board of directors.
- In the second quarter of 2016, we initiated a Phase 2 clinical trial pilot study in patients with prostate cancer entitled, "G-202-005: An Open-Label, Single-Arm, Phase II Study to Evaluate the Safety and Activity of G-202 Administered in the Neoadjuvant Setting Followed by Radical Prostatectomy in Patients with Adenocarcinoma of the Prostate", via a collaborative agreement with a single site in the U.S., in which one patient has been enrolled as of October 20, 2016.
- In second quarter of 2016, we initiated a Phase 2 clinical trial pilot study in patients with clear cell renal cell carcinoma entitled, "G-202-006: An Open-Label, Single-Arm, Phase II Study to Evaluate the Safety and Activity of G-202 in Patients with Clear Cell Renal Cell Carcinoma that Expresses PSMA" via a collaborative agreement with a single site in the U.S. As of October 20, 2016, two patients have been enrolled.

Product Development of Mipsagargin

Our ability to execute our product development plan is dependent on the amount and timing of cash, if any, that we are able to raise. Should we not raise sufficient funds to execute our product development plan, our priority is the continuation and completion of our ongoing Phase 2 clinical study in glioblastoma and completion of the non-clinical study of mipsagargin in combination with Nexavar. We are actively seeking a potential development and commercialization partner at both multi-national and regional levels to assist with the development of mipsagargin through clinical trials in liver cancer. Our current product development plan of mipsagargin contemplates the following major initiatives:

- Initiation of our next clinical trial in HCC.
- Completion of a non-clinical study of mipsagargin in combination with Nexavar in liver cancer tumor models anticipated during the second quarter of 2017.
- Development and enrollment into a Phase 1b clinical study of mipsagargin in combination with Nexavar® in patients with Nexavar naïve HCC during the first half of 2017.
- Continue ongoing business development discussions with potential development partners.
- Continue our Phase 2 clinical trial in patients with glioblastoma which is being conducted at the University of California San Diego Moores Cancer Center.
- Completion of a non-clinical study of mipsagargin in combination with standard of care in orthotopic glioblastoma tumor models anticipated in mid 2017.
- Continue enrollment in our Phase 2 clinical trial pilot studies in prostate cancer and in clear renal cell carcinoma.

Financial

To date, we have devoted a substantial portion of our efforts and financial resources to the development of our proposed drug candidates. Mipsagargin is the only product candidate for which we have conducted clinical trials, and we have not received FDA approval to market, distribute or sell any products. Since our inception in 2003, we have generated no revenue from product sales and have funded our operations principally through the private and public sales of our equity securities. We have never been profitable and, as of September 30, 2016, we had an accumulated deficit of approximately $47.5 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our product candidates and advance them through clinical trials.

Our cash and cash equivalents balance at September 30, 2016 was approximately $0.3 million, representing 61% of total assets. Based on our current expected level of operating expenditures, we expect to be able to fund our operations into the fourth quarter of 2016. This period could be shortened if there are any significant increases in spending that were not anticipated or other unforeseen events.

We anticipate raising additional cash through the private or public sales of equity or debt securities, collaborative arrangements, licensing agreements or a combination thereof, to continue to fund our operations and the development of our product candidates. There is no assurance that any such collaborative arrangement will be entered into or that financing will be available to us when needed in order to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient funds in a timely manner, we may be forced to curtail operations, delay or stop our ongoing clinical trials, cease operations altogether, or file for bankruptcy. We currently do not have commitments for future funding from any source.

Going Concern

Our auditors' report on our December 31, 2015 financial statements expressed an opinion that our capital resources as of the date of their audit report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Accordingly, our current cash level raises substantial doubt about our ability to continue as a going concern past the fourth quarter of 2016. If we do not obtain additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders will lose their entire investment.

Critical Accounting Policies and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make significant judgments and estimates 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 expenses during the reporting period. Management bases these significant judgments and estimates on historical experience and other assumptions it believes to be reasonable based upon information presently available. Actual results could differ from those estimates under different assumptions, judgments or conditions. There were no material changes to our critical accounting policies and use of estimates previously disclosed in our 2015 Annual Report on Form 10-K.

Social Corporate Website

From time to time we may announce material, non-public information regarding Inspyr Therapeutics using the company website (www.inspyrtx.com), its investor relations website, SEC filings, press releases, public conference calls and webcasts.

Result of Operations

Three Months Ended September 30, 2016 Compared to Three Months Ended September 30, 2015

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future. We did not have revenue during the three months ended September 30, 2016 and 2015, and we do not anticipate generating any revenues during 2016. Net losses for the three months ending September 30, 2016 and 2015, were approximately $1.2 million and $1.4 million, respectively, resulting from the operational activities described below.

Operating Expenses

Operating expense totaled approximately $0.9 million and $1.4 million during the three months ended September 30, 2016 and 2015, respectively. The decrease in operating expenses is the result of the following factors.

	Three months ended September 30,		Change in 2016 versus 2015	
	2016	2015	$	%
	(amount in thousands)			
Operating Expenses				
Research and development	$ 379	$ 459	$ (80)	(17)%
General and administrative	509	915	(406)	(44)%
Total operating expenses	$ 888	$ 1,374	$ (486)	(35)%

Research and Development Expenses

Research and development expenses totaled approximately $0.4 million and $0.5 million for the three months ended September 30, 2016 and 2015, respectively. The decrease of approximately $0.08 million, or 17%, for the three months ended September 30, 2016 compared to the same period in 2015 was primarily due to a decrease in manufacturing expense as a result of sponsored research incurred in prior year related to creating a sustainable source of high quality thapsigargin, as well as a decrease in legal expenses as we resolved our outstanding patent litigation, partially offset by an increase in compensation cost related to the appointment of our chief medical officer/senior vice president in August 2016.

Our research and development expenses consist primarily of expenditures related to manufacturing, clinical trials, employee compensation, consulting, and patent related costs.

General and Administrative

General and administrative expenses totaled approximately $0.5 million and $0.9 million for the three months ended September 30, 2016 and 2015, respectively. The decrease of approximately $0.4 million, or 44%, for the three months ended September 30, 2016 compared to the same period in 2015, was primarily as a result of a decrease from prior year spending related to corporate communication and business development costs. Additionally, compensation costs associated with senior management decreased as a result of our former CEO ceasing employment and accordingly, the company is no longer accruing bonuses related thereto.

Our general and administrative expenses consist primarily of expenditures related to employee compensation, legal, accounting and tax, other professional services, and general operating expenses.

Other Income (Expense)

Other income (expense) totaled approximately ($333,000) and 1,000 for the three months ended September 30, 2016 and 2015, respectively.

	Three Months Ended September 30,		Change in 2016 Versus 2015	
	2016	2015	$	%
	(amount in thousands)			
Gain (loss) on change in fair value of derivative liability	$ (334)	$ —	$ (334)	(100)%
Interest income (expense), net	1	1	—	—
Total other income (expense)	$ (333)	$ 1	$ (334)	(100)%

Gain on change in fair value of derivative liability

As a result of a change in the fair value of our derivative liability, we realized a loss of approximately $334,000 during the three months ended September 30, 2016 compared to no gain or loss during the three months ended September 30, 2015. The change in the fair value of our derivative liability from the prior year was the result of our private placement in December 2015, where we issued convertible preferred stock containing 18-month anti-dilutive features and warrants. Refer to Note 6 in our Financial Statements for further discussion on our derivative liability.

Interest income (expense)

We had net interest income of approximately $1,000 in each of the three months ended September 30, 2016 and 2015, respectively.

Nine months Ended September 30, 2016 Compared to Nine months Ended September 30, 2015

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future. We did not have revenue during the nine months ended September 30, 2016 and 2015, and we do not anticipate generating any revenues during 2016. Net losses for the nine months ending September 30, 2016 and 2015, were approximately $2.2 million and $4.7 million, respectively, resulting from the operational activities described below.

Operating Expenses

Operating expense totaled approximately $2.6 million and $4.7 million during the nine months ended September 30, 2016 and 2015, respectively. The decrease in operating expenses is the result of the following factors.

	Nine months ended September 30,		Change in 2016 versus 2015	
	2016	2015	$	%
	(amount in thousands)			
Operating Expenses				
Research and development	$ 1,025	$ 1,885	$ (860)	(46)%
General and administrative	1,600	2,864	(1,264)	(44)%
Total operating expenses	$ 2,625	$ 4,749	$ (2,124)	(45)%

Research and Development Expenses

Research and development expenses totaled approximately $1.0 million and $1.9 million for the nine months ended September 30, 2016 and 2015, respectively. The decrease of approximately $0.9 million, or 46%, for the nine months ended September 30, 2016 compared to the same period in 2016 was primarily due to a decrease in clinical trial expense due to completion of our Phase II clinical trial in liver cancer, as well as a decrease in manufacturing expense from the prior year as a result as sponsored research incurred in prior year related to creating a sustainable source of high quality thapsigargin, and a decrease in legal expenses as we resolved our outstanding patent litigation. These decreases were partially offset by an increase in compensation cost related to the appointment of our chief medical officer/senior vice president in August 2016.

Our research and development expenses consist primarily of expenditures related to manufacturing, clinical trials, employee compensation, consulting, and patent related costs.

General and Administrative

General and administrative expenses totaled approximately $1.6 and $2.9 million for the nine months ended September 30, 2016 and 2015, respectively. The decrease of approximately $1.3 million, or 44%, for the nine months ended September 30, 2016 compared to the same period in 2015, was primarily the result of a decrease from prior year spending on corporate communication and business development costs. Additionally, compensation costs decreased as a result of our former CEO ceasing employment, and accordingly, the company is no longer accruing bonuses related thereto.

Our general and administrative expenses consist primarily of expenditures related to employee compensation, legal, accounting and tax, other professional services, and general operating expenses.

Other Income (Expense)

Other income (expense) totaled approximately $424,000 for the nine months ended September 30, 2016, with none for the three months ended September 30, 2015.

	Nine months Ended September 30,		Change in 2016 Versus 2015	
	2016	2015	$	%
	(amount in thousands)			
Gain on change in fair value of derivative liability	$ 421	$ —	$ 421	100%
Interest income (expense), net	3	—	3	100%
Total other income (expense)	$ 424	$ —	$ 424	100%

Gain on change in fair value of derivative liability

As a result of a change in the fair value of our derivative liability, we realized a gain of approximately $421,000 during the nine months ended September 30, 2016 compared to no gain or loss during the nine months ended September 30, 2015. The change in the fair value of our derivative liability from the prior year was the result of our private placement in December 2015, where we issued convertible preferred stock with 18-month anti-dilutive features and warrants. Refer to Note 6 in our Financial Statements for further discussion on our derivative liability.

Interest income (expense)

We had net interest income of approximately $3,000 for the nine months ended September 30, 2016, compared to none for the nine months ended September 30, 2015, respectively. The increase of $3,000 was attributable to an increase in interest earned on higher average outstanding cash balances during the period, as well as the conversion of outstanding notes payable into the company's common stock in the prior year.

Liquidity and Capital Resources

We have incurred losses since our inception in 2003 as a result of significant expenditures on operations, research and development and the lack of any approved products to generate revenue. We have an accumulated deficit of $47.5 million as of September 30, 2016 and anticipate that we will continue to incur additional losses for the foreseeable future. To date, we have funded our operations through the private sale of our equity securities and exercise of options and warrants, resulting in gross proceeds of $34.9 million. Cash and cash equivalents at September 30, 2016 were $0.3 million.

Our auditors' report on our December 31, 2015 financial statements expressed an opinion that our capital resources as of the date of their audit report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Based on our current level of expected operating expenditures, we expect to be able to fund our operations into the fourth quarter of 2016. This assumes that we spend minimally on general operations and only continue conducting our ongoing clinical trials, and that we do not encounter any unexpected events or other circumstances that could shorten this time period. If we do not obtain additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders will lose their entire investment.

We are actively seeking sources of financing to fund our continued operations and research and development programs. To raise additional capital, we may sell equity or debt securities, or enter into collaborative, strategic and/or licensing transactions. There can be no assurance that we will be able to complete any financing transaction in a timely manner or on acceptable terms or otherwise. If we are not able to raise additional cash, we may be forced to further delay, curtail, or cease development of our product candidates, or cease operations altogether.

	Nine months ended September 30,		Change in 2016 versus 2015	
	2016	2015	$	%
	(amount in thousands)			
Cash at beginning of period	$ 2,465	$ 2,316	$ 149	6%
Net cash used in operating activities	(2,135)	(3,620)	1,485	41%
Net cash used in investing activities	—	(4)	4	100%
Net cash provided by financing activities	—	2,548	(2,548)	(100)%
Cash at end of period	$ 330	$ 1,240	$ (910)	(73)%

Cash totaled approximately $0.3 million and $1.2 million as of September 30, 2016 and 2015, respectively. The decrease of approximately $910,000 at September 30, 2016 compared to the same period in 2015 was primarily attributable to a 2015 private placement in which we raised approximately $2.2 million in net proceeds, together with proceeds of $287,000 from the exercise of warrants, with no cash provided by financing activities in 2016, partially offset by having $150,000 more in cash at the beginning of 2016 compared to the beginning of 2015, as well as a decrease in cash used in operations.

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately $2.1 million and $3.6 million for the nine months ended September 30, 2016 and 2015, respectively. Cash used for operations declined by approximately $1.5 million, or 41%, during the nine months ended September 30, 2016, compared to the same period in 2015, due to our net loss decreasing approximately $2.5 million compared to prior year as a result of a decrease in research and development related costs, as well as a decrease in general and administrative costs, as described above. This decrease in our net loss was partially offset by the gain recognized for our derivative liability during the current period.

Net Cash Provided by Investing Activities

There was no cash used in investing activities for the nine months ended September 30, 2016, compared to cash used in investing activities of $4,000 for the nine months ended September 30, 2015. The cash used in investing activities was due to purchases of office equipment in the prior year.

Net Cash Provided by Financing Activities

There was no cash provided by financing activities for the nine months ended September 30, 2016, compared to approximately $2.5 million provided for the nine months ended September 30, 2015. The decrease of $2.5 million, or 100%, in cash provided by financing activities for the nine months ended September 30, 2016 compared to 2015 is attributable to a 2015 private placement in which we raised approximately $2.2 million in net proceeds, together with proceeds of $287,000 from the exercise of warrants.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are not required to provide the information required by this item as we are considered a smaller reporting company, as defined by Rule 229.10(f)(1).

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures and Changes in Internal Control over Financial Reporting

Our management, with the participation of our principal executive officer and principal accounting officer (both positions are held by our Chief Executive Officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Exchange Act of 1934, as amended (the Exchange Act)), as of September 30, 2016. Based on that evaluation, management has concluded that due to limited resources and limited number of employees, its internal control over financial reporting was ineffective as of September 30, 2016 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. Generally Accepted Accounting Principles. To mitigate the current limited resources and employees, we rely heavily on direct management oversight of transactions, along with the use of legal and accounting professionals. As we grow, we expect to increase the number of employees, which would enable us to implement adequate segregation of duties within the internal control framework.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15f of the Exchange Act) that occurred during the first nine months of 2016 that has materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Limitations on Internal Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Except as described below, as of the date of this Report, there are no material pending legal or governmental proceedings relating to our company or properties to which we are a party, and, to our knowledge, there are no material proceedings to which any of our current directors, executive officers or affiliates are a party adverse to us or which have a material interest adverse to us.

On March 16, 2016, Dr. Craig Dionne provided us his notice of termination as the company's Chief Executive Officer and Chief Financial Officer. Dr. Dionne's notice of termination alleges that such termination was for "Good Reason" as a result of a purported material change in his authority, functions, duties and responsibilities as chief executive officer. In the event that termination was for "Good Reason", Dr. Dionne would be entitled to certain severance payments as well as other benefits. His notice of termination, in additional to requesting such severance, also requests the payment of Dr. Dionne's annual and long term bonus for 2014 and 2015. On April 11, 2016, we received a letter from Dr. Dionne demanding approximately $2.3 million as a result of the foregoing.

The Company vigorously disputes that the termination of his employment was for "Good Reason," as that term is defined in his employment agreement and under applicable law. This matter is at the early stages. While no litigation is pending at this time, there can be no assurance that this matter will be resolved in such a manner as to avoid litigation. Accordingly, the Company is unable at this time to predict the outcome of this matter, and any views formed as to the viability of these claims or the costs to the Company which could result may change from time to time as the matter proceeds through its course.

ITEM 1A. RISK FACTORS

We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Quarterly Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Quarterly Report should be considered carefully in evaluating us, our business and the value of our securities. The following important factors, among others, could cause our actual business, financial condition and future results to differ materially from those contained in forward-looking statements made in this Quarterly Report or presented elsewhere by management from time to time.

Risks Related to our Financial Position and Need to Raise Additional Capital

We may not be able to continue as a going concern if we do not obtain additional financing during the fourth quarter of 2016.

Our cash and cash equivalents balance at September 30, 2016 was $0.3 million. Based on our current expected level of operating expenditures, we expect to be able to fund our operations into the fourth quarter of 2016, at which time we will need additional capital. Our ability to continue as a going concern is wholly dependent upon obtaining sufficient financing to fund our operations. We have no committed sources of additional capital and our access to capital funding is always uncertain. Accordingly, despite our ability to secure capital in the past, there is no assurance that additional equity or debt financing will be available to us when needed. In the event that we are not able to secure financing, we may be forced to curtail operations, delay or stop ongoing clinical trials, cease operations altogether or file for bankruptcy.

Our auditors have expressed substantial doubt about our ability to continue as a going concern.

Our auditors' report on our December 31, 2015 financial statements expressed an opinion that our capital resources as of the date of their audit report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Our current cash level raises substantial doubt about our ability to continue as a going past the fourth quarter of 2016. If we do not obtain additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders will lose their entire investment.

Risks Relating to Our Stage of Development and Business

If we are unable to successfully retain and integrate a new management team, our business could be harmed.

On March 16, 2016, our former President, Chief Executive Officer, Chief Financial Officer and founder provided us his notice of termination thereby ceasing his employment. On August 2, 2016, we appointed Christopher Lowe as our new chief executive officer, president and principal accounting officer. On August 8, 2016, we appointed Ronald Shazer, MD, as our chief medical officer and senior vice president. We also commenced a search for additional senior management personnel. Our success depends largely on the development and execution of our business strategy by our senior management team. The recent transitions in our executive team may be disruptive to our business, and if we are unable to manage an orderly transition, our business may be adversely affected. Additionally, since our management team consists of a limited number of individuals, the loss of these members of our senior management team or key personnel would likely harm our ability to implement our business strategy and respond to the rapidly changing market conditions in which we operate. There may be a limited number of persons with the requisite skills to serve in these positions, and we cannot assure you that we would be able to identify or employ such qualified personnel on acceptable terms, if at all. We cannot assure you that management will succeed in working together as a team. In the event we are unsuccessful, our business and prospects could be harmed.

We are an early-stage company, have no product revenues, are not profitable and may never be profitable.

From inception through September 30, 2016, we have raised approximately $34.9 million through the sale of our securities and exercise of outstanding warrants. During this same period, we have recorded an accumulated deficit of approximately $47.5 million. Our net losses for the two most recent fiscal years ended December 31, 2015 and 2014 were $5.9 million and $7.0 million, respectively. Our net loss for the nine months ended September 30, 2016, was approximately $1.2 million. None of our products in development have received approval from the FDA, or other regulatory authorities; we have no sales and have never generated revenues nor do we expect to for the foreseeable future. Currently, our only product candidate in clinical development is mipsagargin, which: (i) has completed an open label single arm Phase 2 clinical trial in refractory liver cancer, (ii) is being tested in an investigator lead open label single arm Phase 2 clinical trial in glioblastoma patients, and (iii) we have commenced enrollment in two Phase 2 pilot studies in prostate and clear cell renal cancer. We expect to incur significant operating losses for the foreseeable future as we continue the research, pre-clinical and clinical development of our product candidates. Accordingly, we will need additional capital to fund our continuing operations. Since we do not generate any revenue, the most likely sources of such additional capital includes the sale of our securities, a strategic licensing collaboration transaction or joint venture involving the rights to one or more of our product candidates, or from grants. To the extent that we raise additional capital by issuing equity securities, our stockholders are likely to experience dilution with regard to their percentage ownership of the company, which may be significant. If we raise additional funds through collaborations or licensing arrangements, we may be required to relinquish some or all the rights to our technologies, product candidates, or grant licenses on terms that are not favorable to us. If we raise additional capital by incurring debt, we could incur significant interest expense and become subject to covenants that could affect the manner in which we conduct our business, including securing such debt obligations with our assets.

Our product candidates are at various stages of early development and significant financial resources are required to develop commercially viable products and obtain regulatory approval to market and sell such products. To date, we have dedicated substantially all of our efforts and financial resources to the development of mipsagargin and depend heavily on its success. We will need to devote significantly more research and development efforts, financial resources and personnel to develop commercially viable products and obtain regulatory approvals. We may encounter hurdles and unexpected issues as we proceed in the development of mipsagargin and our other product candidates. While initial data from our completed clinical trials appear promising, the outcome of the current trials is uncertain and these trials or future trials may ultimately be unsuccessful. If we fail to develop and successfully commercialize our product candidates, our business may be materially harmed and could fail.

We have a limited operating history as a company, and may not be able to effectively operate our business.

Our limited staff and operating history means that there is a high degree of uncertainty regarding our ability to:

- develop and commercialize our technologies and proposed products;
- obtain regulatory approval to commence the marketing of our products;
- identify, hire and retain the needed personnel to implement our business plan;
- manage growth;
- achieve market acceptance or insurance reimbursement for any of our proposed products, if successfully developed; or
- respond to competition.

No assurances can be given as to exactly when, if at all, we will be able to fully develop, and take the necessary steps to derive any revenues from our proposed product candidates.

Raising capital may be difficult as a result of our history of losses and limited management and operating history.

When making investment decisions, investors typically look at a company's earnings and historical performance in evaluating the risks and operations of the business and our future prospects. Our history of losses and relatively limited management and operating history in our current stage of development makes such evaluation, as well as any estimation of our future performance, substantially more difficult. As a result, investors may be unwilling to invest in us or on terms or conditions which are favorable or acceptable to us. If we are unable to secure additional financing, we may need to materially scale back our business plan and/or operations or cease operations altogether.

Risks Related to Commercialization

The market for our proposed products is rapidly changing and competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change and innovation. Developments by others may render our proposed products noncompetitive or obsolete, or we may be unable to keep pace with technological developments and other market factors. Competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

As a pre-revenue company, our resources are limited and we may experience challenges inherent in the early development of novel therapeutics. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic efforts compared to our proposed products. Our competitors may develop therapies that are safer, more effective and less costly than our proposed products and therefore, present a serious competitive threat to us.

The acceptance of therapies that are alternatives to ours may limit market acceptance of our proposed products, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medications and treatments. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of other competing therapies may limit the potential for our proposed products, even if commercialized.

Our proposed products may not be accepted by the healthcare community.

Our proposed products, if approved for marketing, may not achieve market acceptance by the healthcare community since hospitals, physicians, patients or the medical community in general may decide not to utilize them. We are attempting to develop products that are likely to be first approved for marketing as a treatment for late stage cancer where there is no truly effective standard of care. If approved for use in late stage cancer, our proposed products might then be evaluated in earlier stages where they could represent a substantial departure from established treatment methods and would most likely compete with a number of more conventional drugs and therapies which are manufactured and marketed by major pharmaceutical companies. It is too early in the development cycle of our proposed products for us to predict our major competitors. The degree of market acceptance of our products, if developed, will depend on a number of factors, including but not limited to:

- our ability to demonstrate the clinical efficacy and safety of our proposed products to the medical community;
- our ability to create products that are superior to alternative products;
- our ability to establish in the medical community the potential advantage of our treatments over alternative treatment methods; and
- the reimbursement policies of government and third-party payors.

If the healthcare community does not accept our products, our business could be materially harmed.

Our potential competitors in the biotechnology and pharmaceutical industries have significantly greater resources than we have.

We compete against numerous companies, many of which have substantially greater resources than we have. Several such competitors have research programs and/or efforts to treat the same diseases we target. Companies such as Merck & Co., Inc., Ipsen, Johnson & Johnson, and Sanofi S.A., as well as others, have substantially greater financial, research, manufacturing and marketing resources than we do. As a result, such competitors may find it easier to compete in our industry and bring competing products to market.

Risks Related to the Development and Manufacturing of Our Product Candidates

We intend to rely exclusively upon third-party FDA-regulated manufacturers and suppliers for our proposed products.

We currently have no internal manufacturing capability, and intend to rely exclusively on FDA-approved licensees, strategic partners or third party contract manufacturers or suppliers for the foreseeable future. Because manufacturing facilities are subject to regulatory oversight and inspection, the failure of any of our third-party FDA regulated manufactures or suppliers to comply with regulatory requirements could result in material manufacturing delays and product shortages, which could delay or otherwise negatively impact our clinical trials and product development plans. Should we be forced to manufacture our proposed products, we cannot give any assurance that we would be able to develop internal manufacturing capabilities or secure third party suppliers for raw materials. In the event we seek third party suppliers or alternative manufacturers, they may require us to purchase a minimum amount of materials or could require other unfavorable terms. Any such event could materially impact our business prospects and could delay the development of our proposed products. Moreover, we cannot give any assurance that the contract manufacturers or suppliers that we select will be able to supply our products in a timely or cost effective manner or in accordance with applicable regulatory requirements or our own specifications.

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize our product candidates.

Our business plan relies heavily on third party collaborators, partners, licensees, clinical research organizations, clinical investigators, vendors or other third parties to support our research and development efforts and to conduct clinical trials for our product candidates. We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, these third parties on a commercially reasonable basis, if at all. Additionally, to commercialize our proposed products, we intend to rely on third party licensees or the outright sale of our proposed products to pharmaceutical partner(s). If we fail to establish or maintain such third-party relationships as anticipated, out business could be adversely effected.

We are dependent upon third parties to develop our product candidates, and such parties are, to some extent, outside of our control.

We depend upon independent contract research organizations, investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical and clinical trials. These individuals and/or entities are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If these third parties fail to devote sufficient time and resources to our programs, or if their performance is substandard, the development of our drug candidates and corresponding FDA approval could be delayed or fail entirely.

Our business is dependent upon securing and importing sufficient quantities of seeds from the plant,* Thapsia garganica *, which grows in very specific locations outside of the United States.

The therapeutic component of mipsagargin is derived from the seeds of the *Thapsia garganica* plant, which grows along the coastal regions of the Mediterranean Sea. We currently secure the seeds from Thapsibiza, SL, a third-party supplier. There can be no assurances that *Thapsia garganica* will continue to grow in sufficient quantities to produce a commercial supply or that the countries from which we can secure *Thapsia garganica* will continue to allow the collect and/or export of such seeds. The process of importing *Thapsia garganica* seeds is subject to U.S. import and export laws and controls. Our supply agreement with Thapsibiza, SL (our sole supplier) expires on April 6, 2017 or April 6, 2022 if extended. In the event we are no longer able to obtain these seeds in the future, we may not be able to produce our proposed drug and our business will be adversely affected.

***We may be required to expend significant capital to locate, secure and finance land for cultivation and harvesting of* Thapsia garganica.**

We believe that we can satisfy our needs for the clinical development of mipsagargin, through completion of Phase III clinical studies and early commercialization from *Thapsia garganica* that grows naturally in the wild. In the event mipsagargin is approved for commercial marketing and is widely adopted by the medical community, our current supply of *Thapsia garganica* may not be sufficient. In order to secure sufficient quantities of *Thapsia garganica* , we would need to secure adequate acreage of land to cultivate and grow *Thapsia garganica* . We have not yet fully assessed the amount of land or other costs that would be associated with a full-scale farming operation. There can be no assurances that we will be able to secure sufficient acres of land, or the capital to purchase or lease such land, to grow sufficient quantities of *Thapsia garganica* to manufacture mipsagargin on a commercial scale. Our inability to secure adequate seeds could adversely impact our business.

The synthesis of our therapeutic compounds must be conducted in special facilities, which limits the locations where it may be manufactured.

We are required to manufacture our therapeutic compounds that are to be used in our clinical trials in FDA approved facilities. There are a limited number of manufacturing facilities qualified to handle and manufacture toxic therapeutic agents and compounds. This limits the number of potential manufacturing sites for our therapeutic compounds derived from *Thapsia garganica* . No assurances can be provided that these facilities will be available for the manufacture of our therapeutic compounds under our time schedules or within the parameters of our manufacturing budget. In the event facilities are not available for the manufacturing of our therapeutic compounds, we may not be able to complete our clinical trials and our business and future prospects would be adversely affected.

Our therapeutic compounds may not be able to be manufactured profitably on a large enough scale to support commercialization.

To date, our therapeutic compounds have only been manufactured at a scale which is adequate to supply our research activities and early-stage clinical trials. There can be no assurance that the procedures currently used to manufacture our therapeutic compounds will work at a scale which is adequate for commercial needs. In the event our therapeutic compounds cannot be manufactured in sufficient quantities for commercialization, our future prospects could be significantly impacted and our financial prospects would be materially harmed.

Risks Relating to our Intellectual Property

Our competitive position is dependent on our intellectual property and we may not be able to withstand challenges to our intellectual property rights.

We rely on our intellectual property, including our issued and applied for U.S. and foreign patents as well as our licenses, as the foundation of our business. If our intellectual property rights are challenged, no assurances can be given that our patents or licenses would survive claims alleging invalidity or infringement on other patents and/or licenses. In addition, disputes may arise regarding inventorship of our intellectual property. It is possible that our intellectual property may be infringing upon existing patents that we are not currently unaware of. As the number of participants in the marketplace grows, the possibility of patent infringement claims against us increases. It is difficult, if not impossible, to determine how such disputes would be resolved. Furthermore, because of the substantial amount of discovery required in connection with patent litigation, there is a risk that some of our confidential information could be required to be publicly disclosed. Any litigation claims against us may cause us to incur substantial costs and could place a significant strain upon our financial resources, divert the attention of management or restrict our core business or result in the public disclosure of confidential information.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

Some or all of our patent applications may not issue as patents, or the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors, if any, may be challenged and subsequently narrowed, invalidated or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position or to determine the scope and validity of third-party proprietary rights. If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company would have the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and we may not have the required resources to pursue such litigation or to protect our patent rights. In addition, there is a risk that the court might decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court could refuse to stop the other party on the ground that such other party's activities do not infringe on our rights contained in these patents.

Furthermore, a third party may claim that we are using inventions covered by their patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could materially increase our operating expenses and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court would order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies.

If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference or other proceeding in the U.S. Patent and Trademark Office, or the PTO, or a court to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

Obtaining and maintaining our patent protection depends upon compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may not be able to adequately protect our intellectual property.

We rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others do not develop the same or similar technologies on their own. Additionally, research with regard to our technologies has been performed in countries outside of the United States and we also anticipate conducting future clinical trials outside the US. The laws in some of these countries may not provide protection for our trade secrets and intellectual property. We have taken steps, including entering into confidentiality agreements with our employees, consultants, service providers, and potential strategic partners to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us are our property. However, these agreements may not be honored, including in foreign countries in which we conduct research, and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ and hire individuals and/or entities who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these individuals, entities or us have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Relating to Marketing Approval and Government Regulations

Thapsia garganica ***is highly toxic and we may be liable for any contamination or injury we may cause or any environmental and safety law we may violate.***

The therapeutic component of our proposed products, including our lead product mipsagargin, is highly toxic. As a consequence, we are subject to numerous environmental and safety laws and regulations, including those governing laboratory procedures and the handling of toxic materials. We may be required to incur significant costs to comply with current or future environmental laws and regulations and may be adversely affected by the cost of compliance with these laws and regulations. Although we believe that our safety procedures for using, handling, storing and disposing of hazardous materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, state or federal authorities could curtail our use of these materials and we could be liable for any civil damages that result, the cost of which could be substantial. Further, any failure by us to control the use, disposal, removal or storage, or to adequately restrict the discharge, or assist in the clean-up of toxic substances could subject us to significant liabilities, including joint and several liabilities under certain statutes. Although we feel this risk may be minimized through our use of third parties, it is possible that the employees of such contractors could suffer medical issues related to the handling of these toxic agents and subsequently seek compensation from us via, for example, litigation. Any such liability could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations. No assurances can be given, despite our contractual relationship with the third-party contractor, that we would not be the subject of litigation. Additional federal, state and local laws and regulations affecting us may be adopted in the future. We may incur substantial costs to comply with these laws and regulations and substantial fines or penalties if we violate any of these laws or regulations, which would adversely affect our business.

Data obtained from clinical trials are susceptible to varying interpretations and may not be sufficient to support approval of our proposed products by the FDA.

The design of our clinical trials is based on many assumptions about the expected effect of our product candidate and if those assumptions are incorrect, our clinical trials may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of early clinical trials. Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials do not necessarily predict the results that may be obtained from later trials. Moreover, pre-clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the potential drug. Our products may not prove to be safe and effective in clinical trials and may not meet all regulatory requirements needed to receive regulatory approval. While data from our completed trials appear promising, the outcome of the current trials is uncertain and these trials or future trials may ultimately be unsuccessful. Our clinical trials may among other things, not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

Our proposed products may not receive FDA or other regulatory approvals.

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacture and marketing of pharmaceutical products through expensive, lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these regulations typically takes several years or more and varies substantially based upon the type, complexity and novelty of the proposed product. Our proposed products are subject to extensive regulation and/or acceptance by numerous governmental authorities in the United States, including the FDA, and authorities in other countries. Most of our proposed products will require governmental approval before they can be commercialized. Our failure to receive the regulatory approvals in the United States or foreign countries would likely cause us to cease operations and go out of business.

Our proposed products may not have favorable results in clinical trials or receive regulatory approval.

Encouraging results from pre-clinical studies and our clinical trials to date should not be relied upon as evidence that our clinical trials will ultimately be successful or our product approved for marketing. Even though the results of our pre-clinical and completed clinical studies to date seem promising, we will be required to demonstrate through further clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates as they proceed through clinical trials. If any product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, then we could experience potentially significant delays in, or be required to abandon, development of that product candidate. While initial data from our completed trials appear promising, the outcome of the current trials is uncertain and these trials or future trials may ultimately be unsuccessful.

We may be unable to complete all of our planned clinical trials of mipsagargin if we do not have adequate enrollment or capital to finance the studies.

We are conducting Phase 2 clinical trials in patients with glioblastoma, prostate cancer and clear cell renal cancer, and we anticipate commencing additional clinical trials in the future. The initiation, continuation and/or completion of these trials are dependent on a number of factors, including adequate capital to fund the clinical trials and patient enrollment at the trial sites. At present, we have limited capital resources and require significant additional capital to complete any ongoing or future clinical trials that we may initiate. Our failure to enroll sufficient patients or to finance our clinical trials could materially harm our business.

If users of our proposed products are unable to obtain adequate reimbursement from third-party payors, market acceptance of our proposed products may be limited and we may not achieve revenues or profits.

The continuing efforts of governments, insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability as well as the future revenues and profitability of our potential customers, suppliers and collaborative partners in addition to the availability of capital. In other words, our ability to commercialize our proposed products depends in large part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations, products and related treatments are obtained by the health care providers of these products and treatments. At this time, we cannot predict the precise impact that recently adopted or future laws will have on these reimbursement levels.

We may be unable to comply with our reporting and other requirements under federal securities laws.

The Sarbanes-Oxley Act of 2002, as well as related new rules and regulations implemented by the United States Securities and Exchange Commission, or SEC, and the Public Company Accounting Oversight Board, require changes in the corporate governance practices and financial reporting standards for public companies. These laws, rules and regulations, including compliance with Section 404 of the Sarbanes-Oxley Act of 2002 relating to internal control over financial reporting, would be expected to materially increase the Company's legal and financial compliance costs and make some activities more time-consuming and more burdensome. Presently we qualify as a non-accelerated filer. Accordingly, we are exempt from the requirements of Section 404(b) and our independent registered public accounting firm is not required to audit the design and operating effectiveness of our internal controls and management's assessment of the design and the operating effectiveness of such internal controls. In the event we become an accelerated filer, we will be required to expend substantial capital in connection with compliance.

We do not have effective internal controls over our financial reporting.

Because of our limited resources, management has concluded that our internal control over financial reporting may not be effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Effective internal controls over financial reporting and disclosure controls and procedures are necessary for us to provide reliable financial and other reports and effectively prevent fraud. If we cannot provide reliable financial or SEC reports or prevent fraud, investors may lose confidence in our SEC reports, our operating results and the trading price of our common stock could suffer materially and we may become subject to litigation.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses and will divert time and attention away from revenue generating activities.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and related SEC regulations, have created uncertainty for public companies and significantly increased the costs and risks associated with accessing the public markets and public reporting. Our management team invests significant time and financial resources to comply with both existing and evolving standards for public companies, which will lead to increased general and administrative expenses and a diversion of management time and attention from developing our business to compliance activities which could have an adverse effect on our business.

Risks Relating to our Securities

Our common stock price may be particularly volatile because of our stage of development and business.

The market prices for the securities of biotechnology and pharmaceutical companies in general, and early-stage drug development companies in particular, such as ours, have been highly volatile and may continue to be highly volatile in the future. The following may have a significant impact on the market price of our common stock:

- our ability to develop a management team;
- the development status of our drug candidates, particularly the results of our clinical trials;
- market conditions or trends related to the biotechnology and pharmaceutical industries, or the market in general;
- announcements of technological innovations, new commercial products, or other material events by our competitors or us;
- disputes or other developments concerning our proprietary rights;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial and developmental performance;
- additions or departures of key personnel;
- loss of any strategic relationship;
- discussions of our business, products, financial performance, prospects, or stock price by the financial and scientific press and online investor communities such as chat rooms;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- public concern as to, and legislative action with respect to, testing or other research areas of biopharmaceutical and pharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs;
- regulatory developments in the United States or foreign countries; and
- economic, political and other external factors.

Broad market fluctuations may cause the market price of our common stock to decline substantially. Additionally, fluctuations in the trading price or liquidity of our common stock may materially and adversely affect, among other things, the interest of investors to purchase our common stock on the open market and, generally, our ability to raise capital.

Our board of directors has broad discretion to issue additional securities.

We are authorized under our certificate of incorporation to issue up to 150,000,000 shares of common stock and 30,000,000 "blank check" shares of preferred stock. Shares of our blank check preferred stock provide the board of directors' with broad authority to determine voting, dividend, conversion, and other rights. As of September 30, 2016, we have issued and outstanding 1,392,079 shares of common stock and 2,760,117 shares of common stock reserved for future grants under our equity compensation plans and for issuances upon the exercise or conversion of currently outstanding shares of preferred stock, options, warrants and other convertible securities. As of September 30, 2016, we have issued and outstanding 1,853 shares of Series A 0% Cconvertible Ppreferred Sstock. Accordingly, we are entitled to issue up to 145,847,804 additional shares of common stock, and 29,998,147 additional shares of "blank check" preferred stock. Our board may generally issue those common and preferred shares, or convertible securities to purchase those shares, without further approval by our shareholders. Any additional preferred shares we may issue could have such rights, preferences, privileges and restrictions as may be designated from time-to-time by our board, including preferential dividend rights, voting rights, conversion rights, redemption rights and liquidation provisions.

It is likely that we will issue a large amount of additional securities to raise capital in order to further our business plans. It is also likely that we will issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our various stock plans. Any issuances could be made at a price that reflects a discount to, or a premium from, the then-current market price of our common stock. These issuances would dilute the percentage ownership interest of our current shareholders, which would have the effect of reducing your influence on matters on which our stockholders vote, and might dilute the net tangible book value per share of our common stock.

Future sales of our common stock could cause our stock price to fall.

Transactions that result in a large amount of newly issued shares become readily tradable, or other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our common stock. In addition, the lack of a robust trading market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock. If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

As of September 30, 2016, we had 1,392,079 shares of common stock and 1,853 shares of Series A 0% Convertible Preferred Stock issued and outstanding. Substantially all of the common shares and common shares underlying the preferred shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. As of September 30, 2016, we had reserved for issuance (i) 535,347 shares of our common stock issuable upon the conversion of 1,853 shares of Series A 0% Convertible Preferred Stock including an additional number of common shares we are contractually obligated to reserve pursuant to our December 2015 Offering; (ii) 1,530,437 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of $19.80 per share, including an additional number of common shares we are contractually obligated to reserve pursuant to our December 2015 Offering; and (iii) 265,863shares of our common stock issuable upon exercise of outstanding stock options under our equity compensation plans at a weighted average exercise price of $26.40 per share. Subject to applicable vesting requirements and holding periods, upon conversion or exercise of the outstanding convertible notes, warrants and options, the underlying shares may be resold into the public market. We cannot predict if future issuances or sales of our common stock, or the availability of our common stock for sale, would harm the market price of our common stock or our ability to raise capital.

The market for our common stock has been illiquid and our investors may be unable to sell their shares as a result.

Our common stock trades with limited volume on the OTCQB tier of the OTC Markets Group Inc. Accordingly, although a limited public market for our common stock exists, it is still relatively illiquid compared to that of a seasoned issuer. Prior to making an investment in our securities, you should consider the limited market for our common stock. No assurances can be given that the trading volume of our common stock will increase or that a liquid public market for our securities will ever materialize.

We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the market price of our common stock appreciates.

Provisions of Delaware law and executive employment agreements may prevent or delay a change of control, which could depress the trading price of our common stock.

We are subject to the Delaware anti-takeover laws regulating corporate takeovers. These anti-takeover laws prevent Delaware corporations from engaging in a merger or sale of more than 10% of its assets with any stockholder, including all affiliates and associates of the stockholder, who owns 15% or more of the corporation's outstanding voting stock, for three years following the date that the stockholder acquired 15% or more of the corporation's assets unless:

- the Board of Directors approved the transaction in which the stockholder acquired 15% or more of the corporation's assets;
- after the transaction in which the stockholder acquired 15% or more of the corporation's assets, the stockholder owned at least 85% of the corporation's outstanding voting stock, excluding shares owned by directors, officers and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or
- on or after this date, the merger or sale is approved by the Board of Directors and the holders of at least two-thirds of the outstanding voting stock that is not owned by the stockholder.

A Delaware corporation may opt out of the Delaware anti-takeover laws if its certificate of incorporation or bylaws so provides. We have not opted out of the provisions of the anti-takeover laws. As such, these laws could prohibit or delay mergers or other takeover or change of control transactions and may discourage attempts by other companies to acquire us.

In addition, employment agreements with certain executive officers provide for the payment of severance and accelerated vesting of options and restricted stock in the event of termination following a change of control. These provisions could have the effect of discouraging potential takeover attempts even if it would be beneficial to shareholders.

Our certificate of incorporation and bylaws contain provisions that could discourage a third-party from acquiring us.

Our certificate of incorporation and bylaws, as applicable, among other things (i) provide our board with the ability to alter the bylaws without stockholder approval and (ii) provide that vacancies on our board of directors may be filled by a majority of directors in office. These provisions, while designed to reduce vulnerability to an unsolicited acquisition proposal, and to discourage certain tactics used in proxy fights, may negatively impact a third-party's decision to acquire us even if it would be beneficial to shareholders.

If securities or industry analysts do not publish research or reports or if they publish unfavorable research or reports, an active market for our common stock may not develop and the price of our common stock could decline.

We are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume. Even if we come to the attention of such persons, they may be reluctant to follow or recommend an unproven company such as ours until such time as we became more seasoned and viable. Generally, the trading market for a company's securities depends in part on the research and reports that securities or industry analysts publish. We currently have limited research coverage by securities and industry analysts. As a consequence, there may be periods of time when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer with significant research coverage. We cannot give you any assurance that a broader or more active public trading market for our common stock will develop or if developed, will be sustained, or that current trading levels could be sustained or not diminish. In addition, in the event any analysts downgrades our securities, the price of our shares would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our securities could decrease, which could cause the price of our common stock and its trading volume, if any, to decline.

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

Our common stock may be considered a "penny stock." The principal result or effect of being designated a penny stock is that securities broker-dealers participating in sales of our common stock may 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.

Other Risks

We received a notice of termination from Dr. Craig Dionne, our former chief executive officer demanding certain payments pursuant to the termination of his employment agreement.

On March 16, 2016, Dr. Craig Dionne provided us his notice of termination as the company's Chief Executive Officer and Chief Financial Officer. Dr. Dionne's notice of termination alleges that such termination was for "Good Reason" as a result of a purported material change in his authority, functions, duties and responsibilities as chief executive officer. On April 11, 2016, we received a letter from Dr. Dionne demanding approximately $2.3 million as a result of the foregoing. The Company disputes such claims, and does not believe Dr. Dionne had "Good Reason" to terminate his employment. However, in the event of litigation, the outcome of such litigation, as well as the costs associated therewith, could have a material adverse effect on our operations. For a further discussion of this matter, please see the section of this quarterly report entitled "Legal Proceedings."

We may be required to make significant payments to our sole employee in the event his employment with us is terminated or if we experience a change of control.

We are a party to employment agreements with our sole employee. In the event we terminate his employment, we experience a change in control or, in certain cases, if such executive terminates his employment with us, such executive will be entitled to receive certain severance and related payments. Additionally, in such instance, certain securities held by such employee will become immediately vested and exercisable. Upon the occurrence of any such event, our obligation to make such payments could significantly impact our working capital and, accordingly, our ability to execute our business plan which could have a materially adverse effect to our business. Also, these provisions may discourage potential takeover attempts that could be beneficial to our stockholders.

If our management team is not effective or if we fail to attract, hire or retain qualified personnel, we may not be able to design, develop or commercialize our products successfully or manage our business.

Our anticipated growth and expansion may require the addition of new personnel and the development of additional expertise by existing management. There is intense competition for qualified personnel in such areas. Accordingly, there can be no assurances that we would be able to attract and retain the qualified personnel necessary for the successful development of our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sale of Unregistered Securities

The following information is given with regard to unregistered securities sold since January 1, 2016. The following securities were issued in private offerings pursuant to the exemption from registration contained in the Securities Act and the rules promulgated thereunder in reliance on Section 4(2) thereof, relating to offers of securities by an issuer not involving any public offering.

- On August 2, 2016, as an inducement to Mr. Lowe's employment, we granted an inducement option to purchase 72,155 shares of Common Stock. The option has a term of seven (7) years, an exercise price of $4.35 per share and vests as follows: (i) 25% of the options vest on over a one year period and (ii) 75% of the options vest upon achievements of certain milestones and time. The options were issued pursuant to our Inducement Award Stock Option Plan.

- On August 9, 2016, as an inducement to Dr. Shazer's employment, we granted an inducement option to purchase 32,470 shares of Common Stock. The option has a term of seven (7) years, an exercise price of $4.50 per share and vests as follows: (i) 25% of the options vest on over a one year period and (ii) 75% of the options vest upon achievements of certain milestones and time. The options were issued pursuant to our Inducement Award Stock Option Plan.

- On October 1, 2016, as an inducement to employment for a new employee, we granted an inducement option to purchase 18,039 shares of Common Stock. The option has a term of seven (7) years, an exercise price of $4.20 per share and vests as follows: (i) 25% of the option vests monthly over 12 months, and (ii) 75% of the option vests upon the achievement of certain milestones and time. The options were issued pursuant to our Inducement Award Stock Option Plan.

- On November 10, 2016, the Company issued 5,556 common shares to a shareholder pursuant to the conversion of 25.00005 shares of Series A 0% Convertible Preferred Stock at a conversion price of $4.50 per common share.

Use of Proceeds

On May 23, 2014, our registration statement on Form S-1 (File No. 333-194687) was declared effective by the Securities and Exchange Commission for our initial public offering pursuant to which we sold an aggregate of 138,799 units at a public offering price of $24.00 per unit. There has been no material change in the planned use of proceeds from our public offering as described in our final prospectus filed with the Securities and Exchange Commission on May 30, 2014 pursuant to Rule 424(b).

ITEM 3. DEFAULT UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Form 10-Q.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed by the undersigned hereunto duly authorized.

INSPYR THERAPEUTICS, INC.

Date: November 18, 2016

/s/ Christopher Lowe

Christopher Lowe
Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

INDEX TO EXHIBITS

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
3.01(i)	Amended and Restated Certificate of Incorporation dated September 4, 2013		8-K	3.01	333-153829	9/6/13
3.02(i)	Amendment to the Amended and Restated Certification of Incorporation, effective August 1, 2016		8-K	3.01	333-153829	8/2/16
3.03(ii)	Amended and Restated Bylaws		8-K	3.02	333-153829	1/11/10
4.01	Specimen of Common Stock Certificate		S-1	4.01	333-153829	10/03/08
4.02	Form of Series A Preferred Stock Certificate		8-K	3.01	000-55331	12/23/15
4.03**	Amended and Restated GenSpera 2007 Equity Compensation Plan amended January 2010		8-K	4.01	333-153829	1/11/10
4.04**	GenSpera Form of 2007 Equity Compensation Plan Grant and 2009 Executive Compensation Plan Grant		8-K	4.02	333-153829	9/09/09
4.05	Form of 4.0% convertible note issued to shareholder		S-1	4.05	333-153829	10/03/08
4.06	Form of 4.0% convertible debenture modification between GenSpera, Inc. and shareholder		8-K	10.02	333-153829	2/20/09
4.07	Form of 4.0% convertible debenture modification between GenSpera, Inc. and shareholder		8-K	10.02	333-153829	2/20/09
4.08**	Amended and Restated 2009 Executive Compensation Plan amended on March 25, 2013		10-K	4.11	333-153829	3/29/13
4.09	Form of Common Stock Purchase Warrant issued Jan - Mar 2010		10-K	4.28	333-153829	3/31/10
4.10	Form of Consultant Warrants issued in May 2010		10-Q	4.29	333-153829	5/14/10
4.11	Form of Common Stock Purchase Warrant - May 18, 2010 offering, and June 2010 Consultant Warrants		8-K	10.02	333-153829	5/25/10

4.12**	Form of 2007 Equity Compensation Plan Restricted Stock Grant and 2009 Executive Compensation Plan Restricted Stock Grant	S-8	4.03	333-171783	1/20/11
4.13	Form of Common Stock Purchase Warrant dated January and February of 2011	8-K	10.02	333-153829	1/27/11
4.14**	Form of 2007 Equity Compensation Plan Restricted Stock Unit Agreement and 2009 Executive Compensation Plan Restricted Stock Unit Agreement	10-K	4.22	333-153829	3/30/11
4.15	Form of Common Stock Purchase Warrant dated April 2011	8-K	10.02	333-153829	5/03/11
4.16**	Form of Executive Deferred Compensation Plan	8-K	99.01	333-153829	7/08/11
4.17	Form of Common Stock Purchase Warrant issued to consultants in December of 2011	10-K	4.26	333-153829	3/06/12
4.18	Form of Common Stock Purchase Warrant issued to LifeTech on January 12, 2012	10-K	4.27	333-153829	3/06/12
4.19	Form of Common Stock Purchase Warrant for December 2012 through March 2013 Offering	8-K	4.01	333-153829	3/28/13
4.20	Form of Securities Purchase Agreement for August 2013 Offering	8-K	10.02	333-153829	8/16/13
4.21	Form of Warrant from August 2013 Offering	8-K	10.04	333-153829	8/16/13
4.22	Form of Series A, B and C Common Stock Purchase Warrant for May 2014 Registered Offering	S-1/A	4.34	333-194687	5/22/14
4.23	Form of Securities Purchase Agreement for May 2014 Registered Offering	S-1/A	10.12	333-194687	5/22/14
4.24	Form of Series D Common Stock Purchase Warrant for June 2014 Private Placement	10-Q	4.36	333-153829	8/8/14
4.25	Form of Securities Purchase Agreement for June 2014 Private Placement	10-Q	4.37	333-153829	8/8/14
4.26	Form of Consultant Common Stock Purchase Warrant issued February, August 2014, January 2015 and May 2015	10-Q	4.38	333-153829	8/8/14
4.27	Form of Securities Purchase Agreement for July 2015 Private Placement	8-K	10.01	000-55331	7/6/15
4.28	Form of Registration Rights Agreement for July 2015 Private Placement	8-K	10.02	000-55331	7/6/15
4.29	Form of Series D and E Common Stock Purchase Warrants for July 2015 Private Placement	8-K	10.03	000-55331	7/6/15

4.30	Form of Securities Purchase Agreement for December 2015 Private Placement		8-K	10.01	000-55331	12/23/15
4.31	Form of Registration Rights Agreement for December 2015 Private Placement		8-K	10.02	000-55331	12/23/15
4.32	Form of Series F and Series G Common Stock Purchase Warrants for December 2015 Private Placement		8-K	10.03	000-55331	12/23/15
4.33	Form of Series H and I Common Stock Purchase Warrants for December 2015 Private Placement		8-K	10.05	000-55331	12/23/15
4.34	Form of Amendment Agreement from December 2015 Private Placement		8-K	10.04	000-55331	12/23/15
4.35**	Inducement Stock Option Plan adopted 7/15/2016		8-K	4.01	000-55331	7/20/16
4.36**	Form of Inducement Award Non-Qualified Stock Option Grant		8-K	4.01	000-55331	7/20/16
10.01	Exclusive Supply Agreement between GenSpera and Thapsibiza dated April 2012		10-K	10.01	333-153829	3/29/13
10.02**	Craig Dionne Employment Agreement		8-K	10.04	333-153829	9/09/09
10.03**	Amendment dated May 14, 2010 to the Employment Agreement of Craig Dionne		10-Q	10.03	333-153829	8/13/10
10.04**	Craig Dionne Severance Agreement		8-K	10.05	333-153829	9/09/09
10.05**	Form of Indemnification Agreement with Directors and Officers		8-K	10.01	000-55331	9/12/16
10.06**	Russell Richerson Employment Agreement		8-K	10.08	333-153829	9/09/09
10.07**	Amendment dated May 14, 2010 to the Employment Agreement of Russell Richerson		10-Q	10.08	333-153829	8/13/10
10.08**	Independent Director Agreement		8-K	10.01	333-153892	06/1/12
10.09	Engagement Letter with H.C. Wainwright for May 2014 Registered Offering		S-1/A	10.11	333-194687	5/22/14
10.10**	Christopher Lowe Employment Agreement		8-K	10.01	000-55331	8/05/16
10.11**	Form of Proprietary Information, Inventions And Competition Agreement		8-K	10.02	000-55331	8/05/16
10.12**	Ronald Shazer Employment Agreement		8-K	10.01	000-55331	8/10/16
31.1	Certification of the Principal Executive Officer Pursuant to Section 3.02 of the Sarbanes-Oxley Act of 2002.	*				
31.2	Certification of the Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*				
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C § 1350.	***				
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C § 1350.	***				
101.INS	XBRL Instance Document	*				
101.SCH	XBRL Taxonomy Extension Schema	*				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	*				
101.DEF	XBRL Taxonomy Extension Definition Linkbase	*				

101.LAB	XBRL Taxonomy Extension Label Linkbase	*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	*

* *Filed Herein*
** *Management contracts or compensation plans or arrangements in which directors or executive officers are eligible to participate.*
*** *Furnished herein*

EXHIBIT 31.1

SECTION 302
CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER

I, Christopher Lowe, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Inspyr Therapeutics, 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(s) and I am 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 unconsolidated investments, 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 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(s) 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:

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

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

Date: November 18, 2016

By: /s/ *Christopher Lowe*
Christopher Lowe, Chief Executive Officer

EXHIBIT 31.2

SECTION 302
CERTIFICATION OF THE PRINCIPAL ACCOUNTING OFFICER

I, Christopher Lowe, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Inspyr Therapeutics, 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(s) and I am 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 unconsolidated investments, 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 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(s) 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:

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

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

Date: November 18, 2016

By: /s/ *Christopher Lowe*
Christopher Lowe, Principal Financial Officer and Principal Accounting Officer

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350 AND EXCHANGE ACT RULES 13a-14(b) AND 15d-14(b)
(Section 906 of the Sarbanes-Oxley Act of 2002)

In connection with the Quarterly Report of Inspyr Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher Lowe, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge and belief:

(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 results of the operation of the Company.

Date: November 18, 2016

/s/ Christopher Lowe
Christopher Lowe
Chief Executive Officer
Inspyr Therapeutics, Inc.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL ACCOUNTING OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AND EXCHANGE ACT RULES 13a-14(b) AND 15d-14(b) (Section 906 of the Sarbanes-Oxley Act of 2002)

In connection with the Quarterly Report of Inspyr Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher Lowe, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge and belief:

(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 results of the operation of the Company.

Date: November 18, 2016

/s/ Christopher Lowe
Christopher Lowe
Principal Financial and Principal Accounting Officer
Inspyr Therapeutics, Inc.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.