

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2016

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: 000-55158

COCRYSTAL PHARMA, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

35-2528215

(I.R.S. Employer Identification No.)

1860 Montreal Road

Tucker, Georgia

(Address of Principal Executive Offices)

30084

(Zip Code)

(678)-892-8800

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Sec.232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer (Do not check if a smaller reporting company)	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

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

As of May 10, 2016, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 704,255,397.

COCRYSTAL PHARMA, INC.

FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2016

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Part I – FINANCIAL INFORMATION
Cocrystal Pharma, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,242	\$ 9,276
Accounts receivable	16	32
Prepaid expenses and other current assets	486	441
Mortgage note receivable, current portion	172	170
Total current assets	10,916	9,919
Property and equipment, net	392	430
Deposits	31	31
Mortgage note receivable, long-term portion	2,333	2,354
In process research and development	146,301	146,301
Goodwill	65,195	65,195
Total assets	\$ 225,168	\$ 224,230
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	3,084	2,585
Derivative liabilities	2,807	4,115
Total current liabilities	5,891	6,700
Long-term liabilities		
Deferred rent	59	61
Deferred tax liability	49,875	49,875
Total long-term liabilities	49,934	49,936
Total liabilities	55,825	56,636
Commitments and contingencies		
Series A convertible preferred stock, \$0.001 par value; 1,000 shares authorized, 0 shares issued and outstanding.		
	-	-
Stockholders' equity:		
Series B convertible preferred stock, \$.001 par value; 5,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, \$.001 par value; 800,000 shares authorized; 704,255 and 694,396 issued and outstanding as of March 31, 2016 and December 31, 2015, respectively	704	694
Additional paid-in capital	235,207	229,456
Accumulated deficit	(66,568)	(62,556)
Total stockholders' equity	169,343	167,594
Total liabilities and stockholders' equity	\$ 225,168	\$ 224,230

Cocrystal Pharma, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)
(in thousands)

	Three months ended	
	March 31,	
	2016	2015
Grant revenues	\$ -	\$ 27
Operating expenses		
Research and development	3,342	1,560
General and administrative	1,992	635
Total operating expenses	5,334	2,195
Loss from operations	(5,334)	(2,168)
Other income (expense)		
Interest income	49	44
Change in fair value of derivative liabilities	1,273	(14,418)
Total other income (expense), net	1,322	(14,374)
Net loss	<u>\$ (4,012)</u>	<u>\$ (16,542)</u>
Comprehensive loss:		
Net loss	\$ (4,012)	\$ (16,542)
Unrealized loss on marketable securities, net of tax	-	(980)
Total comprehensive loss	<u>\$ (4,012)</u>	<u>\$ (17,522)</u>
Net loss per common share:		
Income (loss) per share, basic	\$ (0.01)	\$ (0.04)
Weighted average common shares outstanding, basic	696,149	439,892
Income (loss) per share, fully diluted	\$ (0.01)	\$ (0.04)
Weighted average common shares outstanding, diluted	697,272	439,892

Cocrystal Pharma, Inc.

CONDENSED CONSOLIDATED STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(unaudited)
(in thousands)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2015	-	\$ -	-	\$ -	694,396	\$ 694	\$ 229,456	\$ (62,556)	\$ 167,594
Exercise of warrants	-	-	-	-	27	-	35	-	35
Exercise of common stock options	-	-	-	-	20	-	3	-	3
Stock-based compensation	-	-	-	-	-	-	719	-	719
Sale of common shares	-	-	-	-	9,812	10	4,994	-	5,004
Net loss	-	-	-	-	-	-	-	(4,012)	(4,012)
Balance as of March 31, 2016	-	\$ -	-	\$ -	704,255	\$ 704	\$ 235,207	\$ (66,568)	\$ 169,343

Cocrystal Pharma, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Three months ended March 31,	
	2016	2015
Operating activities:		
Net loss	\$ (4,012)	\$ (16,542)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	56	45
Stock-based compensation	719	93
Change in fair value of derivative liabilities	(1,273)	14,418
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(29)	(72)
Accounts payable and accrued expenses	497	499
Net cash used in operating activities	<u>(4,042)</u>	<u>(1,559)</u>
Investing activities:		
Purchase of fixed assets	(18)	(5)
Principal payments received on mortgage note receivable	19	19
Net cash provided by investing activities	<u>1</u>	<u>14</u>
Financing activities:		
Proceeds from issuance of common stock	5,004	11,812
Proceeds from exercise of stock options	3	20
Net cash provided by financing activities	<u>5,007</u>	<u>11,832</u>
Net increase in cash and cash equivalents	966	10,287
Cash and cash equivalents at beginning of period	9,276	3,970
Cash and cash equivalents at end of period	<u>\$ 10,242</u>	<u>\$ 14,257</u>
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized loss on marketable securities net of tax	\$ -	\$ (980)
Estimated fair value of warrants exchanged for common shares	-	9,426
Cashless exercise of warrants	35	-

Cocrystal Pharma, Inc.
Notes to the Condensed Consolidated Financial Statements
March 31, 2016
(unaudited)

Note 1- Organization and Significant Accounting Policies

Overview

Cocrystal Pharma, Inc. (“the Company”) was formerly incorporated in Nevada under the name Biozone Pharmaceuticals, Inc. On January 2, 2014, Biozone Pharmaceuticals, Inc. sold substantially all of its assets to MusclePharm Corporation (“MusclePharm”), and, on the same day, merged with Cocrystal Discovery, Inc. (“Discovery”) in a transaction accounted for as a reverse merger. Following the merger, the Company assumed Discovery’s business plan and operations. On March 18, 2014, the Company reincorporated in Delaware under the name Cocrystal Pharma, Inc.

Effective November 25, 2014, Cocrystal Pharma, Inc. and affiliated entities completed a series of merger transactions as a result of which Cocrystal Pharma, Inc. merged with RFS Pharma, LLC, a Georgia limited liability company (“RFS Pharma”). We refer to the surviving entity of this merger as “Cocrystal” or the “Company.”

Cocrystal is a biotechnology company which develops novel medicines for use in the treatment of human viral diseases. Cocrystal has developed proprietary structure-based drug design technology and antiviral nucleoside chemistry to create antiviral drug candidates. In addition, we have licensed gene editing technologies. Our focus is to pursue the development and commercialization of broad-spectrum antiviral drug candidates that will transform the treatment and prophylaxis of hepatitis C, norovirus, influenza, hepatitis B and human papillomavirus. By concentrating our research and development efforts on viral replication inhibitors, we plan to leverage our infrastructure and expertise in these areas.

The Company operates in only one segment. Management uses cash flow as the primary measure to manage its business and does not segment its business for internal reporting or decision-making.

The Company’s activities since inception have consisted principally of acquiring product and technology rights, raising capital, and performing research and development. Successful completion of the Company’s development programs, obtain regulatory approvals of its products and, ultimately, the attainment of profitable operations are dependent on future events, including, among other things: its ability to access potential markets, secure financing, develop a customer base, attract, retain and motivate qualified personnel, and develop strategic alliances. Through March 31, 2016, the Company has funded its operations through equity offerings.

As of March 31, 2016, the Company had an accumulated deficit of \$66.6 million. During the three month period ended March 31, 2016, the Company had a loss from operations of \$4.0 million. Cash used in operating activities was approximately \$4.0 million for the three months ended March 31, 2016. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its’ drug development activities. These conditions raise substantial doubt as to the Company’s ability to continue as a going concern. The Company expects to continue to incur substantial operating losses and negative cash flows from operations over the next several years during its pre-clinical and clinical development phases.

Basis of Presentation and Significant Accounting Policies

The accompanying condensed consolidated financial statements have been prepared pursuant to the rules of the Securities and Exchange Commission (“SEC”). Certain information and footnote disclosures, normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles (“GAAP”), have been condensed or omitted pursuant to those rules and regulations. We believe disclosures made are adequate to make the information presented not misleading. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary to fairly state the financial position, results of operations and cash flows with respect to the interim condensed consolidated financial statements have been included. The results of operations for the interim periods are not necessarily indicative of the results of operations for the entire fiscal year. All intercompany accounts and transactions have been eliminated in consolidation. Reference is made to the audited annual financial statements of Cocrystal Pharma, Inc. included in our Annual Report on Form 10-K for the year ended December 31, 2015 filed on March 15, 2016 (“Annual Report”) which contain information useful to understanding the Company’s businesses and financial statement presentations. The condensed consolidated balance sheet as of December 31, 2015 was derived from the Company’s most recent audited financial statements, but does not include all disclosures required by GAAP for a year-end balance sheet. Our significant accounting policies and practices are presented in Note 2 to the financial statements included in the Form 10-K.

Use of Estimates

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

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 requires management to determine whether substantial doubt exists regarding the entity’s going concern presumption, which generally refers to an entity’s ability to meet its obligations as they become due. If substantial doubt exists but is not alleviated by management’s plan, the footnotes must specifically state that “there is substantial doubt about the entity’s ability to continue as a going concern within one year after the financial statements are issued”. In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose (a) principal conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern (before consideration of management’s plans, if any); (b) management’s evaluation of the significance of those conditions or events in relation to the entity’s ability to meet its obligations; and (c) management’s plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity’s ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management’s plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The ASU applies prospectively to all entities for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption is permitted. The Company has not adopted the provisions of this ASU. Upon adoption, the Company will use this guidance to evaluate going concern.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The Company is currently evaluating the impact of its pending adoption of the new standard on its consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-09, *Stock Compensation Topic 718: Improvements to Employee Share-based Payment Accounting*. This ASU simplifies the accounting for stock compensation on income tax accounting, classification of awards as either equity or liabilities, estimating forfeitures, and cash flow presentation. Based on this ASU, an entity should recognize all excess tax benefits and tax deficiencies, including tax benefits of dividends on share-based payment awards, as income tax expense or benefit in the income statement; they do not need to include the effects of windfalls and shortfalls in the annual effective tax rate estimate from continuing operations used for interim reporting purposes. As a result of including income tax effects from windfalls and shortfalls in income tax expense, the calculation of both basic and diluted EPS will be affected. The ASU also provides an accounting policy election for awards with service conditions to either estimate the number of awards that are expected to vest (consistent with existing U.S. GAAP) or account for forfeitures when they occur. The ASU increases the allowable statutory tax withholding threshold to qualify for equity classification from the minimum statutory withholding requirements up to the maximum statutory tax rate in the applicable jurisdiction(s). The ASU clarifies that cash paid to a taxing authority by an employer when directly withholding equivalent shares for tax withholding purposes should be considered similar to a share repurchase, and thus classified as a financing activity. All other employer withholding taxes on compensation transactions and other events that enter into the determination of net income continue to be presented within operating activities. The new standard takes effect in 2017 for public business entities and 2018 for all other entities. The Company has not adopted the provisions of ASU No. 2016-09. The Company is currently evaluating the impact of adopting ASU 2016-09 on its consolidated financial statements.

Note 2 – Fair Value Measurements

ASC 820 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 — quoted prices in active markets for identical assets or liabilities.
- Level 2 — other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.
- Level 3 — significant unobservable inputs that reflect management’s best estimate of what market participants would use to price the assets or liabilities at the measurement date.

The Company categorized its cash equivalents as Level 1 fair value measurements. The Company categorized its warrants potentially settleable in cash as Level 3 fair value measurements. The warrants potentially settleable in cash are measured at fair value on a recurring basis and are being marked to fair value at each reporting date until they are completely settled or meet the requirements to be accounted for as component of stockholders’ equity. The warrants are valued using the Black-Scholes option-pricing model as discussed in Note 4 below.

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The following table presents a summary of fair values of assets and liabilities that are re-measured at fair value at each balance sheet date as of March 31, 2016 and December 31, 2015, and their placement within the fair value hierarchy as discussed above (in thousands):

Description	March 31, 2016	Quoted Prices		
		in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	\$ 10,242	\$ 10,242	\$ -	\$ -
Total assets	<u>\$ 10,242</u>	<u>\$ 10,242</u>	<u>\$ -</u>	<u>\$ -</u>
Liabilities:				
Warrants potentially settleable in cash	\$ 2,807	\$ -	\$ -	\$ 2,807
Total liabilities	<u>\$ 2,807</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 2,807</u>
Description	December 31, 2015	Quoted Prices		
		in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	\$ 9,276	\$ 9,276	\$ -	\$ -
Total assets	<u>\$ 9,276</u>	<u>\$ 9,276</u>	<u>\$ -</u>	<u>\$ -</u>
Liabilities:				
Warrants potentially settleable in cash	\$ 4,115	\$ -	\$ -	\$ 4,115
Total liabilities	<u>\$ 4,115</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 4,115</u>

The Company has not transferred any financial instruments into or out of Level 3 classification during the three months ended March 31, 2016 or 2015. A reconciliation of the beginning and ending Level 3 liabilities for the three months ended March 31, 2016 and 2015 is as follows:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	2016	2015
	Balance, January 1,	\$ 4,115
Estimated fair value of warrants exchanged for common shares	(35)	(9,426)
Change in fair value of warrants	(1,273)	14,418
Balance at March 31	<u>\$ 2,807</u>	<u>\$ 13,456</u>

Note 3 – Stockholders’ equity

Preferred Stock — The Company has authorized up to 5,000,000 shares of preferred stock, \$0.001 par value per share, for issuance. In connection with the Merger Agreement with Discovery, the Company issued to Discovery’s security holders 1,000,000 shares of the Company’s Series B Convertible Preferred Stock (“Series B”). The Series B shares automatically converted into 205,083,086 shares of the Company’s common stock on March 3, 2015 as a result of the Company’s shareholders approving an increase in the number of the Company’s authorized common shares to 800,000,000.

In connection with the merger with RFS Pharma in November 2014, the Company created a new series of Series A Preferred Stock (“Series A”). The Series A shares automatically converted into 340,760,802 shares of the Company’s common stock on March 3, 2015 as a result of the Company’s shareholders approving an increase in the number of the Company’s authorized common shares to 800,000,000.

Common Stock — The Company has authorized up to 800,000,000 shares of common stock, \$0.001 par value per share, and had 704,255,407 shares issued and outstanding as of March 31, 2016.

On March 15, 2016, Cocrystal Pharma, Inc. (the “Company”) accepted subscription agreements representing investor commitments totaling \$5,004,370 in a private placement offering to investors who participated in the March 2015 private placement on a pro-rata basis to their participation in the March 2015 private placement (the “Offering”) of 9,812,491 shares of the Company’s common stock at a purchase price of \$0.51 per share. The purchasers included 7 members of the Company’s board of directors including Dr. Raymond F. Schinazi and Dr. Phil Frost.

Shares of common stock are reserved for future issuance as follows as of March 31, 2016 (in thousands):

	As of March 31, 2016
Stock options issued and outstanding	43,051
Authorized for future option grants	29,485
Warrants outstanding	6,175
Total	<u>78,711</u>

Note 4 – Warrants

The following is a summary of activity in the number of warrants outstanding to purchase the Company’s common stock for the three months ended March 31, 2016 and 2015 (in thousands):

	Warrants accounted for as:			Warrants accounted for as:					Total
	Equity			Liabilities					
	January 2012 warrants	March 2013 warrants	April 2013 warrants	February 2012 warrants	August 2013 warrants	October 2013 warrants	October 2013 Series A warrants	January 2014 warrants	
Outstanding, December 31, 2014	650	455	1,864	1,000	10,000	200	7,000	5,500	26,669
Warrants exercised	-	-	(364)	-	(7,000)	(200)	(6,125)	(300)	(13,989)
Warrants Issued									
Outstanding, March 31, 2015	650	455	1,500	1,000	3,000	-	875	5,200	12,680
Outstanding, December 31, 2015	650	455	1,500	1,000	-	-	675	4,000	8,280
Warrants Expired	(650)	(455)		(889)					(1,994)
Warrants exercised				(111)					(111)
Outstanding, March 31, 2016	-	-	1,500	-	-	-	675	4,000	6,175
Expiration date	January 11, 2016	March 1, 2016	April 25, 2018	February 28, 2016	August 26, 2023	October 18, 2018	October 24, 2023	January 16, 2024	

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Warrants consist of warrants potentially settleable in cash, which are liability-classified warrants, and equity-classified warrants.

Warrants classified as liabilities

Liability-classified warrants consist of warrants issued in connection with equity financings in February 2012, August 2013, October 2013 and January 2014. The remaining warrants issued in February 2012 expired during the first quarter of 2016 and all of the August 2013 warrants have been exercised as of December 31, 2015. The remaining outstanding warrants are potentially settleable in cash and were determined not to be indexed to the Company's own stock and are therefore accounted for as liabilities.

The estimated fair value of outstanding warrants accounted for as liabilities is determined at each balance sheet date. Any decrease or increase in the estimated fair value of the warrant liability since the most recent balance sheet date is recorded in the consolidated statement of comprehensive loss as changes in fair value of derivative liabilities. The fair value of the warrants classified as liabilities is estimated using the Black-Scholes option-pricing model with the following inputs as of March 31, 2016:

	October 2013 warrants	January 2014 warrants
Strike price	\$ 0.50	\$ 0.50
Expected term (years)	7.6	7.8
Cumulative volatility %	100%	100%
Risk-free rate %	1.64%	1.66%

The Company's expected volatility is based on a combination of implied volatilities of similar publicly traded entities given that the Company has limited history of its own observable stock price. The expected life assumption is based on the remaining contractual terms of the warrants. The risk-free rate is based on the zero coupon rates in effect at the balance sheet date. The dividend yield used in the pricing model is zero, because the Company has no present intention to pay cash dividends.

Warrants classified as equity

Warrants that were recorded in equity at fair value upon issuance, and are not reported as liabilities on the balance sheet, are included in the above table which shows all warrants.

Note 5 – Stock-based compensation

The Company recorded approximately \$719,000 and \$93,000 of stock-based compensation related to employee stock options for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2016, there was \$10,557,000 of unrecognized compensation cost related to outstanding options that is expected to be recognized as a component of the Company's operating expenses over a weighted average period of 4.0 years.

As of March 31, 2016, an aggregate of 72,536,000 shares of common stock were reserved for issuance under the Company's Equity Incentive Plans, including 43,051,000 shares subject to outstanding common stock options granted under the plan and 29,485,000 shares available for future grants. The administrator of the plan determines the times when an option may become exercisable at the time of grant. Vesting periods of options granted to date have not exceeded five years. The options generally will expire, unless previously exercised, no later than ten years from the grant date. The Company is using unissued shares for all shares issued for options and restricted share awards.

The following schedule presents activity in the Company's outstanding stock options for the three months ended March 31, 2016 (in thousands, except per share amounts):

	Number of shares available for grant	Total options outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Balance at December 31, 2015	29,485	43,071	\$ 0.48	\$ 9,252
Exercised	-	(20)	0.15	(11)
Granted	-	-	-	-
Cancelled	-	-	-	-
Balance at March 31, 2016	<u>29,485</u>	<u>43,051</u>	\$ 0.48	\$ 9,041

As of March 31, 2016, options to purchase 43,051,200 shares of common stock, with an aggregate intrinsic value of \$9,041,000, were outstanding that were fully vested or expected to vest with a weighted average remaining contractual term of 4.0 years. As of March 31, 2016, options to purchase 20,104,482 shares of common stock, with an intrinsic value of \$9,794,970 were exercisable with a weighted average exercise price of \$0.20 per share and a weighted average remaining contractual term of 3.9 years. The aggregate intrinsic value of outstanding and exercisable options at March 31, 2016 was calculated based on the closing price of the Company's common stock as reported on the Over-the-Counter Bulletin Board and the OTCQx markets on March 31, 2016 of \$0.69 per share less the exercise price of the options. The aggregate intrinsic value is calculated based on the positive difference between the closing fair market value of the Company's common stock and the exercise price of the underlying options.

Note 6 – Net Loss per Share

The Company accounts for and discloses net loss per common share in accordance with FASB ASC Topic 260, *Earnings Per Share*. Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding (which includes the common share equivalents of the outstanding Series B preferred shares prior to their conversion to common stock in March 2015). Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants. Because the inclusion of potential common shares would be anti-dilutive for the three months ended March 31, 2015, diluted net loss per common share is the same as basic net loss per common share for these periods.

The following table sets forth the number of potential common shares excluded from the calculations of net loss per diluted share because their inclusion would be anti-dilutive (in thousands):

	Three months ended March 31,	
	2016	2015
Options to purchase common stock	43,051	21,144
Warrants to purchase common stock	-	12,680
Total	<u>43,051</u>	<u>33,824</u>

Note 7 - Mortgage Note Receivable

In June 2014, the Company acquired a mortgage note from a bank for \$2,626,290 which is collateralized by, among other things, the underlying real estate and related improvements. The property subject to the mortgage is owned by an entity managed by Daniel Fisher, one of the founders of Biozone, and is currently under lease to MusclePharm. At March 31, 2016, the carrying amount of the mortgage note receivable was \$2,505,000, which consisted of \$2,388,000 of principal, \$93,000 of interest and \$24,000 of fees paid to the selling bank. The mortgage note has a maturity date of August 1, 2032 and bears an interest rate of 7.24%. The Company records its mortgage note receivable at the amount advanced to the borrower, which includes the stated principal amount and certain loan origination and commitment fees that are recognized over the term of the mortgage note. Interest income is accrued as earned over the term of the mortgage note. The Company evaluates the collectability of both interest and principal of the note to determine whether it is impaired. The note would be considered to be impaired if, based on current information and events, the Company determined that it was probable that it would be unable to collect all amounts due according to the existing contractual terms. If the note were considered to be impaired, the amount of loss would be calculated by comparing the recorded investment to the value determined by discounting the expected future cash flows at the note's effective interest rate or to the fair value of the Company's interest in the underlying collateral, less the cost to sell. No impairment loss has been recognized in connection with the mortgage note receivable.

However, on December 23, 2015, the Company issued notice of default letters to 580 Garcia Properties, Daniel Fisher and Sharon Fisher for failure to remit certain payments on a promissory note executed between the parties in June 2014. Cocrystal Pharma, Inc. also exercised a failure to pay provision within that note to escalate the interest rate from 7.24% to 11.24%. As of March 31, 2016, the additional amounts due Cocrystal Pharma, Inc. total approximately \$245,000. Due to the contingent nature of this default action, Cocrystal Pharma, Inc. has not recorded a receivable for this amount in its 2015 or 2016 financial statements.

Note 8 – Income Taxes

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. The Company has recorded a net deferred tax liability of \$49,875,000 as of March 31, 2016 and December 31, 2015 as it has not considered the deferred tax liability, which is related to acquired in-process research and development, to be a future source of taxable income in evaluating the need for a valuation allowance against its deferred tax assets due to the in-process research and development asset being considered an indefinite-lived intangible asset.

FASB ASC Topic 740, Income Taxes ("ASC 740"), prescribes a recognition threshold and a measurement criterion for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be considered more likely than not to be sustained upon examination by taxing authorities. The Company records interest and penalties related to uncertain tax positions as a component of the provision for income taxes. As of March 31, 2016 and December 31, 2015, the Company had no unrecognized tax benefits.

The Company currently files income tax returns in the United States federal and various state jurisdictions. The Company is not currently under examination in any jurisdiction

Note 9 - Contingencies

From time to time, the Company is a party to, or otherwise involved in, legal proceedings arising in the normal course of business. As of the date of this report, except as described below, the Company is not aware of any proceedings, threatened or pending, against it which, if determined adversely, would have a material effect on its business, results of operations, cash flows or financial position.

The Company has been named as a party to a lawsuit filed on April 15, 2014 in Contra Costa County, California by an entity managed by Mr. Daniel Fisher. Also named in this action are two of the Company's subsidiaries – BioZone Laboratories and Cocystal Discovery. The action seeks recovery on a promissory note purportedly executed by BioZone Laboratories in the principal amount of \$295,000 in 2007, or almost seven years before the Company's acquisition of Cocystal Discovery. Motions challenging the sufficiency of the allegations in the complaint were filed in the third quarter, 2014. The motions were granted and plaintiff was given an opportunity to amend the complaint, and plaintiff has filed an amended complaint. On July 2, 2015 the Company, along with its subsidiaries and other named defendants, filed a motion to bifurcate the action, and stay discovery on one of the causes of action. This motion was granted on August 27, 2015 and the Court limited the scope of discovery in the first phase of the case. The Court also ordered that the Company post a bond for the amount of \$295,000, and the Company complied with the Order by posting the bond on September 29, 2015. This is recorded as a short-term deposit. At a hearing held April 19, 2016 the Court ordered the parties to attempt resolution through a mediation. This mediation will be scheduled to take place in May or June 2016.

On October 13, 2013, Plaintiff Shefa LMV, LLC ("Plaintiff") filed a First Amended Complaint in Los Angeles Superior Court for civil penalties and injunctive relief against numerous retailers and manufacturers of products, and alleged violations of California Health & Safety Code Sec. 25249.6 (part of the "Safe Drinking Water and Toxic Enforcement Act") and California Business & Professional Code Sec. 17200, et seq. (California's "Unfair Competition Law"). The case is captioned Shefa LMV, LLC v. Walgreens Co., et al., LASC Case No. BC520416. The complaint alleges that the retailers and manufacturers failed to place a clear and reasonable warning on the products which contained "Cocamide DEA" pursuant to the Safe Drinking Water and Toxic Enforcement Act, and further requested that the defendants be enjoined from manufacturing or selling products with Cocamide DEA in the State of California. Numerous actions that had been filed alleging similar claims against defendants who manufactured and/or sold Cocamide DEA products have been coordinated, with a new Judicial Council Coordination Proceeding Case No. JCCP 4765. On October 17, 2014, Plaintiff filed an amendment to the Complaint, adding BioZone Laboratories, Inc. a California corporation, as Doe Defendant No. 9. The Company filed an Answer to the First Amended Complaint on October 13, 2015. No discovery has taken place yet.

In October 2015, Cocystal Pharma, Inc. received a subpoena from the staff of the Securities and Exchange Commission seeking the production of documents. The Company is fully cooperating with the inquiry. The Company cannot predict or determine whether any proceeding may be instituted in connection with the subpoena or the outcome of any proceeding that may be instituted.

In December 2015, Cocystal Pharma, Inc. issued notice of default letters to 580 Garcia Properties, Daniel Fisher and Sharon Fisher for failure to remit certain payments on a promissory note executed between the parties in June, 2014. Cocystal Pharma, Inc. also exercised a failure to pay provision within that note to escalate the interest rate from 7.24% to 11.24%. As of March 31, 2016 the additional amounts due Cocystal Pharma, Inc. total approximately \$245,000. Due to the contingent nature of this default action, Cocystal Pharma, Inc. has not recorded a receivable for this amount in its 2015 or 2016 financial statements.

Note 10 - Transactions with Related Parties.

As part of the merger (that occurred on November 25, 2014) with RFS Pharma, LLC, Cocystal assumed the lease for RFS Pharma facilities located in Tucker, Georgia. This lease was amended on January 1, 2014 and expires on December 31, 2016 for approximately 5,626 square feet of office and laboratory space. Cocystal leases the Tucker, Georgia facility from a trust established, in part, for the benefit of one of Cocystal's Directors, Dr. Raymond Schinazi. This lease terminates December 31, 2016. The total rent expense was \$46,000 and \$45,000 for the three months ended March 31, 2016 and 2015, respectively.

Emory University: Cocystal Pharma has an exclusive license from Emory University for use of certain inventions and technology related to inhibitors of HCV that were jointly developed by Emory and Cocystal Pharma employees. The License Agreement is dated March 7, 2013 wherein Emory agrees to add to the Licensed Patents and Licensed Technology Emory's rights to any patent, patent application, invention, or technology application that is based on technology disclosed within three (3) years of March 7, 2013. The agreement includes payments due to Emory ranging from \$40,000 to \$500,000 based on successful achievement of certain drug development milestones. Additionally, Cocystal may have royalty payments at 3.5% of net sales due to Emory with a minimum in year one of \$25,000 and increase to \$400,000 in year five upon product commercialization. One of Cocystal's Directors, Dr. Raymond Schinazi, is also a faculty member at Emory University and may share in these royalty payments with Emory.

Duke University and Emory University: Cocystal Pharma has entered an agreement to license various patents and know-how to use CRISPR/Cas9 technologies for developing a possible cure for hepatitis B virus (HBV) and human papilloma virus (HPV). This license allows Cocystal Pharma to develop and potentially commercialize a cure for HBV and HPV utilizing the underlying patents and technologies developed by the universities. This agreement includes a non-refundable \$100,000 license fee payable to Duke upon a determination of rights letter from the U.S. Veterans Administration with respect to patents and know-how that disclaims any ownership interest. Future royalties may be payable to Duke, ranging from 2-5% of net sales depending on achieving certain sales milestones, if commercial products are developed using this know-how. One of Cocystal's Directors, Dr. Raymond Schinazi, is also a faculty member at Emory University and may share in these royalty payments with Emory.

We have engaged seven physicians that comprise our Scientific Advisory Board. These physicians are compensated approximately \$25,000 per quarter collectively for providing their expertise. Three of these physicians are also investors in our company.



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

Overview

Cocrystal is a biotechnology company working to develop novel medicines for use in the treatment of human viral diseases. Cocrystal has developed proprietary structure-based drug design technology and antiviral nucleoside chemistry to create first-in-class and best-in-class antiviral drug candidates. Our focus is to pursue the development and commercialization of broad-spectrum antiviral drug candidates that will transform the treatment and prophylaxis of hepatitis C, norovirus, and influenza. By concentrating our research and development efforts on viral replication inhibitors, we plan to leverage our infrastructure and expertise in these areas.

Highlights

During the last three months, the Company focused on its research and development efforts as it moves toward seeking regulatory approval to commence clinical trials.

- **Hepatitis C.** For our HCV Non-Nucleoside Polymerase Inhibitor CC-31244, IND enabling studies have been completed and our first in-human studies began in April, 2016. The preclinical safety profile, drug resistance profile and antiviral activity of this potential best-in-class pan-genotypic HCV NNI continues to suggest that the compound may be an important component of an all-oral, short duration HCV regimen.
- We are working out scalable chemistry for CC-1845 nucleotide diastereomer separation and will focus on developing a single diastereomer with the best product profile for potential clinical advancement. This will extend the preclinical timeline. A backup nucleoside inhibitor for HCV is currently undergoing scale-up for further preclinical evaluation. We will select the nucleotide with the best profile and initiate IND-enabling studies.
- We have evaluated four possible diastereomers of CC-2068 (HCV NS5A inhibitor) in several HCV replicons representing different genotypes and resistance mutants. CC-2069 was found to have superior characteristics and was selected from among those four candidates for further preclinical profiling.
- We are also developing pan-genotypic HCV NS3 helicase inhibitors that specifically block the unwinding activity of HCV NS3 helicase. We have demonstrated a strong synergistic effect of these inhibitors with other HCV direct-acting antiviral agents (DAA) in vitro. Our novel NS3 helicase inhibitor could be developed as part of an all oral, pan-genotypic combination regimen.
- **Norovirus.** We continue to identify and develop nucleoside and non-nucleoside polymerase inhibitors.
- **Influenza.** We are developing novel PB2 inhibitors that are designed to be effective against all strains of influenza A and B viruses. Current lead candidates target an enzyme complex essential to influenza viral replication, and showed excellent in vitro potency and acceptable pharmacokinetic properties.

Results of Operations for the Three Months Ended March 31, 2016 compared to the Three Months Ended March 31, 2015

Revenue

As stated above, we are focused on research and development of novel medicines for use in the treatment of human viral diseases. We had \$0 and \$27,000 in grant revenue for our collaboration with the University of Mississippi on an R01 grant from the National Center of Complementary and Alternative Medicine for the three months ended March 31, 2016 and 2015.

Research and Development Expense

Research and development expense consists primarily of compensation-related costs for our employees dedicated to research and development activities and for our Scientific Advisory Board members, as well as lab supplies, lab services, and facilities and equipment costs. We expect research and development expenses to increase in future periods as we expand our pre-clinical development activities.

Total research and development expenses were approximately \$3,342,000 for the three months ended March 31, 2016, compared with \$1,560,000 for the three months ended March 31, 2015. The increase of \$1,782,000, or 114%, was due to a \$1,142,000 increase in pre-clinical and clinical costs as we ramp up drug development programs, a \$390,000 increase in professional fees for consulting services engaged to support initiation of a Phase I clinical trial, and \$250,000 in compensation and other operating costs.

General and Administrative Expense

General and administrative expense includes compensation-related costs for our employees dedicated to general and administrative activities, legal fees, audit and tax fees, consultants and professional services, and general corporate expenses.

General and administrative expenses were approximately \$1,992,000 for the three months ended March 31, 2016, compared with \$635,000 for the three months ended March 31, 2015. The increase of \$1,357,000, or 214%, was due to a \$758,000 increase in compensation-related costs primarily related to stock options and additions of key executive staff, increased professional fees of \$454,000 primarily for expenses related to ongoing legal proceedings (See Part II, Item I-Legal Proceedings), and other operating expenses of \$145,000 (primarily travel and facility-related expenses).

Interest Income/Expense

Interest income was \$49,000 for the three months ended March 31, 2016, compared to \$44,000 for the three months ended March 31, 2015. These amounts represents interest earned on the mortgage note we acquired in June 2014. Interest expense was negligible for each of the three months ended March 31, 2016 and 2015. The key objectives of our investment policy are to preserve principal and ensure sufficient liquidity, so our invested cash may not earn as high a level of income as longer-term or higher risk securities, which generally have less liquidity and more volatility.

Other Income/Expense

Other income for the three months ended March 31, 2016 was \$1,273,000 which was a non-cash item resulting from a decrease in the fair value of the outstanding warrants to purchase our common stock, which are accounted for as liabilities, as our stock price decreased during the period, 111,111 warrants were exercised and 888,889 expired. Under accounting principles generally accepted in the United States, we record other income or expense for the change in fair value of our outstanding warrants that are accounted for as liabilities during each reporting period. If the fair value of the warrants were to decrease during the period, which it did in the three months ended March 31, 2016, we record other income. The fair value of our outstanding warrants is inversely related to the fair value of the underlying common stock; as such, an increase in the fair value of our common stock during a given period generally results in other expense while a decrease in the fair value of our common stock, which occurred during the three months ended March 31, 2016, generally results in other income. For the three months ended March 31, 2015, we recorded other expense of \$14,418,000 as our stock price increased substantially during the period, leading to an increase in the fair value of the warrants. This other income or expense is non-cash. We believe investors should focus on our operating loss rather than net loss for the periods presented. Our operating loss for the three months ended March 31, 2016 was \$5,334,000 compared to \$2,168,000 for the same period in 2015.

Income Taxes

As a result of our cumulative losses, we have concluded that a full valuation allowance against our net deferred tax assets is appropriate. We have recorded a net deferred tax liability of \$49,875,000 as of March 31, 2016 and December 31, 2015 as we have not considered the deferred tax liability, which is related to acquired in-process research and development, to be a future source of taxable income in evaluating the need for a valuation allowance against our deferred tax assets due to the in-process research and development asset being considered an indefinite-lived intangible asset.

Net Loss

As a result of the above factors, for the three months ended March 31, 2016, we had a net loss of approximately \$4,012,000 compared to a net loss of approximately \$17,522,000 for the same period in 2015. The decrease in net loss is primarily attributable to the \$15.7 million difference in the amount recorded during the periods related to the change in the fair value of our warrant liabilities, as described above, offset by increases in operating costs. We believe investors should focus on our operating loss rather than net loss for the periods presented. Our operating loss, which does not include the change in the value of derivative liabilities, a non-cash expense, for the three months ended March 31, 2016 was \$5,334,000 compared to \$2,168,000 for the same period in 2015.

Liquidity and Capital Resources

Net cash used in operating activities was approximately \$4,042,000 for the three months ended March 31, 2016 compared to \$1,559,000 for the same period in 2015. For the three months ended March 31, 2016, net cash used by operating activities consisted primarily of \$5,334,000 in operating expenses net of changes in operating assets and liabilities.

Net cash provided by investing activities was \$1,000 for the three months ended March 31, 2016 compared to \$14,000 for the same period in 2015. Principal payments received on our mortgage note receivable of \$19,000 were mostly offset by capital spending of \$18,000 during the period ended March 31, 2016.

Net cash provided by financing activities was approximately \$5,007,000 for the three months ended March 31, 2016 compared to cash provided by financing activities of \$11,832,000 for the same period in 2015. Net cash provided by financing activities for the three months ended March 31, 2016 amounted to approximately \$5,004,000 in proceeds from a private placement and \$3,000 in proceeds from the exercise of stock options for the three months ended March 31, 2016. For the three months ended March 31, 2015, cash provided by financing activities was a result of our sale of common stock and warrants, which resulted in proceeds of \$11,812,000, and proceeds from the exercise of stock options of \$20,000.

We have a history of operating losses as we have focused our efforts on raising capital and research and development activities. The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has never been profitable, has no products approved for sale, has not generated any revenues to date from product sales, and has incurred significant operating losses and negative operating cash flows since inception. For the year ended December 31, 2015, the Company recorded a net loss of approximately \$50.1 million and used approximately \$10.3 million of cash in operating activities. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its drug development activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

In March 2016, the Company received \$5,004,370 in a private placement. The Company does not believe that its cash on hand of \$7.6 million as of May 10, 2016, will be sufficient to allow the Company to fund its current operating plan for at least the next 12 months. As the Company continues to incur losses, achieving profitability is dependent upon the successful development, approval and commercialization of its product candidates, and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through additional private or public equity offering and may seek additional capital through arrangements with strategic partners or from other sources. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all. Any equity financing may be very dilutive to existing shareholders.

Tabular Disclosure of Contractual Obligations

Contractual Obligations (\$ in thousands)

	Payments due by period			
	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations	\$ 361	\$ 341	\$ -	\$ -

Cautionary Note Regarding Forward-Looking Statements

This report includes forward-looking statements including statements regarding our drug development activities, future equity offering, cash flow deficit and liquidity. The words “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “could,” “target,” “potential,” “is likely,” “will,” “expect” and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs.

The results anticipated by any or all of these forward-looking statements might not occur. Important factors that could cause actual results to differ from those in the forward-looking statements include the continued strength of the market for bio pharma equity offerings, unanticipated events which adversely affect the timing and success of our regulatory filings, failure to develop products which are deemed safe and effective and other issues which affect our ability to commercialize our product candidates. Further information on our risk factors is contained in our filings with the SEC, including our Annual Report on Form 10-K. We undertake no obligation to publicly update or revise any forward-looking statements, whether as the result of new information, future events or otherwise.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 requires management to determine whether substantial doubt exists regarding the entity’s going concern presumption, which generally refers to an entity’s ability to meet its obligations as they become due. If substantial doubt exists but is not alleviated by management’s plan, the footnotes must specifically state that “there is substantial doubt about the entity’s ability to continue as a going concern within one year after the financial statements are issued”. In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose (a) principal conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern (before consideration of management’s plans, if any); (b) management’s evaluation of the significance of those conditions or events in relation to the entity’s ability to meet its obligations; and (c) management’s plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity’s ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management’s plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The ASU applies prospectively to all entities for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption is permitted. The Company has not adopted the provisions of this ASU. Upon adoption, the Company will use this guidance to evaluate going concern.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The Company is currently evaluating the impact of its pending adoption of the new standard on its consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-09, *Stock Compensation Topic 718: Improvements to Employee Share-based Payment Accounting*. This ASU simplifies the accounting for stock compensation on income tax accounting, classification of awards as either equity or liabilities, estimating forfeitures, and cash flow presentation. Based on this ASU, an entity should recognize all excess tax benefits and tax deficiencies, including tax benefits of dividends on share-based payment awards, as income tax expense or benefit in the income statement; they do not need to include the effects of windfalls and shortfalls in the annual effective tax rate estimate from continuing operations used for interim reporting purposes. As a result of including income tax effects from windfalls and shortfalls in income tax expense, the calculation of both basic and diluted EPS will be affected. The ASU also provides an accounting policy election for awards with service conditions to either estimate the number of awards that are expected to vest (consistent with existing U.S. GAAP) or account for forfeitures when they occur. The ASU increases the allowable statutory tax withholding threshold to qualify for equity classification from the minimum statutory withholding requirements up to the maximum statutory tax rate in the applicable jurisdiction(s). The ASU clarifies that cash paid to a taxing authority by an employer when directly withholding equivalent shares for tax withholding purposes should be considered similar to a share repurchase, and thus classified as a financing activity. All other employer withholding taxes on compensation transactions and other events that enter into the determination of net income continue to be presented within operating activities. The new standard takes effect in 2017 for public business entities and 2018 for all other entities. The Company has not adopted the provisions of ASU No. 2016-09. The Company is currently evaluating the impact of adopting ASU 2016-09 on its consolidated financial statements.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the year ended December 31, 2015, we disclosed our critical accounting policies and estimates upon which our financial statements are derived. There have been no changes to these policies since December 31, 2015. Readers are encouraged to review these disclosures in conjunction with the review of this report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

There has been no material change in our assessment of sensitivity to market risk since our presentation set forth in Item 7A “Quantitative and Qualitative Disclosures about Market Risk” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

ITEM 4. CONTROLS AND PROCEDURES

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act. Our management is also required to assess and report on the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 (“Section 404”). Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2016. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework (2013)*. During our assessment of the effectiveness of internal control over financial reporting as of March 31, 2016, we identified the following material weaknesses:

COSO Components – Control Environment

We did not maintain an effective control environment, which is the foundation and structure necessary for effective internal control over financial reporting, as evidenced by: (i) lack of segregation of duties over individuals responsible for certain key control activities; (ii) an insufficient number of personnel appropriately qualified to perform control monitoring activities, including the recognition of the risks and complexities of transactions; and (iii) an insufficient number of personnel with the appropriate level of GAAP knowledge and experience commensurate with our financial reporting requirements. This control environment material weakness contributed to the company not having effective controls to ensure that potential errors or misstatements may occur, but may not be detected.

Risk Assessment, Monitoring Activities and Control Activities - Segregation of Duties

We did not maintain adequate segregation of duties in our accounting and financial reporting processes. We have not appropriately restricted access to our accounting applications to appropriate users and do not have processes in place that ensure that appropriate segregation of duties is maintained. Certain personnel have access to financial applications, programs and data beyond that needed to perform their individual job responsibilities and without independent monitoring. This allows for the creation, review and processing of certain financial data without independent review and authorization. There are also certain financial personnel that have incompatible duties, including in the areas of cash disbursements, payroll, and journal entry reviews. We have not yet completed the process of assigning different people the responsibilities of authorizing transactions, recording transactions, and maintaining custody of assets to reduce the opportunities to allow any person to be in a position to both perpetrate and conceal errors or fraud in the normal course of the person’s duties. Particularly in the areas of purchases, cash disbursements, and payroll, certain individuals have incompatible duties that limit our ability to identify and detect errors or fraud that may occur.

Risk Assessment, Monitoring Activities and Control Activities - Supervision and Review of Complex Accounting Areas

The Company lacks sufficient qualified personnel to review conclusions reached regarding the accounting for complex transactions and related analyses to record amounts resulting from such transactions in our financial records. For calculations related to stock-based compensation and the fair value of our derivative liabilities in particular, there is a lack of review of assumptions used and the underlying calculations made by the preparer of this information that are then used to record amounts in our financial statements. There is also a lack of review of assumptions used and documentation of the sources of information used in our evaluation of the fair value of our in-process research and development intangible asset. Our internal control over these processes would not allow for employees to detect a material misstatement in these areas in the normal course of performing their duties.

Risk Assessment, Information and Communication - Authorization, Identification and Reporting of Related Party Transactions

We do not have processes in place to ensure that all related party transactions, including those entered into with or on behalf of related parties, (1) have been identified, (2) are properly authorized prior to entering into the transaction, and (3) are properly monitored and evaluated for appropriate recording and presentation in the financial statements.

Monitoring Activities and Control Activities - Financial Reporting Process

We did not maintain an effective financial reporting process to prepare financial statements in accordance with U.S. GAAP. Specifically, our process lacked timely and complete financial statement reviews and procedures to ensure all required disclosures were made in our financial statements. We also lacked a process to review information used to prepare our financial statements and disclosures and did not have adequate segregation of duties over preparation of the financial statements.

The material weaknesses identified by management could result in a material misstatement to our annual or interim financial statements that would not be prevented or detected. Management has concluded that our internal control over financial reporting was not effective as of March 31, 2016 due to the material weaknesses identified.

A material weakness (within the meaning of PCAOB Auditing Standard No. 5) is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness; yet important enough to merit attention by those responsible for oversight of Cocrystal's financial reporting.

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

Remediation Plan

The Company recognized that it did not maintain an effective control environment during 2015 and the first quarter of 2016 which contributed to the company not having effective controls to ensure that potential errors or misstatements may occur, but may not be detected. During Q1 2016, the company began evaluation of the various risk control matrices to identify the key versus non-key activities and related controls.

Segregation of Duties-The Company has developed a Segregation of Duties Matrix and is in the process of updating business processes, documentation and job roles to fully implement this matrix. We have not yet completed the process of assigning different people the responsibilities of authorizing transactions, recording transactions, and maintaining custody of assets to reduce the opportunities to allow any person to be in a position to both perpetrate and conceal errors or fraud in the normal course of the person's duties. Our financial software does not provide robust administrative tools to effectively segregate roles, especially with limited financial staff. The Company will be evaluating a replacement financial system in 2016 but will also focus on effective compensating controls until the financial software can be upgraded or replaced.

Supervision and Review of Complex Accounting Areas-During 2015, the Chief Financial Officer was responsible for calculations related to stock-based compensation and the fair value of derivative liabilities. As conducted in 2015, this process did not provide the appropriate level of review of assumptions and underlying calculations to detect material misstatements. For first quarter 2016, the Controller prepared these complex calculations and the Chief Financial Officer reviewed those prior to adjusting any valuations in the financial statements.

Authorization, Identification and Reporting of Related Party Transactions- During 2015, the Company added a General Counsel position to the organization. The Company is in the process of developing contracting procedures that will require both the General Counsel and Chief Financial Officer to review and approve all new contracts and agreements, prior to approval by the Chief Executive Officer. The Company is also in the process of tightening procurement processes to ensure competitive bids are requested and the vendors participating in these bids are more thoroughly researched prior to any Company commitments.

More formal financial statement review processes will be established and will include the CEO and General Counsel, in addition to the CFO. A disclosure checklist is being developed to help ensure the adequacy and timeliness of all financial statement disclosures.

Changes in Internal Control over Financial Reporting

The addition of a contract Controller to our organization in early 2016, has helped further segregate roles within the finance organization. The Controller provided all the calculations related to stock-based compensation and the fair value of derivative liabilities. This Controller also performed most of the journal entry processing and review of the Accountant's account analysis. These changes resulted in having the CFO perform oversight and review instead of direct processing. No other changes were made to our internal control over financial reporting during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, the Company is a party to, or otherwise involved in, legal proceedings arising in the normal course of business. As of the date of this report, except as described below, the Company is not aware of any proceedings, threatened or pending, against it which, if determined adversely, would have a material effect on its business, results of operations, cash flows or financial position.

The Company has been named as a party to a lawsuit filed on April 15, 2014 in Contra Costa County, California by an entity managed by Mr. Daniel Fisher. Also named in this action are two of the Company's subsidiaries – BioZone Laboratories and Cocystal Discovery. The action seeks recovery on a promissory note purportedly executed by BioZone Laboratories in the principal amount of \$295,000 in 2007, or almost seven years before the Company's acquisition of Cocystal Discovery. Motions challenging the sufficiency of the allegations in the complaint were filed in the third quarter, 2014. The motions were granted and plaintiff was given an opportunity to amend the complaint, and plaintiff has filed an amended complaint. On July 2, 2015 the Company, along with its subsidiaries and other named defendants, filed a motion to bifurcate the action, and stay discovery on one of the causes of action. This motion was granted on August 27, 2015 and the Court limited the scope of discovery in the first phase of the case. The Court also ordered that the Company post a bond for the amount of \$295,000, and the Company complied with the Order by posting the bond on September 29, 2015. This is recorded as a short-term deposit. At a hearing held April 19, 2016 the Court ordered the parties to attempt resolution through a mediation. This mediation will be scheduled to take place in May or June 2016.

On October 13, 2013, Plaintiff Shefa LMV, LLC ("Plaintiff") filed a First Amended Complaint in Los Angeles Superior Court for civil penalties and injunctive relief against numerous retailers and manufacturers of products, and alleged violations of California Health & Safety Code Sec. 25249.6 (part of the "Safe Drinking Water and Toxic Enforcement Act") and California Business & Professional Code Sec. 17200, et seq. (California's "Unfair Competition Law"). The case is captioned Shefa LMV, LLC v. Walgreens Co., et al., Los Angeles Superior Court Case No. BC520416. The complaint alleges that the retailers and manufacturers failed to place a clear and reasonable warning on the products which contained "Cocamide DEA" pursuant to the Safe Drinking Water and Toxic Enforcement Act, and further requested that the defendants be enjoined from manufacturing or selling products with Cocamide DEA in the State of California. Numerous actions that had been filed alleging similar claims against defendants who manufactured and/or sold Cocamide DEA products have been coordinated, with a new Judicial Council Coordination Proceeding Case No. JCCP 4765. On October 17, 2014, Plaintiff filed an amendment to the Complaint, adding our subsidiary BioZone Laboratories, Inc. a California corporation, as Doe Defendant No. 9. The Company filed an Answer to the First Amended Complaint on October 13, 2015. No discovery has taken place yet.

In October 2015, Cocystal Pharma, Inc. received a subpoena from the staff of the Securities and Exchange Commission seeking the production of documents. The Company is fully cooperating with the inquiry. The Company cannot predict or determine whether any proceeding may be instituted in connection with the subpoena or the outcome of any proceeding that may be instituted.

In December 2015, Cocystal Pharma, Inc. issued notice of default letters to 580 Garcia Properties, Daniel Fisher and Sharon Fisher for failure to remit certain payments on a promissory note executed between the parties in June, 2014. Cocystal Pharma, Inc. also exercised a failure to pay provision within that note to escalate the interest rate from 7.24% to 11.24%. As of March 31, 2016, the additional amounts due Cocystal Pharma, Inc. total approximately \$245,000. Due to the contingent nature of this default action, Cocystal Pharma, Inc. has not recorded these amounts in our 2015 and 2016 financial statements.

ITEM 1.A RISK FACTORS

You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, and adversely affect the value of an investment in our common stock. There may be additional risks that we do not know of or that we believe are immaterial that could also impair our business and financial position.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors before deciding whether to invest in the Company. If any of the events discussed in the risk factors below occur, our business, financial condition, results of operations or prospects could be materially and adversely affected. In such case, the value and marketability of the common stock could decline.

RISKS RELATED TO OUR FINANCIAL CONDITION AND NEED FOR ADDITIONAL CAPITAL

We have never generated revenue and expect that due to the regulatory constraints on a drug development company with products in the pre-clinical stage, we may not ever generate revenue and may continue to incur significant losses for the foreseeable future.

We are a preclinical-stage, biopharmaceutical discovery and development company. Since inception, our operations have been limited to organizing and staffing the Company, acquiring and developing intellectual property rights, developing our technology platform, undertaking basic research on viral replication enzyme targets and conducting preclinical studies for our initial programs. Thereafter, because of the need to complete clinical trials, establish safety and efficacy and obtaining regulatory approval, we do not anticipate generating revenue for at least 5 years and will continue to sustain large losses.

Based on cash on hand as of March 31, 2016 of \$10.2 million which includes first quarter 2016 financing received of \$5.0 million, Cocrystal does not have the capital to finance operations for the next 12 months. This raises doubt about our ability to fund operations over the next twelve months and be a going concern.

We have not and may never file a New Drug Application (NDA) or its foreign equivalent, necessary to legally sell products in the U.S. of foreign markets.

We have devoted the majority of our financial resources to research and development. We have financed our operations primarily through the sale of equity securities. The results of our operations will depend, in part, on the rate of future expenditures and our ability to obtain funding through equity or debt financings, strategic alliances or grants. We anticipate our expenses will increase substantially if and as we continue our research and preclinical development of our product candidates. We anticipate that if we undertake clinical studies our expenses will increase even further.

Because we have yet to generate any revenue on which to evaluate our potential for future success and to determine if we will be able to execute our business plan, it is difficult to evaluate our future prospects and the risk of success or failure of our business.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with partners, to successfully complete the development of, obtain the regulatory approvals for and commercialize pharmaceutical product candidates. We have no pharmaceutical product candidates that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of pharmaceutical products in the near future, and might never generate revenues from the sale of pharmaceutical products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following:

- identifying and validating new therapeutic strategies;
- completing our research and preclinical development of pharmaceutical product candidates;
- initiating and completing clinical trials for pharmaceutical product candidates;
- seeking and obtaining regulatory marketing approvals for pharmaceutical product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing pharmaceutical product candidates for which we obtain regulatory marketing approval, with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting, enforcing, defending and expanding our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we cannot predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. Our expenses could increase beyond expectations if we are required by the FDA or foreign regulatory agencies to perform unanticipated studies and trials.

Even if one or more pharmaceutical product candidates we independently develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved pharmaceutical product candidate. Moreover, if we can generate revenues from the sale of any approved pharmaceutical products, we may not become profitable and may need to obtain additional funding to continue operations.

If we do not raise additional debt or equity capital, we may not be able to remain operational.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is very expensive. We expect our research and development expenses to substantially increase as we advance our product candidates toward clinical programs. In order to conduct these trials, we will need to raise additional capital to support our operations and such funding may not be available to us on acceptable terms, or at all.

As we move lead compounds through toxicology and other preclinical studies, also referred to as nonclinical studies, we will be required to file an Investigational New Drug application (“IND”) or its equivalent in foreign countries, and as we conduct clinical development of product candidates, we may have adverse results that may cause us to consume additional capital. Our partners may not elect to pursue the development and commercialization of our product candidates subject to our respective agreements with them. These events may increase our development costs more than we expect. We may need to raise additional capital or otherwise obtain funding through strategic alliances if we initiate clinical trials for new product candidates other than programs currently partnered. We will require additional capital to obtain regulatory approval for, and to commercialize, product candidates.

If we must secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we cannot raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of any product candidates;
- seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or any product candidates we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects or sufficient enough to render the Company unable to continue operations at all.

RISKS RELATED TO THE DISCOVERY AND DEVELOPMENT OF PRODUCT CANDIDATES

Because the approach we are taking to discover and develop drugs is novel, it may never lead to marketable products.

We are concentrating our antiviral therapeutic product research and development efforts using our proprietary technology, and our future success depends on the continued successful development of this technology and the products derived from it. We have no drug products or drug product candidates. The scientific discoveries that form the basis for our efforts to discover and develop drug product candidates are relatively new and unproven. The scientific evidence to support the feasibility of developing product candidates based on our approach is limited. If we do not successfully develop and commercialize drug product candidates based upon our technological approach, we may not become profitable and the value of our stock may decline.

Further, our focus on Cocrystal's technology for developing drugs, as opposed to relying entirely on more standard technologies for drug development, increases the risks associated with the ownership of our stock. If we are unsuccessful in developing any product candidates using Cocrystal's technology, we may be required to change the scope and direction of our product development activities. We may not identify and implement successfully an alternative product development strategy, and may as a result cease operations.

If we do not succeed in our efforts to identify or discover potential product candidates, your investment may be lost.

The success of our business depends primarily upon our ability to identify, develop and commercialize antiviral drug products, an extremely risky business. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for several reasons, including:

- our research methodology or that of our partners may be unsuccessful in identifying potential product candidates;
- potential product candidates may have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- we or our partners may change their development profiles for potential product candidates or abandon a therapeutic area.

Such events may force us to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

If we are unable to successfully complete preclinical testing and clinical trials of our product candidates or experience significant delays in doing so, our business will be materially harmed.

We intend to invest a significant portion of our efforts and financial resources in the identification and preclinical development of product candidates that target viral replication enzymes. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates.

The commercial success of our product candidates will depend on several factors, including:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing and pricing approvals from regulatory authorities;
- obtaining and maintaining patent and trade secret protection for product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and
- commercializing our products, if and when approved, whether alone or in collaboration with others.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete development of, or to successfully commercialize, our product candidates, which would materially harm our business. Most pharmaceutical products that do overcome the long odds of drug development and achieve commercialization still do not recoup their cost of capital. If we are unable to design and develop each drug to meet a commercial need far in the future, the approved drug may become a commercial failure and our investment in those development and commercialization efforts will have been commercially unsuccessful.

We may be unable to demonstrate safety and efficacy of our product candidates to the satisfaction of regulatory authorities or we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of product candidates, we or our partners must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Events that may cause a delay or unsuccessful completion of clinical development include, as examples:

- delays in agreeing with the FDA or other regulatory authorities on final clinical trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in agreeing on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each clinical trial site;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to product side effects or disease progression;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers in producing and delivering sufficient supply of clinical trial materials.

If we or our partners must conduct additional clinical trials or other testing of any product candidates beyond those that are contemplated, or are unable to successfully complete clinical trials or other testing of any the product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our partners may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- remove the product from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule if at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any inability to successfully complete preclinical and clinical development, whether independently or with our partners, could cause additional costs to us or impair our ability to generate revenues from our product candidates, including product sales, milestone payments, profit sharing or royalties.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events (“AEs”), that may be observed during clinical trials of our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt such trials and could cause denial of regulatory approval. If AEs are observed in any clinical trials of our product candidates, including those our partners may develop under our alliance agreements, our or our partners’ ability to obtain regulatory approval for product candidates may be negatively impacted.

Serious or unexpected side effects caused by an approved product could result in significant negative consequences, including:

- regulatory authorities may withdraw prior approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- we may be required to add labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

These events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our products and impair our ability to generate revenues from the commercialization of these products either by us or by our partners.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a product.

Neither we nor any partners we may have can commercialize a product until the appropriate regulatory authorities, such as the FDA or its foreign equivalent, have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or foreign regulatory authority recommends restrictions on approval or recommends non-approval.

Following regulatory approval for a product candidate, we will still face extensive regulatory requirements and the approved product may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The holder of an approved New Drug Application (“NDA”), must monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and other applicable federal and state laws, and are subject to FDA review.

Drug product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices (“cGMP”), and adherence to commitments made in the NDA. If we or a regulatory agency discover previously unknown problems with a product such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we or our partners fail to comply with regulatory requirements following approval of our product candidates, a regulatory agency may:

- issue a warning letter asserting we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Our defense of any government investigation of alleged violations of law, or any lawsuit alleging such violations, could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may prevent or inhibit our ability to commercialize our products and generate revenues.

We may not succeed in obtaining or maintaining necessary rights to drug compounds and processes for our development pipeline through acquisitions and in-licenses.

We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and more established companies are also pursuing strategies to license or acquire third-party intellectual property rights we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve using hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. If contamination occurs or injury results from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although our workers' compensation insurance may cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against other potential liabilities. We may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may cause substantial fines, penalties or other sanctions.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our technology.

The Animal Welfare Act ("AWA"), is the federal law that covers the treatment of certain animals used in research. The AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements. Some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

Public perception of ethical and social issues may limit or discourage the type of research we conduct.

Our clinical trials will involve people, and we and third parties with whom we contract also do research using animals. Governmental authorities could, for public health or other purposes, limit the use of human or animal research or prohibit the practice of our technology. In addition, animal rights activists could protest or make threats against our facilities, which may cause property damage and delay our research. Ethical and other concerns about our methods, such as our use of human subjects in clinical trials or our use of animal testing, could adversely affect our market acceptance.

We have limited experience in conducting and managing the preclinical development activities and clinical trials necessary to obtain approvals for marketing our product candidates, including approval by the FDA.

Our efforts to develop our product candidates are at an early stage. To date we have not entered a compound into human clinical trials. We may be unable to progress our product candidates undergoing preclinical testing into clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will succeed, and favorable initial results from a clinical trial do not determine outcomes in subsequent clinical trials. The indications of use for which we are pursuing development may have clinical effectiveness endpoints not previously reviewed or validated by the FDA or foreign regulatory authorities, which may complicate or delay our effort to obtain marketing approval. We cannot guarantee that our clinical trials will succeed. In fact, most compounds fail in clinical trial, even at companies far larger and more experienced than us.

We have not obtained marketing approval or commercialized any of our product candidates. We may not successfully design or implement clinical trials required for marketing approval to market our product candidates. If we are unsuccessful in conducting and managing our preclinical development activities or clinical trials or obtaining marketing approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

If we form strategic alliances which are unsuccessful or are terminated, we may be unable to develop or commercialize certain product candidates and we may be unable to generate revenues from our development programs.

We are likely to use third party alliance partners for financial, scientific, manufacturing, marketing and sales resources for the clinical development and commercialization of certain of our product candidates. These strategic alliances will likely constrain our control over development and commercialization of our product candidates, especially once a candidate has reached the stage of clinical development. Our ability to recognize revenues from successful strategic alliances may be impaired by several factors including:

- a partner may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a partner may cease development in therapeutic areas which are the subject of our strategic alliances;
- a partner may change the success criteria for a program or product candidate delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a partner could also delay payment of milestones tied to such activities, impacting our ability to fund our own activities;
- a partner could develop a product that competes, either directly or indirectly, with an alliance product;
- a partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a partner may exercise its rights under the agreement to terminate a strategic alliance;
- a dispute may arise between us and a partner concerning the research, development or commercialization of a program or product candidate resulting in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- a partner may use our proprietary information or intellectual property to invite litigation from a third party or fail to maintain or prosecute intellectual property rights possibly jeopardizing our rights in such property.

Termination of a strategic alliance may require us to seek out and establish alternative strategic alliances with third-party partners; this may not be possible, or we may not be able to do so on terms acceptable to us, in which case it may be necessary for us to limit the size or scope of one or more of our programs or increase our expenditures and seek additional funding by other means. Such events would likely have a material adverse effect on our results of operations and financial condition.

We expect to rely on third parties to conduct some or all aspects of our compound formulation, research and preclinical testing, and those third parties may not perform satisfactorily.

We do not expect to independently conduct most and certainly not all aspects of our drug discovery activities, compound formulation research or preclinical testing of product candidates. We rely and expect to continue to rely on third parties to conduct some aspects of our preclinical testing.

If these third parties terminate their engagements, we will need to enter into alternative arrangements which would delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For product candidates we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND-enabling preclinical studies and clinical trials are conducted under the respective study plans and trial protocols.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies under regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the necessary preclinical studies to enable us or our partners to select viable product candidates for IND submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

We intend to rely on third-party manufacturers to produce our preclinical supplies, and we intend to rely on third parties to produce clinical supplies of any product candidates we advance into clinical trials and commercial supplies of any approved product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to meet any product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or that is costly or damaging to us;
- the reliance on a few sources, and sometimes, single sources for raw materials, such that if we cannot secure a sufficient supply of these product components, we cannot manufacture and sell product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for any raw materials currently purchased from a single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs beyond our control; and
- failing to deliver products under specified storage conditions and in a timely manner.

These events could lead to clinical study delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

Because we expect to rely on limited sources of supply for the drug substance and drug product of product candidates, any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.

We intend to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, the drug substance, and the drug product of any product candidate for which we are responsible for preclinical or clinical development. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and its processes must be qualified by the FDA or foreign regulatory authorities prior to commercialization. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA or marketing authorization supplement, which could cause further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of drug substance or drug product on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution to proceed with any clinical trials and obtain regulatory approval for commercial marketing. We may identify significant impurities or stability problems, which could cause increased scrutiny by regulatory agencies, delays in clinical programs and regulatory approval, significant increases in our operating expenses, or failure to obtain or maintain approval for product candidates or any approved products.

We expect to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We expect to rely on Clinical Research Organizations (“CROs”) and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we will have agreements governing their activities, we and our partners will have limited influence over their actual performance. Nevertheless, we or our partners will be responsible for ensuring that each of our clinical trials is conducted in accordance with its protocol, and all legal, regulatory and scientific standards. Our reliance on the CROs does not relieve us of our regulatory responsibilities.

We, our partners and our CROs must comply with current Good Clinical Practices (“cGCPs”), as defined by the FDA and the International Conference on Harmonization, for conducting, recording and reporting the results of IND-enabling preclinical studies and clinical trials, to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. If our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, fail to recruit properly qualified patients or fail to properly record or maintain patient data, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our contracted CROs will not be our employees, and we cannot control whether they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to failing to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not obtain regulatory approval for, or successfully commercialize our product candidates. Our financial results and the commercial prospects for such products and any product candidates we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We also expect to rely on other third parties to store and distribute drug products for any clinical trials we may conduct. Any performance failure by our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we cannot obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our future products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications we own or in-license may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found; such prior art can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may cause such patents to be narrowed or invalidated. Even if unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

If the patent applications we hold or have in-licensed regarding our programs or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize products. We cannot offer any assurances about which patents will issue or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Since patent applications in the United States and most other countries are confidential for a period after filing, and some remain so until issued, we cannot be certain that we were the first to invent a patent application related to a product candidate. In certain situations, if we and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding can be initiated to determine which applicant is entitled to the patent on that subject matter. Patents have a limited lifespan. In the United States, the natural expiration of a patent is 20 years after it is filed, although various extensions may be available. However the life of a patent, and the protection it affords, is limited. Once the patent life has expired for a product, we may be open to competition from generic medications. Further, if we encounter delays in regulatory approvals, the time during which we could market a product candidate under patent protection could be reduced.

Besides the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology not covered by patents. Although each of our employees agrees to assign their inventions to us through an employee inventions agreement, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is considering whether to make additional information publicly available on a routine basis, including information we may consider to be trade secrets or other proprietary information, and it is not clear how the FDA's disclosure policies may change, if at all.

The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. We may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is substantial litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexaminations and other post-grant proceedings before the U.S. Patent and Trademark Office ("U.S. PTO"), and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our partners are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be patent applications currently pending that may later result in patents that our product candidates may infringe. Third parties may obtain patents in the future and claim that use of our technologies infringes these patents. If any third-party patents were to be held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making intellectual property claims against us may obtain injunctive or other equitable relief, which could block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a claim of infringement against us succeeds, we may have to pay substantial damages, possibly including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may need to obtain licenses to intellectual property rights from third parties.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist that might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales and other activities, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter such infringement or unauthorized use, we may be required to file infringement claims, or we may be required to defend the validity or enforceability of such patents, which can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue because our patents do not cover that technology. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions regarding our patents or patent applications or those of our partners or licensors. An unfavorable outcome could require us to cease using the related technology or to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may cause substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Because of the substantial amount of discovery required in intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our securities.

We may be subject to claims our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we succeed, litigation could cause substantial cost and be a distraction to our management and other employees.

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

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our competitors may have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may cause even more resources being concentrated in our competitors. Competition may increase further because of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may develop, acquire or license drug products that are more effective or less costly than any product candidate we may develop.

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All of our programs are in a preclinical development stage and are targeted toward indications for which there are approved products on the market or product candidates in clinical development. We will face competition from other drugs that are or will be approved for the same therapeutic indications. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development to:

- discover and develop therapeutics superior to other products in the market;
- attract qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our technology platform and product candidates;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapeutics.

The availability of our competitors' products could limit the demand, and the price we can charge, for any products we may develop and commercialize. We will not achieve our business plan if the acceptance of these products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or reserve our products for use in limited circumstances. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. Any new product that competes with an approved product must typically demonstrate advantages, such as in efficacy, convenience, tolerability or safety, to overcome price competition and to succeed. Our competitors may obtain patent protection, receive approval by FDA and/or foreign regulatory authorities or discover, develop and commercialize product candidates before we do, which would have a material adverse impact on our business.

The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.

Assuming one or more product candidates achieve regulatory approval and we commence marketing such products, the market acceptance of any product candidates will depend on several factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any AEs;
- limitations or warnings in the label approved by FDA and/or foreign regulatory authorities for such products;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the effectiveness of our or any collaborators' sales and marketing strategies;
- our ability to obtain hospital formulary approval; and
- our ability to obtain and maintain sufficient third-party payor coverage or reimbursement.

If our current product candidates are approved, we expect sales to generate substantially all of our product revenues for the foreseeable future, and as such, the failure of these products to find market acceptance would harm our business.

If coverage and adequate reimbursement are not available for our product candidates, it could make it difficult for us to sell products profitably.

Market acceptance and sales of any product candidates we develop will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that coverage and adequate reimbursement will be available for any product candidates. Also, inadequate reimbursement amounts may reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize product candidates we develop.

We cannot be certain if and when we will obtain formulary approval to allow us to sell any products we may develop and commercialize into our target markets. Obtaining formulary approval from hospitals and from payors can be an expensive and time-consuming process. Failure to obtain timely formulary approval will limit our commercial success.

There have been numerous legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for drug products, following approval. The availability of generic treatments may also substantially reduce reimbursement for our future products. The potential application of user fees to generic drug products may expedite approval of additional generic drug treatments. We expect to experience pricing pressures in connection with sale of any of our products, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. If we fail to successfully secure and maintain reimbursement coverage for our future products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. The European Union, or EU, provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of Cocrystal placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our products. Historically, products launched in the EU do not follow price structures of the U.S. and tend to be priced significantly lower.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.

We do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or arrange with third parties to perform these services.

Our current and future partners may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future strategic partners do not successfully commercialize the product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could cause increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is endemic;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

RISKS RELATED TO OUR BUSINESS OPERATIONS AND INDUSTRY

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in our compensation costs, our business may materially suffer.

We depend on principal members of our executive and research teams, the loss of whose services may adversely impact the achievement of our objectives. We are highly dependent on our management team and our Chairman of the Board, Dr. Raymond Schinazi. We do not carry “key-man” life insurance on the lives of any of our employees or advisors. Furthermore, our future success will also depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire, and retain additional personnel. We may not be able to attract and retain personnel on acceptable terms the competition among numerous pharmaceutical companies for individuals with similar skill sets. Because of this competition, our compensation costs may increase significantly. If we lose key employees, our business may suffer.

If we expand our organization, we may experience difficulties in managing growth, which could disrupt our operations.

We have 24 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, scientific and operational, commercial, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may cause weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as developing additional product candidates. If our management cannot effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete will depend, in part, on our ability to manage any future growth.

Any relationships with customers and third party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain FDA approval for any of our product candidates and commercialize those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. We may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to violate any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, and curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our results of operations.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.

Using our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Regardless of merit or eventual outcome, product liability claims may cause:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We do not have any product liability insurance coverage. We anticipate obtaining such insurance prior to the commencement of any clinical trials but any such insurance coverage we obtain may not reimburse us for all expenses or losses we may suffer. Insurance coverage is becoming increasingly expensive and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Occasionally, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Business interruptions could delay us in developing our future products.

We have locations in Washington and Georgia. We are vulnerable to natural disasters such as earthquakes and tornados as well as other events that could disrupt our operations. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

If our information technology systems are hacked, a third party may misappropriate our trade secrets which could harm our business and future results of operations.

We keep some of our intellectual property, including trade secrets and results of our preclinical research on a central server, and our employees email such information to each other and to third parties outside of our offices. In addition, since we do not encrypt all of this information, there is a risk that hackers could misappropriate our intellectual property. Any such misappropriation could harm our business and future results of operations.

RISKS RELATED TO OUR COMMON STOCK

Because we are subject to the “penny stock” rules, brokers cannot generally solicit the purchase of our common stock which adversely affects its liquidity and market price.

The Securities and Exchange Commission (“SEC”) has adopted regulations which generally define “penny stock” to be an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The market price of our common stock on the Bulletin Board has been substantially less than \$5.00 per share and therefore we are currently considered a “penny stock” according to SEC rules. This designation requires any broker-dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities.

Due to factors beyond our control, our stock price may be volatile.

Companies trading in the stock market in general, and particularly the over-the-counter markets, including the OTCQB, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Our common stock price recently has experienced significant gains even though there has been no disclosure by us of any positive factors. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters which require stockholder approval.

As of May 10, 2016, our executive officers, directors, 5% stockholders and their affiliates beneficially owned approximately 80% of our common stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. These stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock you may believe are in your best interest as one of our stockholders.

Future sales and issuances of our common stock or rights to purchase common stock, including under our equity incentive plan, could cause additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Under our Equity Incentive Plans, our management may grant stock options and other equity-based awards to our employees, directors and consultants. During 2015, our Board of Directors authorized an additional 50 million shares for grant to our employees, directors and consultants. These additional shares are offered under our 2015 Equity Incentive Plan. During 2015, 21,970,000 stock options were granted under this plan. The number of shares available for future grant under the Equity Incentive Plans is approximately 29.5 million shares.

If we are subject to securities class action litigation, we may sustain material costs.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could cause substantial costs and a diversion of management's attention and resources, which could harm our business.

As a public company, we are subject to investigations by the SEC and other federal and state regulatory agencies.

The Company cannot predict or determine whether any proceeding may be instituted in connection with any subpoena or the outcome of any proceeding that may be instituted. Responding to such investigations may consume significant financial resources and limit us from other programs with those resources. In addition, any adverse investigation result could have a significant adverse effect on the Company share price and on the ability of the Company to raise necessary capital.

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

Under Section 382 of the Internal Revenue Code of 1986 if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carry forwards ("NOLs"), and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We believe that, with the RFS Pharma and Cocrystal Discovery mergers and other transactions that have occurred over the past three years, we may have triggered an "ownership change" limitation. We may also experience ownership changes in the future because of subsequent shifts in our stock ownership. If we earn net taxable income, our ability to use our pre-change net operating loss carry forwards to offset U.S. federal taxable income may be subject to limitations, which could result in increased future tax liability to us. At the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We anticipate we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Because we may not attract the attention of major brokerage firms, it could have a material impact upon the price of our common stock.

It is not likely that securities analysts of major brokerage firms will provide research coverage for our common stock since the firm itself cannot recommend the purchase of our common stock under the penny stock rules referenced in the previous risk factor. The absence of such coverage limits the likelihood that an active market will develop for our common stock. It may also make it more difficult for us to attract new investors when we acquire additional capital.

Because many of our outstanding shares are freely tradable, sales of these shares could cause the market price of our common stock to drop significantly, even if our business is performing well.

As of May 10, 2016, we had approximately 704 million shares of common stock outstanding, approximately 106 million of which may be publicly sold under Rule 144. In general, Rule 144 provides that any non-affiliate of Cocystal, who has held restricted common stock for at least six months, is entitled to sell their restricted stock freely, provided that we stay current in our SEC filings. After one year, a non-affiliate may sell without any restrictions.

An affiliate of the Company may sell after six months (subject to contractual restrictions as described above) with the following restrictions:

- (i) we are current in our filings,
- (ii) certain manner of sale provisions, and
- (iii) filing of Form 144.

Future sales of our common stock could cause the market price of our common stock to drop significantly, even if our business is performing well.

We may issue preferred which could make it more difficult for a third party to acquire us and could depress our stock price.

In accordance with the provisions of our Certificate of Incorporation and the Stockholder Rights Agreement described above, our Board may issue one or more additional series of preferred stock that have more than one vote per share, so long as the Board obtains the majority approval of each of the groups of shareholders who formerly held our Series A and Series B. This could permit our Board to issue preferred stock to investors who support our management and give effective control of our business to our management. Issuance of preferred stock could block an acquisition resulting in both a drop in our stock price and a decline in interest of our common stock. This could make it more difficult for shareholders to sell their common stock. This could also cause the market price of our common stock shares to drop significantly, even if our business is performing well.

If we are not successful in completing preclinical or clinical testing or are unable to demonstrate safety and efficacy of our product candidates to the satisfaction of the regulatory authorities, we may suffer impairment on our IPR&D assets.

In-process research and development (IPR&D) represents a series of awarded patents, filed patent applications and an in-process research program acquired in the acquisition of RFS Pharma that are integral to the development of the Company's planned future products. In-process research and development represents an indefinite-lived intangible asset. Any series of preclinical and clinical outcomes that reduce the probability for technical and regulatory success, may trigger interim impairment testing. If our IPR&D becomes impaired, writedown on the carrying amount of these assets may result, which could depress our stock price. During 2015, we lowered our forecasts of future cash flows, which caused a reduction in our IPR&D, resulting in an impairment charge of \$38.7 million.

We continue to have material weaknesses in internal control over financial reporting, which could negatively impact our ability to raise capital and could result in increased costs to ensure compliance with Sarbanes-Oxley Section 404.

During our assessment of the effectiveness of internal control over financial reporting as of December 31, 2015, we identified the following material weaknesses:

We did not maintain adequate segregation of duties in our accounting and financial reporting processes. We have not appropriately restricted access to our accounting applications to appropriate users and do not have processes in place that ensure that appropriate segregation of duties is maintained. The Company lacks sufficient qualified personnel to review conclusions reached for complex accounting transactions. Our internal control over this process would not allow for employees to detect a material misstatement in these areas in the normal course of performing their duties.

We do not have processes in place to ensure that all related party transactions, including those entered into with or on behalf of related parties, (1) have been identified, (2) are properly authorized prior to entering into the transaction, and (3) are properly monitored and evaluated for appropriate recording and presentation in the financial statements. We did not maintain an effective financial reporting process to prepare financial statements in accordance with U.S. GAAP. Specifically, our process lacked timely and complete financial statement reviews and procedures to ensure all required disclosures were made in our financial statements. We also lacked a process to review information used to prepare our financial statements and disclosures and did not have adequate segregation of duties over preparation of the financial statements.

Increased costs could be incurred to remediate these material weaknesses and could involve upgrading or replacing the Company's accounting software, adding additional staff and providing additional training.

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

On March 9, 2016, Cocrysal Pharma, Inc. (the “Company”) accepted subscription agreements representing investor commitments totaling \$5,004,370 in a private placement offering to investors who participated in the March 2015 private placement on a pro-rata basis to their participation in the March 2015 private placement (the “Offering”) of 9,812,491 shares of the Company’s common stock at a purchase price of \$0.51 per share. The purchasers included 7 members of the Company’s board of directors including Dr. Raymond F. Schinazi and Dr. Phil Frost. As of the date of this report, the Company has received all of the committed funds.

The Company intends to use the net proceeds of the Offering for working capital and general corporate purposes. The form of Securities Purchase Agreement was attached as Exhibit 10.1 to our 2015 Form 10-K and is incorporated herein by reference.

All of the securities were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933 (the “Act”) and Rule 506 promulgated thereunder. These securities may not be offered or sold in the United States in the absence of an effective registration statement or exemption from the registration requirements under the Act. The investors are accredited investors and there was no general solicitation.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable

ITEM 5. OTHER

None

ITEM 6. EXHIBITS

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

SIGNATURES

Pursuant to the requirements 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.

Cocrystal Pharma, Inc.

Dated: May 10, 2016

By: /s/ Jeffrey Meckler
Jeffrey Meckler
Chief Executive Officer
(Principal Executive Officer)

Dated: May 10, 2016

By: /s/ Curtis Dale
Curtis Dale
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed or Furnished Herewith
		Form	Date	Number	
10.1	Securities Purchase Agreement	10-K	3/15/16	10.1	Filed
31.1	Certification of Principal Executive Officer (302)				Filed
31.2	Certification of Principal Financial Officer (302)				Filed
32.1	Certification of Principal Executive and Principal Financial Officer (906)				Furnished**
101.INS	XBRL Instance Document				Filed
101.SCH	XBRL Taxonomy Extension Schema Document				Filed
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				Filed
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				Filed
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				Filed
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				Filed

** This exhibit is being furnished rather than filed and shall not be deemed incorporated by reference into any filing, in accordance with Item 601 of Regulation S-K.

Copies of this report (including the financial statements) and any of the exhibits referred to above will be furnished at no cost to our shareholders who make a written request to our Corporate Secretary at Cocrystal Pharma, Inc., 1860 Montreal Road, Tucker GA 30084.

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Jeffrey Meckler, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cocrystal Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

/s/ Jeffrey Meckler
Jeffrey Meckler
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Curtis Dale, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cocrystal Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

/s/ Curtis Dale

Curtis Dale

Chief Financial Officer

(Principal Financial Officer)

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

In connection with the quarterly report of Cocrystal Pharma, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2016, as filed with the Securities and Exchange Commission on the date hereof, I, Jeffrey Meckler, certify, pursuant to 18 U.S.C. Sec.1350, as adopted pursuant to Sec.906 of the Sarbanes-Oxley Act of 2002, that to my 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.

/s/ Jeffrey Meckler
Jeffrey Meckler
Chief Executive Officer
(Principal Executive Officer)

Dated: May 10, 2016

In connection with the quarterly report of Cocrystal Pharma, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2016, as filed with the Securities and Exchange Commission on the date hereof, I, Curtis Dale, certify, pursuant to 18 U.S.C. Sec.1350, as adopted pursuant to Sec.906 of the Sarbanes-Oxley Act of 2002, that to my 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.

/s/ Curtis Dale
Curtis Dale
Chief Financial Officer
(Principal Financial Officer)

Dated: May 10, 2016