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

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**FORM 10-Q**

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(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, 2016**

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number **001-36577**

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**ContraFect Corporation**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**28 Wells Avenue, 3<sup>rd</sup> Floor, Yonkers, NY**  
(Address of principal executive offices)

**39-2072586**  
(I.R.S. Employer  
Identification No.)

**10701**  
(Zip Code)

**(914) 207-2300**  
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  (do not check if smaller reporting company) Smaller reporting company

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

The number of shares of the registrant's Common Stock outstanding as of May 5, 2016 was 27,485,542.

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CONTRAFECT CORPORATION  
PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CONTRAFECT CORPORATION  
Balance Sheets

|  | March 31,<br>2016<br>(unaudited) | December 31,<br>2015<br>(audited) |
|--|----------------------------------|-----------------------------------|
| <b>Assets</b>  |                                  |                                   |
| Current assets:  |                                  |                                   |
| Cash and cash equivalents  | \$ 7,638,646                     | \$ 9,972,781                      |
| Marketable securities  | 18,627,367                       | 22,948,872                        |
| Prepaid expenses and other current assets  | 1,109,706                        | 1,176,895                         |
| Total current assets   | 27,375,719                       | 34,098,548                        |
| Property and equipment, net  | 1,516,198                        | 1,618,968                         |
| Other assets   | 143,621                          | 143,621                           |
| Total assets   | <u>\$ 29,035,538</u>             | <u>\$ 35,861,137</u>              |
| <b>Liabilities and stockholders' equity</b>  |                                  |                                   |
| Current liabilities:   |                                  |                                   |
| Accounts payable   | \$ 1,821,341                     | \$ 1,517,417                      |
| Accrued liabilities  | 3,109,737                        | 2,251,767                         |
| Total current liabilities  | 4,931,078                        | 3,769,184                         |
| Deferred rent  | 987,260                          | 972,119                           |
| Warrant liabilities  | 256,054                          | 444,324                           |
| Total liabilities  | 6,174,392                        | 5,185,627                         |
| Commitments and contingencies  | —                                | —                                 |
| Stockholders' equity:  |                                  |                                   |
| Preferred stock, \$0.0001 par value, 25,000,000 shares authorized and none outstanding at March 31, 2016 and December 31, 2015   | —                                | —                                 |
| Common stock, \$0.0001 par value, 100,000,000 shares authorized; 27,485,542 and 27,482,692 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively | 2,748                            | 2,748                             |
| Additional paid-in capital   | 149,363,352                      | 148,282,546                       |
| Accumulated other comprehensive loss   | (2,381)                          | (30,373)                          |
| Accumulated deficit  | (126,502,573)                    | (117,579,411)                     |
| Total stockholders' equity   | 22,861,146                       | 30,675,510                        |
| Total liabilities and stockholders' equity   | <u>\$ 29,035,538</u>             | <u>\$ 35,861,137</u>              |

See accompanying notes.

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**CONTRAFECT CORPORATION**  
**Unaudited Statements of Operations**

|   | <b>Three Months Ended March 31,</b> |                    |
|---|-------------------------------------|--------------------|
|   | <b>2016</b>                         | <b>2015</b>        |
| Operating expenses:                                   |                                     |                    |
| Research and development                              | \$ 4,430,670                        | \$ 2,422,106       |
| General and administrative                            | <u>4,724,133</u>                    | <u>2,272,970</u>   |
| Total operating expenses                              | <u>9,154,803</u>                    | <u>4,695,076</u>   |
| Loss from operations                                  | (9,154,803)                         | (4,695,076)        |
| Other income (expense):                               |                                     |                    |
| Interest income                                       | 43,371                              | 55,368             |
| Change in fair value of warrant liabilities           | <u>188,270</u>                      | <u>(212,055)</u>   |
| Total other income (expense)                          | <u>231,641</u>                      | <u>(156,687)</u>   |
| Net loss  | <u>(8,923,162)</u>                  | <u>(4,851,763)</u> |
| Per share information:                                |                                     |                    |
| Net loss per share of common stock, basic and diluted | \$ (0.32)                           | \$ (0.24)          |
| Basic and diluted weighted average shares outstanding | <u>27,483,909</u>                   | <u>20,221,463</u>  |

*See accompanying notes.*

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**CONTRAFECT CORPORATION**  
**Unaudited Statements of Comprehensive Loss**

|   | <u>Three Months Ended March 31,</u> |                       |
|---|-------------------------------------|-----------------------|
|   | <u>2016</u>                         | <u>2015</u>           |
| Net loss  | \$ (8,923,162)                      | \$ (4,851,763)        |
| Other comprehensive loss:                                   |                                     |                       |
| Net unrealized gain (loss) on available-for-sale securities | <u>27,992</u>                       | <u>(47,706)</u>       |
| Comprehensive loss  | <u>\$ (8,895,170)</u>               | <u>\$ (4,899,469)</u> |

*See accompanying notes.*

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**CONTRAFECT CORPORATION**  
**Unaudited Statements of Cash Flows**

|   | <b>Three Months Ended March 31,</b> |                      |
|---|-------------------------------------|----------------------|
|   | <b>2016</b>                         | <b>2015</b>          |
| <b>Cash flows from operating activities</b>                                 |                                     |                      |
| Net loss  | \$(8,923,162)                       | \$ (4,851,763)       |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                     |                      |
| Depreciation  | 134,381                             | 134,336              |
| Stock-based compensation expense  | 1,080,806                           | 420,029              |
| Change in fair value of warrant liabilities                                 | (188,270)                           | 212,055              |
| Increase in deferred rent   | 15,141                              | 14,826               |
| Other non-cash charges and expenses   | —                                   | (28,977)             |
| Net amortization of premium paid on marketable securities                   | 133,529                             | —                    |
| Changes in operating assets and liabilities:                                |                                     |                      |
| Decrease in prepaid expenses and other current assets                       | 67,187                              | 97,061               |
| Increase (decrease) in accounts payable and accrued liabilities             | 1,161,894                           | (491,406)            |
| Net cash used in operating activities                                       | (6,518,494)                         | (4,493,839)          |
| <b>Cash flows from investing activities</b>                                 |                                     |                      |
| Purchases of marketable securities  | (1,994,030)                         | (9,374,346)          |
| Proceeds from maturities of marketable securities                           | 6,210,000                           | 500,000              |
| Purchases of property and equipment   | (31,611)                            | —                    |
| Net cash provided by (used in) investing activities                         | 4,184,359                           | (8,874,346)          |
| <b>Cash flows from financing activities</b>                                 |                                     |                      |
| Proceeds from exercise of warrants  | —                                   | 400                  |
| Net cash provided by financing activities                                   | —                                   | 400                  |
| Net decrease in cash and cash equivalents                                   | (2,334,135)                         | (13,367,785)         |
| Cash and cash equivalents at beginning of period                            | 9,972,781                           | 25,722,453           |
| Cash and cash equivalents at end of period                                  | <u>\$ 7,638,646</u>                 | <u>\$ 12,354,668</u> |

*See accompanying notes.*

**ContraFect Corporation**  
**Notes to Unaudited Financial Statements**  
**March 31, 2016**

**1. Organization and Description of Business**

**Organization and Business**

ContraFect Corporation (the “Company”) is a clinical-stage biotechnology company focused on protein and antibody therapeutic products for life-threatening infectious diseases, particularly those treated in hospital-based settings. The Company intends to address multi-drug resistant infections using its therapeutic product candidates from its lysin and monoclonal antibody platforms to target conserved regions of either bacteria or viruses. The Company’s most advanced product candidates are CF-301, a lysin for the treatment of Staph aureus bacteremia, and CF-404, a combination of mAbs for the treatment of life-threatening seasonal and pandemic varieties of influenza.

The Company has incurred losses from operations since inception as a research and development organization and has relied on its ability to fund its operations through public and private debt and equity financings. Management believes its cash, cash equivalents and marketable securities balances will be sufficient to fund operations into the first half of 2017 and expects operating losses and negative cash flows to continue at more significant levels in the future as it initiates additional clinical trials. Transition to profitability is dependent upon the successful development, approval, and commercialization of its product candidates and achieving a level of revenues adequate to support the Company’s cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through additional public or private equity financings, and may seek additional capital through arrangements with strategic partners or from other sources. There can be no assurances that such financing will be available to the Company on satisfactory terms, or at all.

In June 2015, the Company completed a private placement of securities to institutional investors whereby the investors received an aggregate of 4,728,128 shares of the Company’s common stock and warrants to purchase an additional 2,364,066 shares of common stock at an exercise price of \$8.00 per share. The Company received net proceeds of \$18.3 million, net of expenses.

On November 2, 2015, the Company’s Class B Warrants to purchase common stock expired in accordance with their terms. As of November 2, 2015, holders of the Class B Warrants had exercised 4,812,328 Class B Warrants, resulting in the issuance of 2,406,164 shares of the Company’s common stock and the receipt by the Company of approximately \$9.6 million in gross proceeds. The 2,068,005 Class B Warrants that were not exercised prior to expiration were terminated and are no longer exercisable.

The significant increases in common stock outstanding in June and November 2015 are expected to impact the year-over-year comparability of the Company’s net loss per share calculations.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying financial information as of March 31, 2016 and for the three months ended March 31, 2016 and 2015 has been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) have been condensed or omitted pursuant to such rules and regulations. The December 31, 2015 balance sheet was derived from the Company’s audited financial statements. The Company’s audited financial statements as of and for the year ended December 31, 2015, including all related disclosures and the complete listing of significant accounting policies as described in Note 2 thereof, are included in the Company’s Annual Report on Form 10-K that was filed with the SEC on March 15, 2016.

In the opinion of management, the unaudited financial information as of March 31, 2016 and for the three months ended March 31, 2016 and 2015 reflects all adjustments, which are normal recurring adjustments, necessary to present a fair statement of financial position, results of operations and cash flows. The results of operations for the three months ended March 31, 2016 are not necessarily indicative of the operating results for the full fiscal year or any future periods.

**Significant Risks and Uncertainties**

The Company’s operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company’s products, the Company’s ability to obtain regulatory approval to market its products, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, the Company’s products, the Company’s ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products and the Company’s ability to raise capital. See “Risk Factors” contained elsewhere in this Quarterly Report on Form 10-Q for additional risks and uncertainties.

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### **Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to accruals, fair value measurements, stock-based compensation, warrant valuation and income taxes. The Company's actual results may differ from these estimates under different assumptions or conditions. There have been no significant changes from the Company's original estimates in any periods presented.

### **Cash and Cash Equivalents**

The Company considers all highly liquid investments with maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposit, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

### **Concentrations of Credit Risk**

Financial instruments which potentially subject the Company to credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds these investments in highly rated financial institutions, and, by policy, limits the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

### **Fair Value of Financial Instruments**

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, convertible notes and warrant liabilities. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The fair value of the Company's warrant liabilities are based upon unobservable inputs, as described further below.

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. Financial Accounting Standards Board ("FASB") ASC Topic 820, *Fair Value Measurements and Disclosures* (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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The Company had no liabilities classified as Level 1 or Level 2. The carrying amounts reported in the accompanying financial statements for accounts payable and accrued expenses approximate their respective fair values due to their short-term maturities. The fair value of the warrant is discussed in Note 4, "Fair Value Measurements."

### **Share-based Compensation**

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and non-employee directors, including employee stock options. Compensation expense based on the grant date fair value is generally amortized over the requisite service period of the award on a straight-line basis.

The fair value of options is calculated using the Black-Scholes option pricing model to determine the fair value of stock options on the date of grant based on key assumptions such as stock price, expected volatility and expected term. The Company's estimates of these assumptions are primarily based on historical data, peer company data and judgment regarding future trends and factors.

### **Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive given the Company's net loss; therefore, basic and diluted net loss per share were the same for all periods presented.

### **Comprehensive Income (Loss)**

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions, and other events and circumstances from non-owner sources, and currently consists of net loss and changes in unrealized gains and losses on available-for-sale securities.

### **Recent Accounting Pronouncements**

In August 2014, the FASB issued a new Accounting Standards Update, *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 provides guidance on management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern within one year of the date the financial statements are issued, and, if such conditions exist, to provide related footnote disclosures. The guidance is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its financial statements and related disclosures.

In November 2015, the FASB issued a new Accounting Standards Update, *Balance Sheet Classification of Deferred Taxes (ASU 2015-17)*. ASU 2015-17 requires all deferred tax assets and liabilities, and any related valuation allowance, to be classified as non-current on the balance sheet. The classification change for all deferred taxes as non-current simplifies entities' processes as it eliminates the need to separately identify the net current and net non-current deferred tax asset or liability in each jurisdiction and allocate valuation allowances. The Company elected to retrospectively adopt this accounting standard in the beginning of the Company's fourth quarter of fiscal 2015. The adoption of this standard did not have any impact on the Company's financial statements due to full valuation allowance recorded on the Company's deferred taxes.

In January 2016, the FASB issued a new Accounting Standards Update, *Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016-01)*. ASU 2016-01 amends the guidance in U.S. GAAP on the classification and measurement of financial instruments. Although the ASU retains many current requirements, it significantly revises an entity's accounting related to (1) the classification and measurement of investments in equity securities and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. The ASU also amends certain disclosure requirements associated with the fair value of financial instruments. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2017, with early adoption permitted for certain changes. The Company is currently evaluating the potential effects the new standard will have of the Company's financial statements and related disclosures.

In February 2016, the FASB issued a new Accounting Standards Update, *Leases (ASU 2016-02)*, ASU 2016-02 is aimed at making leasing activities more transparent and comparable and requires most leases be recognized by lessees on the balance sheets as a right-of-use asset and corresponding lease liability, regardless of whether they are classified as finance or operating leases. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the impact of the new pronouncement on the Company's financial statements and related disclosures.

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In March 2016, the FASB issued a new Accounting Standards Update, *Improvements to Employee Share-Based Payment Accounting (ASU 2016-09)*. ASU 2016-09 requires all income tax effects of awards to be recognized in the income statement when the awards vest or are settled, thus eliminating APIC pools. Accounting for an employee's use of shares to satisfy the employer's statutory income tax withholding obligation and for forfeitures will change. Companies will have to elect whether to account for forfeitures by recognizing forfeitures of awards as they occur or estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The new standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of the new pronouncement on the Company's financial statements and related disclosures.

### 3. Marketable Securities

Marketable securities at March 31, 2016 and December 31, 2015 consisted of investments in short-term corporate debt securities. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, *Investments – Debt and Equity Securities*. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit) and a component of total comprehensive loss in the statements of comprehensive loss, until realized. The fair value of these securities is based on quoted prices for identical or similar assets. Realized gains and losses are included in investment income on a specific-identification basis. There were no realized gains or losses on marketable securities for the three months ended March 31, 2016.

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the statements of operations if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

Marketable securities at March 31, 2016 consist of the following:

| <u>Marketable Securities</u> | <u>Amortized Cost</u> | <u>Unrealized Gains</u> | <u>Unrealized Losses</u> | <u>Fair Value</u> |
|------------------------------|-----------------------|-------------------------|--------------------------|-------------------|
| Current:                     |                       |                         |                          |                   |
| Corporate debt               | \$ 18,629,748         | \$ 1,315                | \$ (3,696)               | \$18,627,367      |

Marketable securities at December 31, 2015 consisted of the following:

| <u>Marketable Securities</u> | <u>Amortized Cost</u> | <u>Unrealized Gains</u> | <u>Unrealized Losses</u> | <u>Fair Value</u> |
|------------------------------|-----------------------|-------------------------|--------------------------|-------------------|
| Current:                     |                       |                         |                          |                   |
| Corporate debt               | \$ 22,979,245         | \$ 199                  | \$ (30,572)              | \$22,948,872      |

At March 31, 2016 and December 31, 2015, the Company held only current investments. Investments classified as current have maturities of less than one year. Investments that would be classified as non-current are those that have maturities of greater than one year and management does not intend to liquidate within the next twelve months.

At March 31, 2016 and December 31, 2015, the Company held 13 and 28 debt securities, respectively, that individually and in total were in an immaterial unrealized loss position for less than one year. The aggregate fair value of debt securities in an unrealized loss position at March 31, 2016 and December 31, 2015 was \$10,577,109 and \$21,137,424, respectively. The Company evaluated its securities for other-than-temporary impairment and considered the decline in market value for the securities to be primarily attributable to current economic and market conditions. It is not more likely than not that the Company will be required to sell the securities, and the Company does not intend to do so prior to the recovery of the amortized cost basis. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of March 31, 2016 and December 31, 2015.

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**4. Fair Value Measurements**

The following fair value hierarchy table presents information about the Company’s financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2016 and December 31, 2015:

|                       | Fair Value Measurement as of March 31, 2016                                |  |  |
|-----------------------|--|--|--|
|                       | Quoted Prices<br>in Active<br>Markets for<br>Identical Assets<br>(Level 1) | Significant<br>Other Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| Cash equivalents      | \$ 7,579,420   | \$ —   | \$ —   |
| Marketable securities | 18,627,367   | —  | —  |
| Warrant liability     | —  | —  | 256,054  |
| Total                 | <u>\$ 26,206,787</u>   | <u>\$ —</u>  | <u>\$ 256,054</u>                                  |

|                       | Fair Value Measurement as of December 31, 2015                             |  |  |
|-----------------------|--|--|--|
|                       | Quoted Prices<br>in Active<br>Markets for<br>Identical Assets<br>(Level 1) | Significant<br>Other Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| Cash equivalents      | \$ 9,607,134   | \$ —   | \$ —   |
| Marketable securities | 22,948,872   | —  | —  |
| Warrant liability     | —  | —  | 444,324  |
| Total                 | <u>\$ 32,556,006</u>   | <u>\$ —</u>  | <u>\$ 444,324</u>                                  |

The Company issued a warrant to the representative of the underwriter of its initial public offering (the “Representative’s Warrant”). The Company evaluated the Representative’s Warrant against current accounting guidance and determined that this warrant should be classified as a liability and considers it as a Level 3 financial instrument (see also Note 8, “Capital Structure”). The warrant will be re-measured at each subsequent reporting period and changes in fair value will be recognized in the statement of operations. The following assumptions were used in a Black-Scholes option-pricing model to determine the fair value of the warrant liability:

|                                       | As of<br>March 31, 2016 | As of<br>December 31, 2015 |
|---------------------------------------|-------------------------|----------------------------|
| Expected volatility                   | 79.90%                  | 78.1%                      |
| Remaining contractual term (in years) | 3.42                    | 3.67                       |
| Risk-free interest rate               | 1.04%                   | 1.54%                      |
| Expected dividend yield               | — %                     | — %                        |

The following tables present a reconciliation of the Company’s financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2016 and 2015:

*Warrant liabilities*

|                                       | Three Months Ended<br>March 31, |                  |
|---------------------------------------|---------------------------------|------------------|
|                                       | 2016                            | 2015             |
| Balance at beginning of period        | \$ 444,324                      | \$313,004        |
| Increase (decrease) in fair value (1) | (188,270)                       | 212,055          |
| Balance at end of period              | <u>\$ 256,054</u>               | <u>\$525,059</u> |

(1) The change in the fair values of the warrant liabilities are recorded in other expenses in the statement of operations.

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The key inputs into the Black-Scholes option pricing model are the per share value and the expected volatility of the Company's common stock. Significant changes in these inputs will directly increase or decrease the estimated fair value of the Company's warrant liability.

### 5. Accrued Expenses

Accrued expenses consist of the following:

|                                       | March 31,<br>2016  | December 31,<br>2015 |
|---------------------------------------|--------------------|----------------------|
| Accrued compensation costs            | \$1,690,113        | \$ 1,133,742         |
| Accrued research and development fees | 624,190            | 590,307              |
| Accrued professional fees             | 543,774            | 317,796              |
| Other                                 | 251,660            | 209,922              |
|                                       | <u>\$3,109,737</u> | <u>\$ 2,251,767</u>  |

### 6. Senior Convertible Notes

The Company issued approximately \$15.0 million in aggregate principal amount of its 8.00% Convertible Notes due May 31, 2015 (the "Convertible Notes") from June 2013 through June 2014. On August 1, 2014, in conjunction with the closing of the Company's initial public offering, the principal amount of the Convertible Notes, and all accrued and unpaid interest thereon, automatically converted into 5,109,988 shares of common stock. Upon the closing of the offering, the Company accelerated the amortization of the remaining debt discount balance to interest expense.

Each purchaser of the Convertible Notes received a warrant (the "Note Warrants"). Upon the closing of the initial public offering and based on the terms of the Note Warrants, the Company determined the total number of shares of the Company's common stock underlying the Note Warrants to be 3,321,416 at an exercise price of \$3.00 per share. There were 3,315,878 shares of common stock underlying the outstanding Note Warrants as of March 31, 2016 and December 31, 2015. The Note Warrants expire five years from the date of issuance.

### 7. Net Loss Per Share of Common Stock

Diluted net loss per share is the same as basic net loss per share for all periods presented because the effects of potentially dilutive items were anti-dilutive given the Company's net loss. Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding.

The following table sets forth the computation of basic and diluted net loss per share for common stockholders:

|  | Three Months Ended March 31, |                  |
|--|------------------------------|------------------|
|  | 2016                         | 2015             |
| Net loss   | \$ (8,923,162)               | \$ (4,851,763)   |
| Weighted average shares of common stock outstanding  | 27,483,909                   | 20,221,463       |
| Net loss per share of common stock—basic and diluted | <u>\$ (0.32)</u>             | <u>\$ (0.24)</u> |

The following potentially dilutive securities outstanding at March 31, 2016 and 2015 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive given the Company's net loss:

|                                   | March 31,         |                   |
|-----------------------------------|-------------------|-------------------|
|                                   | 2016              | 2015              |
| Options to purchase common stock  | 4,711,508         | 3,791,577         |
| Warrants to purchase common stock | 13,503,107        | 14,577,261        |
|                                   | <u>18,214,615</u> | <u>18,368,838</u> |

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### **8. Capital Structure**

#### **Common Stock**

As of March 31, 2016, the Company was authorized to issue 100,000,000 shares of common stock at \$0.0001 par value per share.

##### *Private Placement*

On June 12, 2015, the Company closed a private placement of its securities with a group of institutional investors (the “PIPE”). Each investor received one share of common stock and a warrant to purchase one-half share of common stock at a price of \$4.23 per common share purchased. The closing of the PIPE resulted in the issuance of an aggregate of 4,728,128 common shares and warrants to purchase an additional 2,364,066 shares of common stock at an exercise price of \$8.00 per full share, which expire three years from the date of issuance (the “PIPE Warrants”). The Company received net proceeds from the PIPE of \$18.3 million, after deducting expenses payable by the Company.

The placement agents in the PIPE received warrants to purchase 4% of the total number of shares of common stock sold in the PIPE (the “Placement Agent Warrants”), for a total of 189,126 shares of common stock underlying the Placement Agent Warrants. The Placement Warrants became exercisable upon issuance at an exercise price of \$4.65 per share and expire on June 11, 2020.

The common stock and accompanying PIPE Warrants and Placement Agent Warrants have been classified as stockholders’ equity in the Company’s balance sheet.

##### *Initial Public Offering*

In July 2014, the stockholders approved an amended certificate of incorporation that became effectively immediately upon the closing of the Company’s IPO. The approved certificate increased the number of authorized shares of common stock to 100,000,000 shares.

On August 1, 2014, the Company closed an initial public offering of its units (the “IPO”). Each unit consisted of one share of common stock, one Class A Warrant to purchase one share of common stock at an exercise price of \$4.80 per share and one Class B Warrant to purchase one-half share of common stock at an exercise price of \$4.00 per full share (the “Units”). The closing of the IPO resulted in the sale of an aggregate of 6,880,333 Units at a public offering price of \$6.00 per Unit, less underwriting discounts and commissions and the underwriter’s expenses, including 880,333 Units issued upon the exercise by the underwriters of their option to purchase additional Units at the public offering price to cover over-allotments. The Company received net proceeds from the IPO of \$35.0 million, after deducting underwriting discounts, commissions, and expenses payable by the Company. Following the IPO, the Units separated and the shares of common stock, Class A Warrants and Class B Warrants began to trade separately. The common stock and accompanying Class A and Class B Warrants have been classified as stockholders’ equity in the Company’s balance sheet.

On November 2, 2015, the Company’s Class B Warrants to purchase common stock expired in accordance with their terms. As of November 2, 2015, holders of the Class B Warrants had exercised 4,812,328 Class B Warrants, resulting in the issuance of 2,406,164 shares of the Company’s common stock and the receipt by the Company of approximately \$9.6 million in gross proceeds. The 2,068,005 Class B Warrants that were not exercised prior to expiration have terminated and are no longer exercisable.

##### *Representative’s Warrant*

The Maxim Group, LLC, the representative of the underwriter in the IPO, received the Representative’s Warrant to purchase 3% of the total number of shares of common stock sold in the IPO, including those shares sold upon the exercise of the over-allotment option, for a total of 206,410 shares of common stock underlying the Representative’s Warrant. The Representative’s Warrant is exercisable at an exercise price of \$7.50 per share beginning 180 days after the effective date of the Company’s registration statement (January 24, 2015) and expiring on August 27, 2019. The Company classified the Representative’s Warrant as a liability since it did not meet the requirements to be included in equity. The fair value of the Representative’s warrant will be re-measured at each reporting period and changes in fair value will be recognized in the statement of operations (see Note 4, “Fair Value Measurements”).

##### *Voting*

The holders of shares of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings.

##### *Dividends*

The holders of shares of common stock are entitled to receive dividends, if and when declared by the board of directors. As of March 31, 2016, no dividends have been declared or paid on the Company’s common stock since inception.

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### *Reserved for Future Issuance*

The Company has reserved for future issuance the following number of shares of common stock as of March 31, 2016 and December 31, 2015:

|                                   | <u>March 31,<br/>2016</u> | <u>December 31,<br/>2015</u> |
|-----------------------------------|---------------------------|------------------------------|
| Options to purchase common stock  | 4,711,508                 | 4,313,755                    |
| Warrants to purchase common stock | <u>13,503,107</u>         | <u>13,503,107</u>            |
|                                   | <u>18,214,615</u>         | <u>17,816,862</u>            |

### *Sales Agreement*

In January 2016, the Company entered into a Sales Agreement with Cowen and Company, LLC (“Cowen”) to sell shares of the Company’s common stock, with aggregate gross sales proceeds of up to \$30 million, through an “at the market” equity offering program under which Cowen will act as sales agent. The Company has not sold any shares under the program.

## **9. Stock Warrants**

As of March 31, 2016 and December 31, 2015, the Company had warrants outstanding as shown in the table below.

|   | <u>March 31,<br/>2016</u> | <u>December 31,<br/>2015</u> |
|---|---------------------------|------------------------------|
| Note Warrants                             | 3,315,878                 | 3,315,878                    |
| Class A Warrants                          | 6,880,333                 | 6,880,333                    |
| PIPE Warrants                             | 2,364,066                 | 2,364,066                    |
| Representative’s Warrant                  | 206,410                   | 206,410                      |
| Placement Agent Warrants                  | 189,126                   | 189,126                      |
| Other warrants (1)                        | <u>547,294</u>            | <u>547,294</u>               |
| Warrants to purchase common stock         | 13,503,107                | 13,503,107                   |
| Weighted-average exercise price per share | \$ 5.02                   | \$ 5.02                      |

- (1) Other warrants are comprised of warrants issued prior to the Company’s IPO, generally in exchange for services rendered to the Company.

The following table summarizes information regarding the Company’s warrants outstanding at March 31, 2016:

| <u>Exercise Prices</u> | <u>Shares<br/>Underlying<br/>Outstanding<br/>Warrants</u> | <u>Expiration Date</u>              |
|------------------------|---|-------------------------------------|
| £ \$4.00               | 3,588,406   | August 31, 2016 – September 1, 2021 |
| \$4.01-\$4.99          | 7,069,459   | February 1, 2017 – June 11, 2020    |
| \$5.00 - \$9.99        | 2,656,900   | December 10, 2016 – June 27, 2021   |
| <sup>3</sup> \$10.00   | <u>188,342</u>  | August 31, 2016 – January 5, 2022   |
|                        | <u>13,503,107</u>   |                                     |

## **10. Stock Option and Incentive Plans**

### *Amended and Restated 2008 Equity Incentive Plan*

In July 2008, the Company adopted the 2008 Equity Incentive Plan (the “Plan”). The Plan allows for the granting of non-qualified stock options, restricted stock, stock appreciation rights and other performance awards to the Company’s employees, members of the board of directors and consultants of the Company.

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Upon the original adoption of the Plan, the number of shares of common stock reserved pursuant to the Plan was 214,285. On December 12, 2011, the Plan was amended to increase the number of shares of common stock available under the Plan to 900,000. On February 24, 2014, the board of directors increased the number of shares of common stock available under the Plan to 1,857,142. On April 29, 2014, the board of directors increased the number of shares of common stock available under the Plan to 2,357,142. The Company expects no further grants to be made under the Plan.

### *2014 Omnibus Incentive Plan*

In April 2014, the Company's board of directors adopted the 2014 Omnibus Incentive Plan (the "2014 Plan"). The 2014 Plan was approved by the Company's stockholders on July 3, 2014. The 2014 Plan allows for the granting of incentive and non-qualified stock options, restricted stock and stock unit awards, stock appreciation rights and other performance-based awards to the Company's employees, members of the board of directors and consultants of the Company. On July 28, 2014, the effective date of the 2014 Plan, the number of shares of common stock reserved pursuant to the 2014 Plan was 571,429. The 2014 Plan provides for an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ended December 31, 2014 and continuing until the expiration of the 2014 Plan, equal to the lesser of (i) 4% of the outstanding shares of common stock on such date or (ii) an amount determined by the Company's board of directors. Consistent with the provision for an annual increase, an additional 1,907,997 shares of common stock have been reserved under the 2014 Plan.

The Company recognized compensation expense for share-based compensation based on the fair value of the underlying instrument. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. A summary of stock option activity for the three months ended March 31, 2016, is summarized as follows:

|  | <b>Number of<br/>Options</b> | <b>Weighted<br/>Average<br/>Exercise Price</b> | <b>Weighted<br/>Average Remaining<br/>Contractual Life<br/>(in years)</b> | <b>Aggregate<br/>Intrinsic Value</b> |
|--|------------------------------|--|---|--------------------------------------|
| Options outstanding at December 31, 2015 | 4,313,755                    | \$ 4.87  |   |                                      |
| Granted                                  | 776,100                      | 3.39   |   |                                      |
| Exercised                                | (21,356)                     | 3.07   |   |                                      |
| Expired                                  | (68,279)                     | 5.10   |   |                                      |
| Forfeited                                | (288,712)                    | 4.61   |   |                                      |
| Options outstanding at March 31, 2016    | <u>4,711,508</u>             | \$ 4.64  | 6.27  | \$ 126,917                           |
| Vested and exercisable at March 31, 2016 | <u>3,251,921</u>             | \$ 4.90  | 5.19  | \$ 27,548                            |

Of the option grants outstanding to purchase 4,711,508 shares of common stock, grants to purchase 667,870 shares of common stock were issued and are outstanding outside the Company's incentive plans.

The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of options granted during the three months ended March 31, 2016 and 2015 was \$3.39 and \$4.62, respectively. Total compensation expense recognized amounted to \$1,080,806 and \$365,729 for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2016, the total remaining unrecognized compensation cost related to unvested stock options was \$4,255,165 which will be recognized over a weighted average period of approximately 2.43 years.

The following assumptions were used to compute the fair value of stock option grants:

|                          | <b>Three Months Ended March 31,</b> |             |
|--------------------------|-------------------------------------|-------------|
|                          | <b>2016</b>                         | <b>2015</b> |
| Risk free interest rate  | 1.21%                               | 1.62%       |
| Expected dividend yield  | —                                   | —           |
| Expected term (in years) | 4.87                                | 5.97        |
| Expected volatility      | 79.7%                               | 73.6%       |

*Expected volatility*—The Company estimated the expected volatility based on an average of the volatility of similar companies with publicly-traded equity securities. The companies were selected based on their enterprise value, risk profiles, position within the industry, and with historical information sufficient to meet the expected term of the associated award.

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*Expected term*—The Company based expected term on the midpoint of the vesting period and the contractual term of each respective option grant.

*Risk-free interest rate*—The Company estimated the risk-free interest rate in reference to yield on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award.

*Expected dividend yield*—The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to common stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in its continued growth.

### **11. Significant Agreements**

On March 25, 2016, the Company entered into a separation agreement and release of claims with its former Chief Executive Officer, Julia P. Gregory. Subject to Ms. Gregory's continued compliance with restrictive covenants contained in her employment agreement with the Company, the separation agreement provides for Ms. Gregory to receive severance payments totaling approximately \$1.2 million for a period of 18 months following the effective date of Ms. Gregory's retirement, the accelerated vesting of all unvested portions of stock option grants dated April 29, 2014 and February 8, 2016, and continued medical, dental and vision coverage paid for by the Company under the Company's group healthcare plans for up to eighteen months following the effective date of Ms. Gregory's retirement. The total amount of these charges was recognized as part of general and administrative expenses for the period ended March 31, 2016. Ms. Gregory will have a period of two years following the effective date of her retirement to exercise her vested Company stock options.

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### 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 in conjunction with the information set forth in our financial statements and the notes to those statements included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed by us with the Securities and Exchange Commission on March 15, 2016.*

#### **Forward-Looking Statements**

*The information in this Quarterly Report on Form 10-Q contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, our beliefs regarding lysins, future operations, future financial position, the sufficiency of our cash and cash equivalents and marketable securities, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates", "believes", "estimates", "expects", "intends", "targets", "may", "plans", "projects", "potential", "will", "would", "could" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. All such forward-looking statements involve significant risks and uncertainties, including, but not limited to, statements regarding:*

- the success, cost, timing and potential indications of our product development activities and clinical trials;*
- our ability to advance into and through clinical development and ultimately obtain FDA approval for our product candidates;*
- our future marketing and sales programs;*
- the rate and degree of market acceptance of our product candidates and our expectations regarding the size of the commercial markets for our product candidates;*
- our research and development plans and ability to bring forward additional product candidates into preclinical and clinical development;*
- the effect of competition and proprietary rights of third parties;*
- the availability of and our ability to obtain additional financing;*
- the effects of existing and future federal, state and foreign regulations;*
- the seeking of joint development, licensing or distribution and collaboration and marketing arrangements with third parties; and*
- the period of time for which our existing cash and cash equivalents will enable us to fund our operations.*

*As more fully described under the heading "Risk Factors" contained elsewhere in this Quarterly Report on Form 10-Q, many important factors affect our ability to achieve our stated objectives and to develop and commercialize any product candidates. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks and uncertainties set forth in our filings with the SEC. You should read this Quarterly Report on Form 10-Q with the understanding that our actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.*

#### **Overview**

We are a clinical-stage biotechnology company focused on discovering and developing therapeutic protein and antibody products for the treatment of life-threatening, drug-resistant infectious diseases, including those caused by drug resistant pathogens, particularly those treated in hospital settings. Drug-resistant infections account for two million illnesses in the United States and 700,000 deaths worldwide each year. We intend to address drug-resistant infections using our therapeutic product candidates from our lysin and monoclonal antibody platforms that target conserved regions of either bacteria or viruses. Lysins are enzymes derived from naturally occurring bacteriophage which are viruses that infect bacteria. When recombinantly produced and then applied to bacteria, lysins cleave a key component of the target bacteria's peptidoglycan cell wall, which results in rapid bacterial cell death. Lysins kill

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bacteria faster than conventional antibiotics, which typically require bacterial cell division and metabolism in order to kill or stop the growth of bacteria. We believe that the properties of our lysins will make them suitable for targeting antibiotic-resistant organisms, such as *Staphylococcus aureus* (“*Staph aureus*”) which causes serious infections such as bacteremia, pneumonia and osteomyelitis. In addition, our lysins have demonstrated the ability to clear biofilms in animal models, and we believe they may be useful for the treatment of biofilm-related infections in prosthetic joints, indwelling devices and catheters. Beyond our lysin programs, we are exploring therapies using monoclonal antibodies (“mAbs”) designed to bind to viral targets. Our approach to antibody therapy employs a combination of multiple mAbs to either achieve greater efficacy or provide broader coverage across pathogenic strains.

We have not generated any revenues and, to date, have funded our operations primarily through the issuance and sale of our Units, which consisted of one share of common stock, one Class A Warrant to purchase one share of common stock at an exercise price of \$4.80 per share and one Class B Warrant to purchase one-half share of common stock at an exercise price of \$4.00 per full share (“Units”), common stock, convertible preferred stock and convertible debt to our investors. As of November 2, 2015, the date of expiration of the Class B Warrants, holders of the Class B Warrants had exercised 4,812,328 Class B Warrants, resulting in the issuance of 2,406,164 shares of the Company’s common stock and the receipt by the Company of approximately \$9.6 million in gross proceeds. In June 2015, the Company completed a private placement of securities to institutional investors whereby the investors received an aggregate of 4,728,128 shares of the Company’s common stock and warrants to purchase an additional 2,364,066 shares of common stock at an exercise price of \$8.00 per share. The Company received net proceeds of \$18.3 million, net of expenses. In August 2014, we completed our initial public offering (“IPO”), raising net proceeds of \$35.0 million, net of an underwriting discount, commissions and offering expenses. In connection with the IPO, our Board of Directors and stockholders approved a 1-for-7 reverse stock split of our common stock. The reverse stock split became effective on July 25, 2014.

We have never been profitable and our net loss from operations was \$8.9 million for the three months ended March 31, 2016 and \$25.1 million for the year ended December 31, 2015. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through preclinical activities and clinical trials to seek regulatory approval and, if approved, commercialize such product candidates. Additionally, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We expect to seek to fund our operations through public or private equity, debt financings, equity-linked financings, collaborations, strategic alliances, licensing arrangements, research grants or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

## **Financial Operations Overview**

### ***Revenue***

We have not generated any revenues to date. In the future, we may generate revenues from product sales. In addition, to the extent we enter into licensing or collaboration arrangements, we may have additional sources of revenue. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of payments that we may recognize upon the sale of our products, to the extent that any products are successfully commercialized, and the amount and timing of fees, reimbursements, milestone and other payments received under any future licensing or collaboration arrangements. If we fail to complete the development of our product candidates in a timely manner, obtain regulatory approval for them, or successfully commercialize them, 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 expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and non-cash share-based compensation expense;
- external research and development expenses incurred under arrangements with third parties such as contract research organizations (“CROs”), contract manufacturers, consultants and academic institutions; and
- facilities and laboratory and other supplies.

We expense research and development costs to operations as incurred. We account for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made.

The following summarizes our most advanced current research and development programs.

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### **CF-301: lead lysin program**

CF-301 is a parenteral, potent, bactericidal lysin targeting Staph aureus bacteria, making it a highly specific therapeutic candidate for the treatment of patients with Staph aureus bacteremia. In December 2015, we concluded a Phase 1 single ascending dose study in healthy volunteers. We have worldwide development and commercial rights to CF-301 and expect to fund the future development and commercialization costs related to this program.

### **CF-404: lead mAb program**

CF-404 is a potent combination of three mAbs targeting the conserved regions of the influenza virus. CF-404 cross-reacts with all human seasonal strains of influenza, making it a highly specific therapeutic candidate for the treatment of patients with life-threatening varieties of influenza. We have worldwide development and commercial rights to CF-404 and expect to fund the future development and commercialization costs related to this program.

To date, a large portion of our research and development work has related to the establishment of both our lysin and antibody platform technologies, the advancement of our research projects to discovery of clinical candidates, manufacturing and preclinical testing of our product candidates and Phase 1 clinical testing of CF-301, the first lysin to enter clinical trials in the U.S. In the future, we intend to continue using our employee and infrastructure resources across multiple development programs as well as research projects. In the three months ended March 31, 2016 and 2015, we recorded approximately \$4.4 million and \$2.4 million, respectively, of research and development expenses. A breakdown of our research and development expenses by category is shown below. We do not currently utilize a formal time or laboratory project expense allocation system to allocate employee-related expenses, laboratory costs or depreciation to any particular project. Accordingly, we do not allocate these expenses to individual projects or product candidates. However, we do allocate some portions of our research and development expenses in product development, external research and licensing costs and professional fees, by project, including CF-301 and CF-404, as shown below.

The following table summarizes our research and development expenses by category for the three months ended March 31, 2016 and 2015:

|  | Three Months Ended<br>March 31, |                    |
|--|---------------------------------|--------------------|
|  | 2016                            | 2015               |
| Product development                    | \$1,714,279                     | \$ 952,562         |
| Personnel related                      | 1,049,636                       | 690,356            |
| Laboratory costs                       | 575,144                         | 453,313            |
| External research and licensing costs  | 317,634                         | 104,704            |
| Professional fees                      | 607,685                         | 140,622            |
| Share-based compensation               | 166,292                         | 80,549             |
| Total research and development expense | <u>\$4,430,670</u>              | <u>\$2,422,106</u> |

The following table summarizes our research and development expenses by program for the three months ended March 31, 2016 and 2015:

|  | Three Months Ended<br>March 31, |                    |
|--|---------------------------------|--------------------|
|  | 2016                            | 2015               |
| CF-301   | \$ 933,368                      | \$ 578,902         |
| CF-404   | 1,523,117                       | 464,651            |
| Other research and development                 | 758,257                         | 607,648            |
| Personnel related and share-based compensation | 1,215,928                       | 770,905            |
| Total research and development expense         | <u>\$4,430,670</u>              | <u>\$2,422,106</u> |

We anticipate that our research and development expenses will increase substantially as the clinical trials for our product candidates progress. However, the successful development of future product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- the feasibility and success of our product formulation and manufacturing processes;
- clinical trial results;

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- the terms and timing of regulatory approvals;
- our ability to market, commercialize and achieve market acceptance for our product candidates in the future; and
- the expense, filing, prosecuting, defending and enforcing of patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of CF-301, CF-404 or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of CF-301, CF-404 or such other product candidates. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of CF-301 or if we experience significant delays in enrollment in any clinical trials of CF-301, we could be required to expend significant additional financial resources and time on the completion of the clinical development of CF-301.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related costs for personnel, including non-cash share-based compensation expense, in our executive, finance, legal, human resource and business development functions. Other general and administrative expenses include facility costs, insurance expenses and professional fees for legal, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as a result of increased headcount, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and increased insurance premiums, among other factors.

### ***Interest Income***

Interest income consists of interest earned on our cash and cash equivalents and marketable securities.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies from the information provided in the section "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K filed by us with the SEC on March 15, 2016.

### **Results of Operations**

The following table summarizes key components of our results of operations for the periods indicated.

|                            | <b>Three Months Ended March 31,</b> |              | <b>Dollar Change</b> |
|----------------------------|-------------------------------------|--------------|----------------------|
|                            | <b>2016</b>                         | <b>2015</b>  |                      |
| Operating expenses:        |                                     |              |                      |
| Research and development   | \$ 4,430,670                        | \$ 2,422,106 | \$ 2,008,564         |
| General and administrative | \$ 4,724,133                        | \$ 2,272,970 | \$ 2,451,163         |
| Other income (expense)     | \$ 231,641                          | \$ (156,687) | \$ 388,328           |

### ***Comparison of three months ended March 31, 2016 and 2015***

#### ***Research and Development Expenses***

Research and development expense was \$4.4 million for the three months ended March 31, 2016, compared with \$2.4 million for the three months ended March 31, 2015, an increase of \$2.0 million. This increase was primarily attributable to a \$1.4 million

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increase in expenditures on our product candidates as we continued to prepare CF-301 for Phase 2 clinical trials and to progress CF-404 through IND-enabling studies and manufacturing activities and a \$0.6 million increase in our research headcount and related salaries, benefits and laboratory costs in support of the discovery and study of additional product candidates.

### *General and Administrative Expenses*

General and administrative expense was \$4.7 million for the three months ended March 31, 2016, compared with \$2.3 million for the three months ended March 31, 2015, an increase of \$2.4 million. This increase was primarily attributable to severance costs totaling \$2.0 million, including \$0.5 million of non-cash share-based compensation expense, an increase in our administrative and headcount, resulting in a \$0.2 million increase in expenses, and a \$0.2 million increase in legal and accounting costs related to our SEC filings.

### *Other income (expense)*

Other income was \$0.2 million for the three months ended March 31, 2016 compared with expense of \$0.2 million for the three months ended March 31, 2015, an increase of \$0.4 million. In the current period, we had non-cash income of \$0.2 million related to the change in fair value of our warrant liability and less than \$0.1 million of interest income from our marketable securities. In the prior year period, we had non-cash expense of more than \$0.2 million related to the change in fair value of our warrant liability, which was partially offset by interest income of less than \$0.1 million from our marketable securities.

## **Liquidity and Capital Resources**

### *Sources of Liquidity*

We have financed our operations to date primarily through proceeds from sales of Units, common stock, convertible preferred stock and convertible debt. To date, we have not generated any revenue from the sale of products. We have incurred losses and generated negative cash flows from operations since inception.

Since the date of our initial public offering, we have received gross proceeds of \$41.3 million from the sale of Units in our IPO, \$9.6 million from the exercise of the Class B Warrants issued as part of the Units sold in our IPO and \$20.0 million from the sale of securities in a private placement.

As of March 31, 2016, our cash and cash equivalents and marketable securities totaled \$26.3 million. We primarily invest our cash and cash equivalents in commercial money market accounts and our marketable securities in highly rated corporate debt securities.

### *Cash flows*

The following table provides information regarding our cash flows for the three months ended March 31, 2016 and 2015:

|                                 | <b>Three Months Ended March 31,</b> |               |
|---------------------------------|-------------------------------------|---------------|
|                                 | <b>2016</b>                         | <b>2015</b>   |
| Net cash provided by (used in): |                                     |               |
| Operating activities            | \$(6,518,494)                       | \$(4,493,839) |
| Investing activities            | \$ 4,184,359                        | \$(8,874,346) |
| Financing activities            | \$ —                                | \$ 400        |

### *Operating Activities*

Net cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. Net cash used in operating activities in the three months ended March 31, 2016 increased by \$2.0 million as compared to the same period in 2015. In the three months ended March 31, 2016, we had an increase in our loss from operations as we advanced our product candidates and expanded our research and administrative headcount.

### *Investing Activities*

Net cash provided by investing activities in the three months ended March 31, 2016 resulted from proceeds from maturities of marketable securities, which were partially offset by the amounts we reinvested. In the prior year period, net cash used in investing activities resulted from the investment of our cash balances into marketable securities.

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### *Financing Activities*

There was no cash provided by financing activities in the three months ended March 31, 2016.

### **Funding Requirements**

All of our product candidates are in early clinical or preclinical development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- initiate the planned clinical trials of our product candidates;
- continue our ongoing preclinical studies, and initiate additional preclinical studies, of our product candidates;
- continue the research and development of our other product candidates and our platform technology;
- seek to identify additional product candidates;
- acquire or in-license other products and technologies;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish, either on our own or with strategic partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

We believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations into the first half of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our lead product candidates;
- the scope, progress, results and costs of compound discovery, preclinical development, laboratory testing and clinical trials for our other product candidates;
- the extent to which we acquire or in-license other products, product candidates or technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish any future collaboration arrangements on favorable terms, if at all.

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, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. Whenever we raise additional capital through the sale of equity or other securities, 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 common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances 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 our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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We incur significant increased costs as a public company that we did not previously incur prior to our IPO, including, but not limited to, increased personnel costs, increased directors fees, increased directors and officers insurance premiums, audit and legal fees, investor relations and external communications fees, expenses for compliance with the Sarbanes-Oxley Act and rules implemented by the SEC and NASDAQ and various other costs and expenses.

### **Contractual Obligations and Commitments**

The following summarizes our significant contractual obligations as of March 31, 2016:

| <b>Contractual Obligations</b>                | <b>Total</b>        | <b>Less than<br/>1 Year</b> | <b>1 to 3 Years</b> | <b>3 to 5 Years</b> | <b>More than<br/>5 Years</b> |
|---|---------------------|-----------------------------|---------------------|---------------------|------------------------------|
| Operating lease obligations (1)               | \$11,212,716        | \$ 856,154                  | \$1,764,020         | \$1,835,287         | \$6,757,255                  |
| License and sponsored research agreements (2) | 1,450,044           | 540,044                     | 310,000             | 400,000             | 200,000                      |
| <b>Total obligations</b>                      | <b>\$12,662,760</b> | <b>\$1,396,198</b>          | <b>\$2,074,020</b>  | <b>\$2,235,287</b>  | <b>\$6,957,255</b>           |

- (1) Represents future minimum lease payments under non-cancelable operating leases for our current facilities in Yonkers, New York which expire in 2027. The minimum lease payments above do not include certain utility costs, common area maintenance charges or real estate taxes.
- (2) Represents certain amounts payable under our licenses and sponsored research agreements with The Rockefeller University ("Rockefeller") and Trellis Bioscience LLC ("Trellis").

We enter into contracts in the normal course of business with contract research organizations, or CROs, for clinical trials, clinical supply manufacturing, non-clinical and preclinical studies and for other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations.

The contractual obligations table also does not include any potential contingent payments upon the achievement by us of specified clinical, regulatory and commercial events, as applicable, or royalty payments we may be required to make under license agreements we have entered into with Rockefeller and Trellis. These occurrence and timing of these events are difficult to predict and subject to significant uncertainty. Since we are unable to reliably estimate the timing and amounts of such milestone and royalty payments, or whether they will occur at all, these contingent payments have been excluded from the table above. See "Note 15—Notes to Financial Statements" on Page F-25 of our Annual Report on Form 10-K filed by us with the SEC on March 15, 2016.

### **Effects of Inflation**

We do not believe that inflation or changing prices had a significant impact on our results of operations for any periods presented herein.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we are currently not party to, any off-balance sheet arrangements.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. As of March 31, 2016, we had cash, cash equivalents and marketable securities of \$26.3 million. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the fair value of our cash equivalents or marketable securities. If a 10% change in interest rates were to have immediately occurred on March 31, 2016, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

While we believe our cash, cash equivalents and marketable securities do not contain excessive credit or liquidity risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

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We do not own any derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative, foreign currency or other financial instruments that would require disclosure under this item.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

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

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of our disclosure controls and procedures. Based on that 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, 2016.

*Changes in Internal Control*

As required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of our internal control over financial reporting to determine whether any changes occurred during the quarter ended March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded that there were no such changes during the quarter ended March 31, 2016 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

### ITEM 1A. RISK FACTORS

*The following description of risk factors includes any material changes to, and supersedes the description of, risk factors associated with the Company's business previously disclosed in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K, filed with the SEC on March 15, 2016. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause the Company's actual results of operations and financial condition to vary materially from past, or from anticipated future, results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect the Company's business, financial condition, results of operations and common stock price. Other factors may exist that we do not consider significant based on information that is currently available. In addition, new risks may emerge at any time, and we cannot predict those risks or estimate the extent to which they may affect us. Past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.*

*The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this Form 10-Q or elsewhere. The following information should be read in conjunction with our financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Quarterly Report on Form 10-Q.*

#### **Risks Related to Our Financial Position and Need for Additional Capital**

***We have incurred significant losses since our inception and do not expect to generate revenue for at least the next several years. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.***

We are a clinical-stage biopharmaceutical company with no approved products, and we have not generated any revenue from product sales to date. To date, we have focused exclusively on developing our product candidates and have funded our operations primarily through public sale of units and private sales of common stock, convertible preferred stock and issuances of convertible debt to our investors. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the pharmaceutical industry, and you should analyze our company in light of such risks and uncertainties.

Since inception, we have incurred significant operating losses. Our net loss was \$8.9 million for the three months ended March 31, 2016 and \$25.1 million for the year ended December 31, 2015. We have devoted substantially all of our efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

We anticipate that our expenses will increase substantially as clinical trials for any of our product candidates commence or progress. Our expenses will increase if and as we:

- seek to discover or develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- in-license or acquire other products and technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

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### ***Our recurring losses from operations could raise substantial doubt regarding our ability to continue as a going concern.***

We currently operate with limited resources. We believe that our cash, cash equivalents and marketable securities balance of \$26.3 million as of March 31, 2016 will be sufficient to fund our projected operations into the first half of 2017. Depending on the level of cash used in or generated from operations, additional capital may be required to sustain operations. We have incurred significant losses since our inception and have never generated revenue or profit, and it is possible we will never generate revenue or profit. Meaningful revenues will likely not be available until and unless any future product candidates are approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company.

### ***We currently have no source of product revenue and have not yet generated any revenues from product sales.***

To date, we have not completed the development of any products and have not generated any revenues from product sales. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully commercialize products, including any of our current product candidates, or other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we may never generate revenues that are significant enough to achieve profitability. Our ability to generate revenue from product sales from our current or future product candidates also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit biologics license applications (“BLAs”) to the FDA, and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell and distribute our products in other markets; and
- obtain coverage and adequate reimbursement from third parties, including government and private payors.

In addition, because of the numerous risks and uncertainties associated with product development, including that any of our product candidates may not advance through development or achieve the desired endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for any product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of our products, we may not become profitable. 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 decrease the value of our company and could impair our ability to raise capital to expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

### ***We have a need for substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.***

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical development of CF-301 and preclinical development of CF-404, and, possibly, acquire and develop new product candidates or technologies. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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

- the complexity, timing and results of our clinical trials of our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of developing our product candidates for additional indications;

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- our ability to establish scientific or business collaborations on favorable terms, if at all;
- the costs of preparing, filing and prosecuting patent or other intellectual property applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the extent to which we in-license or acquire other product candidates or technologies; and
- the scope, progress, results and costs of product development for our product candidates.

Conducting 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 to obtain marketing approval and achieve product sales. In addition, if approved, CF-301, CF-404 or any other product candidate that we develop may not achieve commercial success. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. 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 our technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, 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 our 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.

***Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We were incorporated in 2008 and commenced active research operations in 2010. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital and acquiring and developing CF-301, CF-404 and other potential product candidates. We have not yet demonstrated our ability to successfully complete Phase 2 or Phase 3 clinical trials, obtain marketing approval, 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 you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a product development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***The timing of the milestone and royalty payments we are required to make under certain agreements, including to Rockefeller and Trellis, is uncertain and could adversely affect our cash flows and results of operations.***

We are party to certain agreements, including with Rockefeller and Trellis, pursuant to which we have acquired licenses to certain patents and patent applications and other intellectual property related to a series of compounds, including CF-301 and CF-404, to develop and commercialize therapeutics. Under our agreements with Rockefeller and Trellis, we have obligations to achieve diligence minimums and to make payments upon achievement of specified development and regulatory milestones. We will also make additional payments upon the achievement of future sales milestones and for royalties on future net sales.

The timing of milestone payments under our licenses and sponsored research agreements is subject to factors relating to the clinical and regulatory development and commercialization of products, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization and marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

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

Under Section 382 and related provisions of the Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our past transactions, we may have experienced an “ownership change.” At this time, we have not completed a study to assess whether an ownership change under Section 382 of the Code has occurred, or whether there have been multiple ownership changes since our formation, due to the costs and complexities associated with such a study. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Thus, our ability to utilize carryforwards of our net operating losses and other tax attributes to reduce future tax liabilities may be substantially restricted. Further, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, we may not be able to take full advantage of these carryforwards for federal or state tax purposes. As of December 31, 2015, we had federal and state net operating loss carryforwards of approximately \$91.6 million and \$96.1 million, respectively, and federal research and development credits of approximately \$1.5 million, the use of which could be limited or eliminated by virtue of one or more “ownership changes.”

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

***We are heavily dependent on the success of our leading product candidates, CF-301 and CF-404. The approval process of the FDA and comparable foreign regulatory authorities is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for CF-301, CF-404 or any other product candidate our business will be substantially harmed.***

Our near-term business prospects are substantially dependent on our ability to develop and commercialize CF-301 and CF-404. We cannot market or sell CF-301, CF-404 or any other product candidate in the United States without FDA approval, but this approval, if ever issued, is at least several years away. To commercialize CF-301, CF-404 or any other product candidate outside of the United States, we will need applicable foreign regulatory approvals. The clinical development of CF-301, CF-404 or any other product candidate is susceptible to the inherent risks of any drug development program, including a failure to achieve efficacy across a broad population of patients, the potential occurrence of severe adverse events and the risks that the FDA or any applicable foreign regulatory authority will determine that a drug product is not approvable.

The process required to obtain approval for commercialization from the FDA and similar foreign authorities is unpredictable, and typically takes many years even after the commencement of clinical trials, depending on numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to obtain regulatory approval may change during the course of a product’s clinical development. We may fail to obtain regulatory approval for CF-301, CF-404 or any other product candidate for many reasons, including the following:

- we may not be able to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that CF-301, CF-404 or any other product candidate is safe and effective for any indication;
- the results of clinical trials may not meet the level of clinical or statistical significance required for approval by the FDA or comparable foreign regulatory authorities;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may not be able to demonstrate that CF-301, CF-404 or any other product candidate’s clinical and other benefits outweigh its safety risks;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in data generated at our clinical trial sites;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the clinical practices of the third-party contract research organizations (“CROs”) we use for clinical trials; and
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators enter into agreements for clinical and commercial supplies.

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This lengthy approval process as well as the unpredictability of future clinical trial results may prevent us from obtaining regulatory approval to market CF-301, CF-404 or any other product candidate, which would significantly harm our business.

***If clinical trials of CF-301, CF-404 or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of CF-301, CF-404 or any other product candidate.***

Before obtaining marketing approval from regulatory authorities for the sale of CF-301, CF-404 or any other product candidate, we must complete preclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing 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. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- clinical trials of our product candidates may produce negative or inconclusive results, or significant adverse side effects, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, 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 third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards (“IRBs”) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may voluntarily suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of CF-301, CF-404 or any other product candidate that we develop beyond those that we contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

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

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Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or may allow our competitors to bring products to market before we do and may impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***We may be required to suspend or discontinue clinical trials due to adverse side effects or other safety risks that could preclude approval of CF-301, CF-404 or any other product candidates.***

Our clinical trials may be suspended at any time for a number of reasons. For example, it is possible that exposure to CF-301 could result in adverse clinical events such as localized inflammation in the region surrounding blood vessels, or having a hypersensitivity reaction, such as serum sickness or anaphylaxis. A clinical trial may be prevented from commencing or may be suspended or terminated by us, our collaborators, IRBs, the FDA or other regulatory authorities due to the risks of or occurrence of such adverse events, an unacceptable safety risk to participants, a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of the data safety monitoring board or IRBs for a clinical trial. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues, if at all, from any of these product candidates will be delayed or eliminated. Any of these occurrences may significantly harm our business.

***Delays in clinical trials are common and have many causes, and any such delays could result in increased costs to us and jeopardize, delay or prevent our ability to obtain regulatory approval and commence product sales as currently contemplated.***

We may experience delays in clinical trials of our product candidates. Our planned clinical trials might not begin on time, might need to be redesigned, might not enroll a sufficient number of patients or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- imposition of a clinical hold by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- adverse side effects in patient populations;
- time required to add new sites;
- delays resulting from negative or equivocal findings of the data safety monitoring board for a trial;
- delays in completing preclinical studies; or
- delays in developing adequate processes for manufacture of, or formulations for, sufficient supplies of clinical trial materials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages 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. Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues.

***We are significantly dependent on our license agreements with Rockefeller that relate to CF-301.***

Under our various license agreements with Rockefeller, we are obligated to use our diligent efforts to develop and commercialize licensed products, including CF-301. Rockefeller may terminate the agreement in the event of our breach of the terms of the license agreements. In the event of such termination, Rockefeller has the right to retain its license and other rights under the agreement, subject to continuing royalties and other obligations. Our breach of the agreement, including non-payment of any milestone payment, and Rockefeller's subsequent termination of the agreement, could result in the loss of our rights to develop and commercialize CF-301, which would seriously harm our ability to generate revenues or achieve profitability.

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***We rely on CROs to conduct our preclinical studies and will rely on CROs to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining, or may ultimately not be able to obtain, regulatory approval for commercialization of CF-301, CF-404 or any other product candidates.***

We have relied and will continue to rely on CROs for the execution of our preclinical studies and to recruit patients and monitor and manage data for our clinical programs for CF-301, CF-404 or any other product candidate. We control only certain aspects of our CROs' activities, but we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards. Our reliance on the CROs does not relieve us of these regulatory responsibilities. We and our CROs are required to comply with the FDA's regulations and current good clinical practices ("GCPs"), which is an international guideline meant to protect the rights and health of clinical trial subjects. The FDA enforces its regulations and GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our product candidates. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. In addition, to evaluate the safety and effectiveness of CF-301, CF-404 or any other product candidate to a statistically significant degree, our clinical trials will require an adequately large number of test subjects. Any clinical trial that a CRO conducts abroad on our behalf is subject to similar regulation. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, we may have to repeat clinical trials, which would delay the regulatory approval process.

In addition, our CROs are not our employees and we cannot control whether or not they devote sufficient time and resources to our non-clinical, preclinical or clinical programs. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize CF-301, CF-404 or any other product candidate that we seek to develop. As a result, our financial results and the commercial prospects for CF-301, CF-404 or any other product candidate that we seek to develop would be harmed, our costs could increase and our ability to generate revenues could be delayed or ended.

***We have no experience as a company in bringing a drug to regulatory approval.***

As a company, we have never obtained regulatory approval for, or commercialized, a drug or biologic. It is possible that the FDA may refuse to accept any or all of our planned BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval of CF-301, CF-404 or any other product candidate. If the FDA does not accept or approve any or all of our planned BLAs, it may require that we conduct additional preclinical, clinical or manufacturing validation studies, which may be costly, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any BLA or application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any delay in obtaining, or an inability to obtain, regulatory approvals would prevent us from meeting our timelines for commercializing CF-301, CF-404 or any other product candidate, generating revenues and achieving and sustaining profitability.

***Even if the FDA approves CF-301, CF-404 or any other product candidate, adverse effects discovered after approval could adversely affect our markets.***

If we obtain regulatory approval for CF-301, CF-404 or any other product candidate that we develop, and we or others later discover that our products cause adverse effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or imposition of a risk management strategy;
- we may be required to change the way the product is administered, conduct additional clinical studies or restrict the distribution of the product;
- we could be sued and held liable for harm caused to patients and our liability insurance may not adequately cover those claims; and
- our reputation may suffer.

Any of these events could prevent us from maintaining market acceptance of the affected product candidate and could substantially increase the costs of, or prevent altogether, the commercialization of our product candidates.

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***There are underlying risks associated with the manufacture of our product candidates, which could include cost overruns, new impurities, difficulties in process or formulation development, scaling up or reproducing manufacturing processes and lack of timely availability of raw materials.***

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture CF-301, CF-404 or any other product candidates.

We employ the services of Fujifilm Diosynth Biotechnologies UK LTD (“Fujifilm UK”) to supply the active pharmaceutical ingredient for CF-301 and Fujifilm Diosynth Biotechnologies U.S.A, Inc. to supply the active pharmaceutical ingredient for CF-404. We have not yet manufactured supplies for late phase human clinical trials, scaled up the process for manufacture of such supplies, validated the processes, or contractually secured our commercial supplies.

We employ the services of CanGene bioPharma (“CanGene”) to produce CF-301 in its final vialled drug product form. We do not have contracts for the commercial supply of CF-301 drug product.

We intend to pursue agreements with third-party manufacturers regarding commercial supply at an appropriate future time. We intend to locate second fill finish third-party manufacturers to supply other world regions such as the European Union or Asia.

Late stage process development activities, including manufacturing process scale up and validation of the bulk drug substance, pose inherent risks that may be greater for biological products than for small molecules. The process will undergo a 35-fold scale up from the current clinical process and then be repeated under protocol successfully three times for validation.

In addition, regulatory requirements could pose barriers to the manufacture of our active pharmaceutical ingredient and finished drug product for our product candidates. Our third-party manufacturers are required to comply with current good manufacturing practices (“cGMPs”). As a result, the manufacturing facilities and processes used by Fujifilm UK and any of our future manufacturers must pass inspection by the FDA as part of our BLA review and before approval of the applicable product candidate. Similar regulations apply to manufacturers of our products for use or sale in foreign countries. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, we will not be able to secure the applicable approval for our product candidates. If these facilities are not deemed compliant with cGMPs for the commercial manufacture of our product candidates, we may need to find alternative manufacturing facilities, which would result in significant delays of up to several years in obtaining approval. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements.

If Fujifilm UK or any alternate supplier of active pharmaceutical ingredient or finished drug product for our product candidates experiences any significant difficulties in its respective manufacturing processes, does not comply with the terms of its agreement with us or does not devote sufficient time, energy and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our product candidates, which could impair our ability to supply our product candidates at the levels required for our clinical trials and commercialization and prevent or delay its successful development and commercialization.

***Developments by competitors, many of which have greater financial and other resources than we do, may render our products or technologies obsolete or non-competitive.***

The pharmaceutical and biotechnology industries are intensely competitive. We compete directly and indirectly with other pharmaceutical companies, biotechnology companies and academic and research organizations in developing therapies to treat diseases. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. We compete with companies that have products on the market or in development for the same indications as our product candidates. We may also compete with organizations that are developing similar technology platforms. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competing products may render our product candidates obsolete or limit our ability to generate revenue from our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drug products that are more effective or less costly than CF-301, CF-404 and our other product candidates.

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***The level of commercial success of CF-301, CF-404 and any other product candidates that we develop will depend upon attaining significant market acceptance of these products among physicians and payors.***

Even if CF-301, CF-404 or any other product candidates that we develop is approved by the appropriate regulatory authorities for marketing and sale, physicians may not prescribe the approved product. Market acceptance of CF-301, CF-404 and any other product candidate that we develop by physicians, patients and payors will depend on a number of factors, many of which are beyond our control, including:

- the indications for which the product is approved;
- acceptance by physicians and payors of each product as a safe and effective treatment;
- the availability, efficacy and cost of competitive drugs;
- the effectiveness of our or any third-party partner's sales force and marketing efforts;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the availability of adequate reimbursement by third parties, such as insurance companies and other health care payors, and/or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA-approved labeling; and
- prevalence and severity of adverse side effects.

Even if the medical community accepts that our product candidates are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt our product candidates as accepted treatments for their approved indications. While we believe our product candidates may demonstrate significant advantages in clinical studies, we cannot assure you that labeling approved by the FDA will permit us to promote these advantages. In addition, our efforts to educate the medical community and third-party payors on the benefits of any product candidates that we develop may require significant resources and may never be successful.

***Coverage and reimbursement may not be available for CF-301, CF-404 or any other product candidates that we develop, which could make it difficult for us to sell our products profitably.***

Market acceptance and sales of CF-301, CF-404 or any other product candidate that we develop will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for CF-301, CF-404 or any other product candidate that we develop. Also, we cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize CF-301, CF-404 or any other product candidate that we develop.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act ("MMA"), changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by those covered by Medicare under a new Part D and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies whereby they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and therefore any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), became law in the United States. The goal of the Affordable Care Act is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. The Affordable Care Act, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on

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manufacturers of certain branded prescription drugs, required manufacturers to participate in a discount program for certain outpatient drugs under Medicare Part D and promoted programs that increase the federal government's comparative effectiveness research, which will impact existing government healthcare programs and will result in the development of new programs. An expansion in the government's role in the United States healthcare industry may further lower rates of reimbursement for pharmaceutical products.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers.

While we cannot predict the impact these new laws will have in general or on our business specifically, they may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of CF-301 or any future products.

We expect to experience pricing pressures in connection with the sale of CF-301, CF-404 and any other product candidate that we develop, due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

***Even if we obtain FDA approval of CF-301, CF-404 or any other product candidate, we may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market CF-301, CF-404 or any other products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in the United States or any foreign country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in the United States or any foreign country and we do not have experience as a company in obtaining regulatory approval in international markets.

***We currently have no marketing and sales organization and have no experience in marketing drug products. If we are unable to establish our own marketing and sales capabilities, or enter into agreements with third parties, to market and sell our products after they are approved, we may not be able to generate revenues.***

We do not have the capabilities to market, sell and distribute any of our drug products. In order to commercialize any products, we must develop these capabilities on our own or make arrangements with third parties for the marketing, sales and distribution of our products. The establishment and development of our own sales force would be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capability. As a result, we may seek one or more third parties to handle some or all of the sales, marketing or distribution for CF-301, CF-404 or any other product candidate in the United States or elsewhere. However, we may not be able to enter into arrangements with third parties to sell CF-301, CF-404 or any other product candidate on favorable terms or at all. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize CF-301, CF-404 or any other product candidate that we develop, which would negatively impact our ability to generate product revenues. Further, whether we commercialize products on our own or rely on a third party to do so, our ability to generate revenue will be dependent on the effectiveness of the sales force. In addition, to the extent we rely on third parties to commercialize our approved products, we may likely receive less revenues or profits than if we commercialized these products ourselves.

***We may form or seek strategic alliances in the future, and we may not realize the benefits of such alliances.***

We may form or seek strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to CF-301, CF-404 and any future product candidate that we may develop. Any of these relationships may require us to incur non-recurring and other

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charges, increase our near-and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for CF-301, CF-404 and any future product candidate because it may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view CF-301, CF-404 and any future product candidate as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements could delay the development and commercialization of CF-301, CF-404 and any other product candidate that we develop, which would harm our business prospects, financial condition and results of operations.

### **Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters**

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, CF-301, CF-404 and any future product candidate, and our ability to generate revenue will be materially impaired.***

CF-301, CF-404 and any other product candidate that we develop and the activities associated with their development and commercialization, including their design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, importation and exportation are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any product from regulatory authorities in any jurisdiction. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. CF-301, CF-404 and any other product candidate that we develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, 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. The FDA and comparable authorities in other countries 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. If we experience delays in obtaining approvals or if we fail to obtain approval of our product candidates that we develop, our ability to generate revenues will be materially impaired.

***Even if we obtain regulatory approval for a product candidate, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.***

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

In addition, drug product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

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

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

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

***If foreign approval for CF-301, CF-404 or any other product candidate is obtained, there are inherent risks in conducting business in international markets.***

Commercialization of our product candidates in international markets is an element of our long-term strategy. If approved for commercialization in a foreign country, we intend to enter into agreements with third parties to market CF-301, CF-404 or any other product candidate whenever it may be approved and wherever we have the right to market it. Consequently, we expect that we will be subject to additional risks related to entering into international business relationships, including:

- potentially reduced protection for intellectual property rights;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with laws for employees working and traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting active pharmaceutical ingredient and/or finished drug product supply or manufacturing capabilities abroad;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and
- failure to comply with the rules and regulations of the Office of Foreign Asset Control, the Foreign Corrupt Practices Act and other applicable anti-bribery rules and regulations in other jurisdictions.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets and therefore materially adversely affect our business.

***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 exposure related to the testing of CF-301, CF-404 and any other product candidate that we develop in human clinical trials and we will face higher degrees of this risk if we commercially sell any products that we develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- distraction of our management or other internal resources from pursuing our business strategies;
- decreased demand for any product candidates or products that we may develop;

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- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We maintain product liability insurance coverage in relation to our clinical trials. Such coverage may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on 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. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we 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.

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. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our product candidates may face competition sooner than anticipated.***

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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***Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which 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 play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers 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 our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare 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 either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal transparency requirements under the Affordable Care Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report to the Department of Health and Human Services information related to physician payments and other transfers of value and ownership and investment interests held by physicians and their immediate family members and payments or other transfers of value made to such physician owners; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and 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 in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

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, exclusion 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 providers or entities with whom we expect to do business are 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.

***The adverse outcome of litigation or arbitration proceedings commenced by or against us could materially harm our business.***

The adverse outcome of any litigation or arbitration proceedings commenced by or against us could have a material adverse effect on our business and impede the achievement of our development and commercialization objectives.

In the ordinary course of our operations, claims involving our actions, actions of third parties or agreements to which we are a party may be brought by and against us. The claims and charges can involve actual damages, as well as contractually agreed upon liquidated sums. These claims, if not resolved through negotiation, are often subject to lengthy and expensive litigation or arbitration proceedings.

### **Risks Related to Employee Matters and Managing Growth**

***Our future success depends on our ability to attract and retain qualified personnel, and changes in management may negatively affect our business.***

We are dependent on the principal members of our management and scientific teams. Our success and the execution of our growth strategy depend largely on the continued service of these employees. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any of these persons could be disruptive to our operations, impede our ability to raise additional funding or delay the achievement of our development and commercialization objectives. Additionally, we cannot be certain that changes in management will not lead to additional management departures or changes, affect our ability to hire or retain key personnel, or otherwise negatively affect our business. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, and sales and marketing personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also compete for the hiring of scientific and clinical 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 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.

***We expect to expand our development, regulatory and sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of drug discovery, drug development, regulatory affairs and commercialization. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the various levels of experience of our management team in managing a company with significant anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

### **Risks Related to Our Intellectual Property**

***If we or our licensors are unable to obtain and maintain patent protection for our owned or licensed technology and products, or if the scope of the patent protection 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 adversely affected.***

Our success depends in large part on our and our licensors’ ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products or technology or products that may have been licensed to us. Similar to our licensors, we seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. This process is expensive and time-consuming, and we or our licensors 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 or our licensors will fail to identify patentable aspects of either our or their research and development output before it is too late to obtain patent protection. Moreover, if we license technology or product candidates from third parties in the future, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering this intellectual property. These agreements could also give our licensors the right to enforce the licensed patents without our involvement, or to decide not to enforce the patents without our consent. Therefore, in these circumstances, we could not be certain that these patents and applications would 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 and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights and any patent rights we may license from a third party are highly uncertain. Our or our licensors’ pending and future patent applications may not result in issued patents that protect our technology or products, 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 or our licensors’ patents or narrow the scope of such patent protection.

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The laws of foreign 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. Assuming the other requirements for patentability are met, historically, in the United States, the first to make the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. The United States currently uses a first-inventor-to-file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent. 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, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, litigation, inter partes review or interference proceedings, in the United States or elsewhere, challenging our 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 current or future product candidates.

Even if our or our licensors' 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 the 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 prevent others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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 and such patents may not be able to claim the benefits of any patent term extension laws or regulations. As a result, our 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, and which could result in our patents or other intellectual property rights becoming invalidated.***

Competitors may infringe our or our licensors' patents, trademarks, copyrights or other intellectual property. To stop infringement or unauthorized use, we or our licensors may be required to file infringement claims, 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 some or all of our patents or other intellectual property rights are not valid or that we or our licensors infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question and therefore cannot be infringed. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid, unenforceable, or not infringed, or that the party against whom we have asserted trademark infringement claims has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such marks. In any infringement litigation, any award of monetary damages may be unlikely or very difficult to obtain, and any such award we may receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that we could incur substantial litigation costs or that some of our confidential information could be compromised by disclosure during this type of litigation.

***Third parties may initiate legal proceedings alleging that we or our licensors 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, or sell our or our licensors' product candidates and use our proprietary technologies without infringing the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including reexamination or interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing or future intellectual property rights.

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If we or our licensors are found to infringe a third party's intellectual property rights, we or our licensors could be enjoined from further using certain products and technology or may be required to obtain a license from such third party to continue developing and marketing such products and 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 or other intellectual property rights of a third party. A finding of infringement could prevent us from commercializing our 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 use customary non-disclosure agreements and 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 we typically 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 executing such an agreement with each party who in fact develops intellectual property that we regard as our own, or such agreements may be inadequately drafted at times thereby not ensuring assignment to us of all potential intellectual property rights. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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 could 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, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct or defend such litigation or proceedings. 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 have a material adverse effect on our ability to compete in the marketplace.

In addition to seeking patents for some of our technology and products, 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. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets, nor can we guarantee that such agreements will always be adequately drafted so as to be enforceable. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, because of potential differences in laws in different jurisdictions, 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.

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***We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.***

Our future trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections from the U.S. Patent and Trademark Office or other applicable foreign intellectual property offices. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections, or have to expend additional resources to secure registrations, such as commencing cancellation proceedings against third-party trademark registrations to remove them as obstacles to our trademark applications. In addition, in the U.S. Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

In addition, we have not yet proposed a proprietary name for our product candidates in any jurisdiction. Any proprietary name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

### **Risks Related to Our Securities**

***The price of our common stock and Class A Warrants may be volatile and you could lose all or part of your investment.***

There has been significant volatility in the market price and trading volume of equity and derivative securities, which is unrelated to the financial performance of the companies issuing the securities. In addition, equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of biotechnology and also newly public companies for a number of reasons, including reasons that may be unrelated to the business or operating performance of the companies. These broad market fluctuations may negatively affect the market price of our common stock.

Prior to our initial public offering, there was no public market for our common stock and Class A Warrants to purchase one share of common stock at an exercise price of \$4.80 per share (the “Class A Warrants”). The trading price of our securities is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report, these factors include:

- our ability to implement our preclinical, clinical and other development or operational plans;
- adverse regulatory decisions;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- new laws or regulations, or new interpretations of existing laws or regulations, applicable to our business;
- actual or anticipated fluctuations in our financial condition or annual or quarterly results of operations;
- our cash position;
- public reaction to our press releases, other public announcements and filings with the SEC;
- changes in investor and financial analyst perceptions of the risks and condition of our business;
- changes in, or our failure to meet, performance expectations of investors or financial analysts (including, without limitation, with respect to the status of development of our lead product candidates);
- changes in market valuations of biotechnology companies;
- changes in key personnel;
- increased competition;
- sales of common stock by us or members of our management team;
- trading volume of our common stock and Class A Warrants;
- issuances of debt or equity securities;

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- the granting or exercise of employee stock options or other equity awards;
- changes in accounting standards, policies, guidance, interpretations or principles;
- ineffectiveness of our internal controls;
- actions by institutional or other large shareholders;
- significant lawsuits, including patent or stockholder litigation;
- general political, market and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ Capital Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock and Class A Warrants, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

***We are required to meet the NASDAQ Capital Market's continued listing requirements and other NASDAQ rules, or we may risk delisting. Delisting could negatively affect the price of our common stock and the Class A Warrants, which could make it more difficult for us to sell securities in a future financing or for you to sell our common stock or the Class A Warrants.***

We are required to meet the continued listing requirements of the NASDAQ Capital Market and other NASDAQ rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of \$1.00 per share. If we do not meet these continued listing requirements, our common stock and the Class A Warrants could be delisted. Delisting from the NASDAQ Capital Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, or on the "pink sheets." In such case, our stockholders' ability to trade, or obtain quotations of the market value of our common stock and the Class A Warrants would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our securities, if delisted from the NASDAQ Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the over-the-counter markets or the pink sheets. Delisting from the NASDAQ Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

***We may issue additional shares of common stock, warrants or other securities to finance our growth.***

We may finance the development of our product pipeline or generate additional working capital through additional equity financing. Therefore, subject to the rules of the NASDAQ, we may issue additional shares of our common stock, warrants and other equity securities of equal or senior rank, with or without shareholder approval, in a number of circumstances from time to time. The issuance by us of shares of our common stock, warrants or other equity securities of equal or senior rank will have the following effects:

- the proportionate ownership interest in us held by our existing shareholders will decrease;
- the relative voting strength of each previously outstanding share of common stock may be diminished; and
- the market price of our common stock or the Class A Warrants may decline.

In addition, if we issue shares of our common stock and/or warrants in a future offering (or, in the case of our common stock, the exercise of outstanding warrants to purchase our common stock), it could be dilutive to our security holders.

***Future sales of our common stock or warrants may cause the market price of our securities to decline.***

Sales of substantial amounts of shares of our common stock or warrants in the public market, or the perception that these sales may occur, could adversely affect the price of our securities and impair our ability to raise capital through the sale of additional equity securities. We have 27.5 million shares of common stock outstanding. As of May 5, 2016, approximately 25.2 million shares of our outstanding common stock are freely tradable, or may become freely tradable, without restriction, in the public market unless held by our "affiliates," as defined under Rule 144 of the Securities Act of 1933, as amended (the "Securities Act"). Additionally, we have Class A Warrants to purchase 6.9 million shares of common stock outstanding as of May 5, 2016. All shares of common stock underlying the Class A Warrants will

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be freely tradable upon exercise of the Class A Warrants unless held by our affiliates. The remaining shares of common stock and the shares of common stock underlying our Class A Warrants are, or will be upon exercise of the Class A Warrants, “restricted securities,” as that term is defined in Rule 144 under the Securities Act, and will be freely tradable subject to the applicable holding period, volume, manner of sale and other limitations under Rule 144 or Rule 701 of the Securities Act.

We have registered 3,358,270 shares of our common stock as of March 31, 2016 that we may issue under our employee benefit plans. These shares can be freely sold in the public market upon issuance, unless pursuant to their terms these stock awards have transfer restrictions attached to them. Additionally, pursuant to the 2014 Omnibus Incentive Plan (the “2014 Plan”), our management is authorized to grant stock options and other equity linked award to our employees, directors and consultants. The number of shares available for future grant under our 2014 Plan will automatically increase on January 1st each year, from January 1, 2015 through January 1, 2024, by an amount equal to four percent of all shares of our capital stock outstanding as of December 31st of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. Unless our board of directors elects not to increase the number of shares underlying our 2014 Plan each year, our stockholders may experience additional dilution, which could cause our stock price to decline.

***Our executive officers and directors hold a significant concentration of our common stock, which could limit the ability of our other stockholders to influence the direction of our Company.***

As calculated by the SEC rules of beneficial ownership, the current executive officers and directors of our Company own 12.8% of our outstanding common stock as of May 5, 2016. Accordingly, they collectively have the ability to significantly influence or determine the election of all of our directors or the outcome of most corporate actions requiring stockholder approval such as: (i) a merger or a sale of our Company, (ii) a sale of all or substantially all of our assets and (iii) amendments to our certificate of incorporation or bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those individuals. These individuals also have significant control over our business as officers and directors of our Company. There is a risk that they may exercise this ability in a manner that advances their best interests and not necessarily those of our other stockholders.

***If shares of our common stock or the Class A Warrants become subject to the penny stock rules, it would become more difficult to trade them.***

The SEC has adopted regulations which generally define a “penny stock” to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions, including an exemption for any securities listed on a national securities exchange. The rules impose additional sales practice requirements on broker-dealers for transactions involving “penny stock”, with some exceptions. If shares of our common stock or the Class A Warrants were delisted from the NASDAQ Capital Market and determined to be “penny stock”, broker-dealers may find it more difficult to trade such securities and investors may find it more difficult to acquire or dispose of such securities on the secondary market.

***The Class A Warrants are a risky investment. You may be unable to exercise your Class A Warrants for a profit.***

The value of the Class A Warrants depends on the value of our common stock, which depends on factors related and unrelated to the success of our clinical development program and cannot be predicted at this time. The Class A Warrants expire on February 1, 2017.

If the price of shares of our common stock does not increase to an amount sufficiently above the exercise price of the Class A Warrants during the exercise period of the Class A Warrants, you may be unable to recover any of your investment in the Class A Warrants. There can be no assurance that any of the factors that could impact the trading price of our common stock will result in the trading price increasing to an amount that will exceed the exercise price or the price required for you to achieve a positive return on your investment in the Class A Warrants.

***Holders of the Class A Warrants have no rights as common stockholders until they acquire our common stock.***

Until holders of the Class A Warrants acquire shares of our common stock upon exercise of the Class A Warrants, such holders have no rights with respect to our common stock issuable upon exercise of the Class A Warrants, including the right to receive dividend payments, vote or respond to tender offers. Upon exercise of a holder’s Class A Warrants, such holder will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

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***Although we are required to use our best efforts to maintain an effective registration statement covering the issuance of the shares of common stock underlying the Class A Warrants at the time that holders of our Class A Warrants exercise their Class A Warrants, we cannot guarantee that a registration statement will be effective, in which case holders of our Class A Warrants may not be able to receive freely tradable shares of our common stock upon exercise of the Class A Warrants.***

Holders of our Class A Warrants are able to exercise the Class A Warrants and receive freely tradable shares only if (i) a current registration statement under the Securities Act relating to the shares of our common stock underlying the Class A Warrants is then effective, or an exemption from such registration is available, and (ii) such shares of our common stock are qualified for sale or exempt from qualification under the applicable securities laws of the states in which the various holders of Class A Warrants reside. Although we have undertaken, and therefore have a contractual obligation, to use our best efforts to maintain a current registration statement covering the shares of common stock underlying the Class A Warrants, we may not be able to do so. If we are not able to do so, holders may not be able to exercise their Class A Warrants and receive freely tradable shares of our common stock but rather may only be able to receive restricted shares upon exercise. In addition, we have agreed to use our best efforts to register the shares of our common stock underlying the Class A Warrants under the blue sky laws of the states of residence of the existing holders of the Class A Warrants, to the extent an exemption is not available. The value of the Class A Warrants may be greatly reduced if a registration statement covering the shares of our common stock issuable upon exercise of the Class A Warrants is not kept current or if the securities are not qualified, or exempt from qualification, in the states in which the holders of Class A Warrants reside.

***There can be no assurance that we will ever provide liquidity to our investors through a sale of our company.***

While acquisitions of pharmaceutical companies like ours are not uncommon, potential investors are cautioned that no assurances can be given that any form of merger, combination, or sale of our company will take place, or that any merger, combination, or sale, even if consummated, would provide liquidity or a profit for our investors. You should not invest in our company with the expectation that we will be able to sell the business in order to provide liquidity or a profit for our investors.

***We incur significant increased costs as a result of operating as a new public company and our management is required to devote substantial time to complying with public company regulations.***

We completed an initial public offering on August 1, 2014. As a new public company, we incur significant legal, accounting and other expenses, including costs associated with our public company reporting requirements under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We must also follow the rules, regulations and requirements subsequently adopted by the SEC and the NASDAQ and any failure by us to comply with such rules and requirements could negatively affect investor confidence in us and cause the market price of our common stock or Class A Warrants to decline. Our executive officers and other personnel will also need to devote substantial time and financial resources to comply with these rules, regulations and requirements.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

***If we do not develop and implement all required accounting practices and policies, we may be unable to provide the financial information required of a U.S. publicly traded company in a timely and reliable manner.***

Prior to the IPO, we did not adopt all of the financial reporting and disclosure procedures and controls required of a U.S. publicly traded company because we were a privately held company. The implementation of all required accounting practices and policies and the hiring of additional financial staff have increased our operating costs and requires significant time and resources from our management and employees. If we fail to maintain effective internal controls and procedures and disclosure procedures and controls, we may be unable to provide financial information and required SEC reports that a U.S. publicly traded company is required to provide in a timely and reliable fashion. Any such delays or deficiencies could penalize us, including by limiting our ability to obtain financing, either in the public capital markets or from private sources and hurt our reputation and could thereby impede our ability to implement our strategy.

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***Reports published by analysts, including projections in those reports that exceed our actual results, could adversely affect the price and trading volume of our common stock or Class A Warrants.***

The projections of securities research analysts may vary widely and may not accurately predict the results we actually achieve. The price of our common stock or Class A Warrants may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, the price of our common stock or Class A Warrants could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, the price or trading volume of our common stock or Class A Warrants could decline.

***If securities or industry analysts do not publish research or reports about our business, the prices of our securities and trading volume could decline.***

The trading market for our securities depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If no securities or industry analysts commence coverage of our company, the trading prices for our securities may be negatively impacted.

***We have broad discretion in the use of the net proceeds from our initial public offering and private placement and may not use them effectively.***

Our management has broad discretion in the application of the net proceeds from our initial public offering and private placement and could spend the proceeds in ways that do not enhance the value of our common stock. Because of the number and variability of factors that will determine our use of the net proceeds from our completed offerings, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could delay the development of our product candidates or have a material adverse effect on our business. Pending their use, we may invest the net proceeds from the offerings in a manner that does not produce income or that loses value. If we do not apply or invest the net proceeds from the offerings in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause the price of our securities to decline.

***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 JOBS Act, and may remain an emerging growth company for up to five years. 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 shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of certain reduced reporting burdens. We cannot predict whether investors will find our securities less attractive if we rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our common stock or the Class A Warrants, and the prices for our securities may be more volatile.

***We have no present intention to pay cash dividends and, even if we change that policy, we may be restricted from paying cash dividends on our common stock.***

We do not intend to pay cash dividends for the foreseeable future. We currently expect to retain all future earnings, if any, for use in the development, operation and expansion of our business. Any determination to pay cash dividends in the future will depend upon, among other things, our results of operations, plans for expansion, tax considerations, available net profits and reserves, limitations under law, financial condition, capital requirements and other factors that our board of directors considers to be relevant.

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***Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for our securities, thereby depressing the market prices of our securities. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may 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:

- 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 of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- 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 stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a shareholder rights plan, or so-called “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 of directors; 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.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

### **Recent Sales of Unregistered Securities**

None

### **Use of Proceeds from Registered Securities**

Pursuant to the Registration Statement on Form S-1 (File No. 333-195378), as amended, that was declared effective by the SEC on July 28, 2014, we registered our units, each unit consisting of one share of common stock, one Class A Warrant to purchase one share of common stock at an exercise price of \$4.80 per share and one Class B Warrant to purchase one-half share of common stock at an exercise price of \$4.00 per full share (the “Units”), to be sold in our IPO (including 900,000 Units with respect to an over-allotment option granted by us to the underwriters in the offering). We sold a total of 6,000,000 Units in the IPO at an initial public offering price per unit of \$6.00 for gross proceeds of \$36,000,000, and the underwriter of the IPO exercised its over-allotment option on August 27, 2014 for another 880,333 Units for additional gross proceeds of \$5,281,998. The net proceeds of the IPO, after underwriting discount, commissions and offering expenses, to the Company were approximately \$35.0 million. As of March 31, 2016, we have used all of the net proceeds from our IPO.

Except as described above, there has been no material change in the planned use of proceeds from our IPO, as described in our final prospectus filed with the SEC on July 29, 2014 pursuant to Rule 424(b)(1) under the Securities Act related to the Company’s IPO.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

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**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

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**EXHIBIT INDEX**

| <u>Exhibit<br/>No.</u> | <u>Description</u>  |
|------------------------|---|
| 3.1                    | Amended and Restated Certificate of Incorporation, dated August 1, 2014, and Certificate of Amendment, dated May 9, 2016 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36577) filed with the SEC on May 10, 2016) |
| 3.2                    | Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36577) filed with the SEC on May 10, 2016)  |
| 10.1                   | Letter Agreement, dated March 21, 2016, between the Company and Steven C. Gilman, Ph.D. (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36577) filed with the SEC on March 22, 2016)                               |
| 10.2                   | Separation Agreement and Release, dated March 25, 2016, between the Company and Julia P. Gregory (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36577) filed with the SEC on March 25, 2016)                      |
| 31.1                   | Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002   |
| 31.2                   | Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002   |
| 32.1                   | Certification of the Principal Executive and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |
| 101.INS                | XBRL Instance Document  |
| 101.SCH                | XBRL Taxonomy Extension Schema Document   |
| 101.CAL                | XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.DEF                | XBRL Taxonomy Extension Definition Linkbase Document  |
| 101.LAB                | XBRL Taxonomy Extension Label Linkbase Document   |
| 101.PRE                | XBRL Taxonomy Extension Presentation Linkbase Document  |

**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.

**ContraFect Corporation**

Date: May 10, 2016

By: /s/ Steven C. Gilman

Steven C. Gilman  
*Interim Chief Executive Officer*

Date: May 10, 2016

By: /s/ Michael Messinger

Michael Messinger  
*Vice President, Finance (Principal Financial and Accounting Officer)*

## CERTIFICATIONS

I, Steven C. Gilman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ContraFect Corporation;

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 10, 2016

/s/ Steven C. Gilman

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**Steven C. Gilman**  
**Interim Chief Executive Officer**  
**(Principal Executive Officer)**

## CERTIFICATIONS

I, Michael Messinger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ContraFect Corporation;

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 10, 2016

/s/ Michael Messinger

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**Michael Messinger**  
**Vice President, Finance**  
**(Principal Financial Officer)**

**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Steven C. Gilman, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of ContraFect Corporation for the quarterly period ended March 31, 2016, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of ContraFect Corporation.

Date: May 10, 2016

By: /s/ Steven C. Gilman  
Name: **Steven C. Gilman**  
Title: **Interim Chief Executive Officer**  
**(Principal Executive Officer)**

I, Michael Messinger, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of ContraFect Corporation for the quarterly period ended March 31, 2016, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of ContraFect Corporation.

Date: May 10, 2016

By: /s/ Michael Messinger  
Name: **Michael Messinger**  
Title: **Vice President, Finance**  
**(Principal Financial Officer)**

*The foregoing certifications are not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and are not to be incorporated by reference into any filing of ContraFect Corporation under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.*