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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

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

ContraFect Corporation

(Exact name of registrant as specified in its charter)

Delaware	**39-2072586**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
28 Wells Avenue, 3rd Floor, Yonkers, NY	**10701**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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 November 14, 2014 was 20,217,263.

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CONTRAFECT CORPORATION
PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CONTRAFECT CORPORATION
Balance Sheets

	September 30, 2014 (unaudited)	December 31, 2013 (audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 31,320,237	$ 4,145,270
Prepaid expenses and other current assets	417,143	198,410
Total current assets	31,737,380	4,343,680
Property and equipment, net	2,320,484	2,735,175
Restricted cash	—	25,000
Other assets	143,621	2,579,980
Total assets	$ 34,201,485	$ 9,683,835
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 389,235	$ 2,124,906
Accrued liabilities	2,963,685	4,095,337
Deferred rent	935,943	896,603
Total current liabilities	4,288,863	7,116,846
Convertible notes payable	—	9,816,365
Warrant liabilities	403,696	3,088,017
Embedded derivatives liabilities	—	2,680,780
Total liabilities	4,692,559	22,702,008
Commitments and contingencies	—	—
Series A convertible preferred stock, $0.0002 par value, none authorized and outstanding at September 30, 2014; 2,200,000 shares authorized, issued and outstanding at December 31, 2013	—	1,964,283
Series B convertible preferred stock, $0.0002 par value, none authorized and outstanding at September 30, 2014; 5,600,000 shares authorized, 4,651,163 shares issued and outstanding at December 31, 2013	—	10,175,750
Series C convertible preferred stock, $0.0002 par value, none authorized and outstanding at September 30, 2014; 9,090,909 shares authorized, issued and outstanding at December 31, 2013	—	27,752,294
Series C-1 convertible preferred stock, $0.0002 par value, none authorized and outstanding at September 30, 2014; 6,060,607 shares authorized and none issued and outstanding at December 31, 2013	—	—
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value, 25,000,000 shares authorized and none outstanding at September 30, 2014; none authorized and outstanding at December 31, 2013	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized, 20,084,883 shares outstanding at September 30, 2014; 28,571,428 shares authorized, 1,011,997 shares outstanding at December 31, 2013	2,008	101
Additional paid-in capital	117,228,694	4,930,310
Accumulated deficit	(87,721,776)	(57,840,911)
Total stockholders' equity (deficit)	29,508,926	(52,910,500)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 34,201,485	$ 9,683,835

See accompanying notes.

CONTRAFECT CORPORATION
Unaudited Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 2,363,957	$ 2,108,397	$ 6,545,496	$ 6,601,105
General and administrative	2,274,569	1,465,708	5,561,432	5,249,485
Total operating expenses	4,638,526	3,574,105	12,106,928	11,850,590
Loss from operations	(4,638,526)	(3,574,105)	(12,106,928)	(11,850,590)
Other income (expense)				
Interest expense, net	(11,067,209)	(784,075)	(12,414,240)	(838,776)
Refundable state tax credits	—	—	424,649	—
Change in fair value of warrant and embedded derivative liabilities	(691,943)	—	(1,315,894)	—
Total other income (expense)	(11,759,152)	(784,075)	(13,305,485)	(838,776)
Net loss	(16,397,678)	(4,358,180)	(25,412,413)	(12,689,366)
Preferred stock dividend in-kind	—	—	(4,468,452)	—
Net loss attributable to common stockholders	$ (16,397,678)	$ (4,358,180)	$ (29,880,865)	$ (12,689,366)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.22)	$ (4.31)	$ (5.76)	$ (12.54)
Basic and diluted weighted average shares outstanding	13,403,595	1,011,997	5,187,920	1,011,670

See accompanying notes.

CONTRAFECT CORPORATION

Unaudited Statement of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C-1 Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2013	2,200,000	$ 1,964,283	4,651,163	$ 10,175,750	9,090,909	$ 27,752,294	—	$ —	1,011,997	$ 101	$ 4,930,310	$(57,840,911)	$(52,910,500)
Issuance of preferred stock for license	—	—	—	—	—	—	151,515	500,000	—	—	—	—	—
Issuance of securities in IPO	—	—	—	—	—	—			6,000,000	600	35,999,400	—	36,000,000
Issuance of common stock for conversion of preferred stock on closing of IPO	(2,200,000)	(1,964,283)	(4,651,163)	(10,175,750)	(9,090,909)	(27,752,294)	(151,515)	(500,000)	6,861,968	686	44,860,093	(4,468,452)	40,392,327
Issuance of common stock for conversion of notes payable and for interest liabilities, recognition of beneficial conversion feature and the reclassification of note-related liabilities on closing of IPO	—	—	—	—	—	—	—	—	5,197,476	520	30,632,169	—	30,632,689
Issuance of securities in IPO, over-allotment	—	—	—	—	—	—	—	—	880,333	88	5,281,910	—	5,281,998
Financing cost of sale of securities in IPO	—	—	—	—	—	—	—	—	—	—	(6,644,713)	—	(6,644,713)
Cancellation of placement agent warrants	—	—	—	—	—	—	—	—	—	—	941,541	—	941,541
Net shares of common stock issued in relation to vesting of retention grants	—	—	—	—	—	—	—	—	133,109	13	532,438	—	532,451
Share-based compensation	—	—	—	—	—	—	—	—	—	—	695,546	—	695,546
Net loss for the nine months ended September 30, 2014	—	—	—	—	—	—	—	—	—	—	—	(25,412,413)	(25,412,413)
Balance, September 30, 2014	—	$ —	—	$ —	—	$ —	—	$ —	20,084,883	$2,008	$117,228,694	$(87,721,776)	$ 29,508,926

See accompanying notes

CONTRAFECT CORPORATION
Unaudited Statements of Cash Flows

	Nine Months Ended September 30, 2014	2013
Cash flows from operating activities		
Net loss	$ (25,412,413)	$ (12,689,366)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	414,691	419,695
Stock-based compensation expense	1,225,984	1,063,709
Issuance of preferred stock and other costs in exchange for licensed technology	1,000,000	—
Issuance of common stock in exchange for licensed technology	—	10,000
Issuance of common stock warrants in exchange for services	—	22,149
Recognition of beneficial conversion feature	7,428,547	—
Amortization of debt issuance costs	1,240,391	196,271
Amortization of debt discount	3,550,527	336,036
Change in fair value of warrant and embedded derivative liabilities	1,315,894	—
Increase in deferred rent	39,340	171,528
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	(218,733)	127,516
Increase in other assets	—	(939,998)
Increase (decrease) in accounts payable and accrued liabilities	(1,621,663)	368,351
Net cash used in operating activities	(11,037,435)	(10,914,109)
Cash flows from investing activities		
Decrease in restricted cash	25,000	955,621
Sales of property and equipment	—	12,987
Net cash used in investing activities	25,000	968,608
Cash flows from financing activities		
Proceeds from issuance of convertible notes	3,036,350	11,863,650
Payment of financing costs of convertible notes	(24,850)	(1,330,935)
Proceeds from initial public offering	41,281,998	—
Payment of financing costs of initial public offering	(6,106,096)	—
Repayment of lease and notes payable	—	(1,281,338)
Net cash provided by financing activities	38,187,402	9,251,377
Net increase (decrease) in cash and cash equivalents	27,174,967	(694,124)
Cash and cash equivalents at beginning of period	4,145,270	7,886,264
Cash and cash equivalents at end of period	$ 31,320,237	$ 7,192,140
Supplemental disclosures of cash flow information and non-cash investing and financing activities		
Cash paid for interest	$ —	$ 54,701
Issuance of common and preferred stock for license received	500,000	10,000
Cancellation of placement agent warrants	941,541	—

See accompanying notes.

ContraFect Corporation
Notes to Unaudited Financial Statements
September 30, 2014

1. Organization and Description of Business

Organization and Business

ContraFect Corporation (the "Company") is a 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 our 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 expects operating losses and negative cash flows to continue at more significant levels in the future as it enters 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. In August 2014, the Company completed its initial public offering of units (the "IPO"), raising net proceeds of $35.0 million, net of underwriting discount, commissions and offering expenses. In conjunction with the closing of the Company's IPO, the principal amount of the Convertible Notes (as defined in Note 6 "Senior Convertible Notes"), and all accrued and unpaid interest thereon, and all outstanding shares of the Company's preferred stock, including the in-kind dividend payable, automatically converted into 11,971,956 shares of common stock. The significant increase in common stock outstanding in August 2014 is 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 September 30, 2014 and for the three and nine months ended September 30, 2014 and 2013 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, 2013 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, 2013, including all related disclosures and the complete listing of significant accounting policies as described in note 2 thereof, are included in the Company's prospectus dated July 28, 2014, filed with the SEC on July 29, 2014 pursuant to Rule 424(b)(1) under the Securities Act, related to the Company's IPO.

In the opinion of management, the unaudited financial information as of September 30, 2014 and for the three and nine months ended September 30, 2014 and 2013 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 and nine months ended September 30, 2014 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.

Reverse Stock Split

The Company's board of directors approved a 1-for-7 reverse split of the Company's outstanding common stock. This reverse split was effected on July 25, 2014. Accordingly, all shares and per share amounts were retroactively adjusted to reflect this reverse split.

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. Actual results could differ from those estimates.

Prior to being a public company, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair market value of its common stock as determined by the board of directors, with input from management. The board of directors determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of redeemable convertible preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company.

As a private company, the Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation,* to estimate the fair value of its common stock. The methodologies included an option pricing method and a probability-weighted expected return methodology that determined an estimated value under an IPO scenario and a sale scenario based upon an assessment of the probability of occurrence of each scenario. Each valuation methodology included estimates and assumptions that required the Company's judgment. These estimates included assumptions regarding future performance, including the successful completion of pre-clinical studies and clinical trials and the time to completing an IPO or sale. Significant changes to the key assumptions used in the valuations could have resulted in different fair values of common stock at each valuation date.

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.

Marketable securities with original maturities greater than three months and less than one year are considered to be short-term investments. Short-term investments are reported at fair market value and unrealized gains and losses (if any) are included as a separate component of stockholders' equity (deficit). Realized gains, realized losses, the amortization of premiums and discounts, interest earned, and dividends earned are included in interest income. The Company did not have any marketable securities as of September 30, 2014 or December 31, 2013.

Deferred Offering Costs

As of December 31, 2013, the Company had approximately $1.2 million of deferred offering costs representing legal, accounting and other costs directly attributable to the Company's offering of its equity securities capitalized as other long term assets. These and additional costs were deferred until the completion of the Company's IPO, at which time they were reclassified to additional paid-in capital as a reduction of the proceeds. See Note 4, "Other Assets."

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts payable, accrued liabilities, notes payable, convertible notes, warrant liabilities and embedded derivatives 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 convertible notes, warrant liabilities and embedded derivatives 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. 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.

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 and embedded derivative liabilities are discussed in Note 3, "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 third-party valuations, historical data, peer company data and judgment regarding future trends and factors. Prior to being a public company, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The board of directors determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of redeemable convertible preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company.

The Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. The methodologies included an option pricing method and a probability-weighted expected return methodology that determined an estimated value under an offering scenario and a sale scenario based upon an assessment of the probability of occurrence of each scenario. Each valuation methodology included estimates and assumptions that required the Company's judgment. These estimates included assumptions regarding future performance, including the successful completion of pre-clinical studies and clinical trials and the time to completing an offering or sale. Significant changes to the key assumptions used in the valuations could have resulted in different fair values of common stock at each valuation date.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued a comprehensive new revenue recognition Accounting Standards Update, *Revenue from Contracts with Customers (Topic 606) (ASU 2014-09).* ASU 2014-09 provides guidance to clarify the principles for recognizing revenue. This guidance includes the required steps to achieve the core principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance is effective for fiscal years and interim periods beginning after December 15, 2016. Early adoption is not 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 June 2014, the FASB issued Accounting Standards Update, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 910, Consolidation (ASU 2014-10).* ASU 2014-10 eliminates the designation of "Development Stage Entity" in the codification and the incremental reporting requirements associated with this designation. This update allows an entity currently designated as "development stage" to remove the designation from its financial statements and the inception-to-date information from its statements of income, cash flows and shareholders' equity. This guidance is effective for fiscal years beginning after December 15, 2014. Early adoption is allowed, and the Company adopted this pronouncement commencing with its financial statements as of June 30, 2014 and for the three and six months ended June 30, 2014, removing the "development stage entity" designation and associated information no longer required.

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 consolidated financial statements and related disclosures.

3. Fair Value Measurements

The Company considered its convertible note related warrant liabilities and embedded derivatives liabilities as Level 3 financial instruments. The valuation of these liabilities therefore requires inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable. The Company determined the estimated fair value of the warrant liabilities and the embedded derivatives liabilities using a probability weighted estimated returns method ("PWERM"). The PWERM considered several "exit strategy" scenarios and various valuations of the Company, including whether or not an initial public offering would be completed and the timing of such events. The scenarios (or nodes of the model) used a Black-Scholes option-pricing model to determine the fair value of each node, which fair values are then probability weighted based on management's estimates of the likelihood of each scenario. The probability weighted values were then discounted to present value at a rate that reflects the specific stage of the Company's development.

The following assumption ranges were used in the Black-Scholes option-pricing model to determine the fair value of the convertible note related warrant and embedded derivatives liabilities immediately prior to the Company's IPO and as of December 31, 2013:

	Immediately Prior to IPO	December 31, 2013
Expected volatility	61.2%	56.8% – 61.2%
Expected term (in years)	4.09	2.99 – 4.08
Risk-free interest rate	1.31%	0.78% – 1.33%
Expected dividend yield	— %	— %

The following estimated fair values per share of the Company's underlying common stock and probability weightings were used to determine the fair value of the convertible note related warrant and embedded derivatives liabilities immediately prior to the Company's IPO and as of December 31, 2013:

	Immediately Prior to IPO		December 31, 2013	
Scenarios	Estimated Fair Value per Common Share	Probability Weighting	Estimated Fair Value per Common Share	Probability Weighting
Early initial public offering	$ 4.00	100%	$ 7.42	20%
Delayed initial public offering	$ —	—	$ 8.61	40%
Dissolution or Sale	$ —	—	$ 0.00	40%

The Company issued a warrant to the underwriter of its IPO and classified it as a liability (see 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:

	Issuance of Underwriter's Warrant
Expected volatility	75.5%
Expected term (in years)	5.00
Risk-free interest rate	1.65%
Expected dividend yield	–%

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 September 30, 2014 and December 31, 2013:

	Fair Value Measurement As of September 30, 2014		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 31,339,914	$ —	$ —
Warrant liability	—	—	403,696
Embedded derivatives liability	—	—	—
Total	$ 31,339,914	$ —	$ 403,696

	Fair Value Measurement As of December 31, 2013		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 3,917,876	$ —	$ —
Warrant liability	—	—	3,088,017
Embedded derivatives liability	—	—	2,680,780
Total	$ 3,917,876	$ —	$ 5,768,797

The Company estimated the fair value of the convertible note related warrant and embedded derivatives liabilities at the time of issuance of the notes and subsequent remeasurement at each reporting date, using a probability weighted expected return method that considers the probability of achieving each scenario and the Black-Scholes option-pricing model using the following inputs: the expected volatility of the price of the underlying common stock, the remaining expected life of the liabilities, the risk-free interest rates, and the expected dividend rates. The estimates are based, in part, on subjective assumptions and could differ materially in the future. Changes to these assumptions as well as the Company's estimated underlying stock price on the measurement date can have a significant impact on the fair value of the warrant liability and the embedded derivatives liability.

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 and nine months ended September 30, 2014 and 2013:

Warrant liabilities

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Balance at beginning of period	$ 5,649,248	$1,783,244	$ 3,088,017	$ —
Issuances of convertible notes	—	282,347	865,635	2,065,591
Cancellation of placement agent warrants (2)	(941,541)	—	(941,541)	—
Increase in fair value (1)	958,176	—	2,653,772	—
Conversion of convertible notes to common stock	(5,665,883)	—	(5,665,883)	—
Issuance of underwriter's warrants	403,696	—	403,696	—
Balance at end of period	$ 403,696	$2,065,591	$ 403,696	$2,065,591

Embedded derivatives liabilities

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Balance at beginning of period	$ 2,146,742	$ 899,167	$ 2,680,780	$ —
Issuances of convertible notes	—	167,824	537,607	1,066,991
Decrease in fair value (1)	(266,233)	—	(1,337,878)	—
Conversion of convertible notes to common stock	(1,880,509)	—	(1,880,509)	—
Balance at end of period	$ —	$1,066,991	$ —	$1,066,991

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

(2) The Company reclassified the balance of the placement agent warrants to additional paid-in capital as a reduction of the offering costs upon their cancellation.

4. Other Assets

Other assets consists of the following:

	September 30, 2014	December 31, 2013
Deferred offering costs	$ —	$ 1,245,660
Debt issuance costs	—	1,190,699
Other	143,621	143,621
	$ 143,621	$ 2,579,980

The Company accumulated the costs representing legal and accounting fees and other costs directly attributable to the Company's IPO as deferred offering costs and classified these costs as other long term assets until the completion of the offering. The Company reclassified its deferred offering costs to additional paid-in capital as a reduction of the gross proceeds received in the offering.

The Company recorded the costs directly related to the issuance of its Convertible Notes (see Note 6, "Senior Convertible Notes" for further information) as debt issuance costs and classified these costs as other long term assets. The costs were amortized to interest expense over the period from the issuance to the maturity of the Convertible Notes using the effective interest method of amortization until the completion of the Company's IPO. Upon the closing of the offering, the Company accelerated the amortization of the remaining balance to interest expense.

5. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2014	December 31, 2013
Accrued compensation costs	$ 1,878,040	$ 2,162,961
Accrued financing costs	—	1,245,660
Accrued settlement and licensing fees	500,000	—
Accrued interest charges	—	462,773
Accrued professional fees	478,649	13,413
Other	106,996	210,530
	$ 2,963,685	$ 4,095,337

6. Senior Convertible Notes

The Company issued approximately $15.0 million aggregate principal amount of its 8.00% Convertible Notes due May 31, 2015 (the "Convertible Notes") from June 2013 through June 2014. Dr. Sol Barer, a director of the Company, purchased $2.0 million principal amount of the Convertible Notes, Alpha Spring Limited, for which Mr. Zan, one of the Company's directors, is the sole director, purchased $831,350 principal amount of the Convertible Notes, Mr. Low, one of the Company's directors, purchased $90,000 principal amount of the Convertible Notes and Ms. Julia P. Gregory, the Company's Chief Executive Officer, purchased $25,000 principal amount of the Convertible Notes.

On August 1, 2014, in conjunction with the closing of the Company's IPO, 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.

Accounting Analysis

The Company determined that both the warrants and the Convertible Notes were free standing instruments for accounting purposes. The terms of the warrants included an exercise price "cap" that is analogous to "down round protection" which precluded the Company from classifying the warrants in equity. As such, the warrants were classified as a liability and allocated their full fair value on day one and the residual value was ascribed to the Convertible Notes. In addition, the Convertible Notes also included embedded derivatives (i.e. penalty provisions) that required bifurcation. The Company aggregated these bifurcated features and reflected the values of these embedded derivatives in the account "embedded derivative liability". These warrants and embedded derivatives were re-measured at each reporting period and immediately prior to the closing of the Company's IPO, and changes in fair value were recognized in the statement of operations (see Note 3, "Fair Value Measurements"). Upon the closing of the offering, the Company reclassified the balances of the convertible note related warrant and embedded derivative liabilities to additional paid-in capital as the terms of the warrants, including any penalty warrants, became fixed and the interest penalties were paid in the Company's common stock, and therefore both the warrants and penalties were no longer considered a liability. Based on the terms of the warrants, the Company determined the total number of shares of the Company's common stock underlying the warrants held by purchasers of the Convertible Notes to be 3,321,416 at an exercise price of $3.00 per share.

At issuance, the Convertible Notes included a beneficial conversion feature for which a discount could not be calculated due to the indeterminable number of shares of common stock that could have been issued upon conversion contingent on the Company's IPO. On the closing of the Company's IPO, this contingency was resolved and the Company determined the amount of the discount to be recognized for each tranche of Convertible Notes issued by calculating the difference between the common stock value on the date of issuance and the effective conversion price, based on the number of shares of common stock actually issued on conversion. The Company determined the aggregate discount of $7,428,547 for the beneficial conversion feature and recognized this amount as additional interest expense upon the closing of its IPO.

As of September 30, 2014 and December 31, 2013, the Convertible Notes consisted of the following:

Liability component	September 30, 2014	December 31, 2013
Principal	$ —	$11,963,650
Less: debt discount, net (1)	—	(2,147,286)
Net carrying amount	$ —	$ 9,816,364

(1) Includes the estimated fair value of the warrants issued to purchasers of the Convertible Notes and the bifurcated embedded derivative features of the Convertible Notes at the time of issuance. The Company recorded interest expense on a quarterly basis and upon the closing of the Company's IPO. The components of interest expense include (i) accrued interest at the stated 8% rate, (ii) the amortization of the debt discount and (iii) the amortization of the deferred issuance costs.

Placement Agent Warrants

The Maxim Group, LLC ("Maxim") received a warrant to purchase 10% of the total number of shares of common stock into which the note purchased by the holder is convertible. The exercise price of the warrant was equal to 110% of the lower of a 25% discount to the initial public offering price, or $10.50 in the event there was no initial public offering within six months of the Company's initial filing. The Company classified this warrant as a liability since it also did not meet the requirements to be included in equity. The warrant was re-measured at each reporting period and changes in fair value were recognized in the statement of operations.

On July 25, 2014, Maxim forfeited the warrant and the warrant was cancelled by the Company. The Company reclassified the balance of the warrant to additional paid-in capital as a reduction of the offering costs.

7. Net Loss Per Share of Common Stock

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss applicable to common stockholders	$ (16,397,678)	$ (4,358,180)	$ (29,880,865)	$ (12,689,366)
Weighted average shares of common stock outstanding	13,403,595	1,011,997	5,187,920	1,011,670
Net loss per share of common stock—basic and diluted	$ (1.22)	$ (4.31)	$ (5.76)	$ (12.54)

The following potentially dilutive securities outstanding at September 30, 2014 and 2013 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been antidilutive:

	September 30,	
	2014	2013
Preferred stock	—	4,554,874
Stock options	2,843,995	2,192,984
Class A Warrants	6,880,333	—
Class B Warrants	3,440,166	—
Warrants	4,256,862	718,322
	17,421,356	7,466,180

The potential dilutive impact of the Company's Convertible Notes and related warrants are not included as of September 30, 2013 as the number of shares was not determinable at that time and would also have been antidilutive.

8. Capital Structure

Common Stock

Initial Public Offering

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 of the Company. The Company received net proceeds from the IPO of $35.0 million, after deducting underwriting discounts, commissions, and expenses payable by the Company. The common stock and accompanying Class A and Class B warrants have been classified to stockholders' equity (deficit) in the Company's balance sheet.

In July 2014, the shareholders 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.

Underwriter's Warrant

Maxim received a 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, for a total of 206,410 shares of common stock underlying the underwriter's warrants. The warrants are exercisable at an exercise price of $7.50 per share beginning 180 days after the effective date of the Company's registration statement and expiring on August 27, 2019. The Company classified this warrant as a liability since it did not meet the requirements to be included in equity. The fair value of the warrant will be re-measured at each reporting period and changes in fair value will be recognized in the statement of operations.

Reserved for Future Issuance

The Company has reserved for future issuance the following number of shares of common stock as of September 30, 2014 and December 31, 2013:

	September 30, 2014	December 31, 2013
Conversion of Series A preferred stock	—	628,570
Conversion of Series B preferred stock	—	1,328,902
Conversion of Series C preferred stock	—	2,597,402
Conversion of Series C-1 preferred stock	—	—
Options to purchase common stock	2,843,995	2,221,652
Class A Warrants to purchase common stock	6,880,333	
Class B Warrants to purchase common stock	3,440,166	
Warrants to purchase common stock	4,256,682	718,322
	17,421,356	7,494,848

Convertible Preferred Stock

Dividends

On May 28, 2014, the board of directors declared a dividend to be paid in-kind to the holders of the Company's preferred stock in accordance with the Company's Fourth Amended and Restated Certificate of Incorporation, whereby each holder of shares of preferred stock will be entitled to a number of additional shares of the applicable series of preferred stock equal to the amount of the accrued and unpaid dividend on such holder's shares (the "Dividend"). The Company determined that 605,645 shares of Series A preferred stock, 1,172,645 shares of Series B preferred stock, 1,379,388 shares of Series C preferred stock and 2,395 shares of Series C-1 preferred stock would be required to satisfy the Dividend.

The Company recorded the in-kind dividend payable and associated expense at fair value of the securities to be issued. The Company was able to assess the value of the preferred stock dividends in terms of its common stock to be issued upon conversion of the preferred stock on the closing of its IPO.

Conversion

On August 1, 2014, in conjunction with the closing of the Company's IPO, all outstanding shares of the Company's preferred stock, including the in-kind dividend payable, were automatically converted into 6,861,968 shares of its common stock.

9. 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. Originally, upon 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 26, 2013, the board of directors approved an amended and restated plan (the "Amended Plan") to increase the number of shares of common stock available under the Amended Plan to 1,571,428 and to reduce the period that exercisable awards remain exercisable upon termination of service from ten years to two years. The board of directors also approved an option exchange offer (the "Exchange Offer") for eligible option holders with outstanding options with an exercise price in excess of $3.50 per share. The offering period for the Exchange Offer commenced on March 11, 2013 and expired on April 9, 2013. Participation in the Exchange Offer was voluntary. Options to purchase 647,521 shares of the Company's common stock, held by a total of 26 participants, including 20 employees, were exchanged under the tender offer. The exchanged option grants were granted at an exercise price of $3.50 per share. The Company recorded expense associated with the modification with an immediate charge for the vested portion of option grants exchanged and additional charges as the remaining unvested portions become vested.

On February 24, 2014, the board of directors increased the number of shares of common stock available under the Company's Amended Plan to 1,857,142.

On April 29, 2014, the board of directors increased the number of shares of common stock available under the Company's Amended Plan to 2,357,142 and approved grants to purchase a total of 559,285 shares of the Company's common stock.

As of the Company's prospectus dated July 28, 2014, filed with the SEC on July 29, 2014 pursuant to Rule 424(b)(1) under the Securities Act, related to the Company's IPO, the Company expects no further grants to be made under the Amended 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 shareholders 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 ending December 31, 2015 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.

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 nine months ended September 30, 2014, is summarized as follows:

	Number of Options	Weighted Average Exercise Price
Options outstanding at December 31, 2013	2,221,652	$ 5.32
Granted	703,556	4.27
Exercised	—	—
Forfeited	(81,213)	5.00
Options outstanding at September 30, 2014	2,843,995	5.07

Of the option grants outstanding to purchase 2,843,995 shares of common stock, grants to purchase 682,154 shares of common stock were issued and are outstanding outside the Company's incentive plans.

The following table summarizes information regarding all stock options outstanding and exercisable at September 30, 2014:

	Options Outstanding Weighted Average Remaining		Options Exercisable Weighted Average Remaining	
Exercise Price	Shares Outstanding	Contractual Life in Years	Shares Outstanding	Contractual Life in Years
$ 3.50	1,435,831	7.44	1,302,661	7.35
$ 4.27	696,413	9.36	213,736	9.20
$ 6.02	35,714	9.22	35,714	9.22
$ 9.03	641,067	6.16	598,925	6.17
$11.55	34,970	5.65	30,684	6.11
	2,843,995		2,181,720	

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 nine months ended September 30, 2014 and 2013 was $4.27 and $3.50, respectively. Total compensation expense recognized amounted to $1,249,124, $248,789, $1,630,300 and $1,063,709 for the three and nine months ended September 30, 2014 and 2013, respectively. As of September 30, 2014, the total remaining unrecognized compensation cost related to unvested stock options was $1,762,160 which will be recognized over a weighted average period of approximately 2.34 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Risk free interest rate	1.65%	— %	1.98%	1.18%
Expected dividend yield	—	—	—	—
Expected term (in years)	5.44	—	5.74	6.29
Expected volatility	75.5%	— %	76.8%	73.2%

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.

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.

10. Retention Bonus Plan

On February 24, 2014, the Company adopted the ContraFect Corporation Retention Bonus Plan (the "Retention Plan"). Under the Retention Plan, participants will vest in and become eligible to receive awards equal to a fixed dollar amount (the "Award Amount"), upon the earliest to occur of any of the following events: (i) the IPO; (ii) a Change of Control (as defined in the Retention Plan); (iii) May 31, 2015; and (iv) a participant's termination of employment due to death or Disability (as defined in the Retention Plan) (each such event, a "Payment Event"). In the event of an IPO or Change of Control, participants who are then employed by the Company shall be eligible to receive a payment in an amount equal to 1.82 times each participant's Award Amount. For an IPO Payment Event, the Company intends to pay each participant's Award Amount in shares of common stock, with a lump sum cash payment in respect of any fractional shares. For a Change of Control Payment Event, the Company intends to pay each participant's Award Amount in the same form of consideration that the holders of common shares receive in the transaction. The Company intends to pay Award Amounts that vest upon an eligible termination or May 31, 2015 in a lump sum cash payment.

As of June 30, 2014, Award Amounts totaling $532,700 had been granted under the Retention Plan. Upon the closing of the Company's IPO, the Company recognized a total of $954,754 of expense associated with the vesting of the grants. On September 11, 2014, the Company issued 133,109 shares of its common stock, net of shares withheld for tax obligations, in payment of the retention grants.

11. Significant Agreements

Trellis Biosciences, LLC

On January 29, 2014, the Company entered into a license agreement with Trellis Biosciences, LLC ("Trellis") that gives it exclusive rights to all Trellis mAbs in the field of influenza discovered from the Trellis CellSpot platform. Particularly, the license provides the Company with three fully human mAbs that bind, neutralize and protect animals from all strains of H1, H3 and B influenza, and that will also cross bind, neutralize and protect animals from all other seasonal or pandemic influenza strains that may arise (including H5N1 and H7N9).

In consideration for the license, the Company paid Trellis $200,000 and issued 151,515 shares of Series C-1 preferred stock, contractually valued at $500,000. An additional $500,000 in shares of Series C-1 preferred stock or in shares of the Company's common stock, valued at the ten-day weighted average price per share for the ten days prior to such issuance, will be issued on the six month anniversary of the agreement. The Company has recorded a liability for the full $500,000 value of the shares to be issued to Trellis. The Company will also be required to pay Trellis up to $1.3 million upon the achievement of specified development and regulatory milestones and make additional payments upon the achievement of future sales and a royalty of 4% of future net sales from products. The Company is allowed to grant sublicenses to third parties.

The license agreement terminates upon the earlier of (i) the Company's decision to terminate the agreement at will or for safety reasons, (ii) material breach by either party that is not cured within ninety (90) days, or (iii) either party's insolvency.

MorphoSys AG

In June 2014, the Company and MorphoSys AG agreed to terminate their license agreement effective as of August 15, 2014 and resolve all outstanding claims thereunder. On August 11, 2014, the Company made the €1,000,000 payment to MorphoSys AG pursuant to the agreed upon settlement.

12. Subsequent events

On October 7, 2014, the Company authorized the issuance of 132,380 shares of common stock to Trellis in satisfaction of the $500,000 remaining due in stock as consideration for the license.

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, 2013 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Registration Statement on Form S-1 filed by us with the Securities and Exchange Commission, or SEC, on July 25, 2014.

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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates", "believes", "estimates", "expects", "intends", "may", "plans", "projects", "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:

- *our research and development, marketing and sales programs (including statements about the regulatory status of our lead product candidate CF-301, which is currently on clinical hold by the FDA);*
- *our ability to advance into and through clinical development and ultimately obtain FDA approval for our product candidates;*
- *our expectations regarding the commercial market for our product candidates;*
- *the effect of competition and proprietary rights of third parties;*
- *the availability of 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. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. 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. 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.

Overview

We are a biotechnology company focused on discovering and developing therapeutic protein and antibody products for life-threatening, drug-resistant infectious diseases, particularly those treated in hospital settings. Due to drug-resistant and newly emerging pathogens, hospital acquired infections are currently the fourth leading cause of death in the United States, following heart disease, cancer and stroke. We intend to address drug-resistant infections using our therapeutic product candidates from our lysin and monoclonal antibody platforms to target conserved regions of either bacteria or viruses. Lysins are enzymes that are produced in the life cycle stage of a bacteriophage, a virus that infects and kills bacteria. Lysins can digest bacterial cell walls and are fundamentally different than antibiotics because they kill bacteria immediately upon contact. We believe the properties of our lysins make them suitable for the treatment of antibiotic-resistant organisms that can cause serious infections such as Staph aureus bacteremia, pneumonia and osteomyelitis, and the treatment of biofilm-related indications for infected prosthetic joints, indwelling devices and catheters. In addition to our lysins, we are exploring therapies using mAbs that block and disarm virulence factors of bacteria and viruses, rendering them vulnerable to the body's natural immune response. Our product candidates have not yet entered clinical trials. Our 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.

We have not generated any revenues and, to date, have funded our operations primarily through sales of common stock and convertible preferred stock and issuances of convertible debt to our investors. From inception through September 30, 2014, we have received gross proceeds of $41.3 million from the sale of units in our initial public offering (the "IPO"), $0.2 million from the sale of common stock, $44.2 million from the sale of convertible preferred stock and $15.0 million from the issuance of our Convertible Notes due 2015. In August 2014, we completed our IPO, raising net proceeds of $35.0 million, net of underwriting discount, commissions and offering expenses.

We have never been profitable and, from inception through September 30, 2014, our net losses attributable to common stockholders have been $87.7 million. Our net loss from operations was $23.6 million for the year ended December 31, 2013 and $25.4 million for the nine months ended September 30, 2014. 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 pre-clinical 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 will seek to fund our operations through public or private equity, equity-linked financings, 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 or obtain regulatory approval for 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 of costs associated with our research activities and the development of our pre-clinical programs, CF-301, for the treatment of Staph aureus bacteremia, and CF-404, for the treatment of life-threatening influenza. Our research and development expenses consist of:

- 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, or 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.

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 and testing to support our IND application for CF-301. In the future, we intend to continue using our employee and infrastructure resources across multiple development as well as research projects. In the three and nine month periods ended September 30, 2014, we recorded approximately $2.4 million and $6.5 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 the product development, external research and licensing and professional fees, by project, including CF-301, as shown below.

The following table summarizes our research and development expenses by category for the three and nine month periods ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Personnel related	$ 731,088	$ 754,688	$2,088,664	$2,416,216
Product development	266,408	389,381	614,998	1,060,789
Laboratory costs	382,649	460,823	1,071,303	1,503,449
External research and licensing costs	195,351	322,657	1,575,111	939,224
Professional fees	259,305	138,541	582,232	492,346
Share-based compensation	529,156	42,307	613,188	189,081
	$2,363,957	$2,108,397	$6,545,496	$6,601,105

The following table summarizes our research and development expenses by program for the three and nine month periods ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
CF-301	$ 438,618	$ 437,897	$ 897,743	$1,344,510
CF-404	—	—	1,200,000	—
Other research and development	665,095	873,505	1,745,901	2,651,298
Personnel related and share-based compensation	1,260,244	796,995	2,701,852	2,605,297
	$2,363,957	$2,108,397	$6,545,496	$6,601,105

We anticipate that our research and development expenses will increase substantially in connection with the commencement of clinical trials for our product candidates. 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;
- clinical trial results;
- 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 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 or such product candidate. 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.

Interest Expense

Interest expense consists primarily of cash and non-cash interest costs, including the accretion of the carrying value of our Convertible Notes due 2015 to face value and the estimated value of equity linked securities issued in conjunction with the issuance of these notes, related to our outstanding debt. We capitalize costs incurred in connection with the issuance of debt. We amortize these costs over the life of our debt agreements as interest expense in our statement of operations. Upon the closing of our IPO, we accelerated the amortization of the remaining balances of debt issuance costs and debt discount to interest expense and recognized the cost of the beneficial conversion feature of our Convertible Notes due 2015 as an additional component of interest expense.

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 Registration Statement on Form S-1 filed by us with the SEC on July 25, 2014.

Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 2,363,957	$ 2,108,397	$ 6,545,496	$ 6,601,105
General and administrative	$ 2,274,569	$ 1,465,708	$ 5,561,432	$ 5,249,485
Other income (expense)	$ (11,759,152)	$ (784,075)	$ (13,305,485)	$ (838,776)

Comparison of three months ended September 30, 2014 and 2013

Research and Development Expenses

Research and development expense was $2.4 million for the three months ended September 30, 2014, compared with $2.1 million for the three months ended September 30, 2013, an increase of $0.3 million. This increase was primarily attributable to a $0.5 million increase in our non-cash stock-based compensation expense as a result of the vesting of retention grants upon the closing of our IPO. This increase was partially offset by a $0.2 million decrease in costs associated with the MorphoSys antibody library, as we no longer incur research expenses related to the MorphoSys agreement.

General and Administrative Expenses

General and administrative expense was $2.3 million for the three months ended September 30, 2014, compared with $1.5 million for the three months ended September 30, 2013, an increase of $0.8 million. This increase was primarily attributable to a $0.5 million increase in our non-cash stock-based compensation expense as a result of the vesting of retention grants upon the closing of our IPO, a $0.1 million increase in our insurance and investor relations costs related to being a public company and a $0.1 million increase in legal expense related to the termination of the MorphoSys agreement.

Other income (expense)

Other expense was $11.8 million for the three months ended September 30, 2014 compared with $0.8 million for the three months ended September 30, 2013, an increase of $11.0 million. This increase was primarily attributable to the non-cash charge of $7.4 million related to the beneficial conversion feature recognized upon conversion of our Convertible Notes due 2015 upon the closing of our IPO, a $2.8 million increase in non-cash interest charges due to the accelerated amortization of the remaining debt discount and debt issuance costs balances upon the closing of our IPO and the non-cash expense of $0.7 million from the change in fair value measurement of our convertible note related warrant and embedded derivative liabilities immediately prior to our IPO.

Comparison of the nine months ended September 30, 2014 and 2013

Research and Development Expenses

Research and development expense was $6.5 million for the nine months ended September 30, 2014, compared with $6.6 million for the nine months ended September 30, 2013, a decrease of $0.1 million. This decrease was primarily attributable to a $0.7 million decrease in our research headcount and related salaries, benefits and laboratory support costs and a $0.4 million decrease in spending associated with our lead product, CF-301, for which we continued to work towards obtaining regulatory approval to initiate clinical trials. These decreases were partially offset by the $0.6 million increase in external research and licensing expense related to the Trellis license and a $0.4 million increase in our non-cash stock-based compensation expense as a result of the vesting of retention grants upon the closing of our IPO.

General and Administrative Expenses

General and administrative expense was $5.6 million for the nine months ended September 30, 2014, compared with $5.2 million for the nine months ended September 30, 2013, an increase of $0.4 million. This increase was primarily attributable to $0.9 million of expenses associated with the termination of the MorphoSys agreement and a $0.1 million increase in our insurance and investor relations costs related to being a public company. These increases were partially offset by a $0.7 million decrease in our administrative headcount and related salaries and benefits.

Other income (expense)

Other expense was $13.3 million for the nine months ended September 30, 2014, compared with $0.8 million for the nine months ended September 30, 2013, an increase of $12.5 million. This increase was primarily attributable to the non-cash charge of $7.4 million related to the beneficial conversion feature recognized upon conversion of our Convertible Notes due 2015 upon the closing of our IPO, a $4.2 million increase in non-cash interest charges due to the period over period increase in days our Convertible Notes due 2015 were outstanding and the accelerated amortization of the remaining debt discount and debt issuance costs balances upon the closing of our IPO and the non-cash expense of $1.3 million from the change in fair value measurement of our convertible note related warrant and embedded derivative liabilities immediately prior to our IPO. These increases were partially offset by the receipt of $0.4 million in refundable state tax credits.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations to date primarily through proceeds from sales of common stock, convertible preferred stock and issuances of 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.

From inception through September 30, 2014, we have received gross proceeds of $41.3 million from the sale of units in our IPO, $0.2 million from the sale of common stock, $44.2 million from the sale of convertible preferred stock and $15.0 million from the issuance of our Convertible Notes due 2015. In August 2014, we completed our IPO, raising net proceeds of $35.0 million, net of underwriting discount, commissions and offering expenses.

As of September 30, 2014, our cash and cash equivalents totaled $31.3 million. We primarily invest our cash and cash equivalents in commercial savings accounts. We believe that our existing cash and cash equivalents will be sufficient to fund our operations and our capital expenditures for at least the next 12 months. The following table summarizes our cash flow activity for each of the periods set forth below:

	Nine Months Ended September 30,	
	2014	2013
Net cash used in operating activities	$(11,037,435)	$(10,914,109)
Net cash provided by investing activities	$ 25,000	$ 968,608
Net cash provided by financing activities	$ 38,187,402	$ 9,251,377

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 nine months ended September 30, 2014 increased by $0.1 million as compared to the same period in 2013. In the period ended September 30, 2014, we were able to substantially reduce our accounts payable and accrued liabilities by approximately $1.6 million after completing our IPO. This use of cash was partially offset by lower overall cash operating expense and the receipt of funds from refundable tax credits.

Investing Activities

Net cash provided by investing activities in the nine months ended September 30, 2014 and 2013 results primarily from the decrease in our restricted cash balances. As of September 30, 2014, we have no restricted cash balances remaining on our balance sheet.

Financing Activities

Net cash provided by financing activities increased in the nine months ended September 30, 2014 as compared to the same period in 2013 due to the completion of our IPO. In the period ended September 30, 2014, we sold 6,880,333 Units for gross proceeds of approximately $41.3 million. Prior to our IPO, we issued an additional $3.0 million of our Convertible Notes due 2015. In the period ended September 30, 2013, we issued approximately $11.9 million of our Convertible Notes due 2015 and repaid approximately $1.3 million of commercial debt.

Funding Requirements

All of our product candidates are still in pre-clinical 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:

- continue the ongoing pre-clinical studies, and initiate the planned clinical trials, 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 for at least the next 12 months. 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, and the extent to which we may enter into collaborations with third parties for 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, pre-clinical development, laboratory testing and clinical trials for our other product candidates;
- the extent to which we acquire or in-license other products and 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, collaborations, strategic alliances and 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 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 your rights as a common 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 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 develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We incur significant increased costs as a public company that we have not previously incurred, 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.

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

As a smaller reporting company (as defined in Rule 12b-2 of the Exchange Act), we are not required to provide the information called for by this Item 3.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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 the design and operation 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 are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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 the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q 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 no such changes during the period covered by this Quarterly Report on Form 10-Q materially affected, or were 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 prospectus filed with the SEC on July 29, 2014 in connection with the Company's IPO. The business, financial condition and operating results of the Company 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.

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 the condensed consolidated 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.

Because of the following factors, as well as other factors affecting the Company's financial condition and operating results, 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.

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 pre-clinical-stage biopharmaceutical company with no approved products, and we have not generated any revenue from product sales to date. Although we commenced active research operations in 2010, we have yet to commence clinical trials of our product candidates in humans, and our lead product candidate, CF-301, is on clinical hold by the FDA, meaning we cannot presently progress the opportunity. To date, we have focused exclusively on developing our product candidates and have funded our operations primarily through public or 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 $23.6 million for the year ended December 31, 2013. From inception through September 30, 2014, our net losses attributable to common stockholders have been $87.7 million. We have financed our operations primarily through public or private sales of common stock, convertible preferred stock and issuances of convertible debt to our investors. 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.

We anticipate that our expenses will increase substantially in connection with commencing clinical trials for any of our product candidates. 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.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

We have had recurring losses from operations and, as a result, our independent registered public accounting firm has expressed substantial doubt concerning our ability to continue as a going concern and has included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. A going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. 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 commence the clinical development of CF-301 and CF-404, make acquisitions of new products and technologies and, possibly, acquire and develop other product candidates. 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;
- 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 products and 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 products. We have not yet demonstrated our ability to successfully complete Phase 1, 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.

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, 2013, we had federal and state net operating loss carryforwards of approximately $50.7 million and $47.7 million, respectively, and federal research and development credits of approximately $0.9 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

Our IND application for CF-301 has been placed on clinical hold by the FDA and there are no assurances that we will be permitted to initiate clinical trials on our intended timeline or at all.

Our IND for our lead product candidate CF-301 has been placed on clinical hold by the FDA. Our IND was placed on clinical hold because the FDA believes that the results of our submitted pre-clinical studies did not provide sufficient information to assess the risks to subjects in our proposed clinical trial, including the risk of serious hypersensitivity reactions. In connection with this risk, the FDA requested additional studies to characterize the potential for hypersensitivity after exposure to CF-301. We have since conducted additional studies in rodents which confirmed that hypersensitivity occurs on a second course of CF-301 therapy. If we are unable to satisfy the FDA's requests, we may not be able to obtain regulatory approval for commencing clinical trials of CF-301. If this were to occur, our financial results and the commercial prospects for CF-301 would be substantially harmed and our ability to generate revenues could be delayed or ended.

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.

We have no products that have been approved for testing in clinical trials or for sale. 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 pre-clinical 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.

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 pre-clinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We have not commenced such studies in humans to date. 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 pre-clinical 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, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical 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.

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 the formation of vascular lesions, 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 in obtaining sufficient supplies of clinical trial materials; or
- delays resulting from negative or equivocal findings of the data safety monitoring board for a trial.

For example, our IND application for CF-301 has been placed on clinical hold by the FDA because the FDA believes that the results of the pre-clinical studies we submitted do not provide sufficient information to assess the risks to subjects in our proposed clinical trial. We are currently in discussions with the FDA regarding additional information and data needed to enter Phase 1 clinical trials.

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.

We rely on CROs to conduct our pre-clinical 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 pre-clinical 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, pre-clinical 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 pre-clinical, 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.

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

Although clinical materials for our contemplated Phase 1 human clinical trials of CF-301 have been produced, we have not yet manufactured all supplies for our contemplated Phase 2 or 3 human clinical trials, scaled up the process for manufacture, validated the process, or contractually secured third parties for manufacture and commercial supply.

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture CF-301. We employ the services of Fujifilm Diosynth Biotechnologies UK LTD ("Fujifilm UK") to supply the active pharmaceutical ingredient for CF-301. We do not yet have contracts to produce a commercial supply of the active pharmaceutical ingredient of CF-301; however, we intend to pursue agreements with Fujifilm UK to do so.

We employ the services of CanGene bioPharma ("CanGene") to produce CF-301 in its final vialed 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.

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.

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 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 the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. 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 reimbursement that results from the MMA 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 Affordability Reconciliation Act (collectively, the "PPACA"), became law in the United States. The goal of PPACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the PPACA 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 reimbursement coverage 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 pre-clinical 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 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 pre-clinical 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 pre-clinical, 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 ("AEs") 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 AEs 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.

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;

- 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 will acquire product liability insurance coverage prior to initiating 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 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;

- 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;
- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; 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.

We are dependent on Julia P. Gregory, who previously served as our Executive Vice President, Chief Financial Officer and is now our Chief Executive Officer as well as the other principal members of our management and scientific teams. 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 impede the achievement of our development and commercialization objectives. 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 will be 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.

Changes in our management may negatively affect our business.

Our success and the execution of our growth strategy depend largely on the continued service of our senior executive management team. In December 2013, Robert Nowinski, Ph.D., our founder and former Chief Executive Officer and a former member of our board of directors, ceased to be an officer or employee of the Company due to medical reasons. Our board of directors then appointed Julia P. Gregory as our Chief Executive Officer. In October 2014, David Huang, M.D., Ph.D., resigned from his position as Chief Medical Officer to pursue his clinical practice. For the past year, the Company has assembled an external team of clinical and regulatory experts to prepare its IND re-submission, including RRD International, a product development organization that provides integrated expert level strategic, regulatory and operational support. The Company intends to continue to use this team of experts to finalize its IND re-submission. A new chief medical officer is expected to be announced in 2015. We cannot be certain that changes in management or our board of directors will not lead to additional management departures or changes, affect our ability to hire or retain key personnel, or otherwise negatively affect our business. Additionally, we cannot be assured of the continued service of our senior management team or our board of directors. The unexpected loss of any additional members of our senior management team could be disruptive to our operations and have an adverse effect on our business.

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.

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 counter 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 and the ability of our licensors and collaborators to develop, manufacture, market, and 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.

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.

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 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 recently completed initial public offering, there was no public market for our common stock and 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 are 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 pre-clinical, 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 Securities and Exchange Commission (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;
- termination of the lock-up agreement or other restrictions on the ability of our shareholders and warrantholders to sell shares after the IPO;
- sales of common stock by us or members of our management team;
- trading volume of our common stock and Warrants;
- issuances of debt or equity securities;
- 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;

- realization of any of the risks described under "Risk Factors" in this Quarterly Report on Form 10-Q; 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 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 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 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 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 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 common shares, 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 Warrants may decline.

In addition, if we issue our common shares and/or warrants in a future offering, it could be dilutive to our securityholders.

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 20.2 million shares of common stock outstanding. Of these outstanding shares, 6.9 million shares of common stock are 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"). The remaining shares of common stock are "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.

Following the IPO, most of the restricted securities became subject to lock-up agreements with the underwriters, restricting the sale of such shares for 180 days after the date of the IPO. These lock-up agreements are subject to a number of exceptions, however, and holders may be released from this agreement with the prior written consent of the representative of the underwriters.

We have registered 3,358,270 shares of our common stock 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, or 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, our executive officers and directors of our Company own 26.2% of our outstanding common stock. 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 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 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 Warrants are a risky investment. You may be unable to exercise your Warrants for a profit.

The value of the 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 January 31, 2017 and the Class B Warrants expire on October 31, 2015.

If the price of shares of our common stock does not increase to an amount sufficiently above the exercise price of the Warrants during the exercise periods of the Warrants, you may be unable to recover any of your investment in the 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 Warrants.

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

Until you acquire shares of our common stock upon exercise of the Warrants, you have no rights with respect to our common stock issuable upon exercise of the Warrants, including the right to receive dividend payments, vote or respond to tender offers. Upon exercise of your Warrants, you 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.

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

Holders of our Warrants are be able to exercise the 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 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 Warrants reside. Although we have undertaken in the Warrants, 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 Warrants following completion of the IPO to the extent required by federal securities laws, and we intend to comply with our undertaking, we may not be able to do so. If we are not able to do so, holders may not be able to exercise their 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 Warrants under the blue sky laws of the states of residence of the existing holders of the Warrants, to the extent an exemption is not available. The value of the Warrants may be greatly reduced if a registration statement covering the shares of our common stock issuable upon exercise of the Warrants is not kept current or if the securities are not qualified, or exempt from qualification, in the states in which the holders of Warrants reside.

Our Warrants may not have any value.

The Class A Warrants will expire on January 31, 2017. The Class B Warrants will expire on October 31, 2015. In the event our common stock price does not exceed the exercise price of the Warrants during the period in which the Warrants are exercisable, the Warrants may not have any value.

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 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.

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 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 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 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 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 recently completed initial public offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from our recently completed initial public offering 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 or use of the net proceeds from our recently completed offering, 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 offering in a manner that does not produce income or that loses value. If we do not apply or invest the net proceeds from the offering 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:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- 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 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 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.

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

Unregistered Sales of Equity 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 the Units to be sold in the 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.

There has been no material changes 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.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.3 of the Company's Registration Statement on Form S-1 (File No. 333-195378) filed with the SEC on July 25, 2014)
3.2	By-laws (incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-1 (File No. 333-195378) filed with the SEC on July 3, 2014)
31.1	Certification of the Company's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's report on Form 10-Q for the quarter ended September 30, 2014
31.2	Certification of the Company's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's report on Form 10-Q for the quarter ended September 30, 2014
32.1	Certification of the Company's 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: November 14, 2014

By: /s/ Julia P. Gregory
Julia P. Gregory
Chief Executive Officer

Date: November 14, 2014

By: /s/ Michael Messinger
Michael Messinger
Chief Accounting Officer

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Julia P. Gregory, 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: November 14, 2014

/s/ Julia P. Gregory
Julia P. Gregory
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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: November 14, 2014

/s/ Michael Messinger

Michael Messinger
Vice President of Finance
(Principal Financial Officer)

Exhibit 32.1

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, Julia Gregory, 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 September 30, 2014, 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: November 14, 2014

By: /s/ Julia P. Gregory
Name: **Julia P. Gregory**
Title: **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 September 30, 2014, 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: November 14, 2014

By: /s/ Michael Messinger
Name: **Michael Messinger**
Title: **Vice President of 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.