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CERULEAN PHARMA INC.

FORM 10-Q
(Quarterly Report)

Filed 05/12/17 for the Period Ending 03/31/17

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017

OR

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

For the transition period from _____to _____.

Commission file number 001-36395

CERULEAN PHARMA INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**20-4139823**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
35 Gatehouse Drive Waltham, MA	**02451**
(Address of Principal Executive Offices)	**(Zip Code)**

(781) 996-4300
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☒

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

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

Number of shares of the registrant's Common Stock, $ 0.0001 par value, outstanding on May 1, 2017: 29,021,455

CERULEAN PHARMA INC.

FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2017

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

CERULEAN PHARMA INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)
(in thousands except share data and par value)

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,028	$ 34,950
Property and equipment held for sale	386	—
Accounts receivable	1,139	823
Prepaid retention payments	1,069	—
Prepaid expenses and other current assets	987	1,017
Total current assets	15,609	36,790
Property and equipment, net	114	668
Other assets	230	230
Total	$ 15,953	$ 37,688
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of loan payable	$ —	$ 8,382
Accounts payable	644	1,446
Accrued expenses	3,538	4,611
Current portion deferred revenue	2,500	2,500
Total current liabilities	6,682	16,939
Long-term liabilities:		
Loan payable, net of current portion	—	4,439
Deferred revenue	1,368	1,993
Other long-term liabilities	162	1,206
Total long-term liabilities	1,530	7,638
Commitments and contingencies		
Stockholders' equity:		
Preferred stock $0.01 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 120,000,000 shares authorized, 29,021,455 and 28,937,185 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	3	3
Additional paid-in capital	214,757	213,788
Accumulated deficit	(207,019)	(200,680)
Total stockholders' equity	7,741	13,111
Total	$ 15,953	$ 37,688

See notes to unaudited condensed consolidated financial statements.

CERULEAN PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)
(in thousands except per share and share data)

	Three Months Ended March 31,	
	2017	2016
Revenue	$ 1,192	$ —
Operating expenses:		
Research and development	4,651	9,770
General and administrative	3,587	3,118
Gain on asset sale	(1,500)	—
Total operating expenses	6,738	12,888
Other income (expense):		
Interest income	33	16
Interest expense	(797)	(663)
Other expense	(29)	(7)
Total other expense, net	(793)	(654)
Net loss attributable to common stockholders	$ (6,339)	$ (13,542)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.22)	$ (0.49)
Weighted-average common shares outstanding:		
Basic and diluted	29,019,582	27,362,643

See notes to unaudited condensed consolidated financial statements.

CERULEAN PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)
(in thousands)

	Three Months Ended March 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (6,339)	$ (13,542)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	906	741
Noncash rent expense	10	124
Depreciation and amortization	66	61
Amortization of debt discount and deferred financing costs	610	127
Loss on disposal of property and equipment	—	4
Impairment of property and equipment	102	—
Deferred revenue	(625)	—
Gain on asset sale	(1,500)	—
Changes in operating assets and liabilities:		
Accounts receivable	(316)	(18)
Prepaid expenses and other current assets	(1,039)	(174)
Accounts payable	(802)	141
Accrued expenses	(1,073)	(724)
Net cash used in operating activities	(10,000)	(13,260)
Cash flows from investing activities:		
Purchases of property and equipment	—	(359)
Decrease in restricted cash	—	117
Proceeds from the sale of assets	1,500	—
Net cash provided by (used in) investing activities	1,500	(242)
Cash flows from financing activities:		
Proceeds from sale of common stock	62	41
Payments on loan payable	(13,077)	(1,932)
Payment of end of term charge on loan payable	(1,407)	—
Net cash used in financing activities	(14,422)	(1,891)
Net decrease increase in cash and cash equivalents	(22,922)	(15,393)
Cash and cash equivalents — Beginning of period	34,950	75,908
Cash and cash equivalents — End of period	$ 12,028	$ 60,515
Supplemental cash flow information — Interest paid	$ 269	$ 372

See notes to the unaudited condensed consolidated financial statements.

CERULEAN PHARMA INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND OPERATIONS

Nature of Business — Cerulean Pharma Inc. (the "Company") was incorporated on November 28, 2005, as a Delaware corporation and is located in Waltham, Massachusetts. The Company was formed to develop novel, nanotechnology-based therapeutics in the areas of oncology and other diseases. In 2013, the Company formed a wholly owned subsidiary, Cerulean Pharma Australia Pty Ltd as an Australian-based proprietary limited company to perform clinical activities in Australia.

The Company's operations have consisted primarily of raising capital, product research and development, and initial market development.

The Company has not generated any revenue related to its primary business purpose to date and is subject to a number of risks common to other development stage life science companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products, and the need to obtain adequate additional financing to fund the development of product candidates. The Company is also subject to a number of risks similar to other companies in the industry, including rapid technological change, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability and dependence on key individuals.

On February 1, 2017, the Company announced that its board of directors had initiated a review of strategic alternatives that could result in changes to the Company's business strategy and future operations. As part of this process, the board determined to review alternatives with the goal of maximizing stockholder value, including a potential sale of the Company, a reverse merger, a business combination or a sale, license or other disposition of company assets.

On March 17, 2017, the Company entered into a payoff letter with Hercules Technology Growth Capital, Inc. ("Hercules") pursuant to which the Company agreed to pay off and thereby terminate its loan with Hercules. Pursuant to the payoff letter, the Company paid, on March 20, 2017, a total of $12.4 million to Hercules, representing the principal, accrued and unpaid interest, fees, costs and expenses outstanding in repayment of its outstanding obligations under the loan agreement (see Note 6 – Loan Agreements).

On March 19, 2017, the Company entered into an asset purchase agreement (the "Novartis Asset Purchase Agreement") with Novartis. Under the Novartis Asset Purchase Agreement the Company agreed to sell and assign to Novartis all of the Company's right, title and interest in and to the patent rights, know-how and third-party license agreements relating to the Company's proprietary Dynamic Tumor Targeting Platform (the "Platform"). At the closing of the Novartis transaction, Novartis will be obligated to pay a purchase price of $6.0 million. Consummation of the Novartis transaction is subject to the Company obtaining, pursuant to Delaware law, the approval of the holders of at least a majority of its common stock for the sale of substantially all of its assets in the Novartis transaction. Each party's obligation to consummate the Novartis transaction is also subject to other customary closing conditions.

On March 19, 2017, the Company also entered into an asset purchase agreement (the "BlueLink Asset Purchase Agreement) with BlueLink Pharmaceuticals, Inc. ("BlueLink"). Under the BlueLink Asset Purchase Agreement the Company sold and assigned to BlueLink all of the Company's right, title and interest in and to its clinical product candidates CRLX101 and CRLX301 (the "Products"). The Company also transferred and assigned to BlueLink the accompanying intellectual property rights and know-how to the Products. On March 21, 2017, BlueLink paid the purchase price of $1.5 million. Also in connection with the BlueLink Asset Purchase Agreement, the Company and BlueLink entered into a license agreement in favor of BlueLink, pursuant to which the Company agreed to grant to BlueLink an exclusive, worldwide, perpetual, sublicensable right and license, under the Platform, to research, develop and commercialize the Products. Pursuant to the Novartis Asset Purchase Agreement between the Company and Novartis, Novartis will assume the BlueLink License upon the closing of the Novartis transaction.

On March 19, 2017, the Company also entered into a stock purchase agreement (the "Stock Purchase Agreement") with Daré Bioscience, Inc. ("Daré"), and the holders of capital stock and securities convertible into capital stock of Daré named therein ("Selling Stockholders"), pursuant to which, among other things, the Selling Stockholders agreed to sell to the Company, and the Company agreed to purchase from the Selling Stockholders, all of the outstanding shares of capital stock, including those issuable upon conversion of convertible securities, of Daré (the "Daré Transaction"). Immediately following the closing of the Daré Transaction, the Selling Stockholders are expected to own between approximately 51% and 70% (depending on the respective net cash (as defined in the Stock Purchase Agreement) of the Company and Daré five business days prior to the closing) of the outstanding equity securities of Cerulean Pharma Inc. on a fully-diluted basis immediately following consummation of the Daré Transaction. Consummation of the Daré Transaction is subject to certain closing conditions, including, among other things, approval by the Company's stockholders. The exchange ratio, and therefore fair value of exchange consideration, are indeterminable at this time, and as such the full disclosures

required under Accounting Standards Codification 805, Business Combinations, are impracticable. The Stock Purchase Agreement contains certain termination rights for both the Company and Daré, and further provides that, upon termination of the Stock Purchase Agreement under specified circumstances, the Company may be required to pay Daré a termination fee of $0.3 million, or Daré may be required to pay the Company a termination fee of $0.45 million. There can be no assurances that the Daré Transaction will be consummated.

With exception of the payoff letter with Hercules and the sale of the clinical product candidates, these transactions are subject to certain closing conditions. There can be no assurances that these transactions will be consummated prior to the exhaustion of the Company's cash and cash equivalent resources, if at all.

The Company has an accumulated deficit of $207.0 million at March 31, 2017. The Company has financed its operations primarily through private placements of its preferred stock, proceeds from borrowings, an initial public offering completed in 2014 and a follow-on offering completed in 2015. As of March 31, 2017, the Company had cash and cash equivalents of $12.0 million. With the sale of its two clinical product candidates, the proposed sale of its Platform, and the reduction of staff to eight full-time employees, the Company has effectively ceased prior clinical research and is focused on maintaining its assets until they are either sold or its corporate business strategy with Daré, as described above, is executed, it completes any other strategic transaction, it determines to continue to operate the Platform or it otherwise decides to liquidate its assets or dissolve. The Company has no other sources of significant liquidity in place as of March 31, 2017.

The foregoing matters give rise to substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. SIGNIFICANT ACCOUNTING POLICIES

There have been no material changes to the significant accounting policies previously disclosed in the 2016 10-K.

Recent Accounting Pronouncements — In November 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update 2016-18, "Statement of Cash Flows - Restricted Cash (Topic 230)". This new standard requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance is effective for annual and interim reporting periods beginning after December 15, 2017, and required retrospective application. The Company is currently evaluating the effect this standard will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued Accounting Standards Update 2016-02, "Leases (Topic 842)" ("ASU 2016-02"), which provides new accounting guidance on leases. ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in ASU 2016-02 are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued Accounting Standards Update 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15 requires management to evaluate, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern and provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. The Company has performed its own assessment of the entity's ability to continue as a going concern for at least one year from the issuance date and provided increased disclosure around this matter as reflected in Note 1 – Nature of Business and Operations.

3. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The Company computes diluted loss per common share after giving effect to the dilutive effect of stock options, warrants and shares of unvested restricted stock that are outstanding during the period, except where the inclusion of such securities would be antidilutive.

The Company has reported a net loss for all periods presented and, therefore, diluted net loss per common share is the same as basic net loss per common share.

The following potentially dilutive securities that were outstanding prior to the use of the treasury stock method have been excluded from the computation of diluted weighted-average shares outstanding, because the inclusion of such securities would have an antidilutive impact due to the losses reported (in common stock equivalent shares):

	As of March 31,	
	2017	2016
Options to purchase common stock	5,441,105	3,991,586
Warrants to purchase common stock	365,564	300,564

4. PROPERTY AND EQUIPMENT AVAILABLE FOR SALE

On March 19, 2017, the Company entered into the Novartis Asset Purchase Agreement under which the Company agreed to sell and assign all of its right, title and interest in and to the patent rights, know-how and third-party license agreements relating to the Platform. In anticipation of the sale of such assets under the Novartis Asset Purchase Agreement, substantially all of the Company's lab research activities have terminated. As a result, the Company determined to dispose of all of its lab equipment and initiated a program in March 2017 to locate a buyer and offer such equipment for sale at a current market price. The Company reclassified $386,000 of such equipment as available for sale on the balance sheet. The Company recorded an impairment charge in March 2017 of $102,000 based on the quoted market price from the sale of the assets, completed in early April 2017, which is included in operating expenses.

5. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	As of March 31, 2017	As of December 31, 2016
Accrued clinical trial costs	$ 3,083	$ 2,648
Accrued contract manufacturing expenses	9	226
Accrued compensation and benefits	146	1,080
Accrued interest	—	82
Other accrued expenses	300	575
Total accrued expenses	$ 3,538	$ 4,611

6. LOAN AGREEMENTS

On January 8, 2015, the Company entered into a loan and security agreement with Hercules to borrow up to $26.0 million (the "Hercules Loan Agreement"). The proceeds were used to repay the Company's then-existing term loan facility and for general corporate and working capital purposes. On March 17, 2017, the Company entered into a payoff letter with Hercules pursuant to which the Company agreed to pay off and thereby terminate the Hercules Loan Agreement. Pursuant to the payoff letter, the Company paid, on March 20, 2017, a total of $12.4 million to Hercules, representing the principal, accrued and unpaid interest, fees, costs and expenses outstanding under the Hercules Loan Agreement in repayment of its outstanding obligations under the Hercules Loan Agreement. This payoff amount included a final end of term charge to Hercules in the amount of $1.4 million, representing 6.7% of the aggregate original principal amount advanced by Hercules. Upon the payment of $12.4 million pursuant to the payoff letter, all outstanding indebtedness and obligations owed to Hercules under the Loan Agreement were deemed paid in full, and the Loan Agreement was terminated. At December 31, 2016, the Company had $12.8 million outstanding under the Hercules Loan Agreement and had accrued $1.1 million of the end of term charge.

In connection with the Hercules Loan Agreement, the Company issued to Hercules a warrant to purchase shares of the common stock of the Company at an exercise price of $6.05 per share. The warrant is exercisable for 171,901 shares of common stock. The warrant is exercisable until January 8, 2020. The Company estimated the fair value of the warrant for shares exercisable on the issue date in January 2015 to be $824,000. The value of the warrant was recorded as a discount to the loan and was being amortized to interest expense using the effective interest method over the term of the loan. The unamortized discount relating to the warrants, or $0.2 million, was expensed as interest expense upon repayment of the loan.

7. STOCK-BASED COMPENSATION

In March 2014, the Company's board of directors adopted and its stockholders approved the 2014 Stock Incentive Plan (the "2014 Plan") and the 2014 Employee Stock Purchase Plan (the "ESPP"), which became effective in April 2014.

Stock Options

The 2014 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards. A summary of stock option activity for employee, director and nonemployee awards under all stock option plans during the three months ended March 31, 2017 is presented below (Aggregate Intrinsic Value in thousands):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2017	4,020,288	$ 4.31	8.4	$ —
Granted	1,479,450	$ 0.82		
Exercised	—	—		
Forfeited	(58,633)	$ 4.21		
Outstanding at March 31, 2017	5,441,105	$ 3.36	8.6	$ —
Options exercisable at March 31, 2017	1,913,734	$ 5.03	7.7	$ —
Options vested and expected to vest at March 31, 2017	4,956,695	$ 3.56	8.5	$ —

The weighted-average per share grant date fair value of options granted during the three months ended March 31, 2017 and 2016 was $0.61 and $1.70, respectively.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions noted in the table below. Expected volatility for the Company's common stock was determined based on an average of the historical volatility of a peer-group of similar public companies. The Company has limited option exercise information, and as such, the expected term of the options granted was calculated using the simplified method that represents the average of the contractual term of the option and the weighted-average vesting period of the option. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The risk-free rate for periods within the contractual life of the option is based upon the U.S. Treasury yield curve in effect at the time of grant.

The Company has recorded stock-based compensation expense related to the issuance of stock option awards to employees of $877,000 and $691,000 for the three months ended March 31, 2017 and 2016, respectively. The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of board services during the three ended March 31, 2017 and 2016 are as follows:

	Three Months Ended March 31,	
	2017	2016
Expected life	4.6 years	5.9-6.1 years
Risk-free interest rate	1.8%	1.3%-1.9%
Expected volatility	67%	61%
Expected dividend rate	— %	— %

The Company recorded stock-based compensation expense related to nonemployee awards of $29,000 and $38,000 for the three months ended March 31, 2017 and 2016, respectively. The compensation expense related to nonemployee awards is included in the total stock-based compensation each year and is subject to re-measurement until the options vest. The fair value of the grants is being expensed over the vesting period of the options on a straight-line basis as the services are being provided. The Black-Scholes assumptions used to estimate fair value for the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended March 31,	
	2017	2016
Expected life	4.6-9.8 years	6.9-9.7 years
Risk-free interest rate	1.8%-2.4%	1.7%-2.0%
Expected volatility	67%-117%	60%-61%
Expected dividend rate	— %	— %

During the three months ended March 31, 2017 the Company granted nonemployee stock options to purchase 151,000 and of the Company's common stock. The weighted-average exercise price and the weighted-average grant date fair value of nonemployee stock options granted for the three months ended March 31, 2017 was $0.82 per share and $0.75 per share, respectively. The Company did not grant any nonemployee stock options during the three months ended March 31, 2016.

During the three months ended March 31, 2017, the Company extended the exercise period for all continuing employees' stock options to two years beyond their termination date. These option modifications were accounted for in the quarter ended March 31, 2017, which resulted in an approximate $267,000 increase of stock-based compensation expense recognized for the quarter ended March 31, 2017.

Employee Stock Purchase Plan

The ESPP permits eligible employees to enroll in a six-month offering period whereby participants may purchase shares of the Company's common stock, through payroll deductions, at a price equal to 85% of the closing price of the common stock on the first day of the offering period or the last day of the offering period, whichever is lower. Purchase dates under the ESPP occur on or about June 30 and December 31 of each year. The board of directors determined not to initiate a new offering period beginning January 1, 2017. The stock-based compensation expense related to the ESPP was $0 and $12,000 for the three months ended March 31, 2017 and 2016, respectively.

8. FAIR VALUE MEASUREMENTS

The Company's financial instruments consist of cash equivalents, accounts payable, accrued expenses, and debt obligations. The carrying amount of accounts payable and accrued expenses are considered a reasonable estimate of their fair value, due to the short-term maturity of these instruments. The carrying amount of debt is also considered to be a reasonable estimate of its fair value based on the short term nature of the debt and because the debt bears interest at the prevailing market rate for instruments with similar characteristics.

Fair value is defined 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 are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs.

The accounting 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 (unadjusted) in active markets that are accessible at the market date for identical unrestricted assets or liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs for which all significant inputs are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

A summary of the financial assets and liabilities that are measured on a recurring basis at fair value as of March 31, 2017 and December 31, 2016, is as follows (in thousands):

		Fair Value Measurements Using		
	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
March 31, 2017				
Money market funds	$ 12,022	$ —	$ 12,022	$ —
December 31, 2016				
Money market funds	$ 34,950	$ —	$ 34,950	$ —

The Company believes that its debt obligations bear interest at rates which approximate prevailing market rates for instruments with similar characteristics and, accordingly, the carrying values for these instruments approximate fair value. The Company's debt obligations are Level 2 measurements in the fair value hierarchy.

The Company's money market funds have been valued on the basis of valuations provided by third-party pricing services, as derived from such services' pricing models. Inputs to the models may include, but are not limited to, reported trades, executable bid and asked prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security. The Company is ultimately responsible for the consolidated financial statements and underlying estimates. Accordingly, the Company assesses the reasonableness of the valuations provided by the third-party pricing services by reviewing actual trade data, broker/dealer quotes and other similar data, which are obtained from quoted market prices or other sources.

No transfers between levels occurred during the periods presented.

9. REVENUE

In October 2016, the Company entered into a research collaboration agreement with Novartis pursuant to which the Company granted to Novartis certain exclusive, world-wide licenses to the Company's intellectual property relating to its platform technology and know-how. Under the collaboration, the Company and Novartis agreed to collaborate, over an initial research term of two years, with respect to the pre-clinical development of nanoparticle drug conjugates comprised of the Company's proprietary polymer covalently linked to Novartis-selected active pharmaceutical ingredients for up to five targets to be agreed upon by the Company and Novartis. Novartis may extend the initial research term by up to two additional one-year periods. In October 2016, the Company received a $5.0 million upfront payment under the collaboration which it recognizes on a straight-line basis over the initial term of the collaboration. The Company also receives funding from Novartis for up to five full-time employees of the Company engaged in activities under the collaboration during the research term. For the three months ended March 31, 2017, the Company recognized revenue of $625,000 in connection with the upfront fee and $567,000 in connection with the funding for activities performed under the collaboration during the research term.

10. RESTRUCTURING

On March 19, 2017, the Company entered into retention agreements with certain key employees. These retention agreements supersede the provisions of such employees' employment agreements and retention letters with the Company. The retention agreements provide for certain lump sum payments ranging from three to 18 months of salary, plus health and dental insurance coverage, while also providing the covered employees with a cash payment upon completion of a change in control. The Company paid $1.1 million in retention payments under the terms of the retention agreements on March 31, 2017, which is included in prepaid expense at March 31, 2017. Under the terms of the retention agreements, the retention payments are earned upon continued employment with the Company for the retention period of three or six months as specified in the retention agreements unless earlier released by the Company. In addition, under the terms of the retention agreements, the Company may be required to pay up to an additional $1.6 million of change in control and severance payments.

On March 20, 2017, the Company announced a restructuring including the termination of approximately 58% of its workforce, from 19 full-time equivalent employees to a total of eight full-time equivalent employees, under a plan expected to be completed during the second quarter of 2017.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are an oncology-focused company applying our proprietary Dynamic Tumor Targeting™ Platform, or the Platform, to develop differentiated therapies. We were incorporated under the laws of the State of Delaware on November 28, 2005, under the name Tempo Pharmaceuticals, Inc. In October 2008, we changed our name to Cerulean Pharma Inc.

On February 1, 2017, we announced that our board of directors had initiated a review of strategic alternatives that could result in changes to our business strategy and future operations. As part of this process, our board determined to review alternatives with the goal of maximizing stockholder value, including a potential sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets.

On March 19, 2017, we entered into a stock purchase agreement, or the Stock Purchase Agreement, with Daré Bioscience, Inc., or Daré, and the holders of capital stock and securities convertible into capital stock of Daré named therein, or the Selling Stockholders, pursuant to which, among other things, the Selling Stockholders agreed to sell to us, and we agreed to purchase from the Selling Stockholders, all of the outstanding shares of capital stock, including those issuable upon conversion of convertible securities, of Daré. We refer to this transaction as the Daré Transaction. Immediately following the closing of the Daré Transaction, we expect that the Selling Stockholders will own between approximately 51% and 70% (depending on the respective net cash (as defined in the Stock Purchase Agreement) of us and Daré five business days prior to the closing) of the outstanding equity securities of Cerulean Pharma Inc. on a fully-diluted basis immediately following consummation of the Daré Transaction.

Consummation of the Daré Transaction is subject to certain closing conditions, including, among others, (1) approval of the issuance of the shares of our common stock in the Daré Transaction by our stockholders in accordance with applicable NASDAQ Stock Market, Inc., or NASDAQ, rules, which (assuming a quorum is present) require the affirmative vote of a majority of the shares of our common stock, present in person or represented by proxy and entitled to vote on the subject matter (excluding broker non-votes and abstentions), (2) the absence of any order, executive order, stay, decree, judgment or injunction or statute, rule or regulation that makes the consummation of the Daré Transaction illegal, or otherwise prohibits the consummation of the Daré Transaction, and (3) the approval of the NASDAQ Initial Listing Application—For Companies Conducting a Business Combination that Results in a Change of Control with respect to the shares of our common stock to be issued in connection with the Daré Transaction. Each party's obligation to consummate the Daré Transaction is also subject to other specified customary conditions, including (1) the representations and warranties of the other party (with Daré and the Selling Stockholders being considered together for such purposes) being true and correct as of the date of the Stock Purchase Agreement and as of the closing date of the Daré Transaction, generally subject to an overall material adverse effect qualification, and (2) the performance in all material respects by the other party (with Daré and the Selling Stockholders being considered together for such purposes) of its obligations under the Stock Purchase Agreement. The Stock Purchase Agreement contains certain termination rights for both us and Daré, and further provides that, upon termination of the Stock Purchase Agreement under specified circumstances, we may be required to pay Daré a termination fee of $0.3 million, or Daré may be required to pay us a termination fee of $0.45 million. There can be no assurances that the Daré Transaction will be consummated.

On March 19, 2017, we also entered into an asset purchase agreement, or the Novartis Asset Purchase Agreement, with Novartis Institutes for BioMedical Research, Inc., or Novartis. Under the Novartis Asset Purchase Agreement, we agreed to sell and assign to Novartis all of our right, title and interest in and to the patent rights, know-how and third-party license agreements relating to the Platform. We refer to this transaction as the Novartis Transaction. At the closing of the Novartis Transaction, Novartis will be obligated to pay us a purchase price of $6.0 million.

Consummation of the Novartis Transaction is subject to us obtaining, pursuant to Delaware law, the approval of the holders of at least a majority of our common stock for the sale of substantially all of our assets in the Novartis Transaction. Each party's obligation to consummate the Novartis Transaction is also subject to other specified customary closing conditions, including (1) the representations and warranties of the other party being true and correct as of the closing date of the Novartis Transaction, generally subject in the case of Novartis' representations and warranties to an overall materiality qualification, and (2) the performance in all material respects by the other party of its obligations under the Novartis Asset Purchase Agreement, including in our case by obtaining all necessary corporate and third-party consents. There can be no assurances that the Novartis Transaction will be consummated.

On March 19, 2017, we also entered into an Asset Purchase Agreement with BlueLink Pharmaceuticals, Inc., or BlueLink, a subsidiary of NewLink Genetics Corporation. We refer to this as the BlueLink Asset Purchase Agreement. Under the BlueLink Asset Purchase Agreement we sold and assigned to BlueLink all of our right, title and interest in and to our clinical product candidates CRLX101 and CRLX301, or the Products. We also transferred and assigned to BlueLink the accompanying intellectual property rights and know-how to the Products. On March 21, 2017, BlueLink paid the purchase price of $1.5 million. Also in connection with the BlueLink Asset Purchase Agreement, we and BlueLink entered into a license agreement in favor of BlueLink, pursuant to which we agreed to grant to BlueLink an exclusive, worldwide, perpetual, sublicensable right and license, under the Platform, to research, develop and commercialize the Products. Pursuant to the Novartis Asset Purchase Agreement, Novartis will assume this license agreement upon the closing of the Novartis Transaction.

We refer to the Daré Transaction, the Novartis Transaction and the BlueLink Asset Purchase Agreement as the 2017 Strategic Transactions.

On March 17, 2017, we entered into a payoff letter with Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.), or Hercules, pursuant to which we agreed to pay off and thereby terminate our Loan and Security Agreement dated as of January 8, 2015, or the Hercules Loan Agreement, with Hercules as lender. Pursuant to the payoff letter, we paid, on March 20, 2017, a total of $12.4 million to Hercules, representing the principal, accrued and unpaid interest, fees, costs and expenses outstanding under the Hercules Loan Agreement in repayment of our outstanding obligations under the Hercules Loan Agreement. This payoff amount included a final end of term charge to Hercules in the amount of $1.4 million, representing 6.7% of the aggregate original principal amount advanced by Hercules. Upon the payment of the $12.4 million pursuant to the payoff letter, all outstanding indebtedness and obligations to Hercules under the Hercules Loan Agreement were deemed paid in full, and the Hercules Loan Agreement was terminated.

On March 20, 2017, we announced a restructuring including the elimination of approximately 58% of our workforce, from 19 full-time equivalent employees to a total of eight full-time equivalent employees, under a plan expected to be completed during the second quarter of 2017.

The Platform is designed to create nanoparticle-drug conjugates, or NDCs, with the aim of providing safer and more effective therapies for patients living with cancer. NDCs consist of anti-cancer therapeutics, or payloads, covalently linked to a proprietary polymer. An important goal for all drugs is to maximize the net clinical benefit by increasing the desired therapeutic effect while reducing adverse effects. This is especially difficult with drugs used to treat cancer, where the goal is to destroy or inhibit growth of cancer cells without damaging healthy cells. We believe NDCs concentrate their anti-cancer payloads inside tumor cells while sparing normal tissue because they are small enough to pass through the leaky pores of new blood vessels in tumors as an entry portal into tumor tissue, but are too large to pass through the pores of healthy blood vessels. Once inside tumors, we believe NDCs are actively taken up into tumor cells where they slowly release their anti-cancer payloads, providing a durable inhibition of their targets.

Based on their properties and design, NDCs have the potential to enable synergistic combination therapies that can offer better tolerability and efficacy. We believe that better tolerability can be achieved through the preferential accumulation of the NDC in the tumor cells while better efficacy can be achieved by combining drugs that have different and complementary mechanisms of action. Cancer is a multi-faceted disease that is rarely adequately addressed by one therapy. Tumor cells are genetically diverse and can rapidly resist and ultimately overcome a single-agent therapy by modulating various adaptive pathways; however, if multiple drugs simultaneously shut down multiple adaptive pathways, there is a greater chance of achieving favorable disease responses for an extended period of time.

The Platform generated two clinical-stage NDCs. The first clinical candidate generated by the Platform, CRLX101, is an NDC with a camptothecin payload. Camptothecin is a potent topoisomerase 1, or topo 1, inhibitor that was too toxic to develop in the clinic; however, CRLX101 reduces the toxicities associated with this highly potent agent, while increasing the payload concentration in tumors. The second clinical candidate generated by the Platform, CRLX301, is an NDC with a docetaxel payload. Docetaxel is a commercially successful oncology drug that suffers from significant toxicities. We sold both clinical candidates to BlueLink on March 19, 2017.

In August 2016, we announced top-line results from our Phase 2, randomized, multi-center clinical trial of CRLX101 in combination with Avastin in the treatment of patients with advanced renal cell carcinoma, or RCC. We refer to this trial as the RCC Trial. The RCC Trial was conducted at 43 sites in the United States and South Korea, and enrolled 115 patients with RCC who progressed through two or three prior lines of therapy. Patients were randomized to receive CRLX101 in combination with Avastin or investigator's choice standard of care, or SOC, therapy. The primary endpoint was progression free survival, or PFS, in the clear cell population assessed by independent radiological review. Secondary endpoints included overall response rate, duration of response and overall survival. The study demonstrated no statistically significant difference in median PFS and objective response rate for the CRLX101 and Avastin combination compared to SOC. The CRLX101 and Avastin combination appeared to be safe and well-tolerated and the safety and tolerability profile of the combination was consistent with that observed in previous studies. We presented the full data set from the RCC Trial at the Fifteenth International Kidney Cancer Symposium in November 2016. Based on these top-line results, we submitted a letter to the United States Food and Drug Administration, or FDA, voluntarily surrendering the Fast Track Designation in metastatic RCC we received in April 2015. We discontinued development of CRLX101 in this indication.

Following the announcement of the RCC Trial data we announced in August 2016 that our board of directors approved a plan to reduce the size of our workforce by approximately 48% to a total of 23 full-time equivalent employees. The workforce reduction, which was substantially completed in December 2016, was designed to reduce our operating expenses while we conducted a review of development options for CRLX101. As of March 31, 2017, we had 18 full-time employees.

In October 2016, we entered into a research collaboration agreement with Novartis. Under the collaboration agreement, we agreed to create NDC candidates using the Platform and Novartis-selected active pharmaceutical ingredients, and Novartis agreed to be responsible for the development and commercialization of NDC products resulting from the collaborative research efforts. The initial research term of the collaboration agreement is two years which may be extended for up to two additional one-year terms. We received a $5.0 million upfront payment under the collaboration agreement, and are entitled to receive additional research, development, regulatory and sales milestone payments, as well as royalties on net sales of any NDC product commercialized by Novartis. In addition, we are entitled to receive funding for up to five full-time employees to be engaged in activities under the collaboration during the research term. If the Novartis Transaction is consummated, this collaboration agreement will be superseded by the Novartis Asset Purchase Agreement.

To date, we have devoted substantially all of our resources to our drug discovery and development efforts, including conducting clinical trials of the Products (which we sold in March 2017 to BlueLink), protecting our intellectual property and the general and administrative support of our operations. We have generated no revenue from product sales and do not expect to generate any revenue from product sales for the next several years, if ever. Through March 31, 2017, we have funded our operations primarily through $84.2 million in proceeds from the sale of shares of our convertible preferred stock in private placements, net proceeds of $59.9 million from sales of shares of our common stock in our initial public offering, or IPO, net proceeds of $37.2 million from the sale of shares of our common stock in April 2015 in an underwritten public offering, $17.3 million in proceeds from our sale of convertible promissory notes, $10.0 million in proceeds from a loan and security agreement with Lighthouse Capital Partners VI, L.P., or Lighthouse Capital, and $21.0 million in proceeds from the Hercules Loan Agreement. We refer to our loan and security agreement with Lighthouse Capital as the Lighthouse Loan Agreement. In October 2016, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC, or Aspire, for a $20.0 million firm commitment at-the-market equity facility, which we refer to as the ATM. In connection with entry into the ATM, Aspire made an initial $1.0 million investment and we have not made any other sales to date under the ATM.

We have never been profitable and have incurred significant operating losses since our incorporation. As of March 31, 2017, we had an accumulated deficit of $207.0 million. We incurred net losses of $6.3 million and $13.5 million for the three months ended March 31, 2017 and 2016, respectively. With the sale of our two clinical product candidates, the proposed sale of our Platform, and the reduction of staff to eight full-time employees, we have effectively ceased prior clinical research and are focused on maintaining our assets until they are either sold or our corporate business strategy with Daré, as described above, is executed, we complete any other strategic transactions, we determine to continue to operate the Platform or we otherwise decide to liquidate our assets or dissolve.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and from year to year. Based on our 2017 operating plan and our estimates as of the date of this Quarterly Report on Form 10-Q regarding our rate of cash expenditures, we estimate that our cash and cash equivalents as of June 30, 2017, assuming we have not consummated either the Novartis Transaction or the Daré Transaction, will be between $4 million and $6 million. If we do not consummate the Novartis Transaction and/or the Daré Transaction, we will need to raise additional capital in the future to support our expenses and operating activities. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate research activities under our collaboration agreement with Novartis, or to scale back, suspend or terminate our business operations. In the event that the Daré Transaction does not close, our board of directors may elect to, among other things, dissolve the company and liquidate its assets whether under Title 7 or Title 11 of the United States Code or otherwise. If our board of directors decides to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, prior to any distribution to stockholders. There can be no assurances as to the amount or timing of available cash left to distribute to our stockholders, if any, after we pay our debts and other obligations and set aside funds for reserves. We expect that the amount of cash left, if any, to distribute to our stockholders would be materially less than the expected cash and cash equivalents amounts set forth herein as of June 30, 2017.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the next several years, if ever. Beginning in the fourth quarter of 2016 we have generated revenue from research and development payments under our collaboration agreement with Novartis. Prior to the fourth quarter of 2016, our only revenue was attributable to a government tax credit that we received in 2010 and payments in each of the years from 2011 through 2014 from four material transfer agreements and a research agreement.

In the future, we may generate revenue from a combination of product sales, license fees, milestone and research and development payments in connection with strategic partnerships, and royalties resulting from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of any such payments. Our ability to generate product revenues will depend on the successful development and eventual commercialization of product candidates. If we fail to complete the development of product candidates in a timely manner or to obtain regulatory approval for such product candidates, our ability to generate future revenue and our results of operations and financial position would be materially adversely affected.

Research and Development Expenses

Research and development expense reflected on our financial statements consists of costs incurred in connection with the discovery and development of the Platform and the NDCs. These expenses consist primarily of:

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, or CROs, investigative sites that conduct our clinical trials and consultants that conduct a portion of our preclinical studies;
- expenses relating to scientific and medical consultants and advisors;
- the cost of acquiring, manufacturing and distributing clinical trial materials;
- facilities, depreciation of fixed assets and other allocated expenses, including direct and allocated expenses for rent and maintenance of facilities and equipment;
- lab supplies, reagents, active pharmaceutical ingredients and other direct and indirect costs in support of our preclinical and clinical activities;
- license fees related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development costs as incurred.

Conducting a significant amount of research and development has been central to our business model for the periods covered by this Quarterly Report on Form 10-Q. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development primarily due to the increased size and duration of late-stage clinical trials. We expect our research and development expenses will decrease for 2017 compared to prior years.

We have used our employee and infrastructure resources across multiple research and development programs. The following summarizes the programs for which we have incurred the most significant research and development expense.

CRLX101 and CRLX301

CRLX101 was our lead product candidate until March 2017. There are two ongoing clinical trials of CRLX101 in this indication: (1) a Phase 1b/2 company-sponsored trial of CRLX101 in combination with weekly paclitaxel in patients with relapsed ovarian cancer in collaboration with GOG Foundation, Inc. (formerly known as the Gynecologic Oncology Group); and (2) a Phase 2 Investigator Sponsored Trial, or IST, exploring CRLX101 as monotherapy and in combination with Avastin in patients with relapsed ovarian cancer, conducted by Massachusetts General Hospital and affiliated Harvard University teaching hospitals.

Additional trials involving CRLX101 are also ongoing, including (1) a Phase 1/2 clinical trial sponsored by the National Cancer Institute, evaluating the combination of CRLX101 and LYNPARZA™ (olaparib) in patients with advanced solid tumors, and (2) a Phase 1b company-sponsored trial exploring a dose-intensive schedule for CRLX101 in patients with solid tumors, which includes an arm exploring weekly CRLX101 in combination with a chemotherapy regimen known as FOLFOX in solid tumor patients.

CRLX301 was our second product candidate until March 2017. CRLX301 is currently being evaluated in a Phase 1/2a trial in patients with advanced solid tumor malignancies in order to establish the safety of the drug and the maximum tolerated dose for two dosing schedules.

In March 2017, we sold and assigned to BlueLink all of our right, title and interest in and to CRLX101 and CRLX301. As a result, we will not incur additional research and development expenses with respect to these programs in future periods.

The Platform

If the Novartis Transaction is not consummated, our board of directors decides to continue to operate the Platform, and if we are able to raise additional funds, we would expect that the expenses related to our NDCs and the development of the Platform would increase in 2017 as compared to 2016 as we would focus on research, development and strategic collaborations with new partners and we would need additional staffing to operate the Platform. We cannot accurately predict future research and development expenses for NDCs because such costs are dependent on a number of variables, including the success of potential future collaborations and preclinical studies of any such NDC. If the Novartis Transaction is consummated, we expect that we would not incur any significant expenses related to the Platform in future periods.

If we continue operating the Platform, the successful development of any NDC, whether by us or a future collaborator, would be highly uncertain. As such, at this time, we cannot reasonably predict with certainty the duration and costs of the current or future preclinical studies or clinical trials of any NDC or if, when or to what extent we will generate revenues from any commercialization and sale of any of NDCs that obtain marketing approval. We or any potential collaborator may never succeed in achieving regulatory approval for any NDCs. The duration, costs and timing of development of NDCs will depend on a variety of factors, including:

- the scope and rate of progress of future clinical trials;
- a continued acceptable safety profile of any product candidate once approved;
- the scope, progress, timing, results and costs of researching and developing NDCs and conducting preclinical and clinical trials;
- results from any future clinical trials;
- significant and changing government regulation in the United States and abroad;
- the costs, timing and outcome of regulatory review or approval of NDCs in the United States and abroad;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to raise additional capital, as and when needed;
- establishment of arrangements with third party suppliers of raw materials and third party manufacturers of finished drug product;
- our ability, or the ability of any collaborator, to manufacture, market, commercialize and achieve market acceptance for any NDCs that we or such collaborator may develop in the future;
- the emergence of competing technologies and products and other adverse market developments; and
- the cost and timing of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims.

Any change in the outcome of any of these variables with respect to the development of an NDC could mean a significant change in the cost and timing associated with the development of that NDC. For example, if the FDA, or a comparable non-U.S. regulatory authority were to require us or a collaborator to conduct clinical trials beyond those anticipated to be required for the marketing authorization of an NDC, or if significant delays in enrollment in any clinical trial occur, significant additional financial resources and time may be necessary to obtain marketing authorization.

As a result of the uncertainties discussed above, we are unable to determine when, or to what extent, we will generate revenues from the commercialization and sale of any NDC either on our own or as part of a collaboration. We anticipate that, if the Novartis Transaction is not consummated, we will make determinations as to which additional programs to pursue, if any, and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data with respect to each NDC, our then-current financial condition, agreements with collaborators, and ongoing assessment of the NDCs' commercial potential. We will need to raise additional capital in the future in order to fund the development of any NDCs.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in our executive, finance, business development, legal and human resources functions. Other general and administrative expenses include patent filing, patent prosecution, professional fees for legal, insurance, consulting, information technology, auditing and tax services and facility costs not otherwise included in research and development expenses. We expect that our general and administrative expenses will decrease for 2017 as compared to 2016 as a result of our reduction in force and other cost control measures.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation.

Interest Expense

Interest expense consists primarily of interest, amortization of debt discount and amortization of deferred financing costs associated with the Hercules Loan Agreement. Interest expense also includes the write off of debt discount and deferred financing costs associated with the repayment of the Hercules Loan Agreement in March 2017. We expect that our interest expense will decrease for 2017 as compared to 2016 as a result of our repayment in full of all amounts outstanding under, and termination of, the Hercules Loan Agreement in March 2017.

Results of Operations

Comparison of Three Months Ended March 31, 2017 and 2016 (Unaudited)

The following table summarizes our consolidated results of operations for the three months ended March 31, 2017 and 2016, together with the changes in those items in dollars and as a percentage (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2017	2016	Dollar	%
Revenue	$ 1,192	$ —	$ 1,192	—
Operating expenses:				
Research and development	4,651	9,770	(5,119)	(52)%
General and administrative	3,587	3,118	469	15%
Gain on sale of asset	(1,500)	—	(1,500)	—
Loss from operations	(5,546)	(12,888)	7,342	(57)%
Total other expense, net	(793)	(654)	(139)	21%
Net loss	$(6,339)	$(13,542)	$ 7,203	(53)%

Research and development. Research and development expense for the three months ended March 31, 2017 was $4.7 million compared to $9.8 million for the three months ended March 31, 2016, a decrease of $5.1 million, or 52%. The decrease in research and development expenses is primarily attributable to a decrease of $3.9 million in external expenses, $0.9 million in salary and benefits expenses, and $0.3 million in operating supplies and expense. The decrease in external expenses is primarily attributable to a decrease of $2.7 million in chemistry, manufacturing, and controls, or CMC, expenses combined with a decrease of $1.1 million associated with ongoing clinical trials. The decrease in CMC expenses is attributable to the absence of manufacturing activities in the first quarter of 2017 compared to increased activity in the first quarter of 2016 to support then-ongoing and future clinical development. The decrease in clinical trials expenses reflects the decrease in clinical activity as we wind down clinical operations.

General and administrative. General and administrative expense for the three months ended March 31, 2017, was $3.6 million compared to $3.1 million for the three months ended March 31, 2016, an increase of $0.5 million, or 15%. The increase in general and administrative costs was attributable to an increase in legal expenses of $1.1 million primarily associated with the 2017 Strategic Transactions. The increase in legal expenses was partially offset by a decrease in salary and benefits expenses of $0.4 million, and a decrease in other general and administrative costs of $0.2 million reflecting a reduction in head count and general cost cutting measures.

Gain on sale of asset . Gain on asset sale reflects the proceeds from the sale of the Products to BlueLink for which there was no corresponding value on the balance sheet. Under the BlueLink Asset Purchase Agreement we sold and assigned to BlueLink all of our right, title and interest in and to the Products. We also transferred and assigned to BlueLink the accompanying intellectual property rights and know-how to the Products.

Other expense, net. Other expense, net was $0.8 million for the three months ended March 31, 2017 compared to $0.7 million for the three months ended March 31, 2016, an increase of $0.1 million or 21%. For the three months ended March 31, 2017 other expense, net, was primarily interest expense associated with repayment of the Hercules Loan Agreement. Interest expense associated with the repayment of the Hercules Loan Agreement includes $0.2 million interest paid, $0.4 million for the remaining balance accrued for the end of term charge and $0.2

million for the write-off of the unamortized balance of debt discount and deferred financing charges. For the three months ended March 31, 2016 other expense, net, was primarily interest expense associated with the Hercules Loan Agreement, including $0.3 million for the amortization of debt discount and deferred financing costs.

Liquidity and Capital Resources

From our incorporation through March 31, 2017, we raised an aggregate of $236.6 million to fund our operations, of which $84.2 million was from the sale of preferred stock in private placements, $59.9 million was from the IPO, $37.2 million was from our follow-on offering in April 2015, $17.3 million was from the sale of convertible promissory notes, $31.0 million was from borrowings under loan and security agreements, $1.0 million was from the private placement of our common stock to Hercules, $1.0 million was from the initial purchase by Aspire under the ATM and $5.0 million was from the upfront payment under the collaboration agreement with Novartis. As of March 31, 2017, we had cash and cash equivalents of $12.0 million.

Indebtedness

Hercules Loan Agreement. On January 8, 2015, we entered into the Hercules Loan Agreement and borrowed $15.0 million from Hercules. We used a portion of those proceeds to repay our outstanding indebtedness under the Lighthouse Loan Agreement. The Hercules Loan Agreement provided for up to three separate tranches of borrowings, the first of which was funded in the amount of $15.0 million on January 8, 2015. On November 24, 2015, we drew a second tranche in the amount of $6.0 million.

Our indebtedness under the Hercules Loan Agreement was scheduled to mature on July 1, 2018. Each advance under the Hercules Loan Agreement accrued interest at a floating per annum rate equal to the greater of (i) 7.30% or (ii) the sum of 7.30% plus the prime rate minus 5.75%. The Hercules Loan Agreement provided for interest-only payments on a monthly basis until December 31, 2015. Thereafter, payments were payable monthly in equal installments of principal and interest to fully amortize the outstanding principal over the remaining term of the loan, subject to recalculation upon a change in the prime rate. At the end of the loan term (whether at maturity, by prepayment in full or otherwise), we were required to pay a final end-of-term charge to Hercules in the amount of 6.7% of the aggregate original principal amount advanced by Hercules.

On March 17, 2017, we agreed with Hercules that Hercules would consent to the sale of assets to BlueLink, pursuant to the BlueLink Asset Purchase Agreement, and that Cerulean would repay Hercules in full. On March 20, 2017, we paid $12.4 million to Hercules, representing the principal, accrued and unpaid interest, fees, costs and expenses outstanding under the Hercules Loan Agreement in full repayment of our outstanding obligations under the Hercules Loan Agreement which was terminated. There were no prepayment charges associated with the early repayment of the loan.

Plan of Operations and Future Funding Requirements

Our primary uses of capital are compensation and related expenses, clinical trial costs, contract manufacturing services, third-party clinical research and development services, laboratory and related supplies, legal and other regulatory expenses and general overhead costs.

As of March 31, 2017, we had cash and cash equivalents of $12.0 million. We have no other sources of significant liquidity in place as of March 31, 2017. Based on our 2017 operating plan and our estimates as of the date of this Quarterly Report on Form 10-Q regarding our rate of cash expenditures, we estimate that our cash and cash equivalents as of June 30, 2017, assuming we have not consummated the transactions contemplated under either the Novartis Transaction or the Daré Transaction, will be between $4 million and $6 million. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate research activities under our collaboration agreement with Novartis, or to scale back, suspend or terminate our business operations. In the event that the Daré Transaction does not close, our board of directors may elect to, among other things, dissolve the company and liquidate its assets whether under Title 7 or Title 11 of the United States Code or otherwise. If our board of directors decides to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, prior to any distribution to stockholders. There can be no assurances as to the amount or timing of available cash left to distribute to our stockholders, if any, after we pay our debts and other obligations and set aside funds for reserves. Based on our 2017 operating plan and its estimates as of the date of filing of this periodic report on Form 10-Q regarding our rate of cash expenditures and the closing date of the Daré Transaction, we estimate that our Net Cash (as defined in the Stock Purchase Agreement) at the time of closing the Daré Transaction, which will be used to calculate the ownership interest of our stockholders, will be between $2.5 million and $4 million if the Novartis Transaction is not consummated and between $8.5 million and $10 million if the Novartis Transaction is consummated.

On May 5, 2017, NASDAQ notified us that we were not in compliance with the $1.00 minimum bid price because the minimum bid price of our common stock fell below $1.00 for 30 consecutive business days. We have been provided an initial period of 180 calendar days, or until November 1, 2017, to regain compliance with the listing requirements. If, at any time before November 1, 2017, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days we may be eligible to regain compliance with the minimum bid requirement. There is no guarantee that we will be able to continue complying with the minimum bid price rule or other NASDAQ Global Market requirements. Delisting from the NASDAQ Global Market could reduce the visibility, liquidity and price of our common stock, and make it more difficult for us to raise additional capital.

Our future capital requirements will depend on many factors, including:

- whether and when we are able to consummate the Daré Transaction and/or the Novartis Transaction;
- the number and development requirements of the NDCs we or any collaborators pursue;
- the scope, progress, timing, results and costs of researching and developing NDCs, and conducting preclinical studies and clinical trials;

- the costs, timing and outcome of regulatory review of NDCs in the United States and abroad;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any NDCs for which we or a collaborator receive marketing approval;
- the revenue, if any, received from commercial sales of any NDCs for which we or a collaborator receive marketing approval;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other medicines and technology;
- our headcount growth and associated costs; and
- the costs of operating as a public company.

Identifying potential NDCs and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our NDCs, if approved, may not achieve commercial success. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings and revenue from collaboration arrangements. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate any product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table sets forth the primary sources and uses of cash for each period set forth below (in thousands):

	Three Months Ended March 31,	
	2017	2016
Net cash used in operating activities	$ (10,000)	$ (13,260)
Net cash provided by (used in) investing activities	1,500	(242)
Net cash used in financing activities	(14,422)	(1,891)
Net decrease in cash and cash equivalents	$ (22,922)	$ (15,393)

Net Cash Used in Operating Activities

The net use of cash in each period resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

During the three months ended March 31, 2017, cash used in operating activities consisted of our net loss of $6.3 million, net cash used in changes in our operating assets and liabilities of $3.2 million and the non-cash adjustment for the gain on sale of asset of $1.5 million, partially offset by net non-cash charges of $1.0 million. Our net non-cash charges during the period consisted primarily of stock-based compensation expense and amortization of debt discount and deferred financing costs offset by deferred revenue. Cash used in changes in our operating assets and liabilities consisted of a decrease in accounts payable and accrued expenses of $1.9 million and an increase in accounts receivable and prepaid expenses of $1.3 million.

During the three months ended March 31, 2016, cash used in operating activities consisted of our net loss of $13.5 million and net cash used in changes in our operating assets and liabilities of $0.8 million. Our net non-cash charges during the period consisted primarily of stock-based compensation expense. Cash used in changes in our operating assets and liabilities consisted of a net decrease in accounts payable and accrued expenses of $0.6 million, and an increase in accounts receivable, prepaid expenses and other current assets of $0.2 million.

Net Cash Provided by (Used in) Investing Activities

During the three months ended March 31, 2017, net cash provided by investing activities was attributable to proceeds of $1.5 million from the sale of assets under the BlueLink Asset Purchase Agreement.

During the three months ended March 31, 2016, net cash used in investing activities was primarily attributable to purchases of property and equipment of $0.4 million partially offset by cash proceeds of $0.1 million from a decrease in restricted cash used to collateralize a stand-by letter of credit issued as a security deposit on our former facility lease.

Net Cash Used in Financing Activities

During the three months ended March 31, 2017, net cash used in financing activities was primarily attributable to principal payments of $13.1 million reflecting payment in full of the principal balance and $1.4 million for the end of term charge due under the Hercules loan Agreement.

During the three months ended March 31, 2016, net cash used in financing activities was primarily attributable to principal payments of $1.9 million under the Hercules Loan Agreement.

Contractual Obligations and Contingent Liabilities

As of March 31, 2017, there were no material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Recent Accounting Pronouncements

Please refer to Note 2 to our consolidated financial statements included in Part I, Item 1, “Financial Statements (Unaudited)” of this quarterly report on Form 10-Q for a description of recent accounting pronouncements applicable to our business.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of March 31, 2017, we had cash and cash equivalents, including restricted cash, of $12.0 million, consisting primarily of investments in money market funds and certificates of deposit. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in cash and cash equivalents. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosures.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2017.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2017, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Our business is subject to numerous risks. The following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in this Quarterly Report on Form 10-Q and other filings with the Securities and Exchange Commission, or SEC, press releases, communications with investors and oral statements. Actual future results may differ materially from those anticipated in our forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Risks Related to our Proposed Transaction with Novartis

Our strategic transaction with Novartis may not be consummated or may not deliver the anticipated benefits we expect.

As part of our board of directors' review of strategic alternatives, in March 2017, we entered into an asset purchase agreement, or the Novartis Asset Purchase Agreement, with Novartis, pursuant to which, among other things, we agreed to sell the Platform to Novartis. We refer to this transaction as the Novartis Transaction. Consummation of the Novartis Transaction is subject to us obtaining, pursuant to Delaware law, the approval of the holders of at least a majority of our common stock for the sale of substantially all of our assets in the Novartis Transaction. At the closing of the Novartis Transaction Novartis will be obligated to pay a purchase price of $6.0 million

We are devoting a significant proportion of our time and resources to consummating the Novartis Transaction, however, there can be no assurance that such activities will result in the consummation of this transaction. Consummation of the Novartis Transaction is subject to us obtaining, pursuant to Delaware law, the approval of the holders of at least a majority of our common stock for the sale of substantially all of our assets in the Novartis Transaction. Each party's obligation to consummate the Novartis Transaction is also subject to other specified customary conditions, including (1) the representations and warranties of the other party being true and correct as of the closing date of the Novartis Transaction, generally subject in the case of Novartis' representations and warranties to an overall materiality qualification, and (2) the performance in all material respects by the other party of its obligations under the Novartis Asset Purchase Agreement, including in our case by obtaining all necessary corporate and third-party consents. In the event that any of these closing conditions is not satisfied, we may not be able to consummate the Novartis Transaction. In addition, even if we are able to consummate the Novartis Transaction, such transaction may not deliver the benefits we anticipate or enhance stockholder value.

Potential litigation filed against us could prevent or delay the completion of the Novartis Transaction or result in the payment of damages following completion of the Novartis Transaction.

We and members of our board of directors or executive officers may in the future be parties, among others, to claims and litigation related to the Novartis Transaction, including putative stockholder class actions. Among other remedies, the plaintiffs in such matters could seek to enjoin the Novartis Transaction. The results of complex legal proceedings are difficult to predict, and could delay or prevent the Novartis Transaction from being completed in a timely manner or at all. In addition, the existence or threat of litigation relating to the Novartis Transaction could impact the likelihood of obtaining approval from our stockholders of the Novartis Transaction. Moreover, any future litigation could be time consuming and expensive, could divert our attention away from regular business, and, if any potential lawsuit is adversely resolved, could have a material adverse effect on our results of operations and financial condition.

One of the conditions to the closing of the Novartis Transaction is that the consummation of the Novartis Transaction not violate any applicable national, supranational, federal, state, local, or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license, or permit of any governmental authority. Consequently, if a settlement or other resolution is not reached in any potential lawsuit and the plaintiffs secure injunctive or other relief prohibiting, delaying or otherwise adversely affecting Novartis' and/or our ability to complete the Novartis Transaction, such injunctive or other relief may prevent the Novartis Transaction from being completed in a timely manner, or at all.

The announcement and pendency of the Novartis Transaction, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects.

The announcement and pendency of the Novartis Transaction, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects. For example, the closing price of our common stock as reported by NASDAQ Global Market on March 17, 2017, prior to our announcement of the Daré Transaction, was $3.32 per share, and the closing price of our common stock as reported by the NASDAQ Global Market on May 8, 2017 was $0.46 per share. This decline may be attributable in part to such announcement. In the event that the Novartis Transaction is not completed, the announcement of the termination of the Novartis Asset Purchase Agreement may also adversely affect the trading price of our common stock and our business prospects.

Failure to consummate the Novartis Transaction could harm our common stock price and our future business and operations.

The Novartis Transaction will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Novartis Asset Purchase Agreement is terminated in accordance with its terms. If the Novartis Transaction is not consummated, the price of our common stock may decline and remain volatile. Additionally, if the Novartis Transaction is not consummated, our ability to consummate the Daré Transaction could be put at risk or, in the event we are nonetheless able to consummate the Daré Transaction, our stockholders may own less of the resulting company after consummation of the Daré Transaction.

Furthermore, if the Novartis Transaction does not close for any reason, our board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of the Platform, attempt to continue the currently existing research collaboration with Novartis, seek to continue to operate the Platform or dissolve our company and liquidate our assets. If we seek another strategic transaction or attempt to sell or otherwise dispose of the Platform, there is no assurance that we will be able to do so, that the terms would be equal to or superior to the terms of the Novartis Transaction or as to the timing of such transaction. If we attempt to continue the currently existing research collaboration with Novartis, Novartis may elect to exercise its termination rights thereunder. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

If we were to seek to continue to operate the Platform, we would need to determine whether and how to continue discovery and research programs. We would also need to raise funds to support continued operations, which we may be unable to do in a timely fashion, upon attractive terms, or at all, and re-assess our workforce requirements in consideration of our previously announced reduction in force.

Risks Related to our Proposed Transaction with Daré

Our strategic transaction with Daré may not be consummated or may not deliver the anticipated benefits we expect.

On February 1, 2017, we announced that our board of directors had initiated a review of strategic alternatives that could result in changes to our business strategy and future operations. As part of this process, our board determined to review alternatives with the goal of maximizing stockholder value, including potentially a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets, and liquidation of our company. As part of this process, in March 2017, we entered into a stock purchase agreement, or the Stock Purchase Agreement, with Daré Bioscience, Inc., or Daré, and the holders of capital stock and securities convertible into capital stock of Daré named therein, or the Selling Stockholders, pursuant to which, among other things, the Selling Stockholders agreed to sell to us, and we agreed to purchase from the Selling Stockholders, all of the outstanding shares of capital stock, including those issuable upon conversion of convertible securities, of Daré. We refer to this transaction as the Daré Transaction. Subject to the terms and conditions of the Stock Purchase Agreement, at the closing of the Daré Transaction, the Selling Stockholders will collectively receive a number of shares of Cerulean common stock equal to the product of the number of shares of Daré stock held by such Selling Stockholder multiplied by an exchange ratio calculated based on the relative valuations of each of Daré and Cerulean at the closing of the Daré Transaction. Also in connection with the Daré Transaction, Cerulean will assume the (i) outstanding stock option awards of Daré, and (ii) outstanding warrants of Daré, each of which will be adjusted to reflect the exchange ratio for the Daré Transaction. Immediately following the closing of the Daré Transaction, we expect that the Selling Stockholders will own between approximately 51% and 70% (depending on the respective net cash (as defined in the Stock Purchase Agreement) of us and Daré five business days prior to the closing) of the outstanding equity securities of Cerulean Pharma Inc. on a fully-diluted basis immediately following consummation of the Daré Transaction.

We are devoting a significant proportion of our time and resources to consummating this transaction, however, there can be no assurance that such activities will result in such consummation. Consummation of the Daré Transaction is subject to certain closing conditions, including, among others, (1) approval of the issuance of the shares of our common stock in the Daré Transaction by our stockholders in accordance with applicable NASDAQ Stock Market, Inc., or NASDAQ, rules, which (assuming a quorum is present) require the affirmative vote of a majority of the shares of our common stock, present in person or represented by proxy and entitled to vote on the subject matter (excluding broker non-votes and abstentions); (2) the absence of any order, executive order, stay, decree, judgment or injunction or statute, rule or regulation that makes the consummation of the Daré Transaction illegal, or otherwise prohibits the consummation of the Daré Transaction, and (3) the approval of the NASDAQ Initial Listing Application—For Companies Conducting a Business Combination that Results in a Change of Control with respect to the shares of our common stock to

be issued in connection with the Daré Transaction. Approval of the NASDAQ Initial Listing Application in particular will require the company, on a combined basis post-Daré Transaction, to meet certain listing criteria, including a minimum market value of publicly held shares, a minimum bid price and a minimum amount of public held shares, some of which are outside our control. Each party's obligation to consummate the Daré Transaction is also subject to other specified customary conditions, including (1) the representations and warranties of the other party (with Daré and the Selling Stockholders being considered together for such purposes) being true and correct as of the date of the Stock Purchase Agreement and as of the closing date of the Daré Transaction, generally subject to an overall material adverse effect qualification, and (2) the performance in all material respects by the other party (with Daré and the Selling Stockholders being considered together for such purposes) of its obligations under the Stock Purchase Agreement. In the event that any of these closing conditions is not satisfied or waived, we may not be able to consummate the Daré Transaction. In addition, even if we are able to consummate the Daré Transaction, such transaction may not deliver the benefits we anticipate or enhance stockholder value. If the Daré Transaction is consummated following the waiver by Daré or us of any of these closing conditions, the Daré Transaction may not deliver the benefits satisfaction of such closing condition would have for our stockholders.

Certain provisions of the Stock Purchase Agreement may discourage third parties from submitting alternative acquisition proposals, including proposals that may be superior to the arrangements contemplated by the Stock Purchase Agreement.

The terms of the Stock Purchase Agreement prohibit each of us and Daré from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances, including when such party's board of directors determines in good faith that an unsolicited alternative takeover proposal is a superior takeover proposal and is reasonably capable of being consummated. In addition, if the Stock Purchase Agreement is terminated by us or Daré under certain circumstances, including because of a decision of our board of directors to recommend a superior proposal, we would be required to pay a termination fee of $300,000 to Daré. This termination fee may discourage third parties from submitting alternative takeover proposals to us or our stockholders, and may cause our board of directors to be less inclined to recommend an alternative proposal.

Potential litigation could prevent or delay the completion of the Daré Transaction or result in the payment of damages following completion of the Daré Transaction.

We and members of our board of directors or executive officers may in the future be parties, among others, to claims and litigation related to the Daré Transaction, including putative stockholder class actions. Among other remedies, the plaintiffs in such matters could seek to enjoin the Daré Transaction. The results of complex legal proceedings are difficult to predict, and could delay or prevent the Daré Transaction from being completed in a timely manner or at all. In addition, the existence or threat of litigation relating to the Daré Transaction could impact the likelihood of obtaining approval from our stockholders of the Daré Transaction. Moreover, any future litigation could be time consuming and expensive, could divert our attention away from regular business, and, if any potential lawsuit is adversely resolved, could have a material adverse effect on our results of operations and financial condition.

One of the conditions to the closing of the Daré Transaction is that no applicable governmental entity shall have enacted, issued, promulgated, enforced or entered any order, executive order, stay, decree, judgment or injunction (preliminary or permanent) or statute, rule or regulation which is in effect and which has the effect of making the Daré Transaction illegal or otherwise prohibiting consummation of the Daré Transaction. Consequently, if a settlement or other resolution is not reached in any potential lawsuit and the plaintiffs secure injunctive or other relief prohibiting, delaying or otherwise adversely affecting Daré's and/or our ability to complete the Daré Transaction, such injunctive or other relief may prevent the Daré Transaction from being completed in a timely manner, or at all.

The announcement and pendency of the Daré Transaction, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects.

The announcement and pendency of the Daré Transaction, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects. For example, the closing price of our common stock as reported by NASDAQ Global Market on March 17, 2017, prior to our announcement of the Daré Transaction, was $3.32 per share, and the closing price of our common stock as reported by the NASDAQ Global Market on May 8, 2017 was $0.46 per share. This decline may be attributable in part to such announcement. In the event that the Daré Transaction is not completed, the announcement of the termination of the Stock Purchase Agreement may also adversely affect the trading price of our common stock and our business prospects.

Failure to consummate the Daré Transaction may result in us paying a termination fee to Daré and could harm our common stock price and our future business and operations.

The Daré Transaction will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Stock Purchase Agreement is terminated in accordance with its terms. If the Daré Transaction is not consummated, we are subject to the following risks, among others:

- if the Stock Purchase Agreement is terminated under certain circumstances, we will be required to pay Daré a termination fee of $300,000;

- the price of our common stock may decline and remain volatile; and
- we may have insufficient assets to continue operating our business or remain solvent and could be forced to dissolve our company and liquidate our assets to pursue a dissolution and liquidation.

If the Daré Transaction does not close for any reason, our board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of our various assets or dissolve our company and liquidate our assets. If we seek another strategic transaction or attempt to sell or otherwise dispose of our various assets, there is no assurance that we will be able to do so, that the terms would be equal to or superior to the terms of the Daré Transaction or as to the timing of such transaction. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

If we do not successfully consummate the transaction with Daré, our board of directors may dissolve our company and liquidate our assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such transaction or liquidation.

If the Daré Transaction does not close for any reason, our board of directors may elect to, among other things, dissolve our company. If we decide to dissolve, whether under the Bankruptcy Code or otherwise, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, prior to any distribution to stockholders. There can be no assurances as to the amount or timing of available cash left to distribute to stockholders, if any, after paying our debts and other obligations and setting aside funds for reserves. If the Cerulean Board decides to pursue a case under the Bankruptcy Code, it will not be required to seek stockholder approval for the commencement of such a case.

In the event of a dissolution, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such dissolution and any related transaction or liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations in preparation for the consummation of the Daré Transaction. In addition, the amount of cash available for distribution in the event of a dissolution will heavily depend on whether we consummate the sale of our Dynamic Tumor Targeting platform technology, or the Platform, to Novartis Institutes of BioMedical Research, Inc., or Novartis, in connection with which we would receive a $6.0 million purchase price. Further, the Stock Purchase Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, we may be required to pay Daré a termination fee of $300,000, which would further decrease our available cash resources. If our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution under Delaware corporate law, we would be required to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. A similar requirement would apply in any dissolution of the company under the Bankruptcy Code. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our clinical trials; (ii) obligations under our employment and retention agreements with certain employees; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve for contingent and unknown obligations. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our, whether under the Bankruptcy Code or otherwise. In the event that we were to pursue a case under Chapter 7 of the Bankruptcy Code, a Chapter 7 trustee would be appointed for us and that trustee would displace our board of directors with respect to decisions regarding our dissolution and any related transaction or liquidation, but the same requirements regarding payment of and provision for obligations, prior to any distributions to stockholders, would apply in that context as well

Risks Related to the Operation of Our Business Without Consummation of the Daré Transaction and/or the Novartis Transaction.

Risks Related to Our Financial Position and Need for Additional Capital

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

We will need to raise additional capital to fund any continued research or development programs using the Platform. As a result of our reduction in force and other cost control measures, we expect our expenses to decrease in the short term. In the future, however, we expect that our expenses may increase in connection with our ongoing activities, particularly if we continue research and

development and initiate any clinical trials of, and seek regulatory approval for nanoparticle-drug conjugates, or NDCs generated through use of the Platform. In addition, if we obtain regulatory approval for any of our NDCs, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs that may be required for the manufacture of any NDC that receives marketing approval may be substantial, and manufacturing our NDCs for commercial sale will require expensive and specialized facilities, processes and materials. Accordingly we will need to obtain substantial additional funding to advance the research and development of any NDC and to fund our continuing operations. We may be unable to raise capital when needed or on attractive terms, and if so we could be forced to delay, reduce or eliminate any research and development programs.

In October 2016, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC, or Aspire, pursuant to which Cerulean has the right to sell certain amounts of its common stock, up to an aggregate total of $20.0 million of our common stock, over a 24-month period, at prices based on a formula linked to current market prices at the time of each sale. We refer to this as the ATM. In connection with entry into the ATM, we issued 700,000 shares of our common stock to Aspire as a commitment fee, and sold 800,000 shares of our common stock at $1.25 per share, for an initial amount of $1.0 million. Up to $19.0 million remains available under the ATM, upon the terms and subject to the conditions and limitations set forth therein. While we have the right to determine the amounts and timing of sales of common stock to Aspire under the ATM, these rights are subject to certain limits and restrictions. These limits and restrictions include limits on the number of shares we can sell to Aspire on any one trading day, as well as stock price trading price restrictions, which prohibit us from making certain sales to Aspire on any trading day on which the closing sale price of our common stock is below $0.50 per share and from making any sales to Aspire on any trading on which the closing sale price is less than $0.25 per share. Accordingly, we may not be able to sell shares under the agreement at prices that we deem acceptable, and there can be no assurance that we will be able to sell the remaining $19.0 million of common stock contemplated under the ATM.

As of March 31, 2017, we had cash and cash equivalents of $12.0 million. We have no other sources of significant liquidity in place as of March 31, 2017. Based on our 2017 operating plan and our estimates as of the date of this Quarterly Report on Form 10-Q regarding our rate of cash expenditures, we estimate that our cash and cash equivalents as of June 30, 2017, assuming we have not consummated the transactions contemplated under either the Novartis Transaction or the Daré Transaction, will be between $4 million and $6 million. In the event that the Daré Transaction does not close, our board of directors may elect to, among other things, dissolve the company and liquidate our assets whether under Title 7 or Title 11 of the United States Code or otherwise. If our board of directors decides to dissolve the company and liquidate its assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, prior to any distribution to stockholders. There can be no assurances as to the amount or timing of available cash left to distribute to our stockholders, if any, after we pay our debts and other obligations and set aside funds for reserves. We expect that the amount of cash left, if any, to distribute to our stockholders would be materially less than the expected cash and cash equivalents amounts set forth herein as of June 30, 2017.

Our future capital requirements will depend on many factors, including:

- the number and development requirements of the NDCs we or any collaborators pursue;
- the scope, progress, timing, results and costs of researching and developing NDCs, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of NDCs in the United States and abroad;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any NDCs for which we or a collaborator receive marketing approval;
- the revenue, if any, received from commercial sales of any NDCs for which we or a collaborator receive marketing approval;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other medicines and technology;
- our headcount growth and associated costs; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory

approval and achieve product sales. In addition, any product candidates we may choose to develop, if approved, may not achieve commercial success. Our commercial revenues, if any, would be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, license and development agreements with collaboration partners or other sources. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, additional debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate any product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Any future indebtedness could adversely affect our ability to operate our business.

Any future indebtedness, combined with current and future financial obligations and contractual commitments, could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, and prepayment and repayment fees and penalties, thereby reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

Failure to make payments or comply with other covenants under any future debt instruments could result in an event of default and acceleration of amounts due. If an event of default occurs and any future lenders to us accelerate the amounts due, we may not be able to make accelerated payments, and such future lenders could seek to enforce security interests in the collateral securing such indebtedness, which could include all or substantially all of our assets.

We have incurred significant losses since incorporation. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since incorporation, we have incurred significant operating losses. As of March 31, 2017, we had an accumulated deficit of $207.0 million. We do not know whether or when we will become profitable. We have not generated any revenues to date from product sales and have financed our operations primarily through public offerings of our common stock, private placements of our preferred stock, convertible debt financings and secured debt financings. We have not completed development of any product candidate and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital. We anticipate that our expenses will increase substantially if and as we:

- continue or start any new discovery and research programs utilizing the Platform;

- embark on new preclinical and clinical development of any NDC generated from the Platform;
- meet corresponding manufacturing, shipping and storage requirements;
- seek regulatory approvals for any NDC that successfully completes clinical trials;
- in the future, establish a sales, marketing and distribution infrastructure in the United States;
- scale up external manufacturing capabilities to commercialize any NDC for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development; and
- hire additional personnel and/or incur severance costs associated with the termination of employment of any existing personnel.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for, and successfully commercialize, one or more product candidates. This will require us to be successful in a range of challenging activities, including discovering product candidates, completing preclinical testing and clinical trials of product candidates obtaining regulatory approval for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for products from private insurance or government payors. We have not yet commenced most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the United States Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, or other regulatory authorities to perform studies in addition to those we may expect to conduct, or if there are any delays in completing our clinical trials or the development of any of any product candidates we may choose to develop, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, or even continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been limited to organizing and managing our staffing, developing and securing our technology, raising capital and undertaking preclinical studies and clinical trials of product candidates. We have not yet demonstrated the ability to successfully complete development of any product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Assuming we obtain marketing approval for any product candidates we may choose to develop, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

Risks Related to the Discovery, Development and Commercialization of Product Candidates

Our approach to the discovery and development of product candidates based on the Platform is unproven, and we do not know whether we will be able to develop any products of commercial value.

We believe that the Platform has the potential to create drugs that may have significant utility in several indications, particularly in combination with other therapies. While the results of preclinical studies and early-stage clinical trials have suggested that certain of our previous product candidates may have such utility, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidate in later stage clinical trials or in obtaining marketing approval thereafter. For example, we have not yet advanced a compound beyond Phase 2 clinical development. Moreover, the product candidate known as CRLX101, which we sold to BlueLink Pharmaceuticals, Inc. in March 2017, failed to meet its primary endpoint in two randomized Phase 2 trials: a Phase 2 clinical trial of single agent CRLX101 in advanced non-small cell lung cancer, or NSCLC, for patients who had progressed through

one or two prior regimens of chemotherapy, and a Phase 2 clinical trial of CRLX101 combined with Avastin (bevacizumab) in relapsed renal cell carcinoma, or relapsed RCC, in patients who had progressed through two or three prior therapies. We refer to this latter trial as our RCC Trial.

In addition, we have never had a product candidate receive approval or clearance from the FDA or a non-U.S. regulatory authority. While the FDA has approved nanoparticles such as Doxil® (doxorubicin hydrochloride liposome injection), Abraxane® (nab-paclitaxel), Onivyde™ (irinotecan liposomal injection) and Marqibo® (vincristine sulfate liposome injection), to our knowledge, the FDA has not yet approved a polymeric nanoparticle such as our NDCs, which are a new way of targeting tumors. The regulatory review process for novel product candidates, such as ours, can be more expensive and take longer than for product candidates based on more well-known or extensively studied technologies due to regulatory authorities' lack of experience with them. As a result, we may be required to conduct additional studies and/or trials beyond those we anticipate and it may take us longer to develop and/or obtain regulatory approval for our existing and any future product candidates than we expect.

We do not currently have a lead product candidate. If we are unable to identify a product candidate to advance through research and development efforts, our business would be materially harmed.

As a result of the sale of CRLX101 and CRLX301 to BlueLink Pharmaceuticals, Inc., a wholly owned subsidiary of NewLink Genetics Corporation in March 2017, we currently have no product candidates suitable for advancing into clinical trials. If the Novartis Transaction is not consummated, and our board decides to continue operating our business based on the Platform, we will need to evaluate our NDCs to determine which, if any, are ready to move further into preclinical and clinical development. If in such event we determine that the Platform has not generated any NDCs worthy of development, our business would be materially harmed.

If we experience delays or difficulties in the enrollment of patients in clinical trials, we may not achieve our clinical development on our anticipated timeline, or at all, and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for any product candidates that we may choose to develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- unexpected or serious adverse events that occur in the trials;
- the proximity of patients to sites;
- the eligibility criteria for the trial;
- the design of the trial;
- efforts to facilitate timely enrollment;
- investigators' engagement with, or enthusiasm about, the trial;
- complexity of initiating or expanding trials with sites outside the United States;
- competing trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for any product candidates we may choose to develop, delay or halt the development of and approval processes for product candidates and jeopardize our ability to achieve clinical development timeline and goals, including the dates by which we will commence, complete and receive results from clinical trials. Enrollment delays may also delay or jeopardize our ability to commence sales and generate revenues from product candidates. Any of the foregoing could cause the value of our company to decline and limit our ability to obtain additional financing, if and when needed.

The FDA and other regulatory agencies may require more extensive or expensive trials for our combination product candidates than may be required for single agent pharmaceuticals.

To obtain regulatory approval for a combination product candidate, the FDA typically requires an applicant to show that each active ingredient in an investigational combination drug candidate makes a contribution to the combined investigational drug

candidate's claimed effects and that the dosage of each component, including amount, frequency and duration, is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy. This could require us to conduct more extensive and more expensive clinical trials than would be the case for a single agent pharmaceutical. As a result, the need to conduct such trials could make it more difficult and costly for us to obtain regulatory approval of combination drug product candidate than of a new drug containing only a single active pharmaceutical ingredient.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates we may choose to develop.

It is impossible to predict when or if any product candidate that we may choose to develop will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we would be required to complete preclinical development and then conduct extensive 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 clinical development of any product candidate that we may choose to develop would be susceptible to the risk of failure inherent at any stage of drug development, including failure to have a sufficient quantity of the product candidate available when needed, failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of severe or medically or commercially unacceptable adverse events, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable non-U.S. regulatory authority that a drug product is not approvable. It is possible that even if a product candidate has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, dose, dosing schedule, design, measurements, conduct or analysis of the applicable clinical trials. Conversely, as a result of the same factors, any clinical trials that we may conduct may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in any clinical trials that we may conduct, we may fail to detect toxicity of or intolerability caused by product candidates, or mistakenly believe that product candidates are toxic or not well tolerated when that is not in fact the case.

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 necessarily predict final results. For example, although the results of the Phase 1b/2 single-arm investigator sponsored trial, or IST, of CRLX101 in patients with relapsed RCC supported our hypothesis that CRLX101 in combination with Avastin may be effective in this setting, the combination of CRLX101 and Avastin failed to meet the primary endpoint in the RCC Trial. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face additional setbacks with respect to any product candidates that we may choose to develop.

The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed and protocol amendments, if any, to address such flaws may not be sufficiently timely or corrective. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

Another challenge is that preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials for a product candidates warrant marketing approval, the FDA or comparable non-U.S. regulatory authorities may disagree and may not grant marketing approval of that product candidate.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size, type and disease progression of the patient populations, changes in and adherence to the clinical trial protocols, variability in the quality of clinical supply batches and the rate of dropout among clinical trial participants. Any Phase 2, Phase 3 or other clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market a product candidate that we have chosen to develop.

If we experience any of a number of possible unforeseen events in connection with clinical trials of any product candidates that we may choose to develop, potential marketing approval or commercialization of those product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval of any product candidate that we may choose to develop, including:

- clinical trials of the product candidate may produce unfavorable, incomplete or inconclusive results;
- we may decide, or regulators may advise us, to conduct additional clinical trials or we may decide to abandon an indication or development program following changes in the regulatory environment or competitive landscape;
- we may decide to add or to change a dosing schedule for any given clinical trial based on relevant data;
- the number of patients required for clinical trials of the product candidate may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our supply of the product candidate may be insufficient to complete our clinical trials as planned due to a batch failure, a lack of funds, a change in priorities, planning errors or other reasons;
- our third party contractors, including those manufacturing the product candidate or components or ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet our expectations in a timely manner or at all;
- we may decide to make changes to a trial protocol and fail to receive timely approval for the amendment from the applicable institutional review board(s) or ethics committee(s);
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- investigators may deviate from the trial protocol, fail to conduct the trial in accordance with regulatory requirements or misreport study data;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- prospective clinical trial sites may be unwilling to participate in one or more of our combination clinical trials due to a perceived difficulty in obtaining reimbursement from managed care plans, government, or other third party payors;
- patients who enroll in a clinical trial, or the investigators enrolling such patients, may misrepresent the patients' eligibility to participate in the trial or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the enrollment size for the clinical trial or extend the clinical trial's duration;
- for any given trial we may find it necessary to open more clinical trial sites than originally planned;
- we may have to suspend or terminate one or more clinical trials of the product candidate for various reasons, including unfavorable, incomplete or inconclusive data, unexpected delays, a change in funding priorities, a determination that the path to commercialization is too difficult or uncertain, a lack of sufficient funding, changes in the competitive or regulatory landscape, a finding that the participants are being exposed to unacceptable health risks, unexpected or serious adverse events or other unexpected characteristics of the product candidate;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their respective standards of conduct, a finding that the participants are being exposed to unacceptable health risks, unexpected or serious adverse events or other unexpected characteristics of the product candidate or other therapeutic agents used in clinical trials or findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate;
- the FDA or comparable non-U.S. regulatory authorities may disagree with our clinical trial design or our interpretation of data from preclinical studies and clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design of our clinical trials;
- the FDA or comparable non-U.S. regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third party manufacturers with which we enter into agreements for clinical and commercial supplies;

- the supply or quality of raw materials or the manufactured product candidate or drugs (whether provided by us or third parties) or other materials necessary to conduct clinical trials of the product candidate may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us will increase if we experience delays in testing or pursuing marketing approvals and we may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of any product candidates that we may choose to develop. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of marketing approval of any product candidate that we may choose to develop.

We may conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or the complexity of regulatory burdens may otherwise adversely impact us.

Opening trial sites outside the United States may involve additional regulatory, administrative and financial burdens, including compliance with foreign and local requirements relating to regulatory submission and clinical trial practices. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practices, including review and approval by an independent ethics committee and informed consent from trial patients. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. Nonetheless, there can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of any applicable product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
- increased costs and heightened supply constraints associated with the acquisition of standard of care drugs and/or combination or comparator agents for which we may bear responsibility in certain jurisdictions;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations;
- more burdensome manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- lack of consistency in standard of care from country to country;
- diminished protection of intellectual property in some countries; and
- changes in country or regional regulatory requirements.

If clinical trials of any product candidates that we may choose to develop fail to demonstrate safety and efficacy to the satisfaction of the FDA and comparable non-U.S. regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable non-U.S. regulatory authorities, such as the EMA, impose similar restrictions. We may never receive such approvals. We must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of the product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We have not previously submitted a new drug application, or an NDA, to the FDA or similar drug approval filings to comparable non-U.S. regulatory authorities for any product candidates.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if (1) we are required to conduct additional or different clinical trials or preclinical testing of product candidates beyond the trials and testing that we contemplate, (2) we are unable to successfully complete clinical trials or preclinical testing of product candidates, (3) the results of these trials or tests are unfavorable, incomplete or inconclusive, or (4) there are unacceptable safety concerns associated with any product candidates that we may choose to develop, we, in addition to incurring additional costs, may:

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

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

We may seek a fast track designation for product candidates that we may seek to develop. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, the FDA may still decide not to grant it. Even if we receive fast track designation, however, fast track designation does not ensure that we will receive marketing approval or that we may experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from or stated intentions of our clinical development program.

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

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

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

If we fail to obtain or maintain orphan drug exclusivity for any product candidates that we may choose to develop, we will miss out on certain valuable incentives including a period of marketing exclusivity as well as federal grants, tax credits and a waiver of Prescription Drug User Fee Act filing fees.

Under the Orphan Drug Act, the FDA has discretion to designate a product as an orphan drug if it is designed to treat a rare disease or condition, which is defined as a patient population of less than 200,000 in the United States. The applicant that first obtains

FDA approval for a designated orphan drug receives marketing exclusivity for use of that drug for the stated condition or disease for a period of seven years and becomes eligible for certain federal grants, tax credits and a waiver of Prescription Drug User Fee Act filing fees.

For any product candidates that we may choose to develop that are eligible, we would plan to rely on the exclusivity period under the Orphan Drug Act to attain a competitive position. If we do not obtain orphan drug exclusivity for any drug products that do not have broad patent protection, our competitors may then sell the same drug to treat the same condition and our revenues would be reduced.

Even if we obtain orphan drug designation for a product candidate, we still may not be the first to obtain marketing approval for the particular orphan indication. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect it from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved and granted orphan drug exclusivity, the FDA can subsequently approve the same drug for the same condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

We may request Priority Review for one or more product candidates that we may choose to develop at the time of the submission of the NDA to the FDA. The FDA may not grant Priority Review for any such product candidates. Moreover, even if the FDA designated Priority Review for any such product candidate, that designation may not lead to a faster regulatory review or approval process and, in any event, would not assure FDA approval.

A ten-month standard NDA review clock will begin at the conclusion of the 60 calendar day filing review period that starts on the date the FDA receives the original submission. This means the FDA has a total of twelve months from its receipt of the original submission to take regulatory action. We may be eligible for Priority Review designation for our NDA submission if the FDA determines that a product candidate that we may have chosen to develop treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The six-month Priority Review clock will begin at the conclusion of the 60 calendar day filing review period that starts on the date of FDA receipt of the original submission. Therefore, if granted Priority Review, the FDA has a total of eight months to take action on an application rather than the standard total of twelve months. We may request Priority Review for any future product candidates if and when we submit an NDA for such product candidate. The FDA has broad discretion whether or not to grant Priority Review to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, even if a product candidate is designated for Priority Review, such a designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving Priority Review from the FDA also does not guarantee approval within the eight-month review cycle or thereafter.

We may seek approval from the FDA or comparable non-U.S. regulatory authorities to use accelerated registration pathways. If unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.

We may seek an Accelerated Approval development pathway for certain indications for product candidates that we may choose to develop. Under the Accelerated Approval provisions in the Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations, the FDA may grant Accelerated Approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of Accelerated Approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The Accelerated Approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, Accelerated Approval is contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical profile or risks and benefits for Accelerated Approval. If such post-approval studies fail to confirm the drug's clinical profile or risks and benefits, the FDA may withdraw its approval of the drug.

If we choose to pursue Accelerated Approval, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such Accelerated Approval. There can be no assurance that the FDA will agree that our endpoint is an appropriate surrogate endpoint. There can also be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for Accelerated Approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue or apply for Accelerated Approval or any other form

of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for Accelerated Approval, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all. The FDA or other non-U.S. authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. Even if the FDA agreed that we could pursue an Accelerated Approval registration pathway, we might not be able to fulfill the FDA's requirements with respect to chemistry, manufacturing and controls in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA.

A failure to obtain Accelerated Approval or any other form of expedited development, review or approval for a product candidate that we may choose to develop would result in a longer time period to commercialize such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Serious adverse events of any product candidates that we may choose to develop may be identified during clinical development. Further, other unexpected properties of product candidates may be identified during manufacture or development. Such adverse events or unexpected properties could delay or prevent the continued development and/or marketing approval of any such product candidate.

Serious adverse events caused by, or other unexpected properties of, any product candidates that we may choose to develop could cause us, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of such product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable non-U.S. regulatory authorities. If any product candidate that we may choose to develop is associated with serious adverse events or other unexpected properties, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which those undesirable characteristics would be expected to be less prevalent, less severe or more tolerable from a risk-benefit perspective. If we learn that the manufacture of any product candidate that we may choose to develop generates unexpected impurities or product degradants, these properties could contribute to serious adverse events and negatively impact our overall development cost and timelines as we address those properties. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause serious or unexpected adverse events and negatively affect overall development costs and timelines, which may even prevent further development of the compound.

While we believe that the Platform has the potential to improve the unfavorable adverse event profiles of multiple chemotherapeutic agents, if this hypothesis is wrong and we experience unexpected or more severe toxicities in clinical trials we conduct in the future, we may not receive approval to market, or achieve commercial success with respect to, any product candidates that we may choose to develop, which could prevent us from ever generating revenues or achieving profitability. In addition, the Platform may have other limitations with respect to targeting tumors and limiting exposure of normal tissue to our NDCs' anti-cancer payload. For example, liver tissue has pore sizes that are generally larger than other normal tissue, and therefore, our NDCs and their anti-cancer payloads may preferentially concentrate in the liver.

We may not be successful in our efforts to identify or discover potential product candidates.

The development of new NDCs based on the Platform is a key area of research for us. The drug discovery that we are conducting using the Platform may not be successful in creating compounds that have commercial value or therapeutic utility. Our research programs may initially show promise in creating potential product candidates, yet fail to yield viable product candidates for clinical development for a number of reasons, including:

- newly designed NDCs may not demonstrate satisfactory efficacy or other benefits, either alone or in combination with other therapeutics; or
- potential product candidates may, on further study, be shown to have harmful toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

To identify new product candidates, our research programs will require substantial technical, financial and human resources. We may be unsuccessful in our efforts to identify new potential product candidates. In addition, we may focus our efforts and resources on one or more potential product candidates that ultimately prove to be unsuccessful. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price.

Even if a product candidate that we have chosen to develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success or the market opportunity for the product candidate may be smaller than we estimate.

We have never commercialized a product. Even if a product candidate that we have chosen to develop is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third party payors on the benefits of product candidates may require significant resources and may not be successful. If any product candidate that we have chosen to develop is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and may not become profitable. The degree of market acceptance of any such product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative treatments;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second-, third- or later line therapy;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- our ability to offer the product for sale at competitive prices;
- our ability to establish and maintain pricing sufficient to realize a meaningful return on our investment;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the strength of sales, marketing and distribution support;
- the availability of alternative treatments already approved or approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product;
- the timing of market introduction of our approved products as well as competitive products and other therapies;
- availability and amount of reimbursement from government payors, managed care plans and other third party payors;
- the strength and efficacy of our marketing and distribution efforts;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for any product candidates that we may choose to develop would be difficult to estimate precisely. Our estimates of the potential market opportunities would be predicated on many assumptions, including industry knowledge and publications, third party research reports and other surveys, and these assumptions would involve the exercise of significant judgment on the part of our management and would be inherently uncertain. If any of the assumptions proves to be inaccurate, the actual markets for any such product candidates could be smaller than our estimates of the potential market opportunities.

If any product candidate that we have chosen to develop receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

Clinical trials of any product candidate that we may choose to develop would be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or, alternatively, fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable, serious or fatal side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we may be required to recall the drug or change the way the drug is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

If we are unable to establish sales, marketing and distribution capabilities or enter into acceptable sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidates that we may choose to develop, if and when those product candidates are approved.

We do not have a sales, marketing or distribution infrastructure and have limited experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. If approved, we expect to commercialize any product candidates that we may choose to develop in the United States directly with a small and highly focused commercialization organization. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. We expect that we will commence the development of these capabilities prior to receiving approval of any product candidates that we may choose to develop. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. Such a delay may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to a product candidate that we may choose to develop, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product candidate independently.

We may seek one or more strategic partners for commercialization of product candidates outside the United States. As a result of entering into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market any products that we may have developed effectively.

If we do not establish sales and marketing capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates that receive marketing approval.

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

The development and commercialization of new drug products is highly competitive. We expect that we will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to any future product candidates that we may seek to develop or commercialize. Specifically, due to the large unmet medical need, global demographics and relatively attractive reimbursement dynamics, the oncology market is fiercely competitive and there are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable adverse events or are less costly than any product candidates that we may develop, which could render any of our potential product candidates obsolete and noncompetitive.

Companies with marketed nanotechnology-based oncology products include Celgene Corporation (Abraxane indicated for breast cancer, NSCLC and pancreatic cancer), Janssen Products, LP (Doxil indicated for ovarian cancer and, in combination with Velcade® (bortezomib), for multiple myeloma), Merrimack Pharmaceuticals, Inc. (Onivyde indicated for pancreatic cancer) and Spectrum Pharmaceuticals, Inc. (Marqibo indicated for relapsed Philadelphia chromosome-negative acute lymphoblastic leukemia). Companies with nanotechnology-based oncology product candidates in clinical development include, without limitation, BlueLink Pharmaceuticals, Inc. (wholly owned subsidiary of NewLink Genetics Corporation, now developing CRLX101 and CRLX301), Celsion Corporation (ThermoDox® (lyso-thermosensitive liposomal doxorubicin) for liver cancer and breast cancer), Cristal Delivery B.V. d/b/a Cristal Therapeutics (CriPec® docetaxel for oncology), Cytimmune Sciences, Inc. (CYT-6091 for NSCLC), Jazz Pharmaceuticals plc (which acquired Celator Pharmaceuticals, Inc. (Vyxeos™ for acute myeloid leukemia)), NanoCarrier Co., Ltd. (NC-6004 for bladder, bile duct and head and neck cancers, and NC-4016, and NC-6300 for solid tumors), NantPharma (Cynviloq™, which received fast-track designation from the FDA for breast and lung cancer), Nektar Therapeutics (OnzyealdTM for breast cancer and brain metastases), Nippon Kayku Seizo Co., Ltd. (NK105 in gastric cancer), Starpharma Holdings Ltd. (DEP® docetaxel for oncology), and Supratek Pharma Inc. (SP1049C for solid tumors).

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

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

If the FDA or comparable non-U.S. regulatory authorities approve generic versions of any products that we may develop that receive marketing approval, or such authorities do not grant such products appropriate periods of data exclusivity before approving generic versions of such products, the sales of such products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a “reference listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations.” Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical studies. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug may be typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. Specifically, in cases in which such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

Competition that any products that we may develop may face from generic versions of such products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

Any product candidate that we may develop in the future may be an NDC that includes a generically available therapeutic as its anti-cancer payload. If physicians and/or third party payors do not believe our product offers substantial advantages over other therapies incorporating the same generic anti-cancer payload, we may not be able to successfully commercialize our product.

Although we may have intellectual property rights, including composition of matter patents, covering any product candidates that we may choose to develop, if approved, we expect that any such product candidates will compete in the same indications against other nanoparticles and delivery platforms incorporating the same generic therapeutics. In particular, if any product candidate that we may choose to develop is approved and becomes commercially successful, other companies may intensify their efforts to develop a competing product that includes the corresponding generic therapeutic. If physicians, rightly or wrongly, do not believe that a product that we develop offers substantial advantages over another nanoparticle or delivery platform incorporating the same generic therapeutic, physicians might not prescribe our product. In addition, third party payors might refuse to provide reimbursement for a product that we develop when another nanoparticle or delivery platform incorporating the same generic therapeutic offers a cheaper alternative therapy in the same indication, or might otherwise encourage use of another nanoparticle or delivery platform incorporating the same generic therapeutic over our product, even if our product possesses favorable pharmaceutical properties.

Even if we are able to commercialize any product candidate that we develop, the product may become subject to unfavorable pricing regulations, third party payor reimbursement practices or healthcare reform initiatives that could harm our business.

The commercial success of any product candidates that we may choose to develop will depend substantially, both domestically and abroad, on the extent to which the costs of such product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third party payors. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize such product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish and maintain pricing sufficient to realize a meaningful return on our investment.

There is significant uncertainty related to third party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if the product candidates obtain marketing approval.

Our ability to commercialize any product candidate will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell any product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable non-U.S. regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we, or others, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition.

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

We face an inherent risk of product liability claims as a result of the clinical testing of any product candidates that we may choose to develop despite obtaining informed consents from our clinical trial participants. We will face an even greater risk if we commercially sell any product that we may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of any applicable product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- loss of existing clinical trial participants or difficulty in enrolling future clinical trial participants;
- significant costs to defend resulting litigation or to reach a settlement;
- substantial payments to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We maintain general liability, product liability and umbrella liability insurance. Our existing insurance coverage may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage as our risks of exposure increase, which, for example, would happen if and when we begin selling any product candidate that receives marketing approval. In addition, certain types of insurance coverage are becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of any product candidates that we may choose to develop, which could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties

We may rely on third parties to conduct ISTs of any future product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of any product candidates that we chose to develop may delay or impair our ability to obtain regulatory approval for such product candidates.

We may rely on academic and scientific research institutions to conduct and sponsor clinical trials relating to any future product candidates. We would not control the design or administration of ISTs, and our reliance on third parties to conduct ISTs could, depending on the actions of such third parties, jeopardize the quality or timeliness of the clinical data generated and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities.

Such arrangements would provide us with certain information rights with respect to ISTs, including access to and the ability to use and reference the data resulting from the IST, including for our own regulatory filings. However, we would not control patient enrollment in, or the quality, timing and reporting of the data from, ISTs, nor would we own the data from the ISTs. Moreover, if we were unable to confirm or replicate the results from the ISTs or if negative results are obtained in the ISTs, we would likely be further delayed or prevented from advancing further clinical development of any applicable product candidates. Further, if investigators or institutions were to breach their obligations with respect to the clinical development of any such product candidates, or if the data were to prove to be unfavorable, incomplete or inconclusive, then our ability to design and conduct any future clinical trials ourselves could be adversely affected.

The FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by ISTs, or our interpretation of preclinical, manufacturing or clinical data from ISTs. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate any planned trials and/or may not accept such additional data as adequate to initiate any planned trials. Moreover, there is typically no independent review of the results of ISTs. Therefore, the investigators may interpret the results of ISTs more favorably than an independent review would.

Moreover, ISTs of any product candidates that we may choose to develop may continue even after we commence company-sponsored trials in the same or different indications. To the extent the results of these ISTs are inconsistent with, or different from, the results of any such company-sponsored trials, the FDA or a non-U.S. regulatory authority may question the results of the company-sponsored trial, or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such other non-U.S. regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing approval of the applicable product candidate.

We may rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We may rely on third party clinical research organizations, or CROs, site management organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct future clinical trials of any product candidates that we may choose to develop. We may also rely on these third parties to collect and monitor adverse event data for clinical trials. Any agreements with these third parties would generally allow the third party to terminate the agreement at any time. If we are required to enter into alternative arrangements because of any such termination the introduction of the applicable product candidate to market could be delayed.

Our reliance on these third parties for research and development activities would reduce our control over these activities but would not relieve us of our responsibilities. For example, we would design our clinical trials and would remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control would not relieve us of these responsibilities and requirements. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we might not be able to obtain, or could be delayed in obtaining, marketing approvals for the applicable product candidates and might not be able to, or could be delayed in our efforts to, successfully commercialize the applicable product candidates.

We also may rely on other third parties to manufacture, store and distribute drug supplies for clinical trials. Any performance failure on the part of such distributors could delay clinical development or marketing approval of any product candidates that we may choose to develop or commercialization of products, producing additional losses and depriving us of potential product revenue.

We may seek to enter into collaborations with third parties for the development and commercialization of product candidates that we may choose to develop and to leverage the Platform for our collaborators' product candidates. If such collaborations are not successful, or we fail to enter into such collaborations, we may not be able to capitalize on the market potential of any such product candidates or the Platform.

We may seek third-party collaborators for development and commercialization of product candidates that we may choose to develop or to leverage the Platform. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, biotechnology companies and certain governmental agencies. We will have limited control over the amount and timing of resources that any of our current or potential future collaborations dedicate to the development or commercialization of product candidates that we may choose to develop or to the use of the Platform. Our ability to generate revenues from these arrangements will depend significantly on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving product candidates that we may choose to develop or the Platform pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of the product candidates that we have chosen to develop or the product candidates we help them develop, or they may elect not to continue or renew research, development or commercialization programs based on preclinical or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- our agreements with collaborators may block us from researching and developing product candidates for our own benefit or for the benefit of other or future collaborators;
- collaborators may not initiate clinical trials or if initiated, they may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new dosing schedule, dose level or formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with products or product candidates that we have chosen to develop if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe our intellectual property rights or the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of relevant products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination or divestiture, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish collaborations, we may have to alter our research, development and commercialization plans.

The Platform, our drug development programs and the potential commercialization of any product candidates that we may choose to develop will require substantial additional cash to fund expenses and we may seek collaborations with pharmaceutical and biotechnology companies to leverage our Platform for the development and potential commercialization of product candidates.

We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement with a potential collaborator will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the value of the Platform and associated intellectual property rights, the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative technology platforms, product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our technology or product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the Platform or a product candidate, reduce or delay research or relevant development

programs, delay potential commercialization of product candidates or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund research, development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further research or develop product candidates or technology to bring them to market and generate product revenue.

We will need to contract with third parties for the manufacture of any future product candidates for preclinical and clinical testing and likely also for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of such product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate manufacturing facilities for the production of clinical trial materials and have limited personnel with manufacturing experience. We will need to rely on third party contract manufacturers to manufacture supplies of any product candidates for preclinical and clinical testing, as well as for commercial manufacture if any product candidates that we may choose to develop receive marketing approval.

NDCs must be manufactured through complex, multi-step synthesis processes that are time-consuming and involve special conditions at certain stages. Drug substance manufacture requires high potency containment, and drug product manufacture requires high potency containment under aseptic conditions, also referred to as sterile manufacture. Failures in either drug substance manufacture or drug product manufacture, whether on the part of our future manufacturers or as a result of our failure to make timely and effective improvements in our manufacturing processes, could materially delay clinical development or marketing approval of any product candidates that we may choose to develop or result in our inability to generate sufficient supplies to meet clinical or commercial demands.

Typically, agreements with our third party manufacturers can be terminated by us or such manufacturers on short notice. If any of our existing manufacturers should become unavailable to us for any reason or should be unable to secure additional manufacturing capacity in the event of higher than anticipated product demand, we may incur additional cost or delay in identifying or qualifying replacements. In addition, we may need to identify a third-party manufacturer capable of providing commercial quantities of drug product. If we are unable to arrange for such a third-party manufacturing source, or fail to do so on commercially reasonable terms, we may not be able to successfully produce and market a product candidate or may be delayed in doing so.

Even if we are able to establish such arrangements with third party manufacturers, reliance on third party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the ability of manufacturers to consistently produce intermediates, drug substance or drug product that meet required quality specifications;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, our ability to secure and/or maintain regulatory approval for product candidates could be adversely affected. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of any such product candidates or products.

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

In addition, we may rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce product candidates for clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that are used in the manufacture of NDCs. Such suppliers may not sell these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We may not have any control over the process or timing of the acquisition of these raw materials by

our manufacturers. Moreover, we may not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of clinical studies, product testing and potential regulatory approval of product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for product candidates that we have chosen to develop, the commercial launch of such product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of the product candidates.

Our anticipated future dependence upon others for the manufacture of any product candidates that we may choose to develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and any products that we may develop or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and any products that we may develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and any product candidates that we may choose to develop.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties or that we develop on third parties' behalf. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

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

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

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

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

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

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

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

Certain aspects of the Platform technology are protected in whole or in part by patents assigned by or exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any products for which we have obtained approval will be harmed.

We are a party to several license agreements and certain aspects of the Platform depend on patents and/or patent applications owned by others. In particular, we hold exclusive licenses from Calando Pharmaceuticals, Inc., or Calando, and California Institute of Technology, or Caltech, and have been assigned certain patents from Calando for CDP-based product candidates. We may enter into additional license agreements as part of the development of our business in the future. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize product candidates could be materially harmed.

Our licensors or licensees may not successfully prosecute certain patent applications under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors or licensees may fail to maintain these patents, may decide not to pursue litigation against third party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. For example, in March 2014, Calando entered Chapter 7 bankruptcy and, as a result, the intellectual property rights we have obtained from Calando are subject to potential risks that may arise in connection with bankruptcy. For instance, while our ability to develop and/or commercialize NDCs and our ability to utilize the Platform are not dependent on the rights that we license from Calando, our license agreements with Calando could be rejected in connection with Calando's bankruptcy, in which case, we could, subject to elections and other rights and defenses that may be available to us, lose certain rights granted to us under such licenses. In March 2015, the bankruptcy court granted Calando's bankruptcy trustee's application to retain a broker to help sell Calando's rights in certain assets including its rights in the license agreements with Cerulean. We reserved our rights with respect to any such sale. The bankruptcy trustee has obtained numerous extensions to the deadline to reject, assume or assume and assign executory contracts including our license agreements. The trustee's last deadline was February 7, 2017. To our knowledge, no sale of such rights was ever consummated.

In addition, in spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to obtain regulatory approval and to market products covered by these intellectual property agreements. If our intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors may have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our intellectual property agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. For example, under our agreements with Calando, which relate to the Platform and future NDCs, if we fail to meet our payment obligations and do not adequately cure such failure, or if we terminate one or both of these agreements, other than for specified safety concerns, we are required to grant Calando an exclusive (even as to Cerulean), royalty-free license under the patent rights assigned pursuant to such terminated agreement and to assign the related IND to Calando. Moreover, if we fail to meet our diligence obligations under one or both of our agreements with Calando, Calando may convert the license to a non-exclusive license, and we will be required to grant Calando a non-exclusive license under the patent rights assigned to us pursuant to such terminated agreement. This could have a material adverse effect on our competitive business position and our business prospects.

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

We are party to multiple intellectual property agreements that impose, and we may enter into additional intellectual property agreements that may impose, various diligence, milestone payment, royalty and other obligations on us. Under our existing intellectual property agreements, we are obligated to pay royalties on the net sales of product candidates or related technologies to the extent they are covered by the agreement. We also have diligence and development obligations under those agreements. If we fail to comply with our obligations under current or future intellectual property agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by the agreement or face other penalties under the agreement. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Some intellectual property which we have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for United States industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have licensed may have been generated through the use of United States government funding and may therefore be subject to certain federal regulations. These United States government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use the inventions for any governmental purpose. In addition, the United States government would have the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The United States government would also have the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the United States government would be permitted to acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

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

Our commercial success depends upon our ability to develop, manufacture, market and sell product candidates and use the Platform and any related intellectual property without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to any products that we may develop and our technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

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

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in timely obtaining such an agreement with each party who in fact develops intellectual property that we regard as our own. Even if timely obtained, such agreements may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, we may lose valuable intellectual property rights or personnel, in addition to paying monetary damages. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology, and potentially seeking patents for product candidates that we chose to develop, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, we face the risk of cybercrime. For instance, someone could hack our information networks and gain illicit access to our proprietary information including our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Even if we are successful in prosecuting such claims, any remedy awarded may be insufficient to fully compensate us for the improper disclosure or misappropriation. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Regulatory Approval and Marketing of Any Product Candidates that We May Choose to Develop and Other Legal Compliance Matters

Even if we complete the necessary clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of any product candidates that we may choose to develop. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize such product candidates, and our ability to generate revenue will be materially impaired.

Drug product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and other similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. Any product candidates that we may choose to develop would be subject to the risks of failure inherent in drug development. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in conducting and managing the clinical trials, and in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Any product candidates that we may choose to develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any product candidate that we may choose to develop receives marketing approval, the accompanying label may limit the approved use of the drug in this way, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates that we may choose to develop, the commercial prospects for such product candidates may be harmed and our ability to generate revenues will be materially impaired.

Even if we successfully complete the necessary clinical trials for a marketing registration in the U.S., the FDA may convene an advisory committee meeting that could influence their approval decision and the timing of that decision.

Upon submission of an application for marketing approval in the United States, the FDA may convene an advisory committee (public or closed) to provide the FDA with independent advice from outside experts with specific questions regarding a pending review matter. The opinions or advice expressed by the advisory committee, or any voting decision, are not binding and the FDA retains the ultimate approval power over an application. Regardless of the committee meeting outcome or the FDA's final approval decision, public presentation of our data may shed positive or negative light on our application. A negative advisory committee meeting could signal a lower likelihood of approval, although the FDA may still end up approving our application. Conversely, an oncologic drugs advisory committee, or ODAC, could vote in favor of approval and the FDA may still not approve our application. For an expedited review such as priority review, where the FDA's oncology office has moved focus to how quickly a drug might be approved and has commonly completed their review and approved products well before the PDUFA goal date, preparations for an ODAC could slow down approval. For us as the applicant, preparation time for an ODAC could take six months or more of dedicated effort by the program team, management, and consultants, in addition to supporting the FDA's review queries or any other activities in the same timeframe, reducing resource efficiency. It should not be assumed that an application brought in front of the ODAC means that a negative decision is pending. The FDA determines whether or not to have an ODAC meeting depending on the quality of the application, the results of the clinical trials, and whether similar issues, such as endpoints or trial designs, have been previously

discussed at these meetings. The FDA has generally taken more problematic or complicated applications to an ODAC, which allows for presentation of their findings and a public discussion of issues at hand. On occasion, the FDA will convene an ODAC to have the public clearly understand their viewpoint on the particular application and its supporting evidence, or if there is a first in class or first in indication compound under review.

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates that we may choose to develop from being marketed abroad.

In order to market and sell products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize any products we develop in any market.

On June 23, 2016, a referendum held in the United Kingdom resulted in a majority of U.K. voters electing to leave the European Union. While the impact of this non-binding referendum is still not clear, at this point the vote creates additional uncertainty with respect to obtaining marketing approval for the sale of any product in the U.K.

Even if we obtain marketing approval for any product candidates that we may develop, the terms of approvals and ongoing regulation of such products may limit how we manufacture and market such products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation governing the labeling, packaging, storage and promotion of the product and record keeping and submission of safety and other post-market information.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive regulatory requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA and other regulatory authorities to monitor and ensure compliance with cGMPs.

Accordingly, assuming we receive marketing approval for any product candidate that we may choose to develop, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for any future products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with any future products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and

recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any product candidate that we choose to develop receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

Regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA and other agencies, including the Department of Justice, closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market products for unapproved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

- litigation involving patients taking such products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of the products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our relationships with healthcare providers, physicians, and third party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians, and third party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drug products to report payments and other transfers of value to physicians and teaching hospitals with data collection beginning in August 2013; and
- analogous state and foreign laws and regulations such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize product candidates and affect the prices we may obtain.

In the United States and some non-U.S. jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of any product candidates that we

may choose to develop, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider any products that we may develop, if approved, to be cost-effective compared to other available therapies, they may not cover such product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to realize a meaningful return on our investment. The United States government, state legislatures and non-U.S. governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for any products that we may develop, if approved.

As a result, the marketability of any products that we may develop, if approved, could suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our products that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. Among the provisions of the ACA of potential importance to our business and any product candidates that we may choose to develop are the following.

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced

Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize products.

In addition, with the new Administration and Congress, there may be additional legislative changes, including potential repeal and replacement of certain provisions of the ACA. It remains to be seen, however, precisely what any new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates. For example, the President and congressional leaders have expressed interest in repealing certain ACA provisions and replacing them with alternatives that may be less costly and provide state Medicaid programs and private health plans more flexibility. It is possible that these repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. The scope and likelihood of potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, however, and it is possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of any product candidates that we may seek to develop, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues from the sales of any products that we may develop, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of the applicable product candidate to other available therapies. If reimbursement of any products that we may develop is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our employees and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees or consultants, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Misconduct by employees or consultants could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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 harm 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 the use of 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. In the event of contamination or injury resulting 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 for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order 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. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Christopher Guiffre, our President and Chief Executive Officer, as well as the other members of our executive and scientific teams. The loss of any of these persons could impede the achievement of our goals. Although we have formal employment agreements with Mr. Guiffre and other officers of the company, these agreements do not prevent any one of them from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, finance and sales and marketing personnel will also be critical to our success. The loss of the services of key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. For example, if key scientific personnel are terminated or voluntary resign, our ability to operate the Platform and generate future product candidates could be materially harmed. Furthermore, replacing executive officers and key employees, including, for example, finance and clinical personnel, may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize any product candidates we may choose to develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Since August 2016, we have twice reduced the size of our organization, and we may encounter difficulties in managing our business as a result of these reductions, or the attrition that may occur following these reductions, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from these reductions.

In August 2016, we implemented a reduction in force that reduced the number of our employees by approximately 48%. In March 2017, we implemented a reduction in force that reduced the number of our employees by approximately 58%. These reductions in force resulted in the loss of employees across all functions, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across our organization, all of which could adversely affect our operations. In addition, as with any reduction in force, there is a risk of reduced employee morale and we may face difficulties retaining employees that we have asked to stay, which could result in further attrition.

We must continue to manage our operations and retain qualified personnel, each of which will be made more challenging by these reductions in force. As a result, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities, and devote a substantial amount of time to managing the organizational changes brought about by these reductions in force. Due to our limited resources, we may not be able to effectively manage the changes in our business operations resulting from these reductions in force, which may result in weaknesses in our operations, risks that we may not

be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage this transition, our expenses may be higher than expected, and we may not be able to implement our business strategy or achieve the anticipated benefits and savings from these reductions in force. We may also determine to take additional measures to reduce costs, which could result in further disruptions to our operations and present additional challenges to the effective management of our company.

Risks Related to our Common Stock

The market price of our common stock has been and may in the future be volatile and fluctuate substantially.

Our stock price has been and may in the future be volatile. From April 10, 2014 to March 31, 2017, the closing price of our common stock as reported by the NASDAQ Global Market ranged from a high of $10.66 per share to a low of $0.63 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- whether we are able to consummate the Daré Transaction and the Novartis Transaction;
- the results of our efforts to discover, develop, acquire or in-license product candidates or products, if any;
- failure or discontinuation of any of our research programs;
- actual or anticipated results from, and any delays in, any future clinical trials, as well as results of regulatory reviews relating to the approval of any product candidates that we may choose to develop;
- the level of expenses related to any product candidates that we may choose to develop or clinical development programs that we may choose to pursue;
- commencement or termination of any collaboration or licensing arrangement;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical trials of product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and
- the other factors described in this “Risk Factors” section.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in companies' stock prices, securities class-action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

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

Although we have listed our common stock on The NASDAQ Global Market, an active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the times they would like to sell. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

If we were to be delisted from The NASDAQ Global Market, it could reduce the visibility, liquidity and price of our common stock.

There are various quantitative listing requirements for a company to remain listed on The NASDAQ Global Market, including maintaining a minimum bid price of $1.00 per share. The closing price per share of our common stock from January 1, 2017 to May 8, 2017 ranged from a high of $3.32 to a low of $0.40. On May 5, 2017, NASDAQ notified us that we were not in compliance with the $1.00 minimum bid price because the minimum bid price of our common stock fell below $1.00 for 30 consecutive business days. We have been provided an initial period of 180 calendar days, or until November 1, 2017, to regain compliance with the listing requirements. If, at any time before November 1, 2017, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days we may be eligible to regain compliance with the minimum bid requirement. Under certain circumstances, NASDAQ could require that the minimum bid price exceed $1.00 for more than ten consecutive business days before determining that we comply with NASDAQ's continued listing standards. We received a similar noncompliance letter on November 17, 2016, however, on February 17, 2017 this minimum bid deficiency was cured because the closing bid price of our common stock had been above $1.00 for the prior 10 consecutive trading days. There is no guarantee that we will be able to continue complying with the minimum bid price rule or other NASDAQ Global Market requirements.

Delisting from the NASDAQ Global Market could reduce the visibility, liquidity and price of our common stock and make it more difficult for us to raise additional capital.

Our executive officers and directors and their affiliates own a significant percentage of our stock and will be able to exercise significant influence over matters submitted to stockholders for approval.

We believe that as of March 15, 2017, our executive officers and directors and their affiliates beneficially owned 20.7% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to exert a significant degree of influence over matters submitted to our stockholders for approval, as well as our management and affairs. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. For example, these persons, if they choose to act together, would be able to have significant influence on the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets, including the outcome of the anticipated stockholder votes with respect to the Daré Transaction and the Novartis Transaction. In particular, each of our directors and their affiliates, beneficially owning in the aggregate approximately 20.7% of our outstanding common stock have each entered into a support agreement in favor of Cerulean in connection with the Daré Transaction

A significant portion of our total outstanding shares may be sold into the public market at any point, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, which we refer to as the Securities Act, or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates of ours.

As of March 31, 2017, there were 5,441,105 shares subject to outstanding options. All of these shares under the Securities Act have been registered on a registration statement on Form S-8. These shares can be freely sold in the public market upon exercise, as permitted by any applicable vesting requirements, except to the extent they are held by our affiliates, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act. Furthermore, as of March 31, 2017, there were 365,564 shares subject to outstanding warrants to purchase common stock. These shares will become eligible for sale in the

public market, to the extent such warrants are exercised, as permitted by Rule 144 under the Securities Act. Moreover, holders of approximately 6.3 million shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

The sale of our common stock to Aspire may cause substantial dilution to our existing stockholders and the sale of shares of our common stock acquired by Aspire could cause the price of our common stock to decline.

In October, 2016, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC, or Aspire, pursuant to which we have the right to sell up to an aggregate of $20.0 million of our common stock over a 24-month period, at prices based on a formula linked to current market prices at the time of each sale. We refer to this as our ATM. As of March 31, 2017, up to $19.0 million remained available for us to sell to Aspire pursuant to the terms and conditions of the ATM. Although we have the right to control the timing and amount of sales of our shares to Aspire under the ATM, we are subject to certain restrictions, including without limitation restrictions on the number of shares we can sell to Aspire on any one trading day, as well as trading restrictions based on the price of our common stock. Accordingly, we may not be able to sell shares of our common stock to Aspire under the ATM at prices that we deem acceptable. There can be no assurance that we will be able to sell the remaining $19.0 million of common stock contemplated under the ATM.

Additionally, our sales of shares to Aspire may result in substantial dilution to the interests of other holders of our common stock, and such sales, or the anticipation of such sales, may cause the trading price of our common stock to decline. Furthermore, Aspire may sell some or all of our shares that it has purchased or may in the future purchase from us under the facility and any such sales may cause the trading price of our common stock to decline.

We have broad discretion in the use of our cash reserves and may not use them effectively.

Our management has broad discretion to use our cash reserves and could use our cash reserves in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses and these financial losses could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of any product candidates that we may choose to develop. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company through 2019. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are currently incurring and expect to continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a newly public company, we are incurring and expect to continue to incur additional significant legal, accounting and other expenses that we did not incur as a private company. We expect that these expenses will further increase after we are no longer an "emerging growth company." We expect that we will need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the requirements of being a public company, and our management and other personnel will need to continue to devote a substantial amount of time towards maintaining compliance with these requirements. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the growth and development of our business. Accordingly, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our certificate of incorporation, our bylaws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions might frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

In addition, we are governed by Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring or merging with us, whether or not it is desired by, or beneficial to, our stockholders.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Item 6. Exhibits.

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

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.

CERULEAN PHARMA INC.

Date: May 12, 2017

By: /s/ Christopher D.T. Guiffre

Christopher D.T. Guiffre
President and Chief Executive Officer
(principal executive officer)

Date: May 12, 2017

By: /s/ Gregg Beloff

Gregg Beloff
Interim Chief Financial Officer
(principal financial officer)

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EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
2.1	Stock Purchase Agreement dated as of March 19, 2017, entered into by and among Cerulean Pharma Inc., Daré Bioscience, Inc. and equityholders of Daré Bioscience, Inc. named therein.	8-K	001-36395	3/20/2017	2.1	
2.2	Asset Purchase Agreement dated as of March 19, 2017, entered into by and between Cerulean Pharma Inc. and Novartis Institutes for BioMedical Research, Inc.	8-K	001-36395	3/20/2017	2.2	
2.3	Asset Purchase Agreement dated as of March 19, 2017, entered into by and between Cerulean Pharma Inc. and BlueLink Pharmaceuticals, Inc.	8-K	001-36395	3/20/2017	2.3	
3.1	Amendment to Amended and Restated By-laws of Cerulean Pharma Inc.	8-K	001-36395	3/20/2017	3.1	
10.1	Support Agreement dated as of March 19, 2017, entered into by and among Cerulean Pharma Inc., Daré Bioscience, Inc. and shareholders of Cerulean Pharma Inc. named therein.	8-K	001-36395	3/20/2017	10.1	
10.2	License Agreement dated as of March 19, 2017, entered into by and between Cerulean Pharma Inc. and BlueLink Pharmaceuticals, Inc.	8-K	001-36395	3/20/2017	10.2	
10.3	Payoff Letter dated as of March 17, 2017, entered into by and between Cerulean Pharma Inc. and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.)	8-K	001-36395	3/20/2017	10.3	
10.4	Retention Agreement dated as of March 19, 2017, entered into by and between Cerulean Pharma Inc. and Christopher D. T. Guiffre.	8-K	001-36395	3/20/2017	10.4	
10.5	Retention Agreement dated as of March 19, 2017, entered into by and between Cerulean Pharma Inc. and Adrian Senderowicz.	8-K	001-36395	3/20/2017	10.5	
10.6	Retention Agreement dated as of March 19, 2017, entered into by and between Cerulean Pharma Inc. and Alejandra Carvajal.	8-K	001-36395	3/20/2017	10.6	
10.7	First Amendment of Lease, dated March 29, 2017, to Lease dated July 9, 2015, between the Registrant and AstraZeneca Pharmaceuticals Limited Partnership	10-K	001-36395	3/31/2017	10.39	
31.1	Certification of principal executive officer pursuant to Rule 13a 14(a)/15d 14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X

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Exhibit Number	Description of Exhibit	Incorporated by Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of Filing		
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	XBRL Instance Document*					X
101.SCH	XBRL Taxonomy Extension Schema Document*					X
101.CAL	XBRL Taxonomy Calculation Linkbase Document*					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*					X
101.LAB	XBRL Taxonomy Label Linkbase Document*					X
101.PRE	XBRL Taxonomy Presentation Linkbase Document*					X

* Submitted electronically herewith

Exhibit 31.1

CERTIFICATION

I, Christopher D.T. Guiffre, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cerulean 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 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)) 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. 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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 12, 2017

/s/ Christopher D.T. Guiffre

Christopher D.T. Guiffre
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Gregg Beloff, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cerulean 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 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)) 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. 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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 12, 2017

/s/ Gregg Beloff
Gregg Beloff
Interim Chief Financial Officer
(principal financial officer)

Exhibit 32.1

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 on Form 10-Q of Cerulean Pharma Inc. (the "Company") for the fiscal quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Christopher D.T. Guiffre, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 12, 2017

/s/ Christopher D.T. Guiffre
Christopher D.T. Guiffre
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

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 on Form 10-Q of Cerulean Pharma Inc. (the "Company") for the fiscal quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Gregg Beloff, Interim Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 12, 2017

/s/ Gregg Beloff
Gregg Beloff
Interim Chief Financial Officer
(principal financial officer)