UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period September 30, 2015.

or

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

For the transition period from _____ to _____.

Commission File Number:

001-37348

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

Delaware	**46-4348039**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
100 River Ridge Road Norwood, MA	**02062**
(Address of principal executive offices)	**(Zip code)**

(617) 963-0100
(Registrant's telephone number, including area code)

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 smaller reporting company)	Smaller reporting company	☒

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

As of November 6, 2015, 37,605,134 shares of the registrant's common stock, $0.0001 par value, were issued and outstanding.

CORBUS PHARMACEUTICALS HOLDINGS, INC.

Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2015

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Balance Sheet

	September 30, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,172,926	$ 6,262,445
Prepaid expenses	98,376	270,556
Total current assets	13,271,302	6,533,001
Restricted cash	13,730	13,728
Property and equipment, net	48,838	54,044
Total assets	13,333,870	$ 6,600,773
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	$ -	$ 144,389
Accounts payable	728,006	344,160
Accrued expenses	466,124	249,491
Deferred revenue, current	681,816	—
Total current liabilities	1,875,946	738,040
Deferred revenue, non-current	284,094	—
Total liabilities	2,160,040	738,040
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock $0.0001 par value:10,000,000 shares authorized, no shares issued and outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized, 37,605,134 and 25,938,332 shares issued and outstanding at September 30, 2015 and December 31, 2014	3,761	2,594
Additional paid-in capital	21,949,288	10,287,214
Accumulated deficit	(10,779,219)	(4,427,075)
Total stockholders' equity	11,173,830	5,862,733
Total liabilities and stockholders' equity	$ 13,333,870	$ 6,600,773

See notes to the unaudited condensed consolidated financial statements.

Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Collaboration revenue	$ 170,454	$ -	$ 284,090	$ -
Operating expenses:				
Research and development	1,634,800	452,600	4,065,486	683,960
General and administrative	790,576	365,603	2,571,521	704,185
Total operating expenses	2,425,376	818,203	6,637,007	1,388,145
Operating loss	(2,254,922)	(818,203)	(6,352,917)	(1,388,145)
Other income (expense):				
Interest expense	-	(650)	(1,372)	(23,045)
Interest income	1,037	802	2,145	1,425
Forgiveness of interest on note payable	-	7,466	-	7,466
Gain on the settlement of debt	-	145,006	-	145,006
Change in fair value of warrant liability	-	-	-	(28,448)
Foreign currency exchange loss	-	5,958	-	5,533
Other income, net	1,037	158,582	773	107,937
Net loss	$ (2,253,885)	$ (659,621)	$ (6,352,144)	$ (1,280,208)
Net loss per share, basic and diluted	(0.06)	(0.03)	(0.22)	(0.07)
Weighted average number of common shares outstanding, basic and diluted	34,770,597	25,542,755	29,242,236	18,242,956

See notes to the unaudited condensed consolidated financial statements.

Corbus Pharmaceuticals Holdings Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (6,352,144)	$ (1,280,208)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	843,527	71,957
Depreciation	26,242	5,034
Loss on foreign exchange	-	(5,533)
Gain on settlement of notes payable, accrued interest and accounts payable		(145,006)
Changes in fair value of derivative warrant liability	-	28,448
Forgiveness of interest on notes payable		(7,466)
Non-cash interest expense	-	23,045
Changes in operating assets and liabilities:		
Increase in restricted cash	(2)	(13,725)
Decrease (increase) in prepaid expenses	172,180	(17,553)
Increase in accounts payable	383,846	308,733
Increase in deferred revenue	965,910	-
Increase in accrued expenses	216,633	(7,703)
Net cash used in operating activities	(3,743,808)	(1,039,977)
Cash flows from investing activities:		
Purchases of property and equipment	(21,036)	(64,448)
	(21,036)	(64,448)
Cash flows from financing activities:		
Principal payments on notes payable	(144,389)	(116,371)
Proceeds from issuance of common stock	10,819,714	8,454,130
Net cash provided by financing activities	10,675,325	8,337,759
Net increase in cash and cash equivalents	6,910,481	7,233,334
Cash and cash equivalent at beginning of the period	6,262,445	303,020
Cash and cash equivalent at end of the period	$ 13,172,926	$ 7,536,354
Supplemental disclosure of cash flow information and non cash transactions:		
Conversion of Series A preferred stock into common stock	$ -	$ 1,108,609
Conversion of notes payable, accrued interest and accounts payable into common stock and a warrant	$ -	$ 396,000
Reclassification of derivative warrant liability to equity	$ -	$ 48,380
Fair value of warrants issued for services	$ -	$ 28,448

See notes to the unaudited condensed consolidated financial statements.

1. NATURE OF OPERATIONS

Business

Corbus Pharmaceuticals Holdings, Inc. ("the Company", "we" or "us") is a clinical stage pharmaceutical company, focused on the development and commercialization of novel therapeutics to treat rare, chronic and serious inflammatory and fibrotic diseases. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. The Company's business is subject to significant risks and uncertainties and the Company will be dependent on raising substantial additional capital before it becomes profitable and it may never achieve profitability.

In the opinion of management of the Company, the accompanying unaudited condensed consolidated interim financial statements reflect all adjustments (which include only normal recurring adjustments) necessary to present fairly, in all material respects, the consolidated financial position of the Company as of September 30, 2015 and the results of its operations and cash flows for the three and nine month periods ended September 30, 2015 and 2014. The December 31, 2014 condensed consolidated balance sheet was derived from audited financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. It is suggested that these condensed consolidated financial statements be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed on February 10, 2015. The results of operations for such interim periods are not necessarily indicative of the operating results for the full fiscal year.

2. LIQUIDITY

The Company has incurred recurring losses since inception and as of September 30, 2015, had an accumulated deficit of approximately $10,779,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its preclinical and clinical programs, strategic alliances and the development of its administrative organization. The Company expects the current cash on hand of approximately $13,173,000 to be sufficient to meet its operating and capital requirements into the fourth quarter of 2016. The Company will need to raise significant additional capital to fund the clinical trials for Resunab ™. The Company may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to the Company's stockholders and those securities may have rights senior to those of the Company's common shares. If the Company raises additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict the Company's operations. Any other third-party funding arrangement could require the Company to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of the Company's clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to the Company. Lack of necessary funds may require the Company, among other things, to delay, scale back or eliminate some or all of the Company's planned clinical trials.

3. SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the financial statements is as follows:

Use of Estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and changes in estimates may occur. The most significant estimates are related to stock based compensation, the value of derivative instruments and the accrual of research and clinical obligations.

Prior to the registration of its common stock and the subsequent public listing of the common stock, the Company had granted stock options at exercise prices not less than the fair value of its common stock as determined by the board of directors, with input from management. The Company's board of directors determined the estimated fair value of the common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the historic prices at which the Company sold shares of preferred stock.

Cash and Cash Equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents. Marketable investments are those maturities when acquired in excess of three months. At September 30, 2015 and December 31, 2014, cash equivalents were comprised of money market funds. The Company had no marketable investments at September 30, 2015 and December 31, 2014. Cash and cash equivalents consist of the following:

	September 30, 2015	December 31, 2014
Cash	$ 111,820	$ 10,974
Money market funds	13,061,106	6,251,471
	$ 13,172,926	$ 6,262,445

Restricted Cash

As of September 30, 2015, the Company had restricted cash of $13,730 due to a stand-by letter of credit in favor of a landlord (See Note 5).

Financial Instruments

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents and accounts payable approximate fair value based on the short-term nature of these instruments. The carrying value of loans payable approximate their fair value due to the market terms.

Property and Equipment

Property and Equipment consists of the following:

	September 30, 2015	December 31, 2014
Computer hardware and software	$ 30,966	$ 17,179
Office furniture and equipment	35,209	27,960
Leasehold improvements	19,310	19,310
Less: accumulated depreciation	(36,647)	(10,405)
Property and equipment, net	$ 48,838	$ 54,044

The estimated life for all property and equipment is three years.

Research and Development Expenses and Collaborative Research Agreements

Costs incurred for research and development are expensed as incurred. For periods prior to 2015, the Company recorded payments received from research and development grants and awards as a reduction in research and development expense in the Statement of Operations. For the development award received from the Cystic Fibrosis Foundation (See Note 13) the Company is recognizing amounts received as revenue under a collaborative research agreement. The research grants prior to 2015 were immaterial, therefore they were not re-classified to revenue.

On April 20, 2015, the Company entered into an award agreement with Cystic Fibrosis Foundation Therapeutics, Inc. ("CFFT") (see Note 13). Pursuant to the terms of this agreement, the Company received a payment of $1,250,000 upon signing the agreement and is entitled to potential milestone payments totaling $3,750,000 dependent upon the achievement of certain milestones. For this agreement and future collaborative research agreements revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered,

collectability of the resulting receivable is reasonably assured, and the Company has fulfilled its performance obligations under the contract. The Company is amortizing the $1,250,000 payment and future milestone payments on a straight-line basis over the expected duration of the performance period of the development program under the award which is expected to conclude in March 2017. In October 2015, the Company achieved a milestone under the CFFT award when the first patient was dosed in the Resunab clinical trial for the treatment of cystic fibrosis. The Company informed the CFFT and will receive an additional $1,250,000 for achieving this milestone (See Note 14).

Accruals for Research and Development Expenses and Clinical Trials

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the three and nine months ended September 30, 2015 and 2014, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Concentrations of Credit Risk

The Company has no significant off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements. The Company may from time to time have cash in banks in excess of Federal Deposit Insurance Corporation insurance limits.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one operating segment, which is developing and commercializing therapeutics to treat rare life-threating, rare inflammatory fibrotic diseases. As of September 30, 2015 and December 31, 2014, all of the Company's assets were located in the United States.

Income Taxes

For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded to reduce a net deferred tax benefit when it is more likely than not that the tax benefit from the deferred tax assets will not be realized. Accordingly, given the cumulative losses since inception, the Company has provided a valuation allowance equal to 100% of the tax benefit in order to eliminate the deferred tax assets amounts. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority.

Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of September 30, 2015 or December 31, 2014.

Impairment of Long-lived Assets

The Company continually monitors events and changes in circumstances that could indicate that carrying amounts of long-lived assets may not be recoverable. An impairment loss is recognized when expected cash flows are less than an asset's carrying value. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of such assets in relation to the operating performance and future undiscounted cash flows of the underlying assets. The Company's policy is to record an impairment loss when it is determined that the carrying value of the asset may not be recoverable. No impairment charges were recorded for the three and nine months ended September 30, 2015 and 2014.

Share-based Payments

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the statement of operations over the service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. The Company accounts for the stock options granted to employees and non-employee directors on a fair value basis which is estimated using the Black-Scholes option pricing model. The initial non-cash charge to operations for non-employee consultant stock options is revalued at the end of each reporting period until vested and recorded as expense over the related vesting period

Derivative Instruments

The Company generally does not use derivative instruments to hedge exposures to cash-flow or market risks; however, certain warrants to purchase common stock that do not meet the requirements for classification as equity are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. Such financial instruments are initially recorded at fair value with subsequent changes in fair value charged (credited) to operations in each reporting period. If these instruments subsequently meet the requirements for classification as equity, the Company reclassifies the fair value to equity.

Net Loss Per Common Share

Basic net loss per share of the Company's common stock has been computed by dividing net loss by the weighted average number of shares outstanding during the period. Diluted net loss per share of the Company's common stock has been computed by dividing net loss for the period by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding stock options, warrants and convertible securities. In a net loss period, options, warrants and convertible securities are anti-dilutive and therefore excluded from diluted loss per share calculations. The following table sets forth the computation of basic and diluted earnings per share for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,	
	2015	2014
Basic and diluted net loss per share of common stock:		
Net loss	$ (2,253,885)	$ (659,621)
Net loss applicable to common stockholders	(2,253,885)	(659,621)
Weighted average shares of common stock outstanding	34,770,597	25,542,755
Net loss per share of common stock-basic and diluted	$ (0.06)	$ (0.03)

	Nine Months Ended September 30,	
	2015	2014
Basic and diluted net loss per share of common stock:		
Net loss	$ (6,352,144)	$ (1,280,208)
Net loss applicable to common stockholders	(6,352,144)	(1,280,208)
Weighted average shares of common stock outstanding	29,242,236	18,242,956
Net loss per share of common stock-basic and diluted	$ (0.22)	$ (0.07)

The following potentially dilutive securities outstanding at September 30, 2015 and 2014 have been excluded from the computation of dilutive weighted average shares outstanding as the inclusion would be antidilutive.

	September 30,	
	2015	2014
Warrants	1,969,250	1,112,180
Preferred stock	-	329,617
Stock options	3,828,065	597,243
Total	5,797,315	2,039,040

Recent Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern,* which states management should evaluate whether there are conditions or events, considered in the aggregate, that raise a substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Management's evaluation should be based on relevant conditions and events that are known and likely to occur at the date that the financial statements are issued. The standard update will be effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter, however, early application is permitted. Management does not expect the adoption of ASU 2014-15 to have material impact on the Company's consolidated financial statements, although there may be additional disclosures upon adoption.

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update 2015-03, *Interest Imputation of Interest (Subtopic 835-30)*: Simplifying the Presentation of Debt Issuance Costs ("ASU 2015-03") which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU requires retrospective adoption and will be effective for fiscal years beginning after December 15, 2015 and for interim periods within those fiscal years. The Company does not expect the adoption of this guidance will have a material impact on the Company's financial statements.

4. FAIR VALUE OF ASSETS AND LIABILITIES

The Company groups its assets and liabilities measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

Level 1—Valuation is based on quoted prices in active markets for identical assets or liabilities. Level 1 assets and liabilities generally include debt and equity securities that are traded in an active exchange market. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2—Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Level 3—Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

The Company uses valuation methods and assumptions that consider, among other factors, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. The Company had no assets or liabilities classified as Level 1 or Level 2. Certain warrants issued for professional services (See Note 10) were classified as Level 3. The fair values of these instruments were determined using models based on market observable inputs and management judgment. There were no material re-measurements of fair value during the three months ended September 30, 2015 and 2014 with respect to financial assets and liabilities, other than those assets and liabilities that are measured at fair value on a recurring basis.

The Company had valued certain warrants as a derivative liability at June 30, 2014 and used the Black-Scholes option pricing model to estimate fair value at September 30, 2014 and used the contractual life according to the remaining terms of the warrants and the following assumptions:

	As of June 30, 2014
Risk free interest rate	1.25%
Expected dividend yield	0%
Contractual term	3.97
Expected volatility	66%

Due to a modification in the terms of these warrants (See Note 11), the derivative liability was reclassified at September 30, 2014 to Additional Paid in Capital. As of September 30, 2015 and December 31, 2014 there were no derivative warrant liabilities.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

	June 30, 2014			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Derivative warrant liability at December 31, 2013	$ —	$ —	$ 19,932	$ 19,932
Change in fair value of the derivative warrant liability	—	—	28,448	28,448
Reclassification of derivative warrant liability	—	—	(48,380)	(48,380)
Derivative warrant liability at September 30, 2014	$ —	$ —	$ —	$ —

5. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitment

On May 30, 2014, the Company entered into a commercial lease for 2,387 square feet of office space in Norwood, MA. The lease commenced on July 1, 2014 and had a three year term. In August 2015, the lease was amended for the relocation of the Company into a new space within the existing building. The Company will be occupying 6,326 square feet under a five year term that is expected to commence in January 2016. The 2014 lease also required a standby letter of credit of $13,730 payable in favor of the landlord (See Note 3-Restricted Cash) which will increase to $36,375 under the lease amendment.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at September 30, 2015, the future minimum rent commitments are as follows for the years ended December 31:

2015 (remainder of year)	$ 14,024
2016	145,498
2017	148,661
2018	151,824
2019	154,987
Total	$ 614,994

Total rent expense for the three months and nine months ended September 30, 2015, was $14,024 and $41,472, respectively. Total rent expense for each of the three months and nine months ended September 30, 2014, was $8,100 and $21,825, respectively

6. NOTES PAYABLE

In October 2014, the Company entered into a loan agreement with a financing company for $192,000. The terms of the loan stipulated equal monthly payments of principal and interest payments of $24,293 over an eight month period. Interest accrued on this loan at annual rate of 3.25%. This loan was fully repaid as of September 30, 2015.

The Company had a note payable outstanding to a vendor as of September 30, 2014 which had no stated interest rate; however the Company had imputed interest cost at a rate of 7% for this note payable but the Company reached an agreement with the vendor to pay off this note payable with no interest.

Interest expense for three months and nine months ended September 30, 2015 totaled $0 and $1,372, respectively. Interest expense for three months and nine months ended September 30, 2014 totaled $650 and $23,045, respectively.

Notes payable consisted of the following:

	September 30, 2015	December 31, 2014
Notes payable	$ —	$ 144,389
Less: current portion	—	(144,389)
Long term portion	$ —	$ —

7. DEFERRED REVENUE

In May 2015, the Company received $1,250,000 after signing the CFFT award agreement (See Note 3 and Note 12). The Company recorded the $1,250,000 as deferred revenue. The Company is amortizing the deferred revenue and recognizing revenue on a straight-line basis over the performance period for the development program which is expected to conclude during the first quarter of 2017. For the three and nine months ended September 30, 2015 the Company recorded revenue of $170,454 and $284,090, respectively. In October 2015, the Company billed the CFFT an additional $1,250,000 that was due upon the milestone achievement of dosing of the first patient (See Note 14). Deferred revenue consists of the following:

	September 30, 2015	December 31, 2014
Deferred revenue	965,910	$ —
Less: current portion	681,816	—
Long-term portion	$ 284,094	$ —

8. COMMON STOCK

The Company has authorized 150,000,000 shares of common stock, $0.0001 par value per share, of which 37,605,134 shares and 25,938,332 shares were issued and outstanding as of September 30, 2015 and December 31, 2014, respectively.

During the nine months ended September 30, 2015, the Company issued 11,666,802 shares of common stock upon the exercise of stock options and warrants to purchase common stock and the Company received net proceeds of $10,819,714 from these exercises.

9. STOCK OPTIONS

In April 2014, the Company adopted the Corbus Pharmaceuticals Holdings, Inc. 2014 Equity Incentive Plan (the “2014 Plan”). Pursuant to the 2014 Plan, the Company’s Board of Directors may grant incentive and nonqualified stock options and restricted stock to employees, officers, directors, consultants and advisors. On January 1, 2015, pursuant to an annual evergreen provision contained in the 2014 Plan, the number of shares reserved for future grants was increased by 1,815,683 shares. As of September 30, 2015, there was a total of 8,666,017 shares reserved for issuance under the 2014 plan and there were 4,699,135 shares available for future grants. Options issued under the 2014 Plan are exercisable for up to 10 years from the date of issuance.

Share-based Compensation

For stock options issued and outstanding for the three months and nine months ended September 30, 2015 the Company recorded non-cash, stock-based compensation expense of $240,664 and $843,527, respectively, net of estimated forfeitures. For stock options issued and outstanding for the three and nine months ended September 30, 2014, the Company recorded non-cash, stock-based compensation expense of $45,545 and $71,857 respectively, net of forfeitures.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model that uses the assumptions noted in the following table. Due to its limited operating history and limited number of sales of its common stock, the Company estimated its volatility in consideration of a number of factors, including the volatility of comparable public companies and, commencing in 2015, the Company also considered the volatility of its own common stock. The Company uses historical data, as well a s subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations within the valuation model. The expected term of options granted under the 2014 Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is based on the average of the 6.25 years. For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The assumptions used principally in determining the fair value of options granted were as follows:

	Nine Month Ended, September 30,	
	2015	2014
Risk free interest rate	1.70%	1.97%
Expected dividend yield	0%	0%
Expected term in years	7.23	6.25
Expected volatility	92.7%	91.5%
Estimated forfeiture rate	3%	20%

A summary of option activity for the nine months ended September 30, 2015 and is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Average Intrinsic Value
Outstanding at December 31, 2014	3,556,691	$ 0.83		
Granted	322,502	$ 2.53		
Exercised	(51,128)	$ 0.11		$ 95,108
Outstanding at September 30, 2015	3,828,065	$ 0.99	8.23	$ 2,649,238
Vested September 30, 2015	1,378,857	$ 0.77	7.51	$ 1,248,819

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2015 was $1.56 per share. As of September 30, 2015 there was approximately $1,395,021 of total unrecognized compensation expense, related to non-vested share-based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 3.36 years.

10. DERIVATIVE INSTRUMENTS

In 2013, the Company's predecessor, JB Therapeutics, Inc., issued warrants for the purchase of 301,778 shares of common stock, which had provisions that included anti-dilution protection, cashless exercise provisions and, under certain conditions, granted holders the right to request the Company repurchase the warrant. Accordingly, these warrants were considered derivative instruments through June 30, 2014 and was recorded as a derivative warrant liability. On June 30, 2014, these warrant agreements were modified to eliminate the anti-dilution protection and accordingly these warrants were no longer considered a derivative liability and the fair value of $48,380 shares was reclassified and charged as an addition to Additional-Paid in Capital.

To value the derivative warrant liability, the Company used the Black-Scholes option pricing model and assumptions that considered, among other factors, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. Changes in fair value of the derivative financial instruments were recognized in the Condensed Statement of Operations as gain or loss on change in fair value of warrant liability. There was a loss on change in fair value of the warrant liability of $28,448 recognized for the nine months ended September 30, 2014.

11. WARRANTS

At September 30, 2015, there were warrants outstanding to purchase 1,969,250 shares of common stock with a weighted average exercise price of $0.97 and a weighted average remaining life of 3.6 years. During the nine months ended September 30, 2015, warrants to purchase 11,615,674 shares of common stock were exercised for net proceeds (See Note 8) of $10,817,326. No warrants were exercised during the nine months ended September 30, 2014. Additionally, in accordance with the warrant agreements, warrants to purchase 371,250 shares of common stock were exercised in cashless exercises resulting the issuance of 255,724 shares. There were no warrants issued or cancelled during the nine months ended September 30, 2015. During the nine months ended September 30, 2014, the Company issued warrants to purchase 13,435,373 shares of common stock. No warrants were cancelled during the nine months ended September 30, 2014.

12. RELATED PARTY TRANSACTIONS

In connection with the formation of Corbus Pharmaceutical Holdings, Inc. in December 2013, certain affiliates of Aegis Capital Corp. ("Aegis" or the "Placement Agent") and certain other parties not affiliated with the Company or the Placement Agent subscribed for an aggregate of 6,000,000 shares of common stock for which they paid an aggregate of $120,000 ($0.02 per share), including David Hochman, one of the Company's directors who purchased 450,000 shares of common stock and whose family trust purchased 90,000 shares of common stock.

Following the initial closing of the 2014 private placement, which took place on April 11, 2014, the Placement Agent had a right to appoint one member of the Company's board of directors for a two-year term (the "Aegis Nominee"). David Hochman was appointed as the Aegis Nominee.

On June 21, 2014, the Company entered into a consulting agreement with Orchestra Medical Ventures, LLC ("Orchestra"), of which David Hochman is Managing Partner. The agreement provided that Orchestra would render a variety of consulting and advisory services relating principally to identifying and evaluating strategic relationships, licensing opportunities, and business strategies. Orchestra was compensated at the rate of $5,000 per month for twelve months, payable quarterly in advance. The consulting agreement expired on April 11, 2015 and the Company is not obligated to make future payments.

The Company entered into a non-exclusive financial advisory agreement with Aegis under which the Company paid Aegis $200,000 upon the execution of the agreement, which commenced on September 1, 2015 and expires on November 30, 2015. The Company also paid Aegis a warrant solicitation fee of $309,215 in connection with the exercise of warrants that were called and exercised in the third quarter of 2015.

13. DEVELOPMENT AWARD

On April 20, 2015, the Company entered into an award agreement with the CFFT, a non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation, pursuant to which it received a development award (the "Award") for up to $5 million in funding. The funding from the Award will help support a first-in-patient Phase 2 clinical trial of the Company's oral anti-inflammatory drug Resunab in adults with cystic fibrosis ("CF"). Upon the execution of the Award agreement, the Company received a payment of $1,250,000 (See Notes 3 and 7). The remainder of the Award will be paid to the Company incrementally upon the achievement of certain milestones related to the progress of the Phase 2 CF clinical trial, as set forth in the Award agreement. In October 2015, the Company billed the CFFT $1,250,000 upon the achievement of a milestone for dosing the first patient.

Pursuant to the terms of the Award agreement, the Company is obligated to make royalty payments to CFFT contingent upon commercialization of Resunab in the Field of Use (as defined in the Award agreement) including a royalty payment equal to five times the amount the Company receives under the Award agreement, up to $25 million, payable in three equal annual installments following the first commercial sale of Resunab, the first of which is due within 90 days following the first commercial sale of Resunab. The Company is also obligated to make a royalty payment to CFFT equal to the amount the Company receives under the Award agreement, up to $5 million, due in the first calendar year in which the aggregate cumulative net sales of Resunab in the Field of Use exceed $500 million. Lastly, the Company is obligated to make royalty payment(s) to CFFT of up to approximately $15 million if the Company transfers, sells or licenses Resunab in the Field of Use other than for certain clinical or development purposes, or if the Company enters into a change of control transaction, with such payment(s) to be credited against the royalty payments due upon commercialization. The Field of Use is defined in the Award as the treatment in humans of CF, asbestosis, bronchiectasis, byssinosis, chronic bronchitis/COPD hypersensitivity pneumonitis, pneumoconiosis, primary ciliary dyskinesis, sarcoidosis and silicosis. Either CFFT or the Company may terminate the agreement for cause, which includes the Company's material failure to achieve certain commercialization and development milestones. The Company's payment obligations survive the termination of the Award agreement. The $1,250,000 million

payment the Company received in May 2015 was recorded as deferred revenue. The Company is amortizing the $1,250,000 payment and future milestone payments on a straight-line basis over the expected duration of the performance period of the development program under the award which is expected to conclude in March 2017. (See Note 7).

14. SUBSEQUENT EVENTS

In October 2015, the Company achieved a milestone under the CFFT award when the first patient was dosed in the Resunab clinical trial for the treatment of cystic fibrosis. The Company informed CFFT and will receive an additional $1,250,000 for achieving the milestone (See Notes 7 and 13). Upon achievement of additional milestones set forth in the Award agreement, the Company has the potential to receive an additional $2,500,000 in future payments under the development award.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Quarterly Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Quarterly Report, particularly those under "Risk Factors."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our lack of operating history and history of operating losses;
- our current and future capital requirements and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our product and obtain approval from the FDA or other regulatory agents in different jurisdictions;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executive members;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements. Please see "Risk Factors" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Overview

We are a clinical stage pharmaceutical company, focused on the development and commercialization of novel therapeutics to treat rare, chronic and serious inflammatory and fibrotic diseases wit. Our product Resunab™ is a novel oral anti-inflammatory

drug that has commenced Phase 2 clinical trials for the treatment of cystic fibrosis, scleroderma and dermatomyositis. We have been granted orphan drug status by the U.S Food and Drug Administration ("FDA") for Resunab for the treatment of diffuse scleroderma and cystic fibrosis. Orphan drug status provides seven years of market exclusivity in the United States under the Orphan Drug Act.

Inflammation is a natural defense mechanism carried out by our immune system to protect our bodies from infection and injury. However, under certain circumstances inflammation is triggered but is unable to be resolved, resulting in a chronic inflammatory disease. Since each organ in the body is capable of protecting itself from infection and injury by recruiting inflammatory cells to its site, each organ can therefore suffer from excessive inflammation leading to inflammatory diseases that may cause discomfort, pain, loss of organ function, disability or even death. There are hundreds of inflammatory diseases, many of which are chronic, life-long and incurable.

A key aspect of the body's inflammatory response is the recruitment of inflammatory cells to the site of tissue infection/injury whereupon these cells act to destroy the infection and/or repair tissue damage. The signaling pathway that modulates the inflammatory response involves the production of bioactive lipids termed eicosanoids by the enzymes COX and LOX, resulting in pro-inflammatory mediators. These mediators trigger the activation and maintenance of a cellular inflammatory state resulting in the further generation of pro-inflammatory mediators termed cytokines. This fundamental pathway is involved in a wide spectrum of inflammatory diseases.

While the onset of inflammation has been well understood for some time, the mechanisms that resolve inflammation have only recently been discovered. This "resolution pathway" involves shifting the production of pro-inflammatory eicosanoids by the COX and LOX enzymes to the production of anti-inflammatory eicosanoids. These anti-inflammatory eicosanoids act to resolve inflammation and promote tissue healing. The lack of sufficient inflammatory resolution is a key contributor to many chronic inflammatory diseases.

Resunab is a synthetic oral small molecule that selectively binds to CB2 receptors found on immune cells. The CB2 receptor plays a natural role in modulating and resolving inflammation by, in effect, turning inflammation "off." Through activation of CB2, Resunab stimulates the production of anti-inflammatory mediators and causes a concomitant reduction in pro-inflammatory mediators and cytokines. Because it acts through this natural resolving pathway, Resunab offers a new mechanism to potentially treat a wide spectrum of chronic inflammatory diseases in which the resolution of inflammation (the "off" switch) fails to occur.

Warrant Redemption

On July 27, 2015, we issued a notice of redemption to investors holding outstanding warrants (the "Warrants") issued to investors in 2014 private placement. Since the start of 2015, 100% of the Warrants were exercised, and Company received net proceeds of approximately $10,817,000.

Financial Operations Overview

We are a clinical stage pharmaceutical company and have not generated any revenues from the sale of products. We have never been profitable and, from inception through September 30, 2015, our losses from operations have been approximately $10.8 million. Our net loss for the nine months ended September 30, 2015 was approximately $6.4 million. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase significantly in connection with our ongoing activities to develop, seek regulatory approval and commercialization of Resunab. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses will increase substantially through the balance of 2015 and for 2016 and in the future in connection with our ongoing activities, as we:

- conduct clinical trials for Resunab in scleroderma, cystic fibrosis, dermatomyositis and other indications;
- continue our research and development efforts;

- manufacture clinical study materials and develop commercial scale manufacturing capabilities;
- seek regulatory approval for our product candidates;
- add personnel to support development of our product candidates; and
- operate as a public company.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to stock-based compensation expense and the fair value determined for stock purchase warrants classified as derivative liabilities. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

Results of Operations

Comparison of Three Months Ended September 30, 2015 and 2014

Collaboration revenue

Collaboration revenue received in connection with our development award from CFFT totaled approximately $170,000 for the three months ended September 30, 2015. The Company did not have any revenue from collaborative research agreements in 2014.

Research and Development.

Research and development expenses for the three months ended September 30, 2015 totaled approximately $1,635,000 an increase of approximately $1,182,000 over the $453,000 recorded for the three months ended September 30, 2014. The increase was primarily attributable to increases of $960,000 for clinical trial costs and $151,000 for compensation costs

General and Administrative.

General and administrative expense for the three months ended September 30, 2015 totaled approximately $791,000 an increase of approximately $425,000 over the $366,000 recorded for the three months ended September 30, 2014. The increase was primarily attributable to increases of approximately $95,000 for investor relations costs $165,000 for stock-based compensation costs and $63,000 for insurance costs.

Other Income (Expense)

Other income for the three months ended September 30, 2015 totaled approximately $1,000, a decrease of approximately $158,000 over the $159,000 of other income recorded for the three months ended September 30, 2014. The decrease was primarily attributable to a gain on the settlement of debt of $145,000 recorded in 2014.

Comparison of Nine Months Ended September 30, 2015 and 2014

Collaboration revenue

Collaboration revenue received in connection with our development award from CFFT totaled approximately $284,000 for the nine months ended September 30, 2015. The Company did not have any revenue from collaborative research agreements in 2014.

Research and Development.

Research and development expenses for the nine months ended September 30, 2015 totaled approximately $4,065,000 an increase of approximately $3,381,000 over the $684,000 recorded for the nine months ended September 30, 2014. The increase was primarily attributable to increases of approximately $350,000 for the manufacturing of Resunab for clinical trials, $173,000 for consulting fees, $2,049,000 for clinical trial costs, $313,000 for compensation costs, $122,000 for stock-based compensation costs.

General and Administrative.

General and administrative expense for the nine months ended September 30, 2015 totaled approximately $2,572,000 an increase of approximately $1,868,000 over the $704,000 recorded for the nine months ended September 30, 2014.The increase was primarily attributable to increases of approximately $281,000 for investor relations costs, $111,000 of costs associated with our uplisting to the NASDAQ Capital Market, $264,000 for legal and accounting costs, $676,000 for stock-based compensation costs, $102,000 for compensation costs $202,000 for insurance costs and $73,000 for board costs.

Other Income (Expense)

Other income for the nine months ended September 30, 2015 totaled approximately $1,000 a decrease of approximately $107,000 over the $108,000 of other income recorded for the nine months ended September 30, 2014. The decrease was primarily attributable to a gain on the settlement of debt of $145,000 recorded in 2014 and a decrease in interest expense of $22,000 and a $28,000 change in the fair value of the warrant liability recorded in 2014.

Liquidity and Capital Resources

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of equity-related securities. At September 30, 2015 our accumulated deficit since inception was approximately $10,779,000.

At September 30, 2015, we had total current assets of approximately $13,361,000 and total current liabilities of approximately $1,965,000 resulting in working capital of $11,396,000. At September 30, 2015, we had total assets of approximately $13,423,000 and total liabilities of approximately $2,249,000 resulting in a stockholders' equity of approximately $11,174,000.

Net cash used in operating activities for the nine months ended September 30, 2015 was approximately $3,744,000 which includes cash used from a net loss of approximately $6,352,000, non-cash expenses of approximately $870,000, $83,000 of cash provided from a decrease in prepaid expenses, $966,000 of cash provided from an increase in deferred revenue and $690,000 of cash provided from a net increase in accounts payable and accrued expenses.

Cash used in investing activities for the nine months ended September 30, 2015 totaled approximately $21,036 for the purchase of property and equipment.

Cash provided from financing activities for the nine months ended September 30, 2015 totaled approximately $10,675,000. Cash provided from the issuance of common stock upon the exercise of warrants and stock options totaled approximately $10,820,000. Cash used for principal payments on notes payable totaled approximately $144,000.

At September 30, 2015, we had a cash balance of approximately $13,173,000. We expect our current cash on hand, together with the expected proceeds from the exercise of warrants to be sufficient to meet our operating and capital requirements into the fourth quarter of 2016. We will need to raise significant additional capital to fund the clinical trials for Resunab. We may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common shares. If we raise additional funds through the

issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials. In October 2015, we achieved a milestone under the CFFT award when the first patient was dosed in the Resunab clinical trial for the treatment of cystic fibrosis. We informed CFFT and will receive an additional $1,250,000 for achieving the milestone. Upon the achievement of additional milestones set forth in the award agreement, we have the potential to receive an additional $2,500,000 in future payments under the development award.

Contractual Obligations and Commitments

On May 30, 2014, we signed a three-year lease that was subsequently amended in August 2015. The amended lease has a five year term and the annual lease payments are as follows:

2015 (remainder of year)	$ 14,024
2016	145,498
2017	148,661
2018	151,824
2019	154,987
Total	$ 614,994

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material. As of September 30, 2015, we had no material Contractual Obligations or Commitments that will affect our future liquidity.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of three months or less. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We do not have any foreign currency or other derivative financial instruments.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act, as amended) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that the information required to be disclosed by us in such reports is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors

An investment in our common stock is speculative and illiquid and involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize, our business, financial condition and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

Risk Related to our Company and our Business

Risks Related to Our Financial Position and Need for Capital

We are a clinical stage pharmaceutical company with a limited operating history.

We are a clinical stage pharmaceutical company with a limited operating history. We must obtain FDA clearance of our Investigational New Drug applications, or INDs, before clinical trials can commence, and must receive regulatory approval of our New Drug Applications, or NDAs, before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to:

- receive FDA approval of INDs for commencing our clinical trials;
- successfully implement or execute our current business plan, or that our business plan is sound;
- Successfully manufacture our clinical product and establish commercial drug supply;

- obtain DEA licenses necessary for the manufacturing of Resunab and for evaluating Resunab in our clinical trials;
- successfully complete clinical trials and obtain regulatory approval for the marketing of Resunab
- secure market exclusivity and/or adequate intellectual property protection for Resunab;
- attract and retain an experienced management and advisory team;
- secure acceptance of Resunab in the medical community and with third party payors and consumers;
- launch commercial sales of Resunab, whether alone or in collaboration with others; and
- raise sufficient funds in the capital markets to effectuate our business plan including clinical development, regulatory approval and commercialization for Resunab.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize Resunab. We have been engaged in developing Resunab since 2009. To date, we have not generated any revenue from Resunab and we expect to incur significant expense to complete our clinical program for Resunab in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of Resunab in any indication in the United States or internationally. Even if we are able to commercialize Resunab or any other product candidate, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net losses for the nine months ended September 30, 2015 and the year ended December 31, 2014 were approximately $6,352,000 and $2,540,000, respectively. As of September 30, 2015, we had an accumulated deficit of approximately $10,779,000.

If we were to obtain FDA approval for Resunab, we would expect that our research and development expenses will continue to increase as we advance to clinical trials for indications for the treatment of cystic fibrosis, systemic sclerosis and dermatomyositis. We may elect to pursue FDA approval for Resunab in other indications, which will result in significant additional research and development expenses. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses will increase. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

Our cash or cash equivalents will only fund our operations for a limited time and we will need to raise additional capital to support our development and commercialization efforts.

We are currently operating at a loss and expect our operating costs will increase significantly as we incur costs related to the clinical trials for Resunab. We believe we have sufficient financial resources to fund our operations into at least the fourth quarter of 2016.

We do not currently have any arrangements or credit facilities in place as a source of funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt.

Equity financing, if obtained, could result in dilution to our then existing stockholders and/or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. In addition, if we are unable to secure sufficient capital to fund our operations, we might have to enter into strategic collaborations that could require us to share commercial rights to Resunab with third parties in ways that we currently do not intend or on terms that may not be favorable to us. If we choose to pursue additional indications and/or geographies for Resunab or otherwise expand more rapidly than we presently anticipate we may also need to raise additional capital sooner than expected.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We depend entirely on the success of Resunab, which has not yet demonstrated efficacy in Phase 2 clinical trials. If we are unable to generate revenues from Resunab, our ability to create stockholder value will be limited.

Our only product candidate currently is Resunab, which has successfully completed Phase 1 safety studies and has commenced Phase 2 clinical studies for cystic fibrosis, systemic sclerosis and dermatomyositis. We do not generate revenues from any FDA approved drug products and have no other product candidates in development. There is no guarantee that our Phase 2 clinical trials will be successful or that we will continue with clinical studies to support an approval from the FDA for any indication. We note that most drug candidates never reach the clinical development stage and even those that do reach clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of Resunab, which may never occur.

If we are not able to obtain any required regulatory approvals for Resunab, we will not be able to commercialize our only product candidate and our ability to generate revenue will be limited.

We must successfully complete clinical trials for Resunab before we can apply for marketing approval. Even if we complete our clinical trials, it does not assure FDA approval. Our Phase 2 clinical trials may be unsuccessful, which would materially harm our business. Even if these Phase 2 clinical trials are successful, we are required to conduct additional clinical trials to establish Resunab's safety and efficacy, before a New Drug Application, or NDA, can be filed with the FDA for marketing approval of Resunab.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize Resunab. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market Resunab as a prescription pharmaceutical product in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. We have never submitted an NDA to the FDA or comparable applications to other regulatory authorities. If our development efforts for Resunab, including regulatory approval, are not successful for its planned indications, or if adequate demand for Resunab is not generated, our business will be harmed.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of Resunab's safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency, or EMA, or other comparable foreign regulatory authorities for marketing approval;
- the dosing of Resunab in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to Resunab;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for Resunab for the foregoing or any other reasons will prevent us from commercializing this product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA, EMA and other regulators have substantial discretion in the approval process and may

refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We are a clinical stage company and we have not submitted an NDA or received regulatory approval to market Resunab in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Resunab may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for Resunab in any indication will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

Resunab is our only product candidate in development. If we fail to successfully commercialize Resunab, we may need to acquire additional product candidates and our business will be adversely affected.

We have never commercialized any product candidates and do not have any other compounds in pre-clinical testing, lead optimization or lead identification stages beyond Resunab. We cannot be certain that Resunab will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize Resunab as a treatment for cystic fibrosis, systemic sclerosis, dermatomyositis or any other indication, whether as a stand-alone therapy or in combination with other treatments, our business would be adversely affected.

Even if we receive regulatory approval for Resunab, we still may not be able to successfully commercialize this product, and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of Resunab will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of Resunab will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, pill burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe Resunab and of the target patient population to try new therapies;
- efficacy of Resunab compared to competing products;
- the introduction of any new products that may in the future become available to treat indications for which Resunab may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which Resunab may show utility;
- pricing and cost-effectiveness;

- the inclusion or omission of Resunab in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If Resunab is approved, but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of Resunab may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize Resunab successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render Resunab not commercially viable. For example, regulatory authorities may approve Resunab for fewer or more limited indications than we request, may not approve the price we intend to charge for Resunab, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve Resunab with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals, such as risk management plans and a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of Resunab. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of Resunab.

Even if we obtain marketing approval for Resunab, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, Resunab could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with Resunab.

Even if we obtain United States regulatory approval of Resunab for an indication, the FDA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Resunab will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S.

Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if Resunab is approved for an indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for Resunab, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses by a company, and any company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or if we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize Resunab and generate revenue. Adverse regulatory action, whether pre-or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

We currently have no sales and marketing organization. If we are unable to secure a sales and marketing partner or establish satisfactory sales and marketing capabilities, we may not successfully commercialize Resunab.

At present, we have no sales or marketing personnel. In order to commercialize products that are approved for commercial sales, we must either collaborate with third parties that have such commercial infrastructure or develop our own sales and marketing infrastructure. If we are not successful entering into appropriate collaboration arrangements, or recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing Resunab, which would adversely affect our business, operating results and financial condition.

We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure we may not realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize Resunab without strategic partners or licensees include:

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

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make Resunab obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to Resunab. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our potential competitors both in the United States and Europe include companies developing and/or marketing drugs for cystic fibrosis, including Vertex, Nivalis Therapeutics, Inc. and PTC Therapeutics (NasdaqGS: PTCT), as well as companies working in the systemic sclerosis field, including Bristol-Myers Squibb and Sanofi.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize Resunab and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for Resunab, restrict or regulate post-approval activities and affect our ability to profitably sell Resunab. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of Resunab, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for Resunab and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and

abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners, and incur substantial costs to ensure compliance.

Despite initiatives to invalidate the Health Care Reform Law, at this time it appears the implementation of the Health Care Reform Law will continue. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize Resunab in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize Resunab in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for Resunab in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of Resunab could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market Resunab in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct may be subject to significant liability. Similarly, industry codes in the European Union and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We are, and will be, completely dependent on third parties to manufacture Resunab, and our commercialization of Resunab could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of Resunab or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in Resunab for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate Resunab as a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when Resunab is approved for commercialization. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of Resunab on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture Resunab must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug

substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to Resunab. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of Resunab or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market Resunab, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market Resunab, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market Resunab.

If for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished Resunab product or should cease doing business with us, we could experience significant interruptions in the supply of Resunab or may not be able to create a supply of Resunab at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of Resunab might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply Resunab at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of Resunab if we decided to transfer the manufacture of Resunab to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of Resunab, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of Resunab over time. If the commercial-scale manufacturing costs of Resunab are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

Our product candidate aljuemic acid, Resunab, is currently classified as a Schedule I controlled substance subject to U.S. controlled substance laws and regulations, including regulations of the Drug Enforcement Agency and the U.S. Food and Drug Administration. Failure to obtain the necessary licenses and registrations and failure to comply with these laws could result in the delay in the manufacturing and distribution of Resunab and could delay the completion of clinical studies. Such delays and the cost of compliance with these laws and regulations, could adversely affect our business operations and our financial condition.

In the United States, our product candidate, Resunab, is currently classified as Schedule I controlled substance as defined in the Controller Substance Act ("CSA") . This designation is based on Resunab's chemical structure and pharmacology (namely, it being a synthetic endocannabinoid mimetic that binds to the CB2 receptor). Even though Resunab's mechanism of action is to modulate the immune system and results to date from clinical studies have demonstrated the drug has no psychotropic effects (which we believe is unlike other members of its chemical class), the DEA classifies Resunab as a Schedule I substance.

Schedule I controlled substances are pharmaceutical products subject to specific regulations under the CSA, that establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other

requirements administered by the DEA. All parties responsible for the manufacturing, distribution and testing the drug in clinical studies must apply for and obtain a license from the DEA before they are permitted to perform these activities with Resunab. Furthermore, these parties must have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All licensed facilities are required to renew their registrations annually if they intend to continue to work with our drug. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. We have been working with our manufacturers, distributors, exporters and clinical sites to obtain the necessary licenses to work with Resunab. The parties responsible for the manufacturing, distribution and export of Resunab have already applied for and have been granted DEA licenses and a number of institutions responsible for conducting our Phase 2 clinical studies have also been granted DEA licenses. However the failure to maintain the necessary registrations and the delay or failure of additional clinical sites to obtain DEA registrations, could delay the manufacturing, distribution and export of Resunab and could delay the completion of the Phase 2 clinical studies. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, could result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. In addition, if the FDA, DEA, or any foreign regulatory authority determines that Resunab may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of Resunab.

Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. The requirement for state registrations could also result in delay of the manufacturing, distribution of Resunab or in the completion of the Phase 2 clinical studies. We and our manufacturing vendors and clinical sites must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

The manufacturing and distribution of Resunab is subject to the DEA's annual manufacturing and procurement quota requirements. The annual quota allocated to us or our contract manufacturers for the controlled substances in Resunab may not be sufficient to complete clinical trials. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers, procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and operations.

Delays in shipping Resunab could have a material adverse effect on our business, results of operations and financial condition.

The import and export of Resunab requires import and export licenses. However, because Resunab is currently a Schedule I controlled substance in the United States, in addition to the FDA and U.S. Customs and Border Protection, its import and export is also regulated by the DEA. We may not be granted, or if granted, maintain, such licenses for import or export from the authorities these regulatory agencies. Even if we obtain the relevant licenses, shipments of Resunab may be held up in transit by any of these authorities, which could cause significant delays and may lead to product batches which no longer meet specifications for use in clinical trials or commercial distribution. Such events could result in delayed development timelines, increased expenses and partial or total loss of revenue from Resunab.

We expect that we will rely on third parties to conduct clinical trials for Resunab. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize Resunab and our business would be substantially harmed.

We expect to enter into agreements with third-party CROs to conduct and manage our clinical programs including contracting with clinical sites to perform our clinical studies. We plan to rely heavily on these parties for execution of clinical studies for Resunab and will control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which

would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for Resunab in consultation with CROs, we expect that the CROs will manage all of the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of Resunab for the subject indication may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or Resunab. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize Resunab. As a result, our financial results and the commercial prospects for Resunab would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Any termination or suspension of or delays in the commencement or completion of any necessary studies of Resunab for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed and placing the clinical study on hold;
- subjects failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing Resunab being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing Resunab, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports of similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGCP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;

- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial.

Product development costs for Resunab will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of Resunab, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of Resunab. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of Resunab could be significantly reduced.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA will view the results as we do or that any future trials of Resunab will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for Resunab may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for Resunab. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status.

We have been granted orphan drug designation for Resunab for the treatment of cystic fibrosis and systemic sclerosis. We also intend to seek orphan drug status for Resunab for the treatment of dermatomyositis. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the United States under the Orphan Drug Act. However, there is no guarantee that the FDA will grant orphan drug designation for Resunab for dermatomyositis or any other indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication or which may receive orphan drug designation in the future will not receive approval prior to us, in which our competitor would have the benefit of the seven year market exclusivity,

and we would be unable to commercialize our product for the same indication until the expiration of the seven-year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for Resunab in the indications of cystic fibrosis, systemic sclerosis, or other inflammatory diseases, if we elect to seek such applications.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market Resunab will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which Resunab is expected to be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell Resunab profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

Risks Relating to Our Intellectual Property Rights

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents (including patents owned by us). We currently have one issued patent and the three pending patent applications for Resunab may never be approved by United States or foreign patent offices and the existing patent and patent applications relating to Resunab and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to Resunab, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent protection or trade secret protection for Resunab or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

Resunab may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of Resunab or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize Resunab, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;

- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent Resunab from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to Resunab or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market Resunab or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign Resunab or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing Resunab or a future product candidate, which could harm our business, financial condition and operating results.

A number of companies, including several major pharmaceutical companies, have conducted research on anti-inflammatory and anti-fibrosis therapies which resulted in the filing of many patent applications related to this research. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims.

If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the United States Patent and Trademark Office, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we 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.

General Company-Related Risks

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

We currently have ten employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Resunab and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

Future capital raises may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced and these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Yuval Cohen, our CEO, Mark Tepper, our President and Chief Scientific Officer, Barbara White, our Chief Medical Officer and Sean Moran, our Chief Financial Officer would adversely impact our business prospects.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract highly qualified managerial, scientific and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. However, we will need to hire additional personnel as we further develop Resunab. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. In connection with the Merger, we entered into employment agreements with certain of our executive officers. However, these employment arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of Yuval Cohen Ph.D., our Chief Executive Officer, Mark Tepper Ph.D., our President and Chief Scientific Officer, Barbara White, M.D., our Chief Medical Officer and Sean Moran, C.P.A., M.B.A., our Chief Financial Officer, would have a material adverse effect on our business. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Resunab.

We face a potential risk of product liability as a result of the clinical testing of Resunab and will face an even greater risk if we commercialize Resunab or any other future product. For example, we may be sued if any product we develop, including Resunab, or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of Resunab. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Resunab or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- the inability to commercialize Resunab; and
- a decline in the value of our stock.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We intend to obtain product liability insurance covering our clinical trials. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to our Common Stock

Our majority stockholders will control our company for the foreseeable future, including the outcome of matters requiring stockholder approval.

Our officers, directors, and five percent stockholders collectively own approximately 31.1% of our outstanding shares of common stock. In addition, these stockholders entered into a voting agreement whereby they agreed to vote in favor of nominees for directors selected by the parties to the voting agreement as described herein. As a result, such entities and individuals will have the ability, acting together, to control the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our articles of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders (including investors in this Offering) with interests different from those entities and individuals. Certain of these individuals also have significant control over our business, policies and affairs as officers or directors of our company. Therefore, you should not invest in reliance on your ability to have any control over our company.

An investment in our company should be considered illiquid.

An investment in our company requires a long-term commitment, with no certainty of return. Because we became a reporting company other than by the traditional means of conducting an initial public offering of our common stock, we may be unable to establish a liquid market for our common stock. In addition, investment banks may be less likely to agree to underwrite primary or secondary offerings on behalf of our company or its stockholders in the future than they would if we had become a public reporting company by means of an initial public offering of common stock. If all or any of the foregoing risks occur, it would have a material adverse effect on our company.

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

Presently, our common stock is traded on the Nasdaq Capital Market and as we are in our early stages, an investment in our company will require a long-term commitment, with no certainty of return. Presently there is limited trading in our stock and in the absence of an active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;
- market visibility for shares of our common stock may be limited; and

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

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

We are currently listed on the Nasdaq Capital Market. If we are unable to maintain listing of our securities on the Nasdaq Capital Market or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our common stock is currently listed on the Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. In addition, a liquid market may not develop for our common stock. If we are unable to maintain listing on the Nasdaq Capital Market or if a liquid market for our common stock does not develop, our common stock may remain thinly traded.

The Listing Rules of the Nasdaq Capital Market require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of investors in general that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

Even if an active trading market for our common stock develops, the market price of our common stock may be significantly volatile.

Even if an active market for our common stock develops, of which no assurances can be given, the market price for our common stock may be volatile and subject to wide fluctuations in response to factors including the following:

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

In particular, the market prices of biotechnology companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to conduct a clinical trial for our product or receive approval from the FDA and other regulatory agencies;
- developments or disputes concerning our product's intellectual property rights;
- our or our competitors' technological innovations;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- failure to complete significant transactions or collaborate with vendors in manufacturing our product.

The securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock.

Future sales of shares by existing stockholders could cause our stock price to decline.

As of September 30, 2015, we had outstanding options to purchase an aggregate of 3,828,065 shares of our common stock at a weighted average exercise price of $0.99 per share and warrants to purchase an aggregate of 1,969,250 shares of our common stock at a weighted average exercise price of $0.97 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

We are an "emerging growth company," and will be able take advantage of reduced disclosure requirements applicable to "emerging growth companies," which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, for as long as we continue to be an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) January 1, 2020, (2) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (3) the date on which we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter or (4) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three-year period.

We intend to take advantage of these reporting exemptions described above until we are no longer an "emerging growth company." Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will incur significantly increased costs and devote substantial management time as a result of operating as a public company particularly after we are no longer an "emerging growth company."

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. In addition, after we are no longer qualify as an "emerging growth company," we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We are just beginning the process of compiling the system and processing documentation needed to comply with such requirements. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In that regard, we currently do not have an internal audit function, and we will need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

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

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. As we are a start-up company, we only have ten full time employees which results in a lack of segregation of duties and are at the very early stages of establishing, and we may be unable to effectively establish such systems, especially in light of the fact that we expect to operate as a publicly reporting company. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

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

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our investors have purchased their shares.

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

We may be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of a Registration Statement filed on Form S-1, or the fiscal year ended December 31, 2015. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

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

If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor

confidence in the accuracy and completeness of our financial reports, which would cause the price of our common s tock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal control and procedures on a quarterly basis.

However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" as defined in the recently enacted JOBS Act, if we take advantage (as we expect to do) of the exemptions contained in the JOBS Act.

At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

Upon dissolution of our company, you may not recoup all or any portion of your investment.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities and distributions required to be made to holders of any outstanding preferred stock will then be distributed to the stockholders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As a result of our merger in April 2014 with Corbus Pharmaceuticals, Inc., our wholly-owned subsidiary, our ability to utilize our federal net operating loss, carryforwards and federal tax credit may be limited under Sections 382 of the Internal Revenue Code. The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Our certificate of incorporation, as amended, allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. We anticipate that our board of directors will have the authority to issue up to 10,000,000 shares of our preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Description
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).*
32.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).*
32.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).*
101.INS	XBRL Instance Document.*
101.SCH	XBRL Taxonomy Extension Schema Document.*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.*

* Filed herewith.

EXHIBIT INDEX

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101.INS	XBRL Instance Document.*
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101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.*

* Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Corbus Pharmaceuticals Holdings, Inc.

Date: November 10, 2015

By: /s/ Yuval Cohen
Name: Yuval Cohen
Title: *Chief Executive Officer*
(Principal Executive Officer)

Date: November 10, 2015

By: /s/ Sean Moran
Name: Sean Moran
Title: *Chief Financial Officer*
(Principal Financial Officer and Chief Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT

TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yuval Cohen, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2015 of Corbus Pharmaceuticals Holdings, 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 are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

5. The registrant's other certifying officer(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 (or persons performing the equivalent functions):

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

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

Date: November 10, 2015

/s/ Yuval Cohen

Yuval Cohen
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT

TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean M. Moran, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2015 of Corbus Pharmaceuticals Holdings, 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 are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

5. The registrant's other certifying officer(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 (or persons performing the equivalent functions):

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

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

Date: November 10, 2015

/s/ Sean Moran

Sean Moran
Chief Financial Officer
(Principal Financial Officer and Chief Accounting Officer)

Exhibit 32.1

Certification of Chief Executive Officer Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Corbus Pharmaceuticals Holdings, Inc. for the quarter ended September 30, 2015, each of the undersigned hereby certifies in his capacity as an officer of Corbus Pharmaceuticals Holdings, Inc. that to such officer's knowledge:

(1) The Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Yuval Cohen

Dated: November 10, 2015

Yuval Cohen
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification of Chief Financial Officer Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Corbus Pharmaceuticals Holdings, Inc. for the quarter ended September 30, 2015, each of the undersigned hereby certifies in his capacity as an officer of Corbus Pharmaceuticals Holdings, Inc. that to such officer's knowledge:

(1) The Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Sean Moran
Sean Moran
Chief Financial Officer
(Principal Financial Officer and Chief Accounting Officer)

Dated: November 10, 2015