UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period March 31, 2018.

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)**
500 River Ridge Drive 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 [X] 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 [X] No [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[X]
Non-accelerated filer	[ ] (Do not check if a smaller reporting company)	Smaller reporting company	[ ]
		Emerging growth company	[X]

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

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

As of May 7, 2018, 57,142,496 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 March 31, 2018

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,955,652	$ 62,537,495
Restricted cash	—	158,991
Prepaid expenses and other current assets	3,531,259	2,808,244
Total current assets	74,486,911	65,504,730
Property and equipment, net	2,593,172	1,432,655
Other assets	59,639	40,776
Total assets	$ 77,139,722	$ 66,978,161
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	$ 208,648	$ 332,861
Accounts payable	4,169,781	3,130,295
Accrued expenses	5,898,274	4,741,519
Total current liabilities	10,276,703	8,204,675
Deferred rent, noncurrent	1,323,415	989,550
Other liabilities	—	375
Total liabilities	11,600,118	9,194,600
Commitments and Contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized, 57,139,892 and 55,603,427 shares issued and outstanding at March 31, 2018 and December 31, 2017	5,714	5,560
Additional paid-in capital	142,927,376	123,476,102
Accumulated deficit	(77,393,486)	(65,698,101)
Total stockholders' equity	65,539,604	57,783,561
Total liabilities and stockholders' equity	$ 77,139,722	$ 66,978,161

See notes to the unaudited condensed consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2018	**2017**
Revenue from awards	$ 950,442	$ 1,293,697
Operating expenses:		
Research and development	9,765,362	6,366,112
General and administrative	3,050,032	2,380,125
Total operating expenses	12,815,394	8,746,237
Operating loss	(11,864,952)	(7,452,540)
Other income (expense):		
Interest income, net	203,421	1,366
Foreign currency exchange loss, net	(33,854)	(14,265)
Other income (expense), net	169,567	(12,899)
Net loss	$ (11,695,385)	$ (7,465,439)
Net loss per share, basic and diluted	$ (0.21)	$ (0.16)
Weighted average number of common shares outstanding, basic and diluted	56,367,548	46,381,482

See notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (11,695,385)	$ (7,465,439)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,884,916	1,583,156
Depreciation and amortization	81,898	31,489
Loss on foreign exchange	9,245	14,265
Deferred rent	333,865	(1,372)
Changes in operating assets and liabilities:		
Decrease in customer receivable	6,250,000	1,000,000
Increase in prepaid expenses	(757,790)	(140,181)
Increase in other assets	(18,863)	—
Increase in accounts payable	1,192,558	191
Increase (decrease) in accrued expenses	1,120,245	(364,557)
Decrease in deferred revenue	—	(1,293,697)
Net cash used in operating activities	(1,599,311)	(6,636,145)
Cash flows from investing activities:		
Purchases of property and equipment	(1,269,711)	(40,131)
Net cash used in investing activities	(1,269,711)	(40,131)
Cash flows from financing activities:		
Principal payments on notes payable	(124,213)	(116,031)
Proceeds from issuance of common stock	11,856,655	41,349,957
Issuance costs paid for common stock financings	(603,576)	(621,862)
Principal payments under capital lease obligation	(678)	(920)
Net cash provided by financing activities	11,128,188	40,611,144
Net increase in cash, cash equivalents, and restricted cash	8,259,166	33,934,868
Cash, cash equivalents, and restricted cash at beginning of the period	62,696,486	15,192,257
Cash, cash equivalents, and restricted cash at end of the period	$ 70,955,652	$ 49,127,125
Supplemental disclosure of cash flow information and non-cash transactions:		
Cash paid during the period for interest	$ 1,826	$ 1,527
Fair value of warrant issued in connection with Investment Agreement	6,215,225	$ —
Stock issuance costs included in accounts payable or accrued expenses	$ 127,293	$ 44,926
Purchases of property and equipment included in accounts payable or accrued expenses	$ 507,800	$ —
Write off of fully amortized leasehold improvements	$ 191,244	$ —

See notes to the unaudited condensed consolidated financial statements.

Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Statement of Stockholders' Equity

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2017	55,603,427	$ 5,560	$ 123,476,102	$ (65,698,101)	$ 57,783,561
Issuance of common stock, net of issuance costs of $505,368	1,500,000	150	11,194,482	—	11,194,632
Stock compensation expense	—	—	1,884,916	—	1,884,916
Issuance of common stock upon exercise of stock options	36,465	4	156,651	—	156,655
Fair value of warrant issued in connection with Investment Agreement	—	—	6,215,225	—	6,215,225
Net loss	—	—	—	(11,695,385)	(11,695,385)
Balance at March 31, 2018 - (Unaudited)	57,139,892	$ 5,714	$ 142,927,376	$ (77,393,486)	$ 65,539,604

See notes to the unaudited condensed consolidated financial statements.

1. NATURE OF OPERATIONS

Business

Corbus Pharmaceuticals Holdings, Inc. (the "Company") 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 March 31, 2018 and the results of its operations and cash flows for the three months ended March 31, 2018 and 2017. The December 31, 2017 condensed consolidated balance sheet was derived from audited financial statements. The Company prepared the condensed consolidated financial statements following the requirements of the SEC for interim reporting. Accordingly, 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, 2017, filed on March 12, 2018. 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 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 has incurred recurring losses since inception and as of March 31, 2018, had an accumulated deficit of $77,393,486.

On January 5, 2018, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement ("January 2018 Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") pursuant to which Cantor Fitzgerald is serving as the Company's sales agent to sell up to $50 million of shares of the Company's common stock through an "at the market offering," of which 1,500,000 shares have been sold for net proceeds of approximately $11.2 million in the first quarter of 2018. (See Note 9).

On January 26, 2018, the Company entered into the Cystic Fibrosis Program Related Investment Agreement ("Investment Agreement") with the Cystic Fibrosis Foundation ("CFF"), a non-profit drug discovery and development corporation, pursuant to which the Company received a development award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b Clinical Trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis, of which the Company received $6.25 million in the first quarter of 2018 and subsequently in May 2018 became entitled to receive an additional $6.25 million upon the Company's achievement of a milestone related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. The Company expects to receive payment from the CFF for this milestone achievement by the end of the second quarter of 2018.

The Company expects the remainder of the 2018 CFF Award will be paid to the Company incrementally upon the achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. (See Note 8).

Pursuant to the terms of the Investment Agreement, the Company issued a warrant to CFF to purchase an aggregate of 1,000,000 shares of the Company's common stock (the "CFF Warrant") (See Note 11). The CFF Warrant is exercisable at a price equal to $13.20 per share and is immediately exercisable for 500,000 shares of the Company's common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to the Company pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 500,000 shares of the Company's common stock.

The Company expects the cash and cash equivalents of $70,955,652 at March 31, 2018 to be sufficient to meet its operating and capital requirements at least 12 months from the filing of this 10-Q.

Should the Company be unable to raise sufficient additional capital, the Company may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities. The Company will need to raise significant additional capital to continue to fund the clinical trials for lenabasum. 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 certain of 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 accrual of research, product development and clinical obligations, the recognition of revenue under the Investment Agreement (See Note 8), and the valuation of the CFF Warrant discussed in Note 11.

Cash, Cash Equivalents and Restricted Cash

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. At March 31, 2018 and December 31, 2017, cash equivalents were comprised of money market funds. For purposes of preparing the statement of cash flows, the Company considers payments of amounts previously accrued for stock issuance costs or property, plant, and equipment as payments for those original purposes.

Restricted cash as of December 31, 2017 in the amount of $108,991 was classified in current assets and included a collateral account for the Company's corporate credit cards. This collateral account was closed in the first quarter of 2018 and accordingly the cash was no longer restricted as of March 31, 2018. Additionally, as of December 31, 2017, restricted cash included a stand-by letter of credit issued in favor of a landlord for $50,000 which was classified in current assets as of December 31, 2017. This stand-by letter of credit was terminated in the first quarter of 2018 in connection with the August 2017 Lease Agreement discussed in Note 5, and accordingly, the cash is no longer restricted as of March 31, 2018.

Cash, cash equivalents, and restricted cash consists of the following:

	March 31, 2018	December 31, 2017
Cash	$ 50,030	$ 206,510
Money market fund	70,905,622	62,330,985
Cash and cash equivalents	70,955,652	62,537,495
Restricted cash	—	158,991
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 70,955,652	$ 62,696,486

Financial Instruments

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, receivables, accounts payable and accrued expenses approximate their fair value based on the short-term nature of these instruments. The carrying values of the notes payable approximate their fair value due to the fact that they are at market terms.

Property and Equipment

The estimated life for the Company's property and equipment is as follows: three years for computer hardware and software and three to five years for office furniture and equipment. The Company's leasehold improvements and assets under capital lease are amortized over the shorter of their useful lives or the respective leases. See Note 4 for details of property and equipment and Note 5 for operating and capital lease commitments.

Research and Development Expenses

Costs incurred for research and development are expensed as incurred.

Nonrefundable advance payments for goods or services that have the characteristics that will be used or rendered for future research and development activities pursuant to executory contractual arrangements with third party research organizations are deferred and recognized as an expense as the related goods are delivered or the related services are performed.

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 terms 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 expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company determines accrual estimates by taking into account discussion with applicable personnel and outside service providers as to the progress of clinical 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 months ended March 31, 2018 and 2017, 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. However, the Company believes the risk of loss is minimal as these banks are large financial institutions.

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-threatening, inflammatory and fibrotic diseases. As of March 31, 2018 and December 31, 2017, 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 asset when it is not more likely than not that the tax benefit from the deferred tax assets will be realized. Accordingly, given the cumulative losses since inception, the Company has provided a valuation allowance equal to 100% of the deferred tax assets 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, as well as accrued interest and penalties, if any, 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 March 31, 2018 or December 31, 2017.

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 undiscounted cash flows of an asset 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. An impairment loss equal to the excess of the fair value of the asset over its carrying amount is recorded when it is determined that the carrying value of the asset may not be recoverable. No impairment charges were recorded during the three months ended March 31, 2018 and 2017.

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 to employees 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. Stock options granted to non-employee consultants are revalued at the end of each reporting period until vested using the Black-Scholes option-pricing model and the changes in their fair value are recorded as adjustments to expense over the related vesting period.

Net Loss Per Common Share

Basic and diluted 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. For periods in which there is a net loss, options and warrants 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 months ended March 31, 2018 and 2017

	Three Months Ended March 31	
	2018	**2017**
Basic and diluted net loss per share of common stock:		
Net loss	$ (11,695,385)	$ (7,465,439)
Weighted average shares of common stock outstanding	56,367,548	46,381,482
Net loss per share of common stock-basic and diluted	$ (0.21)	$ (0.16)

The impact of the following potentially dilutive securities outstanding during the three months ended March 31, 2018 and 2017 have been excluded from the computation of dilutive weighted average shares outstanding as the inclusion would be anti-dilutive.

	March 31,	
	2018	**2017**
Warrants	2,288,500	1,288,500
Stock options	9,342,584	7,513,130
Total	11,631,084	8,801,630

Recent Accounting Pronouncements

Revenue Recognition

In May 2014, the FASB issued guidance codified in *Accounting Standards Codification (ASC) 606, Revenue Recognition — Revenue from Contracts with Customers* ("ASC 606") which amends the guidance in former *ASC 605, Revenue Recognition* ("ASC 605"), and is effective for public companies for annual and interim periods beginning after December 15, 2017. Specifically, the new standard differs from ASC 605 in many respects, such as in the accounting for variable consideration received, including milestone payments or contingent payments. Under the Company's accounting policy prior to the adoption of ASC 606 in the first quarter of 2018, milestone payments were initially recognized only in the period that the payment-triggering event occurred or was achieved (See Note 8). ASC 606, however, may require a company to recognize such payments before the payment-triggering event is completely achieved based on the Company's estimate of the amount of consideration to which it will be entitled in exchange for transferring the services, subject to management's assessment of whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company adopted ASC 606 in the first quarter of 2018 using the modified retrospective method according to which the cumulative effect of initially applying ASC 606 is recognized at the date of initial application. Since the Company has concluded its performance obligations and has completed recognizing revenue under the 2015 CFFT Award discussed in Note 8 in the third quarter of 2017, there was no cumulative effect to record at the date of the Company's adoption of ASC 606 and no revenue to recognize for the first quarter of 2018 related to the 2015 CFFT Award. Revenue for the three months ended March 31, 2018 was $950,442, recognized in accordance with ASC 606 and pertains only to the 2018 CFF Award discussed in Note 8. The total impact to revenue for the three months ended March 31, 2018 as a result of the adoption of ASC 606 was $450,442. Total revenue recorded in the three months ended March 31, 2018 under ASC 606 was $950,442, as compared to $500,000 that would have been recorded under ASC 605, resulting in a contract asset of $915,667 as of March 31, 2018 under ASC 606 which is included in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheet.

The Company will assess any new agreements it enters into under ASC 606, including whether such agreements fall under the scope of such standard. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Revenue associated with the performance obligation is being recognized as revenue as the research and development services are provided using an input method, according to the costs incurred as related to the research and development activities and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The research and development services related to this performance obligation are expected to be performed over an approximately two and a half-year period expected to be completed in the second quarter of 2020. Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion. Amounts recognized as revenue, but not yet received or invoiced are generally recognized as contract assets.

Accounting for Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). Under ASU 2016-02, a lessee will be required to recognize assets and liabilities for all leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP, which requires only capital leases to be recognized on the balance sheet, ASU 2016-02 will require both types of leases to be recognized on the balance sheet. ASU 2016-02 will take effect for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018, with early application permitted. The adoption of ASU 2016-02 will have an impact on the Company's financial position as the Company has operating lease commitments for office space as of March 31, 2018 with future non-cancelable lease payments amounting to $5,381,790 (see Note 5) for which ASU 2016-02 would apply.

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	March 31, 2018	December 31, 2017
Computer hardware and software	$ 197,074	$ 136,522
Office furniture and equipment	718,809	287,048
Leasehold improvements	1,931,832	191,244
Construction in progress	—	1,181,730
Property and equipment, gross	2,847,715	1,796,544
Less: accumulated depreciation	(254,543)	(363,889)
Property and equipment, net	$ 2,593,172	$ 1,432,655

Depreciation expense was $81,898 and $31,489 for the three months ended March 31, 2018 and 2017, respectively. In the first quarter of 2018, the Company wrote off $191,244 of fully amortized leasehold improvements related to the termination of the September 2016 Amendment in February 2018 as discussed in Note 5.

On December 30, 2015, the Company entered into a lease agreement for a copier machine. The cost of the machine was approximately $12,000 and is included in office furniture and equipment category in the table above. The lease payments commenced when the machine was placed in service in January 2016. The machine is being amortized over the life of the lease, which is for a three-year term and includes a bargain purchase option at the end of the term. See Note 5 for details of this capital lease commitment.

5. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitment

In September 2016, the Company amended its commercial lease for office space to expand into an additional 4,088 square feet of office space within the same building for an aggregate total of 10,414 square feet of leased office space ("September 2016 Amendment"). The Company began occupying this space in early November 2016 and the final lease payment was to be due in January 2021. The September 2016 Amendment required an increase in the standby letter of credit to $50,000 (See Note 3). The September 2016 Amendment was terminated upon the commencement date of the August 2017 Lease Agreement discussed below.

On August 21, 2017, the Company entered into a lease agreement ("August 2017 Lease Agreement") with the same landlord, pursuant to which the Company agreed to lease 32,733 square feet of office space ("Leased Premises"). The initial term of the August 2017 Lease Agreement is for a period of seven years which began with the Company's occupancy of the Leased Premises in February 2018. The base rent for the Leased Premises ranges from approximately $470,000 for the first year to approximately $908,000 for the seventh year. Per the terms of the August 2017 Lease Agreement, the landlord agreed to reimburse the Company for $1,080,189 of leasehold improvements. The reimbursements have been deferred and will be recognized as a reduction of rent expense over the term of the lease. Additionally, the August 2017 Lease Agreement required a standby irrevocable letter of credit of $400,000, which may be reduced, if the Company is not in default under the August 2017 Lease Agreement, to $300,000 and $200,000 on the third and fourth anniversary of the commencement date, respectively, The Company entered into an unsecured letter of credit for $400,000 in connection with the August 2017 Lease Agreement for which it incurred interest expense of $1,774 for the three months ended March 31, 2018.

The Company records the total rent payable during the lease term on a straight-line basis over the term of the lease and records the difference between the rents paid and the straight-line rent as deferred rent, which is classified in deferred rent, noncurrent in the Company's balance sheet as of March 31, 2018 and December 31, 2017.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at March 31, 2018, the future minimum rent commitments are as follows:

2018 (remainder of year)	$	352,500
2019		623,958
2020		784,243
2021		830,600
2022		855,150
Thereafter		1,935,339
Total	$	5,381,790

Total rent expense for the three months ended March 31, 2018 and 2017 was $146,991 and $58,508, respectively.

Capital Lease Commitment

The lease payments under the capital lease agreement for the copier machine commenced when the machine was placed in service in January 2016. The lease is for a three-year term and includes a bargain purchase option at the end of the term. In the accompanying balance sheet as of March 31, 2018 and December 31, 2017, the current portion of this capital lease obligation is classified in accrued expenses and the long-term portion of the capital lease obligation is classified in other long-term liabilities. Pursuant to the terms of this capital lease agreement, the future minimum capital lease commitments are as follows as of March 31, 2018:

2018 (remainder of year)	3,407
2019	379
Total future minimum lease payments	3,786
Less: interest	(177)
Future capital lease obligations	3,609
Less: current portion	(3,609)
Long-term portion	$ —

6. NOTES PAYABLE

In October 2016, the Company entered into a loan agreement with a financing company for $348,750 to finance one of the Company's insurance policies. The terms of the loan stipulate equal monthly payments of principal and interest payments of $39,114 over a nine-month period. Interest accrued on this loan at an annual rate of 2.25%. This loan was fully repaid in July 2017.

In November 2017, the Company entered into a loan agreement with a financing company for $415,265 to finance one of the Company's insurance policies. The terms of the loan stipulate equal monthly payments of principal and interest payments of $41,975 over a ten-month period. Interest accrues on this loan at an annual rate of 2.35%.

Prepaid expenses as of March 31, 2018 and December 31, 2017, included $255,726 and $368,976, respectively, related to this insurance policy.

Interest expense for notes payable for the three months ended March 31, 2018 and 2017 totaled $1,660 and $1,278, respectively.

7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	March 31, 2018	December 31, 2017
Accrued clinical operations and trials costs	$ 3,267,875	$ 2,003,799
Accrued product development costs	1,484,701	1,255,439
Accrued compensation	577,116	1,335,672
Accrued other	568,582	146,609
Total	$ 5,898,274	$ 4,741,519

8. DEVELOPMENT AWARDS AND DEFERRED REVENUE

2015 CFFT Award

On April 20, 2015, the Company entered into an award agreement (the "2015 CFFT Award Agreement ") with the Cystic Fibrosis Foundation Thereapeutics, Inc ("CFFT"), a non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation ("CFF") pursuant to which the Company received a development award (the "2015 CFFT Award") for up to $5 million in funding. The funding from the 2015 CFFT Award supported a first-in-patient Phase 2 clinical trial of the Company's oral anti-inflammatory drug lenabasum in adults with cystic fibrosis ("CF"). The Company has received $5.0 million in payments since the inception of the 2015 CFFT Award as outlined below. The payments received under the 2015 CFFT Award were recorded as deferred revenue when the triggering event to receive those amounts had occurred and were amortized on a straight-line basis over the expected duration of the remaining performance period under the 2015 CFFT Award which concluded in the third quarter of 2017.

Upon the execution of the 2015 CFFT Award Agreement, the Company received a payment of $1,250,000 in May 2015. In November 2015, the Company received a second payment of $1,250,000 upon the achievement of a milestone for dosing the first patient. In August 2016, the Company received a third payment from the CFFT in the amount of $1,000,000 for achieving a milestone in July 2016 related to dosing the median clinical trial patient. In January 2017, the Company received a fourth payment from the CFFT in the amount of $1,000,000 for achieving a milestone in December 2016 related to completing the final visit for the final patient, which was billed by the Company to CFFT in December 2016 and was classified in grants receivable as of December 31, 2016. The Company received the final payment from CFFT in the amount of $500,000 in November 2017 for achieving the final milestone in September 2017 related to the issuance to CFFT of the final integrated statistical report for to the Phase 2 CF clinical trial. At that time the Company had completed all its performance obligations under the contract and therefore the performance period had concluded.

In accordance with ASC 605, the Company recorded $1,293,697 of revenue during the three months ended March 31, 2017 under the 2015 CFFT Award Agreement. No revenue was recorded under the 2015 CFFT Award Agreement during the three months ended March 31, 2018 as the final performance period concluded in the third quarter of 2017. Under ASC 605, milestone payments were initially recognized only in the period that the payment-triggering event occurred or was achieved. Effective January 1, 2018, ASC 605 was superceded by ASC 606 (See Note 3). The Company adopted ASC 606 in the first quarter of 2018 using the modified retrospective method according to which the cumulative effect of initially applying ASC 606 is recognized at the date of initial application. Since the Company concluded its performance obligations and completed recognizing revenue under the 2015 CFFT Award Agreement in the third quarter of 2017, there was no cumulative effect to record at the date of the Company's adoption of ASC 606.

Pursuant to the terms of the 2015 CFFT Award Agreement, the Company is obligated to make royalty payments to CFFT contingent upon commercialization of lenabasum in the Field of Use (as defined in the 2015 CFFT Award Agreement) as follows: (i) a royalty payment equal to five times the amount the Company receives under the 2015 CFFT Award Agreement, up to $25 million, payable in three equal annual installments following the first commercial sale of lenabasum, the first of which is due within 90 days following the first commercial sale of lenabasum, (ii) a royalty payment to CFFT equal to the amount the Company receives under the 2015 CFFT Award Agreement, up to $5 million, due in the first calendar year in which the aggregate cumulative net sales of lenabasum in the Field of Use exceed $500 million, and (iii) royalty payment(s) to CFFT of up to approximately $15 million if the Company transfers, sells or licenses lenabasum 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 2015 CFFT 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, if any, would survive the termination of the 2015 CFFT Award Agreement.

2018 CFF Award

On January 26, 2018, the Company entered into the Cystic Fibrosis Program Related Investment Agreement with the CFF ("Investment Agreement"), a non-profit drug discovery and development corporation, pursuant to which the Company received an award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b Clinical Trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis, of which the Company has received $6.25 million in the first quarter of 2018 and subsequently in May 2018 became entitled to receive an additional $6.25 million upon the Company's achievement of a milestone related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. The Company expects to receive payment from the CFF for this milestone achievement by the end of the second quarter of 2018.

The Company expects that the remainder of the 2018 CFF Award will be paid incrementally upon the Company's achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement.

Pursuant to the terms of the Investment Agreement, the Company is obligated to make certain royalty payments to CFF, including a royalty payment of one and one-half times the amount of the 2018 CFF Award, payable in cash within sixty days upon the first receipt of approval of lenabasum in the United States and a second royalty payment of one and one-half times the amount of the 2018 CFF Award upon approval in another major market, as set forth in the Investment Agreement (the "Approval Royalty"). At the Company's election, the Company may satisfy the first of the two Approval Royalties in registered shares of the Company's common stock.

Additionally, the Company is obligated to make (i) royalty payments to CFF of two and one-half percent of net sales from lenabasum due within sixty days after any quarter in which such net sales occur in the Field, as defined in the Investment Agreement, (ii) royalty payments to CFF of one percent of net sales of Non-Field Products, as defined in the Investment Agreement due within sixty days after any quarter in which such net sales occur, and (iii) royalty payments to CFF of ten percent of any amount the Company and its stockholders receive in connection with the license, sale, or other transfer to a third party of lenabasum, if indicated for the treatment or prevention of CF, or a change of control transaction, except that such payment shall not exceed five times the amount of the 2018 CFF Award, with such payments to be credited against any other net sales royalty payments due. Either CFF or the Company may terminate the Investment 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 Investment Agreement.

Pursuant to the terms of the Investment Agreement, the Company issued a warrant to CFF to purchase an aggregate of 1,000,000 shares of the Company's common stock (the "CFF Warrant"). The CFF Warrant is exercisable at a price equal to $13.20 per share and is immediately exercisable for 500,000 shares of the Company's common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to the Company pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 500,000 shares of the Company's common stock. The CFF Warrant expires on January 26, 2025. Any shares of the Company's common stock issued upon exercise of the CFF Warrant will be unregistered and subject to a one-year lock-up.

The Company recorded $950,442 of revenue during the three months ended March 31, 2018 under the Investment Agreement. The Company assessed the 2018 CFF Award for accounting under ASC 606, which it adopted in the first quarter of 2018 (Note 3). To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, CFF, is a customer. The Company identified the following material promise under the arrangement: research and development activities and related services under the Phase 2b Clinical Trial. Based on these assessments, the Company identified one performance obligation at the outset of the Investment Agreement, which consists of: Phase 2b Clinical Trial research and development activities and related services.

To determine the transaction price, the Company included the total aggregate payments under the Investment Agreement which amount to $25 million and reduced the revenue to be recognized by the payment to the customer of $6,215,225 in the form of the CFF Warrant representing its fair value, leaving the remaining $18,784,775 as the transaction price as of the outset of the arrangement, which will be recognized as revenue over the performance period as discussed below. The Company billed and collected $6,250,000 in milestone payments during the three months ended March 31, 2018 which was recorded as an increase to deferred revenue. Deferred revenue was reduced by the $6,215,225 fair value of the warrant which was also recorded as an increase to additional paid in capital. Deferred revenue was further reduced by the $950,442 of revenue that was recognized during the three months ended March 31, 2018 for the 2018 CFF Award, resulting in a negative deferred revenue position of $915,667 which was reclassified to a contract asset and is classified in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheet as of March 31, 2018.

The CFF Warrant is accounted for as a payment to the customer under ASC 606. See Note 11 for further information related to the CFF Warrant. The Company notes that the Investment Agreement contains an initial payment that was received upon contract execution and subsequent milestone payments, which are a form of variable consideration that require evaluation for constraint considerations. The Company concluded that the related performance milestones are generally within the Company's control and as result are considered probable. Revenue associated with the performance obligation is being recognized as revenue as the research and development services are provided using an input method, according to the costs incurred as related to the research and development activities on each program and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The research and development services related to this performance obligation are expected to be performed over an approximately two and a half year period expected to be completed in the second quarter of 2020. The amounts received that have not yet been recognized as revenue are recorded in deferred revenue and the amounts recognized as revenue, but not yet received or invoiced are generally recognized as contract assets on the Company's condensed consolidated balance sheet.

9. COMMON STOCK

The Company has authorized 150,000,000 shares of common stock, $0.0001 par value per share, of which 57,139,892 shares and 55,603,427 shares were issued and outstanding as of March 31, 2018 and December 31, 2017, respectively.

During the three months ended March 31, 2018 and 2017, the Company issued 36,465 and 160,549 shares of common stock upon the exercise of stock options to purchase common stock and the Company received proceeds of $156,655 and $80,248 from these exercises, respectively.

On January 5, 2018, the Company entered into a sales agreement with Cantor Fitzgerald under which the Company may direct Cantor Fitzgerald as its sales agent to sell common stock up to an aggregate offering of up to $50 million under an "At the Market Offering" ("January 2018 Sales Agreement"). Sales of common stock under the January 2018 Sales Agreement were made pursuant to an effective registration statement for an aggregate offering of up to $50 million. In the first quarter of 2018, the Company sold 1,500,000 shares of its common stock to an institutional investor under the January 2018 Sales Agreement for which the Company received net proceeds of approximately $11.2 million. In the first quarter of 2017, the Company sold 1,413,633 shares of its common stock under a sales agreement that the Company entered into in November 2016 with Cantor Fitzgerald ("Sales Agreement") for net proceeds of $13,268,208. The Sales Agreement was terminated in October 2017.

On February 28, 2017, the Company entered in a securities purchase agreement providing for the issuance and sale by the Company of 3,887,815 shares of its common stock in a registered direct offering to institutional and accredited investors at a purchase price of $7.00 per share with gross proceeds to the Company totaling $27,214,705 less issuance costs of $36,291.

10. 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, 2017, pursuant to an annual evergreen provision contained in the 2014 Plan, the number of shares reserved for future grants was increased by 3,127,722 shares. As of December 31, 2017, there was a total of 13,043,739 shares reserved for issuance under the 2014 Plan and there were 4,460,334 shares available for future grants. Options issued under the 2014 Plan generally vest over 4 years from the date of grant in multiple tranches and are exercisable for up to 10 years from the date of issuance.

Pursuant to the terms of an annual evergreen provision in the 2014 Plan, the number of shares of common stock available for issuance under the 2014 Plan shall automatically increase on January 1 of each year by at least seven percent (7%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, or, pursuant to the terms of the 2014 Plan, in any year, the Board of Directors may determine that such increase will provide for a lesser number of shares. In accordance with the terms of the 2014 Plan, effective as of January 1, 2018, the number of shares of common stock available for issuance under the 2014 Plan increased by 2,500,000 shares, such amount being less than seven percent (7%) of the outstanding shares of common stock on December 31, 2017. As of January 1, 2018, the 2014 Plan had a total reserve of 15,543,739 shares and there were 6,960,334 shares available for future grants. As of March 31, 2018, there were 5,426,251 shares available for future grants.

Share-based Compensation

For stock options issued and outstanding for the three months ended March 31, 2018 and 2017, respectively, the Company recorded non-cash, stock-based compensation expense of $1,884,916 ($1,840,789 for employees and $44,127 for non-employees) and $1,583,156 ($884,307 for employees and $698,849 for non-employees), respectively, net of estimated forfeitures.

The fair value of each option award for employees is estimated on the date of grant and for non-employees is estimated at the end of each reporting period until vested using the Black-Scholes option pricing model that uses the assumptions noted in the following table. Due to its limited operating history, the Company estimates its volatility including the volatility of comparable public companies and its own common stock, taking into account the expected life of the option. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations in order to estimate its forfeiture rate. 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 between the vesting period and the contractual life of the options which is 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 weighted average assumptions used principally in determining the fair value of options granted to employees were as follows:

	Three Months Ended March 31,	
	2018	**2017**
Risk free interest rate	2.34%	2.17%
Expected dividend yield	0%	0%
Expected term in years	6.25	6.35
Expected volatility	88.1%	85.8%
Estimated forfeiture rate	5%	5%

A summary of option activity for the three months ended March 31, 2018 is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2017	7,844,966	$ 3.75		
Granted	1,574,500	8.32		
Exercised	(36,465)	4.30		
Forfeited	(40,417)	7.28		
Outstanding at March 31, 2018	9,342,584	$ 4.50	7.85	$ 29,325,265
Vested at March 31, 2018	5,049,555	$ 2.41	6.93	$ 24,544,006

The weighted average grant-date fair value of options granted during the three months ended March 31, 2018 and 2017 was $6.20 and $6.66 per share, respectively. The aggregate intrinsic value of options exercised during the three months ended March 31, 2018 and 2017 was approximately $142,949 and $1,402,164, respectively. The total fair value of options that were vested as of March 31, 2018 and 2017 was $9,911,261 and $3,503,337, respectively. As of March 31, 2018, there was approximately $19,188,549 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 weighted average period of 3.15 years as of March 31, 2018.

11. WARRANTS

No warrants were exercised during the three months ended March 31, 2018 and 2017.

At March 31, 2018, there were warrants outstanding to purchase 2,288,500 shares of common stock with a weighted average exercise price of $6.33 and a weighted average remaining life of 3.64 years, including the warrant issued to CFF pursuant to the terms of the Investment Agreement (Note 8). The Company issued a warrant to CFF to purchase an aggregate of 1,000,000 shares of the Company's common stock (the "CFF Warrant"). The CFF Warrant is exercisable at a price equal to $13.20 per share and is immediately exercisable for 500,000 shares of the Company's common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to the Company pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 500,000 shares of the Company's common stock. The CFF Warrant expires on January 26, 2025. Any shares of the Company's common stock issued upon exercise of the CFF Warrant will be unregistered and subject to a one-year lock-up. The CFF Warrant is classified as equity as it meets all the conditions under ASC 815-40 for equity classification. In accordance with ASC 815-40, the Company has calculated the fair value of the warrant for initial measurement and will reassess whether equity classification for the warrant is appropriate upon any changes to the warrants or capital structure, at each balance sheet date. The weighted average assumptions used in determining the $6,215,225 fair value of the CFF Warrant were as follows:

Risk free interest rate	2.60%
Expected dividend yield	0%
Expected term in years	7.00
Expected volatility	83.5%

12. RELATED PARTY TRANSACTIONS

On September 20, 2016, the Company entered into a consulting agreement (the "2016 Consulting Agreement") with Orchestra Medical Ventures, LLC ("Orchestra"), of which a member of the Company's Board of Directors, David Hochman, is Managing Partner. Under this agreement, Orchestra rendered a variety of consulting and advisory services relating principally to identifying and evaluating strategic relationships, licensing opportunities, and business strategies. The term of the 2016 Consulting Agreement commenced on September 20, 2016 and expired on March 20, 2017. Pursuant to the terms of the 2016 Consulting Agreement, the Company paid to Orchestra cash compensation in an aggregate amount of $100,000, of which $50,000 was expensed during the three months ended March 31, 2017. In connection with this agreement, the Company granted an equity incentive award to Mr. Hochman consisting of options to purchase 50,000 shares ("Option Shares") of common stock (the "Option Award") pursuant to the Company's 2014 Equity Compensation Plan, of which fifty percent (50%) vested on the three (3) month anniversary of the date of grant of the Option Award and the remainder of the Option Shares vested on the six (6) month anniversary of the date of grant of the Option Award. The Option Shares were granted with an exercise price of $7.14 per share. The Company recorded stock-based compensation expense of approximately $222,000 during the year ended December 31, 2016 and $171,000 during the first quarter of 2017 in respect of the Option Award. No stock-based compensation expense was recorded after the first quarter of 2017 related to the Option Shares as they were fully vested in March 2017.

13. SUBSEQUENT EVENTS

Amended and Restated Employment Agreements

On April 11, 2018, the Company entered into amended and restated employment agreements with certain of the Company's executive officers, Yuval Cohen, Ph.D., Chief Executive Officer; Barbara White, M.D., Chief Medical Officer; Mark Tepper, Ph.D., President and Chief Scientific Officer; and Sean Moran, Chief Financial Officer (the "Amended and Restated Employment Agreements"). The Amended and Restated Employment Agreements each provide for a two-year term, and provide for base salaries in the amounts of $540,000, $424,000, $390,000 and $375,000, for Dr. Cohen, Dr. White, Dr. Tepper and Mr. Moran, respectively, and provide that the executives are eligible to receive annual bonuses targeted at up to 55%, 40%, 45% and 40% of the base salary for each of Dr. Cohen, Dr. White, Dr. Tepper and Mr. Moran, respectively, which may be adjusted by the Company's Board of Directors based on the executives individual performance and the Company's performance as a whole.

2018 CFF Award

On May 8, 2018, the Company became entitled to receive an additional $6.25 million upon its achievement of a milestone related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. The Company expects to receive payment from the CFF for this milestone achievement by the end of the second quarter of 2018.

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 Phase 3, clinical stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, chronic and serious inflammatory and fibrotic diseases with clear unmet medical needs. Our product, lenabasum, is a novel synthetic, oral, endocannabinoid-mimetic drug designed to resolve chronic inflammation and halt fibrotic processes without causing immunosuppression. We are currently developing lenabasum to treat four life-threatening diseases: systemic sclerosis (SSc), cystic fibrosis (CF), dermatomyositis (DM) and systemic lupus erythematosus (SLE).

Lenabasum is a synthetic, rationally-designed, oral small-molecule drug that selectively binds to the cannabinoid receptor type 2, or CB2 found on activated immune cells, fibroblasts and other cell types including muscle and bone cells. Lenabasum stimulates the production of Specialized Pro-Resolving Lipid Mediators (SPMs) that act to resolve inflammation and halt fibrosis by activating endogenous pathways. These pathways are activated in healthy individuals during the course of normal immune responses but are dysfunctional in patients with chronic inflammatory and fibrotic diseases. By its binding to CB2, lenabasum drives innate immune responses from the activation phase into the resolution phase. CB2 plays a central role in modulating and resolving inflammation by, in effect, turning heightened inflammation “off” and restoring homeostasis. This has been demonstrated in animal models lacking CB2 as well as humans with genetic polymorphism in the CB2 gene, as these exhibit excessive inflammation and fibrosis in response to activators of the innate immune system.

Lenabasum has generated positive clinical data in three consecutive Phase 2 studies in diffuse cutaneous SSc, CF and skin-predominant DM. Lenabasum is currently being evaluated in a Phase 3 SSc study that is expected to enroll 354 patients, a Phase 2b CF study that is expected to enroll 415 patients (that is being supported by a development award for up to $25 million in funding (the “2018 CFF Award”) from the Cystic Fibrosis Foundation (“CFF”)), and a Phase 2 SLE study that is expected to enroll 100 patients and is being funded by a grant through the National Institutes of Health (“NIH”) grant. In DM, the Company plans to consult with the FDA on the protocol design for the next clinical study, which the Company expects to commence before the end of 2018. Open-label extension studies are ongoing in SSc and DM following the completion of the Phase 2 studies in these indications.

In May 2018, the first patient was dosed in the Phase 2b CF study.

The U.S. Food and Drug Administration, or the FDA, has granted lenabasum Orphan Designation as well as Fast Track Status for both SSc and CF. The European Medicines Authority, or the EMA, has granted lenabasum Orphan Designation for both SSc and CF.

Since our inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Our research and development activities have included conducting pre-clinical studies, developing manufacturing methods and the manufacturing of our drug lenabasum for clinical trials and conducting clinical studies in patients. Three of the four clinical programs for lenabasum have been supported, by non-dilutive awards and grants. The National Institutes of Health, or NIH, has funded the majority of the clinical development costs for the DM Phase 2 clinical trial and is funding the SLE Phase 2 clinical trials. In cystic fibrosis, the Phase 2b clinical trial is being supported by the 2018 CFF Award and the Phase 2 clinical trial was partially funded by a $5 million award (the “2015 CFFT Award Agreement”) from the Cystic Fibrosis Foundation Therapeutics, Inc., or CFFT, a non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation.

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 at March 31, 2018, we had an accumulated deficit of approximately $77,393,000. Our net losses for the three months ended March 31, 2018 and 2017 were approximately $11,695,000 and $7,465,000, respectively. We expect to continue 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 of and commercialize lenabasum. 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 government grants and 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 in 2018 and in the future in connection with our ongoing activities, as we:

- conduct clinical trials for lenabasum in scleroderma, cystic fibrosis, systemic lupus erythematosus 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 condensed 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. 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.

Revenue Recognition

In May 2014, the FASB issued guidance codified in *Accounting Standards Codification (ASC) 606, Revenue Recognition — Revenue from Contracts with Customers* ("ASC 606") which amends the guidance in former *ASC 605, Revenue Recognition* ("ASC 605"), and is effective for public companies for annual and interim periods beginning after December 15, 2017. Specifically, the new standard differs from ASC 605 in many respects, such as in the accounting for variable consideration received, including milestone payments or contingent payments. Under our accounting policy prior to the adoption of ASC 606 in the first quarter of 2018, milestone payments were initially recognized only in the period that the payment-triggering event occurred or was achieved. ASC 606, however, may require a company to recognize such payments before the payment-triggering event is completely achieved based on the company's estimate of the amount of consideration to which it will be entitled in exchange for transferring the services, subject to management's assessment of whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We adopted ASC 606 in the first quarter of 2018 using the modified retrospective method according to which the cumulative effect of initially applying ASC 606 is recognized at the date of initial application. Since we have concluded our performance obligations and have completed recognizing revenue under the 2015 CFFT Award discussed in the third quarter of 2017, there was no cumulative effect to record at the date of the our adoption of ASC 606 and no revenue to recognize for the first quarter of 2018 related to the 2015 CFFT Award. Revenue for the three months ended March 31, 2018 was $950,442, recognized in accordance with ASC 606 and pertains only to the 2018 CFF Award.

We will assess any new agreements we enter into under ASC 606, including whether such agreements fall under the scope of such standard. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The five-step model is applied to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Revenue associated with the performance obligation is being recognized as revenue as the research and development services are provided using an input method, according to the costs incurred as related to the research and development activities and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The research and development services related to this performance obligation are expected to be performed over an approximately two and a half-year period expected to be completed in the second quarter of 2020. Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion. Amounts recognized as revenue, but not yet received or invoiced are generally recognized as contract assets.

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 March 31, 2018 and 2017

Revenue

To date, we have not generated any revenues from the sales of products. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for the marketing of lenabasum, which we expect will take a number of years and is subject to significant uncertainty.

We have recognized $950,442 and $1,293,697 of revenue in the three months ended March 31, 2018 and 2017, respectively. Amounts recognized in 2017 related to an award agreement (the "2015 CFFT Award Agreement) we entered into in fiscal 2015 with the CFFT, pursuant to which we received a development award (the "2015 CFFT Award") for up to $5 million in funding. We received a total of $5 million in payments under the 2015 CFFT Award as outlined below. The payments received under the 2015 CFFT Award were recorded as deferred revenue when the triggering event to receive those amounts occurred and were amortized on a straight-line basis over the expected duration of the remaining performance period under the 2015 CFFT Award, which concluded in the third quarter of 2017.

Amounts recognized in revenue for the three months ended March 31, 2018 were in connection with the our entry on January 26, 2018 into the Cystic Fibrosis Program Related Investment Agreement ("Investment Agreement) with the Cystic Fibrosis Foundation ("CFF"), a non-profit drug discovery and development corporation, pursuant to which we received a development award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b Clinical Trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis of which we received $6.25 million in the first quarter of 2018 and subsequently in May 2018 became entitled to receive an additional $6.25 million upon our achievement of a milestone related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. We expect to receive payment from the CFF for this milestone achievement by the end of the second quarter of 2018. The remainder of the 2018 CFF Award is payable to us incrementally upon the achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. We recorded $950,442 of revenue during the three months ended March 31, 2018 under the 2018 CFFT Award Agreement. We assessed the 2018 CFF Award for accounting under ASC 606, which we adopted in the first quarter of 2018. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Research and Development Expenses

Research and development expenses are incurred for the development of lenabasum and consist primarily of payroll and payments to contract research and development companies. To date, these costs are related to generating pre-clinical data and the cost of manufacturing lenabasum for clinical trials and conducting clinical trials. These costs are expected to increase significantly in the future as lenabasum is continued to be evaluated in additional later stage clinical trials.

Research and development expenses for the three months ended March 31, 2018 totaled approximately $9,765,000 an increase of approximately $3,399,000 over the $6,366,000 recorded for the three months ended March 31, 2017. The increase was primarily attributable to increases of $2,109,000 in clinical trial costs, $861,000 in compensation costs, and $429,000 in stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll, rent and professional services such as accounting and legal services. We anticipate that our general and administrative expenses will increase significantly during 2018 and in the future as we increase our headcount to support our continued research and development and the potential commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, and tax-related services associated with maintaining compliance with NASDAQ exchange listing and SEC requirements, director and officer insurance, and investor relations costs associated with being a public company.

General and administrative expense for the three months ended March 31, 2018 totaled approximately $3,050,000, an increase of approximately $670,000 over the $2,380,000 recorded for the three months ended March 31, 2017. The increase was primarily attributable to increases of approximately $348,000 in compensation costs, $257,000 in consulting expense and an aggregate net increase of approximately $192,000 primarily for other general and administrative costs, partially offset by a decrease of $127,000 in stock-based compensation expense.

Other Income, Net

Other income, net consists primarily of interest income we earn on interest-bearing accounts, interest expense incurred on our outstanding debt, and foreign currency exchange transaction losses and gains.

Other income, net for the three months ended March 31, 2018 totaled approximately $170,000 as compared to other expense, net for the three months ended March 31, 2017 of approximately $13,000, and was primarily attributable to an increase in net interest income of approximately $202,000 due to increased cash balances in the first quarter of 2018 as compared to the first quarter of 2017, offset partially by increases in foreign currency exchange transaction losses of approximately $19,000.

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. In addition, the majority of the costs of the DM and SLE clinical trials have been or are expected to be funded by NIH grants, and our Phase 2 cystic fibrosis clinical trial was partially funded by the 2015 CFFT Award. Our Phase 2b cystic fibrosis trial is being supported by the 2018 CFF Award. At March 31, 2018, our accumulated deficit since inception was approximately $77,393,000.

At March 31, 2018, we had total current assets of approximately $74,487,000 and total current liabilities of approximately $10,277,000, resulting in working capital of approximately $64,210,000.

Net cash used in operating activities for the three months ended March 31, 2018 was approximately $1,599,000, which includes a net loss of approximately $11,695,000, adjusted for non-cash expenses of approximately $2,310,000 largely related to stock-based compensation expense, and approximately $7,786,000 of cash provided by net working capital items principally related to the receipt of $6,250,000 under the 2018 CFF Award and increases in accounts payable and accrued expenses.

Cash used in investing activities for the three months ended March 31, 2018 totaled approximately $1,270,000 which was principally related to the construction costs of our office space that we began occupying in February 2018.

Cash provided by financing activities for the three months ended March 31, 2018 totaled approximately $11,128,000. On January 5, 2018, we entered into a Controlled Equity Offering^{SM} Sales Agreement ("January 2018 Sales Agreement") with Cantor Fitzgerald pursuant to which Cantor Fitzgerald is serving as our sales agent to sell up to $50 million of shares of our common stock through an "at the market offering," of which we sold 1,500,000 shares for net proceeds of approximately $11.2 million in the first quarter of 2018.

During the three months ended March 31, 2018, the Company issued 36,465 shares of common stock upon the exercise of stock options to purchase common stock and the Company received proceeds of $156,655 from these exercises. Cash provided by financing activities for the three months ended March 31, 2018 included principal payments on notes payable of approximately $124,000 in connection with our loan agreement with a financing company. The terms of the loan that we entered into in November 2017 stipulate equal monthly payments of principal and interest payments of $41,975 over a ten-month period. Interest accrues on this loan at an annual rate of 2.35%.

We expect our cash and cash equivalents of approximately $71.0 million at March 31, 2018 and the up to $25 million of proceeds that we expect to receive under the 2018 CFF Award, of which we have received $6.25 million to date through March 31, 2018 and subsequently in May 2018 became entitled to receive an additional $6.25 million upon our achievement of a milestone related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement, to be sufficient to meet our operating and capital requirements through the end of the fourth quarter of 2019, based on current planned expenditures. The remainder of the up to $25 million 2018 CFF Award is payable to us incrementally upon the achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement.

We will need to raise significant additional capital to continue to fund operations and the clinical trials for lenabasum.

We may seek to sell common stock, including sales under our January 2018 Sales Agreement, preferred stock or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing. In addition, we may seek to raise cash through collaborative agreements or from government grants. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of 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 expenses including some or all of our planned clinical trials.

Contractual Obligations and Commitments

The following table presents information about our known contractual obligations as of March 31, 2018. It does not reflect contractual obligations that may have arisen or may arise after that date. Except for historical facts, the information in this section is forward-looking information.

	Payments due by period				
Contractual Obligations	**Total**	**Remainder of Fiscal 2018**	**Fiscal 2019-2020**	**Fiscal 2021-2022**	**After Fiscal 2022**
Operating lease obligations (1)	$ 5,381,790	$ 352,500	$ 1,408,201	$ 1,685,750	$ 1,935,339
Capital lease obligations (2)	3,786	3,407	379	—	—
Total	$ 5,385,576	$ 355,907	$ 1,408,580	$ 1.685,750	$ 1,935,339

(1) On August 21, 2017, we entered into a lease agreement ("the August 2017 Lease Agreement") with the initial term of a period of seven years which commenced in February 2018. The base rent pursuant to the August 2017 Lease Agreement ranges from approximately $470,000 for the first year to approximately $908,000 for the seventh year. The September 2016 Amendment was terminated upon the commencement date of the August 2017 Lease Agreement. Additionally, the August 2017 Lease Agreement required us to provide a standby irrevocable letter of credit of $400,000, which may be reduced, if we are not in default under the August 2017 Lease Agreement, to $300,000 and $200,000 on the third and fourth anniversary of the commencement date, respectively, We entered into an unsecured letter of credit with a commercial bank for $400,000 in connection with the August 2017 Lease Agreement.

(2) On December 30, 2015, we entered into a lease agreement for a copier machine. The machine was placed in service in January 2016. The lease is for a three-year term and includes a bargain purchase option at the end of the term.

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 March 31, 2018, other than the items in the table above, we had no material contractual obligations or commitments that will affect our future liquidity.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors, other than future royalty payments under development award agreements discussed as follows:

2015 CFFT Award

Pursuant to the terms of the 2015 CFFT Award agreement, we are obligated to make royalty payments to CFFT contingent upon commercialization of lenabasum in the Field of Use (as defined in the 2015 CFFT Award Agreement) as follows: (i) a royalty payment equal to five times the amount we receive under the 2015 CFFT Award Agreement, up to $25 million, payable in three equal annual installments following the first commercial sale of lenabasum, the first of which is due within 90 days following the first commercial sale of lenabasum, (ii) a royalty payment to CFFT equal to the amount we receive under the 2015 CFFT Award Agreement, up to $5 million, due in the first calendar year in which the aggregate cumulative net sales of lenabasum in the Field of Use exceed $500 million, and (iii) royalty payment(s) to CFFT of up to approximately $15 million if we transfer, sell or license lenabasum in the Field of Use other than for certain clinical or development purposes, or if we enter 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 CFFT Award Agreement 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 we may terminate the 2015 CFFT Award Agreement for cause, which includes our material failure to achieve certain commercialization and development milestones. Our payment obligations, if any, would survive the termination of the 2015 CFFT Award Agreement.

2018 CFF Award

Pursuant to the terms of the Investment Agreement, we are obligated to make certain royalty payments to CFF, including a royalty payment of one and one-half times the amount of the 2018 CFF Award, payable in cash within sixty days upon the first receipt of approval of lenabasum in the United States and a second royalty payment of one and one-half times the amount of the 2018 CFF Award upon approval in another major market, as set forth in the Investment Agreement (the "Approval Royalty"). At our election, we may satisfy the first of the two Approval Royalties in registered shares of our common stock.

Additionally, we are obligated to make (i) royalty payments to CFF of two and one-half percent of net sales from lenabasum due within sixty days after any quarter in which such net sales occur in the Field, as defined in the Investment Agreement, (ii) royalty payments to CFF of one percent of net sales of Non-Field Products, as defined in the Investment Agreement due within sixty days after any quarter in which such net sales occur, and (iii) royalty payments to CFF of ten percent of any amount that we and our stockholders receive in connection with the license, sale, or other transfer to a third party of lenabasum, if indicated for the treatment or prevention of CF, or a change of control transaction, except that such payment shall not exceed five times the amount of the 2018 CFF Award, with such payments to be credited against any other net sales royalty payments due. Either CFF or we may terminate the Investment Agreement for cause, which includes our material failure to achieve certain commercialization and development milestones. Our payment obligations survive the termination of the Investment Agreement.

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

Evaluation of Our Disclosure Controls

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.

Evaluation of Changes in 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

From time to time, we make changes to our internal control over financial reporting that are intended to enhance its effectiveness and which do not have a material effect on our overall 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 have to complete clinical studies and receive regulatory approval of a New Drug Application, or NDA, 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:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound;
- successfully manufacture our clinical product and establish commercial drug supply;
- obtain Drug Enforcement Administration, or DEA, licenses necessary for the manufacturing of lenabasum and for evaluating lenabasum in our clinical trials;
- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of lenabasum;
- secure market exclusivity and/or adequate intellectual property protection for lenabasum;
- attract and retain an experienced management and advisory team;
- secure acceptance of lenabasum in the medical community and with third party payors and consumers;
- launch commercial sales of lenabasum, whether alone or in collaboration with others; and
- raise sufficient funds in the capital markets to effectuate our business plan.

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 we achieve profitability, 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 lenabasum. We have been engaged in developing lenabasum since 2009. To date, we have not generated any revenue from lenabasum and we expect to incur significant expense to complete our clinical program for lenabasum in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of lenabasum in any indication in the United States or internationally. Even if we are able to commercialize lenabasum 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 years ended December 31, 2017, 2016 and 2015 were approximately $32,422,000, $19,999,000 and $8,851,000, respectively, and our net losses for the three months ended March 31, 2018 and 2017 were approximately $11,695,000 and $7,465,000, respectively. As of March 31, 2018, we had an accumulated deficit of approximately $77,393,000.

If we were to obtain FDA approval for lenabasum, we would expect that our research and development expenses will continue to increase as we advance clinical trials for indications for the treatment of cystic fibrosis, systemic sclerosis, DM and systemic lupus erythematosus, or SLE. We may elect to pursue FDA approval for lenabasum 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 further costs related to the clinical trials for lenabasum. As of March 31, 2018, our consolidated cash and cash equivalents balance was approximately $71.0 million. On January 5, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement ("January 2018 Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") pursuant to which Cantor Fitzgerald is serving as our sales agent to sell up to $50 million of shares of our common stock through an "at the market offering," of which we have sold 1,500,000 shares for net proceeds of $11.2 million to date. On January 26, 2018, we entered into the Cystic Fibrosis Program Related Investment Agreement (the "Investment Agreement") with the Cystic Fibrosis Foundation ("CFF"), a non-profit drug discovery and development corporation, pursuant to which we received a development award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b Clinical Trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis, of which we received $6.25 million in the first quarter of 2018, and subsequently in May 2018 became entitled to receive an additional $6.25 million upon our achievement of a milestone related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. We expect to receive payment from the CFF for this milestone achievement by the end of the second quarter of 2018. We expect that the remainder of the Award will be paid to us incrementally upon the achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement.

We expect our cash and cash equivalents of approximately $71.0 million at March 31, 2018 and the up to $25 million of proceeds that we expect to receive under the 2018 CFF Award, of which we have received $6.25 million to date, to be sufficient to meet our operating and capital requirements through the end of the fourth quarter of 2019, based on current planned expenditures.

Other than the January 2018 Sales Agreement and the Investment Agreement, 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, including pursuant to the January 2018 Sales Agreement due to limiting terms contained therein and sales thereunder being subject to market conditions and pursuant to the Investment Agreement due to the dependency of our receiving future payments thereunder on our achieving certain milestones described therein. If we are not successful in raising additional capital, we may not be able to continue as a going concern. 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 may choose to pursue, as an alternative, strategic collaborations that could require us to share commercial rights to lenabasum 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 lenabasum 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 lenabasum. If we are unable to generate revenues from lenabasum, our ability to create stockholder value will be limited.

Our only product candidate currently is lenabasum, for which we have completed Phase 1 safety studies and are evaluating in subsequent clinical studies. 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 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 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 lenabasum, which may never occur.

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

Our clinical trials may be unsuccessful, which would materially harm our business. Even if our ongoing clinical trials are successful, we will be required to conduct additional clinical trials to establish lenabasum's safety and efficacy, before a New Drug Application, or NDA, can be filed with the FDA for marketing approval of lenabasum.

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 lenabasum. 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 lenabasum as a prescription pharmaceutical product in the United States until we receive approval of an NDA from the FDA or comparable regulatory agencies for sales in foreign markets 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 lenabasum, including regulatory approval, are not successful for its planned indications, or if adequate demand for lenabasum is not generated, our business will be harmed.

Receipt of necessary regulatory approval is 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 lenabasum'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 lenabasum 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 lenabasum;

● 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 lenabasum 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 our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidates. 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 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. Lenabasum 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 lenabasum in any indication will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

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 lenabasum 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 lenabasum may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for lenabasum. 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.

Lenabasum is our only product candidate in development. If we fail to successfully commercialize lenabasum, 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 lenabasum. We cannot be certain that lenabasum will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize lenabasum as a treatment for cystic fibrosis, systemic sclerosis, DM, SLE 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 lenabasum, 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 lenabasum will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of lenabasum 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 lenabasum and of the target patient population to try new therapies;
- safety, tolerability and efficacy of lenabasum compared to competing products;
- the introduction of any new products that may in the future become available to treat indications for which lenabasum may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which lenabasum may show utility
- pricing and cost-effectiveness;
- the inclusion or omission of lenabasum 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 lenabasum 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 lenabasum 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 lenabasum 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 lenabasum not commercially viable. For example, regulatory authorities may approve lenabasum for fewer or more limited indications than we request, may not approve the price we intend to charge for lenabasum, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve lenabasum 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 lenabasum. 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 lenabasum.

Even if we obtain marketing approval for lenabasum, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, lenabasum 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 lenabasum.

Even if we obtain United States regulatory approval of lenabasum 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. Lenabasum 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, continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval, continued compliance with the CSA and ongoing review by the DEA. 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.

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 lenabasum 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 lenabasum, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. 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 or 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;

- 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 of, 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 lenabasum 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 lenabasum.

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 in 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 lenabasum, 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 lenabasum 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 lenabasum;

- 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 lenabasum 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 lenabasum. 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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize lenabasum 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 lenabasum, restrict or regulate post-approval activities and affect our ability to profitably sell lenabasum. 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 lenabasum, 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, under the Medicare Modernization Act, or MMA, Medicare Part D provides coverage to the elderly and disabled for outpatient prescription drugs by approving and subsidizing prescription drug plans offered by private insurers. The MMA also authorizes 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. The Part D plans use their formulary leverage to negotiate rebates and other price concessions from drug manufacturers. Also under the MMA, Medicare Part B provides coverage to the elderly and disabled for physician-administered drugs on the basis of the drug's average sales price, a price that is calculated according to regulatory requirements and that the manufacturer reports to Medicare quarterly.

Both Congress and the Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. For example, under the 2010 Affordable Care Act, drug manufacturers are required to provide a 50% discount on prescriptions for branded drugs filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." There have been legislative proposals to repeal the 'non-interference" provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for lenabasum and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors.

The 2010 Affordable Care Act is intended to broaden access to health insurance and reduce or constrain the growth of healthcare spending. Further, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also increased the amount of the rebates drug manufacturers must pay to state Medicaid programs, required that Medicaid rebates be paid on managed Medicaid utilization, and increased the additional rebate on "line extensions" (such as extended release formulations) of solid oral dosage forms of branded products. The law also contains substantial provisions affecting fraud and abuse compliance and transparency, which may require us to modify our business practices with healthcare practitioners, and incur substantial costs to ensure compliance.

The President and the majority party in both Houses of the U.S. Congress have indicated their desire to repeal the Affordable Care Act. It is unclear whether, when and how that repeal will be effectuated and what the effect on the healthcare sector will be. In addition to the potential repeal of the Affordable Care Act, there are indications that the Medicaid program may be restructured, which could lead to revisions in Medicaid coverage for prescription drugs. While we are unable to predict what legislation, if any, may potentially be enacted, to the extent that future changes affect how our product candidates could be paid for and/or reimbursed by the government and private payers, our business could be adversely affected.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 included, among other things, provisions that have led to 2% across-the-board reductions in Medicare payment amounts. Several states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional 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 lenabasum in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize lenabasum in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for lenabasum 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 lenabasum 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 lenabasum 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 lenabasum, and our commercialization of lenabasum 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 lenabasum 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 the finished lenabasum drug product in tablet form, for use in our clinical trials or for commercial product, if any. As a result, we will be obligated to rely on contract manufacturers if and when lenabasum is approved for commercialization.

We currently rely on a single foreign supplier for manufacturing the starting chemical intermediates and finished bulk drug product. We also rely on a single foreign supplier for the manufacturing of the finished lenabasum capsules. The facilities used by our two contract manufacturers to manufacture lenabasum 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 processes of, and are completely dependent on, our two 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 lenabasum. 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 lenabasum 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 lenabasum, 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 lenabasum, 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 lenabasum.

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 active pharmaceutical ingredient, or API, or our finished lenabasum product or should cease doing business with us, we could experience significant interruptions in the supply of lenabasum or may not be able to create a supply of lenabasum at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of lenabasum 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 lenabasum 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 lenabasum if we decided to transfer the manufacture of lenabasum 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 lenabasum, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to manufacture lenabasum at commercial scale on a cost-effective basis. If the commercial-scale manufacturing costs of lenabasum 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.

There are risks associated with scaling up manufacturing to commercial scale. If our contract manufacturers are unable to manufacture our product candidate, lenabasum on a commercial scale, this could potentially delay regulatory approval and commercialization or materially adversely affect our results of operations.

There are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical problems with process scale-up, process reproducibility, stability issues, and lot consistency. Even if we obtain regulatory approval for lenabasum, there is no assurance that our contract manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of the approved product for commercialization, either on a timely basis or at all, our commercialization efforts would be impaired, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Schedule I controlled substances are pharmaceutical products subject to specific regulations under the CSA, which 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 of the drug in clinical studies must apply for and obtain a license from the DEA before they are permitted to perform these activities with lenabasum. 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 lenabasum. The parties responsible for the manufacturing, distribution and export of lenabasum have already applied for and have been granted DEA licenses and a number of institutions responsible for conducting our current 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 lenabasum and could delay the completion of the 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 lenabasum 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 lenabasum.

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 and distribution of lenabasum or in the completion of our 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 lenabasum 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 lenabasum 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.

While lenabasum is a Schedule I controlled substance, if lenabasum is approved for medical use by the FDA, it will have satisfied the "accepted medical use" requirement of the CSA. If and when lenabasum receives FDA approval, the DEA will make a scheduling determination and place lenabasum in a schedule other than Schedule I or declassify it in order for it to be prescribed to patients in the United States. As part of the scheduling determination, FDA will assess the abuse and dependence potential of lenabasum and make a scheduling recommendation to DEA. If approved by the FDA, the length of time the DEA takes to complete the rescheduling or declassification of lenabasum is uncertain and could be lengthy and we will not be able to sell the drug until the rescheduling is complete. Any delays in the rescheduling could have a material adverse impact on our results of operations.

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

The import and export of lenabasum requires import and export licenses. However, because lenabasum 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 lenabasum 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 lenabasum.

We expect that we will rely on third parties to assist us in conducting clinical trials for lenabasum. 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 lenabasum and our business would be substantially harmed.

We expect to enter into agreements with third-party CROs to assist us in conducting and managing our clinical programs, including contracting with clinical sites to perform our clinical studies. We plan to rely on these parties for execution of clinical studies for lenabasum and we will control only certain aspects of conducting the clinical studies. 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 lenabasum 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, or if they breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of lenabasum 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 lenabasum. 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 lenabasum. As a result, our financial results and the commercial prospects for lenabasum 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 lenabasum 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 lenabasum 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 lenabasum, 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 lenabasum 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 lenabasum, 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 lenabasum. 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 lenabasum could be significantly reduced.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We have been granted orphan drug designation in the United States and in the European Union for lenabasum for the treatment of cystic fibrosis and systemic sclerosis. We also intend to seek orphan drug status for lenabasum for the treatment of DM. 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 lenabasum for DM 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 case our competitor would have the benefit of the seven years of 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 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 lenabasum for the treatment of DM, or other inflammatory disease indications, if we elect to seek such applications.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for lenabasum for the treatment of cystic fibrosis and systemic sclerosis in the United States and European Union and may seek fast track designation or priority review of applications for approval of our product candidate for future indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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

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

Designation of a product candidate as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe our product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

Our ability to successfully market lenabasum 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 lenabasum 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 lenabasum 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 maintaining and obtaining additional 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 in our pending applications or, the enforceability of our existing and future patents. Our pending patent applications for lenabasum and its uses may never be approved by United States or foreign patent offices and the existing patents and patent applications relating to lenabasum and related technologies may be challenged, invalidated or circumvented by third parties and may not protect us against competitors with similar products or technologies.

The degree of our current and 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 lenabasum, or important to our business. We cannot be certain that any patents or patent application owned by a third party will not have priority over patents and 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 maintain or obtain additional patent protection or trade secret protection for lenabasum 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.

Lenabasum 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 lenabasum 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 lenabasum, 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 lenabasum from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to lenabasum or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market lenabasum 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 lenabasum 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 lenabasum 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.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not aware of any asserted third-party claims challenging inventorship on our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, strategic partners, commercial counterparties or other third parties associated with us or one of our predecessors in ownership of lenabasum have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we cannot fully control the enforcement of these policies by third parties with which we contract, nor can we be certain that assignment agreements between us and our employees, between us and our counterparties, or between our counterparties and their employees or between our predecessors of ownership and their employees and counterparties, will effectively protect our interests as to any party who conceives or develops intellectual property that we regard as our own. Among other issues, the assignment of intellectual property rights may not be self-executing, the assignment agreements may be breached, or we may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. As we approach potential commercialization of our product candidates, we are more closely analyzing all facts that we believe might be used to assert an inventorship claim against us. Determinations like these involve complex sets of fact and applications of sometimes-unsettled patent law, resulting in inherent uncertainties regarding ownership rights. Determining the history of development of certain of our intellectual property is made more difficult by the fact that certain of our intellectual property was developed by other companies for other indications before being acquired by us. Consequently, we cannot be sure that we have all of the documentary records relevant to such an analysis. In the course of our analysis we have identified a potential issue regarding incomplete inventorship on certain aspects of our lenabasum portfolio that were developed prior to our acquisition of lenabasum. We are currently analyzing our options with respect to this matter, and are considering the option to negotiate commercial terms with a third party for an assignment with respect to this subject matter. In the event we proceed with this option and do not reach agreement on commercially reasonable terms, the matter may result in a dispute as to inventorship with respect to certain patent rights, which may need to be ultimately resolved by litigation.

If claims challenging inventorship are made against us, we may need to resort to litigation to resolve those claims. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of valuable intellectual property rights or the right to assert those rights against third-parties marketing competing products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

General Company-Related Risks

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

As of March 31, 2018, we had 50 full-time 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 lenabasum 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 Chief Executive Officer, 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 the price of our common stock 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 lenabasum. 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 in April 2014 with Corbus Pharmaceuticals, Inc., our wholly-owned subsidiary, 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 lenabasum.

We face a potential risk of product liability as a result of the clinical testing of lenabasum and will face an even greater risk if we commercialize lenabasum or any other future product. For example, we may be sued if any product we develop, including lenabasum, 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 lenabasum. 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 lenabasum 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 lenabasum; 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, assets or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses, assets 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 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 affiliates may control our company for the foreseeable future, including the outcome of matters requiring stockholder approval.

Our officers, directors, and five percent stockholders collectively owned approximately 19.1% of our outstanding shares of common stock as of March 31, 2018. 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 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 active, liquid trading market for our common stock may not be sustained.

Presently, our common stock is traded on the Nasdaq Global Market, or Nasdaq, and as we are in our early stages, an investment in our company may require a long-term commitment, with no certainty of return. If we are unable to maintain an active, liquid 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 could impair 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 Global Market. If we are unable to maintain listing of our securities on the Nasdaq Global 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 Global Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded.

The Listing Rules of Nasdaq 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.

The market price of our common stock may be significantly volatile.

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 a company's intellectual property rights;
- technological innovations of such companies or their competitors;
- changes in market valuations of similar companies;
- announcements by such companies or their 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 a 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 March 31, 2018, we had outstanding options to purchase an aggregate of 9,342,584 shares of our common stock at a weighted average exercise price of $4.50 per share and warrants to purchase an aggregate of 2,288,500 shares of our common stock at a weighted average exercise price of $6.33 per share.

On January 26, 2018, pursuant to the terms of the Investment Agreement, we issued a warrant to CFF to purchase an aggregate of 1,000,000 shares of our common stock (the "CFF Warrant"). The CFF Warrant is exercisable at a price equal to $13.20 per share and was immediately exercisable for 500,000 shares of our common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to us pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 500,000 shares of our common stock. The CFF Warrant expires on January 26, 2025. Any shares of our common stock issued upon exercise of the CFF Warrant will be unregistered and subject to a one-year lock-up.

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 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 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 $1.07 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 incur significantly increased costs and devote substantial management time as a result of operating as a public company, , and we expect these costs to increase 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 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 of March 31, 2018, we had 50 full-time employees, which results in a lack of segregation of duties, 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 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 detect or prevent error or fraud could materially adversely impact us.

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

We are 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. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting.

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 stock 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.

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 prior to that date 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new tax legislation, or the Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. This periodic report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation.

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
4.1	Warrant to Purchase Common Stock, dated as of January 26, 2018, issued to the Cystic Fibrosis Foundation (incorporated by reference to Exhibit 4.8 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2018).
10.1	Controlled Equity Offering[SM] Sales Agreement, dated January 5, 2018, by and between Corbus Pharmaceuticals Holdings, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 filed with the SEC on January 5, 2018).
10.2	Cystic Fibrosis Program Related Investment Agreement, dated January 26, 2018, between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company (incorporated by reference to Exhibit 10.33 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2018).#
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.

** Furnished, not filed.

Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.

EXHIBIT INDEX

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101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.*

* Filed herewith.

** Furnished, not filed.

Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.

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: May 10, 2018

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

Date: May 10, 2018

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 March 31, 2018 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 financing 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: May 10, 2018

/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 March 31, 2018 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 financing 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: May 10, 2018

/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 March 31, 2018, 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*
Yuval Cohen
Chief Executive Officer
(Principal Executive Officer)

Dated: May 10, 2018

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 March 31, 2018, 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: May 10, 2018