
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

OR

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

Commission File Number: 001-36577

ContraFect Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

28 Wells Avenue, 3rd Floor
Yonkers, NY
(Address of principal executive offices)

39-2072586
(IRS Employer
Identification No.)

10701
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Class</u>	<u>Name of Exchange on Which Registered</u>
Common Stock, Par Value \$0.0001 per share	NASDAQ Capital Market
Class A warrant, exercisable for one share of common stock	NASDAQ Capital Market
Class B warrant, exercisable for one-half share of common stock	NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a 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 Act). Yes No

The registrant did not have a public float as of the last business day of the most recently completed second fiscal quarter, as there was no public market for the registrant's common stock and warrants as of such date.

As of March 19, 2015, there were 20,229,041 shares of Common Stock, \$0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2015 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days of the end of the registrant's fiscal year ended December 31, 2014 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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References to ContraFect

Throughout this Annual Report on Form 10-K, the “Company,” “ContraFect,” “we,” “us,” and “our,” except where the context requires otherwise, refer to ContraFect Corporation, and “our board of directors” refers to the board of directors of ContraFect Corporation.

Forward Looking Information

The information in this Annual Report on Form 10-K 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,” “potential,” “will,” “would,” “could” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. All such forward-looking statements involve significant risks and uncertainties, including, but not limited to, statements regarding:

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

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

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Item 1. Business

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 (“mAb”) platforms. 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 bacterial infections. In addition to our lysins, we are exploring therapies using mAbs that target conserved regions of either bacteria or viruses, rendering them vulnerable to the body’s natural immune response. By creating drugs that target the conserved regions of bacteria and viruses, our lysin and antibody drug development approach could mitigate evolutionary escape mechanisms, preventing resistance to our drugs.

Our most advanced lysin product candidate, CF-301, is entering Phase 1 human clinical trials, and we intend to pursue an initial indication for the treatment of Staph aureus bacteremia, including endocarditis, caused by methicillin-sensitive (“MSSA”) or methicillin-resistant (“MRSA”) Staph aureus. We believe CF-301 may also be developed for the treatment of Staph aureus pneumonia, osteomyelitis, and biofilm-related indications for infected prosthetic joints, indwelling devices and catheters. Our second product candidate is CF-404, a combination of three human mAbs for the treatment of life-threatening seasonal and pandemic varieties of influenza.

Our Strategy

Our strategy is to use our therapeutic products to achieve a leading market position in the treatment of life-threatening infectious diseases, including drug-resistant pathogens. We plan to pursue commercialization of therapeutic products through discovery, acquisition and development as follows:

- Advance our lead product candidate, CF-301, through clinical trials and demonstrate superiority of combination therapy over standard-of-care (“SOC”) drugs alone for the treatment of Staph aureus bacteremia;
- Advance CF-404 through pre-clinical studies and clinical trials for the treatment of life-threatening complicated influenza;
- Advance additional product candidates from our lysin portfolio, including lysins to gram-negative bacteria;
- Acquire additional foundation technologies that enable the efficient discovery of anti-infective agents; and
- Acquire clinical stage therapies that treat infectious diseases through unique mechanisms of action.

Our Indications

Staph aureus bacteremia

Staph infections occur in both hospital and community settings, and in the United States (“US”) alone there are approximately 120,000 cases annually of Staph bacteremia, a bloodstream infection, which causes approximately 30,000 deaths. Of further concern, drug-resistant strains of Staph are now evolving additional resistance against SOC antibiotics, which may ultimately result in an increase in the number of cases and in mortality from Staph bacteremia.

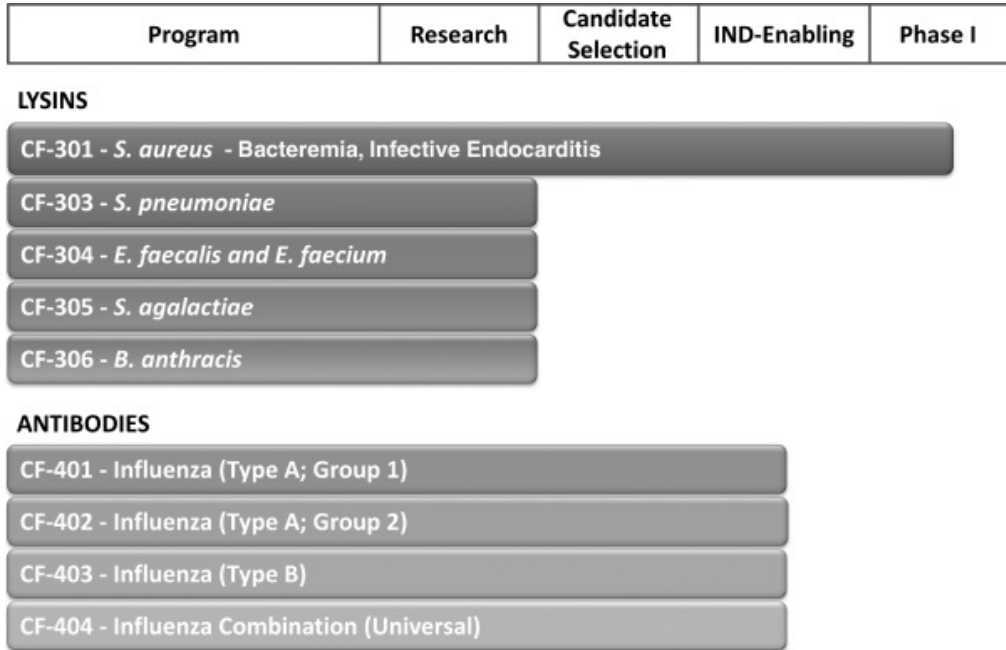
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Influenza

On a global basis, approximately 20% of children and 5% of adults develop symptomatic influenza annually, resulting in approximately 4 million severe cases and 375,000 deaths each year. Of further concern, despite the widespread availability of annual vaccines in the US, approximately 30 million people will contract influenza, resulting in over 200,000 hospitalizations and up to 36,000 deaths each year in the US alone. As a result of genetic drift and genetic shift, mutations in influenza occur each year as it circulates through the population. These mutations may result in drug-resistance of the virus and avoidance of the vaccine, which causes the need for annual reformulation of the vaccine. In addition, influenza has multiple chromosomes, and the virus can grow in a variety of species, such as human, swine, bird, etc., which may result in novel strains of influenza entering into human circulation, as did the “swine flu”. These new viruses have the potential to cause worldwide pandemics.

Our Pipeline

Our product candidates are intended to treat antibiotic-resistant infections and viruses through novel mechanisms and our current pipeline of product candidates and advanced research programs is reflected in Figure 1:



Lysins

Bacteria can be divided into two groups based on structural differences of the bacteria’s outermost walls: (a) “gram-positive” and (b) “gram-negative”. Gram-positive bacteria have an outermost cell wall of peptidoglycan (a structure consisting of sugars and amino acids), which, when exposed to a dye known as the “Gram-stain,” absorb the dye and appear dark blue or violet when viewed under a microscope. Gram-negative bacteria have an additional outer membrane that prevents the Gram-stain from penetrating the peptidoglycan and, therefore, do not appear dark blue or violet when viewed microscopically. The additional outer membrane has also made gram-negative bacteria harder for lysins to penetrate. However, we have discovered and have multiple research programs on lysins that kill gram-positive and gram-negative bacteria.

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Lysins are bacteriophage enzymes that digest the peptidoglycan of the bacteria cell wall. Once the cell wall is breached, the bacteria virtually bursts due to the high internal osmotic pressure of its cytoplasm. We believe lysins are unlike SOC antibiotics, especially regarding their mechanism and speed of action. Traditional antibiotics, and most cytotoxic agents, require bacterial cell division and metabolism to occur in order to exert their effect (i.e., cell death or cessation of growth). Based on in vitro tests, lysins, however, are fundamentally different in that they kill bacteria immediately upon contact.

In collaboration with The Rockefeller University (“Rockefeller”), we have built a deep pipeline of recombinant forms of lysins for use as human therapeutics. We acquired worldwide exclusive license rights to patents for composition of matter for nine lysins from Rockefeller. Each lysin targets specific gram-positive bacteria, including drug-sensitive and drug-resistant forms of Staph aureus, pneumococcus, group B streptococcus, enterococcus and anthrax. Significantly, our lysins kill only the specific types of bacteria they target, which we believe will avoid the damaging side effects that often occur when conventional antibiotic treatments kill the body’s healthy, desirable bacteria. Table 1 sets forth the lysins for which we have acquired licenses to patents from Rockefeller, the bacteria that each lysin targets and the diseases associated with such bacteria.

Table 1: Lysins Licensed from The Rockefeller University

<u>Lysin</u>	<u>Bacteria</u>	<u>Disease</u>
CF-301	Staphylococcus aureus	Bacteremia*
CF-302	Staphylococcus aureus	Abscesses* Pneumonia Endocarditi Meningitis
CF-303	Pneumococcus	Pneumonia*
CF-309	Pneumococcus	Bacteremia* Endocarditis* Meningitis* Otitis Media*
CF-304	Enterococcus	Serious Intestinal Infections
CF-305	Group B Strep	Neonatal Meningitis*
CF-306	Anthrax	Serious Bacteremia*
CF-307	Anthrax	
CF-308	Anthrax	

* Indicates published data.

Our Lead Lysin Program: CF-301

CF-301: Pursuing the Market Opportunity

We are commencing our first Phase 1 human clinical trial with CF-301. CF-301 represents a first-in-class anti-bacterial therapeutic agent. We intend to pursue an initial indication for CF-301 to be used in combination with SOC for the treatment of Staph aureus bacteremia, including endocarditis, caused by MSSA or MRSA. If we are able to obtain approval of CF-301 for this initial indication, we believe CF-301 can be further developed for the treatment of Staph aureus pneumonia, osteomyelitis, and biofilm-related indications for infected prosthetic joints, indwelling devices and catheters.

The issue of antibiotic-resistant bacterial infections has been widely recognized as an increasingly urgent public health threat, including by the World Health Organization, the Centers for Disease Control and Prevention

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and the Infectious Disease Society of America. Antibiotic resistance has limited the effectiveness of many existing drugs, and the discovery of new antibiotics to address resistance has not kept pace with the increasing incidence of difficult-to-treat micro-organisms. According to the Infectious Diseases Society of America, as of 2010 the estimated cost to the U.S. healthcare system of antibiotic-resistant infections was approximately \$21 billion to \$34 billion annually, a substantial portion of which is due to increased length of hospital stays.

Staph aureus bacteremia is a serious bacterial infection worldwide associated with high morbidity and mortality infections. The incidence of Staph aureus bacteremia in the United States has increased from approximately 112,000 in 2006 to 119,000 in 2011. By 2020, the number of infections is expected to grow to approximately 132,000. Major factors contributing to the growth of Staph aureus bacteremia incidence include increasing numbers of patients with prosthetic devices, especially cardiac devices which contribute substantially to the growing prevalence of Staph aureus bacteremia, and secondary infections such as infective endocarditis.

CF-301: Potential Advantages

Our pre-clinical studies to date have shown that CF-301 has the following attributes:

- ***Highly specific to all forms of Staph aureus bacteria.*** CF-301 exhibits activity specific to all forms of Staph aureus, including MSSA, MRSA and vancomycin-resistant Staph aureus (“VRSA”). Significantly, CF-301 kills only the specific target bacteria, Staph aureus, which we believe will avoid damaging side effects that often occur when conventional antibiotic treatments kill the body’s healthy, desirable bacteria.
- ***Rapid bactericidal activity.*** In vitro, CF-301 kills Staph aureus bacteria in seconds after contact. Currently, mortality from Staph bacteremia remains close to 30% with treatment on SOC drugs. The average length of hospitalization due to Staph aureus bacteremia is 21 days and the average total cost of hospitalization is \$114,000. We believe CF-301, combined with SOC antibiotics, has the potential to improve patient outcomes, shorten treatment times and reduce the length of hospital stays.
- ***Synergy with standard-of-care antibiotics.*** We have discovered a strong synergy between CF-301 and several SOC antibiotics, including daptomycin, vancomycin and oxacillin. We intend to seek approval for CF-301 in combination with these SOC antibiotics. We believe that the use of CF-301 in combination with, rather than as a replacement for, SOC antibiotics, may help speed adoption of our product by physicians.
- ***Eradicates biofilms.*** CF-301 eradicates biofilms that protect bacterial infections in the body, rendering infections up to 1,000-fold more resistant to antibiotics. Infected human tissues, such as a valve in endocarditis or bone in osteomyelitis, or indwelling medical devices, such as central venous catheters, prosthetic joints and pacemakers, are common sites for biofilm formation, providing a hurdle for effective treatment with antibiotics alone.
- ***Minimal resistance.*** To date, bacteria show minimal resistance to CF-301’s killing activity in vitro.
- ***Minimal competition.*** There are only two FDA approved drugs for the treatment of MRSA bacteremia, vancomycin and daptomycin. MRSA bacteremia has shown resistance to both drugs. CF-301 works synergistically with both of these drugs and is intended to be used in combination, not as a replacement for, SOC antibiotics.
- ***Patent protection.*** If issued as we expect, our three CF-301 patents would have protection through 2032.

CF-301: Pre-clinical Data

A key feature of lysins that distinguishes them from SOC antibiotics is their ability to target pathogenic antibiotic-resistant bacteria, as well as those that are antibiotic-sensitive. Table 2 sets forth the ability of CF-301 to kill all Staph aureus isolates tested, regardless of their antibiotic-resistance profile. In this experiment, we tested 250 different drug sensitive and resistant isolates of Staph aureus. The isolates (which are classified by the

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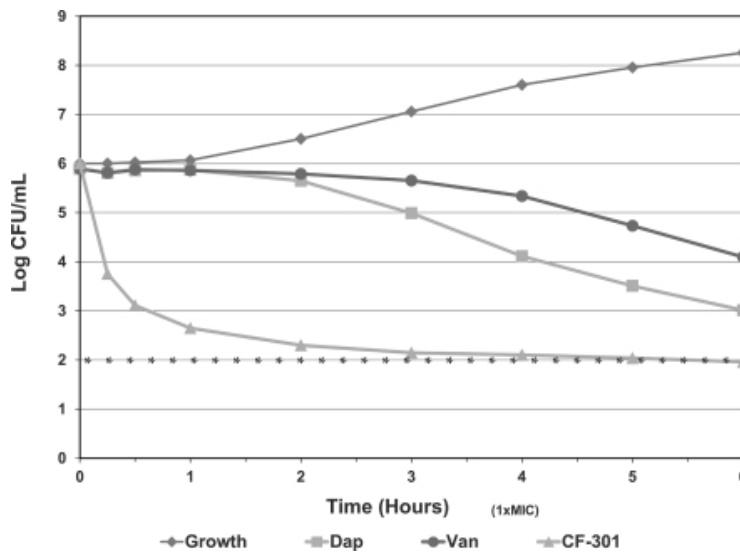
particular drugs they are sensitive or resistant too) tested included MSSA, MRSA, VRSA, linezolid-resistant (“LRSa”) and daptomycin-resistant (“DRSA”) Staph aureus. The isolates were all analyzed to determine their sensitivity to CF-301 and SOC antibiotics as measured by the Minimum Inhibitory Concentration (“MIC”) value. The MIC value is the minimum dose of drug that is required to kill a standard amount of bacteria over a 24-hour period. Based on demonstrated MIC values, CF-301 was shown to be active against all the strains tested (+), while subsets of the Staph aureus strains were resistant to daptomycin, vancomycin or linezolid (-).

Table 2: In Vitro Sensitivity of Antibiotic-Sensitive and Antibiotic-Resistant Staph aureus to CF-301

Strain (n=250)	CF-301	Daptomycin	Vancomycin	Linezolid
MSSA (103)	+	+	+	+
MRSA (120)	+	+	+	+
VRSA (14)	+	+	-	+
LRSa (5)	+	+	+	-
DRSA (8)	+	-	+	+

Lysins have been shown to kill bacteria upon contact and demonstrate bactericidal activity (a 3-log drop in colony forming units (“CFU”) per mL) in minutes. The figure below compares the rate at which lysins kill bacteria to the rates at which SOC antibiotics kill bacteria. CF-301 reduced the number of Staph aureus bacteria in tests on 62 strains (20 MSSA; 42 MRSA) by 3-logs (99.9%) within 30 minutes. In contrast, daptomycin required six hours to achieve the same level of cell kill, while vancomycin failed to achieve a 2-log, or 99%, cell kill during the same six-hour test period. The rapid bactericidal activity of lysins is one of the primary reasons we believe they could be a highly desirable therapeutic option for the treatment of rapidly advancing bacterial infections.

Figure 2: CF 301’s Rapid Bactericidal Activity In Vitro



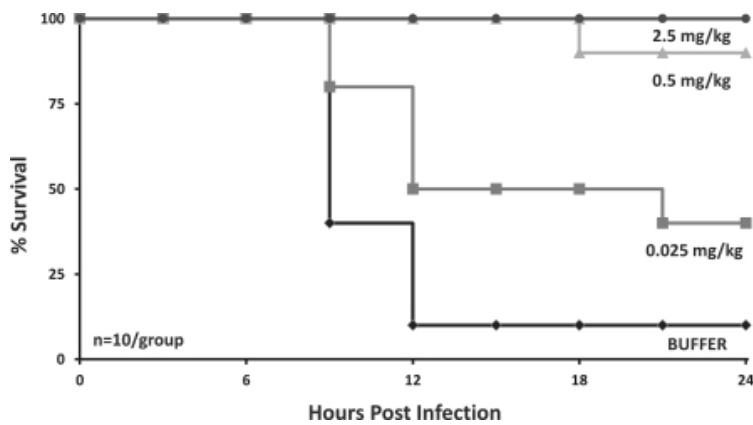
* The star symbols indicate the limit of detection in the plating assay.

CF-301: Synergy with Standard-of-Care Antibiotics

Synergy is defined as the interaction of two or more agents so that their combined effect is greater than the sum of their individual effects. We discovered a strong synergy between lysins and several SOC antibiotics, including daptomycin, vancomycin and oxacillin through our in vitro testing (data not shown). When used in combination, lysins and antibiotics offer a dual attack on pathogenic bacteria that is far greater than the sum of their individual contributions. The result is significantly improved killing of bacteria.

To demonstrate this synergy in vivo, we have developed animal models where CF-301 could be tested as single agent (monotherapy) or in combination with a SOC antibiotic (combination therapy). Our Standard Bacteremia Model utilizes animals infected with 10 million CFU of MRSA and treated 3 hours later with various doses of therapy or buffer. When used alone, CF-301 has potent anti-Staph activity that demonstrates a dose/response effect. Figure 3 below presents the dose/response of animals treated with various doses of CF-301 in the Standard Bacteremia Model. As pictured on the graph below, all mice receiving at least 0.5 mg/kg of CF-301 demonstrated at least 90% survival, whereas doses below 0.5 mg/kg resulted in lesser survival rates.

Figure 3: CF-301 Dose Response in Mice in the Standard Bacteremia Model

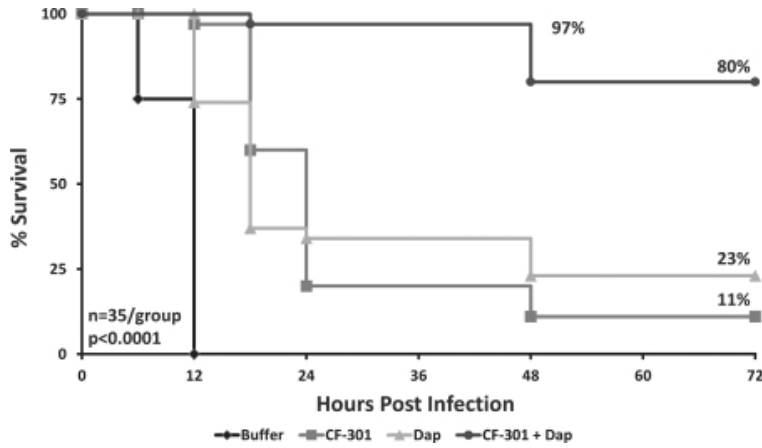


We also developed the Drug Failure Bacteremia Model, where the bacterial infection burden was so high (one billion CFU) that SOC antibiotics used at their humanized doses failed to have significant cure rates. We tested daptomycin, vancomycin and oxacillin in this model (data not shown for vancomycin and oxacillin). We then titrated the dose of CF-301 down in this model so that CF-301 alone would also fail to have significant cure rates. As the hallmark of our strategy for the development of CF-301 is its synergy with SOC antibiotics, we then treated groups of animals in the Drug Failure Bacteremia Model with the drugs alone and in combinations to evaluate if there was synergy and therefore an improvement in efficacy.

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Figure 4 below presents the results of the combination of CF-301 and daptomycin when used in the Drug Failure Bacteremia Model. Control mice treated with buffer (diamonds) succumbed to bacterial infection within 12 hours. Administration of a clinical dose of daptomycin as a single agent (triangles) resulted in clinical failure, as only 23% of mice survived. When CF-301 (squares) was dosed as a single agent at this chosen dose, only 11% of mice survived. In contrast, when mice received the *combination* of CF-301 plus daptomycin (circles), 80% survived the bacterial challenge, demonstrating superiority of the combination therapy over the single-drug regimens.

Figure 4: Combination Therapy of CF-301 with Daptomycin in Drug Failure Bacteremia Model



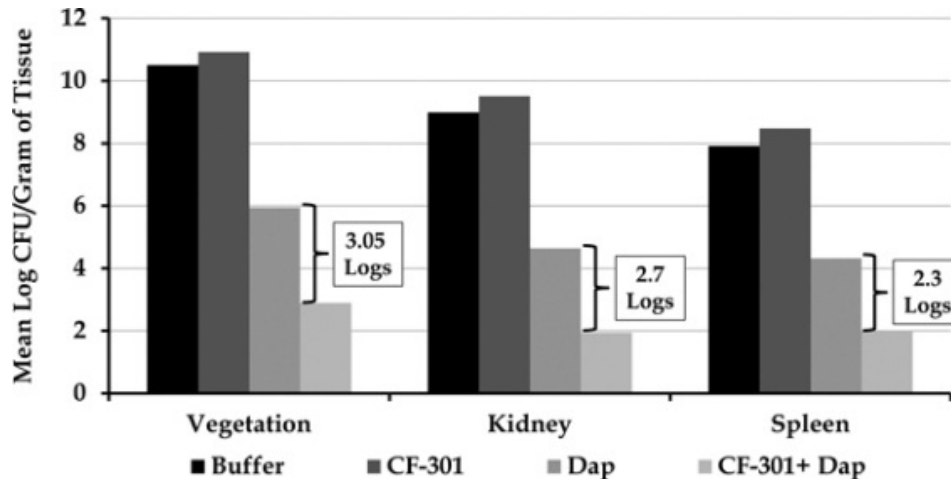
We have tested the combination of CF-301 with daptomycin, vancomycin and oxacillin in 30 different experiments (including both the Standard and Drug Failure Bacteremia Models) with over 1,700 mice. In each experiment the combination therapy was shown to be superior to therapy with a single drug alone. As a result, we believe this provides a strong foundation on which to pursue clinical development of the combination of CF-301 and SOC antibiotics for the treatment of Staph aureus bacteremia, as CF-301’s first indication.

To further explore the activity of CF-301 in combination with SOC antibiotics for the treatment of life-threatening, drug-resistant infections, we engaged the LA Biomed Research Institute at Harbor-UCLA Medical Center (“UCLA”) to perform a study in their rat infective endocarditis model (“IE Model”). The IE Model was developed at UCLA and has become a well-established experimental animal model and has been used for assessing possible efficacy of therapeutic agents in infective endocarditis. The primary endpoint of the IE Model is a reduction in the amount of bacteria (measured as CFUs) on the heart valve, in the kidney and in the spleen. Survival during the course of the treatment period was considered a secondary endpoint, as the study was not designed to see the long-term effects of the treatment on overall survival. Our study examined the activity of CF-301 alone and in combination with daptomycin, in UCLA’s prototypical high-burden biofilm-based IE Model. Using daptomycin as the comparator, management and the investigator believe that an agent that achieves a 2-log (or 99%) decrease in the CFU in the vegetation on the heart valve, spleen and kidney compared to daptomycin alone would be a very good result and an agent that achieves a 3-log (or 99.9%) reduction would be impressive. We worked directly with UCLA to design the study, and the description of the methods and results follows below.

Figure 5 presents the results of the combination of CF-301 alone and in combination with daptomycin as compared to both buffer and daptomycin alone in the IE Model. In this study, a single dose of CF-301

significantly increased the activity of daptomycin. This study was designed to mimic the planned clinical approach (single dose of CF-301 on top of multiple days of SOC antibiotic therapy) in a difficult to treat biofilm-based infection. In this study, a single dose of CF-301, when combined with four days of daptomycin treatment, resulted in a 3-log drop in bacterial burden in the cardiac vegetations and >2-log drop in the kidney and spleen of infected animals relative to daptomycin treatment alone. Importantly, in the combination treatment groups 4 of 9 animals were determined to be culture negative, whereas no animals in any other treatment arms approached this level of disease eradication.

Figure 5: Single Dose of CF-301 with Daptomycin in Rat Infective Endocarditis Model



As a result, we believe this additional data supports our human clinical study plan to evaluate the combination of CF-301 and SOC antibiotics for the treatment of patients with invasive Staph aureus infections, including endocarditis, caused by MSSA or MRSA.

CF-301: Impact on Antibiotic-Resistant Biofilms

Biofilm formation is a common protective mechanism for bacteria and a key feature associated with bacterial pathogenesis. Biofilms are characterized by densely packed bacterial cells that grow in communities and are enclosed within a complex matrix of dead bacteria and excess cell wall components. This densely packed biofilm matrix renders biofilm-based infections up to 1,000-fold more resistant to antibiotics. Infected human tissues, such as the heart valve in endocarditis or bone in osteomyelitis, or indwelling medical devices, such as central venous catheters, prosthetic joints and pacemakers, are common sites for biofilm formation, providing a hurdle for effective treatment with antibiotics alone. Biofilm coating of bacterial infections in human medicine is estimated to occur in more than 60% of bacterial infections, costing the healthcare system billions of dollars, yet no product capable of eradicating biofilms is on the market today. For this reason, novel treatment strategies and antimicrobial agents with activity toward biofilms remain a serious unmet medical need.

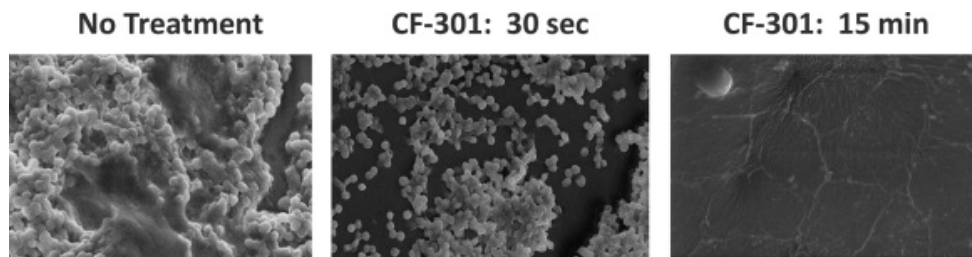
Since CF-301 disrupts the outer wall of Staph aureus by enzymatic lysis, we performed studies to determine if CF-301 would also disrupt biofilms. For this purpose, we cultured MRSA for 24 hours within wells of polystyrene dishes typically used for the culture of cells, at which point a dense biofilm formed on the dish surface. Dishes were incubated for up to 24 hours with high-dose (1,000x MIC) daptomycin, vancomycin or linezolid, or lower-dose (1xMIC) CF-301. After the four-hour treatment, dishes were washed and stained with a

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dye that stains the biomass of a biofilm a dark blue color. In dishes treated with CF-301, there was no visual biofilm present after two hours of treatment, whereas in dishes treated with antibiotics for up to 24 hours, the biofilm biomass remained intact (images not shown). These findings are consistent with the inability of these antibiotics to penetrate and clear biofilm material. This demonstrated that CF-301 was at least 1,000-fold more potent than SOC antibiotics at destroying bacterial biofilms.

To microscopically visualize CF-301's disruption of biofilms, we inoculated MRSA into a medically relevant device (a catheter) where it attached to the wall of the plastic and formed a dense 3-dimensional structure. We then treated the interior of the catheter with CF-301 at 1x MIC. At various time intervals after treatment the interior of the catheter was sectioned and examined by scanning electron microscopy ("SEM"), select images shown below in Figure 6. In the untreated catheter (left panel) the majority of MRSA cells (little circles in the pictures below) were found within a biofilm. However, within 30 seconds of exposure to CF-301, the dense biofilm was largely removed and only single cells were observed (middle panel). Fifteen minutes following exposure to CF-301 (right panel), the biofilm was completely stripped and residual MRSA cells which had been beneath the biofilm were killed, in effect, sterilizing the catheter. These images emphasize the rapid and potent activity of CF-301 against bacterial biofilms. Taken together with the lack of efficacy that antibiotics display against biofilms, we believe CF-301 represents a new therapeutic option against what were previously untreatable biofilms.

Figure 6: Sensitivity of Staph Aureus (MRSA) Biofilms Grown on Catheters to CF-301



CF-301: Product Development

Product development is generally accomplished in four steps, which may overlap: (1) pre-clinical activities to demonstrate consistent manufacturing, safety and efficacy in animals; (2) Phase 1 clinical trials, in healthy volunteers, to determine pharmacokinetics ("PK"), safety, tolerability, immunogenicity, dosing, effects in special populations, and other issues; (3) Phase 2 clinical trials in patients to determine dose, safety, tolerability, PK and immunogenicity; and (4) Phase 3 clinical trials, the pivotal trials in patients to test for efficacy and safety at the proposed commercial dose.

Non-Clinical Activities

Chemistry, Manufacturing and Controls

Manufacturing of CF-301 utilizes a proprietary engineered *E. coli* strain that expresses the product in a recombinant manner during the fermentation process. This technology allows production of up to nine grams of CF-301 per liter of fermentation broth. After fermentation, the broth containing CF-301 is separated and purified through a process containing two chromatographic columns. The resulting product has greater than 99% purity. The CF-301 produced by this process has been used in animal studies submitted to the IND and may be used for our planned Phase 1 and Phase 2 clinical trials.

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We intend to further optimize the manufacturing process for increased purity and yield. Once completed, we will begin a program to manufacture Phase 3 material. The process will then be scaled 35-fold from the current 100 liter fermentation to 5,000 liters. This process will then be validated in a series of manufacturing batches to demonstrate consistency. In parallel to the validation, we intend to conduct a comparability program that demonstrates comparability between the final product used in Phase 3 and commercial manufacturing. We will include the results in the biologics license application (“BLA”) that will be submitted to the FDA. Following submission, the FDA will conduct pre-approval inspections of all manufacturing facilities and determine whether it agrees that our commercial material is sufficiently comparable to our Phase 3 material.

Safety Pharmacology and Toxicology

Pre-clinical safety pharmacology and toxicology studies have been completed in connection with our IND application for CF-301. These studies demonstrate that CF-301 was well tolerated in rats for a single two-hour IV administration of doses up to 25mg/kg (determined by us to be the no observable adverse effect level) and that a dose of 2.5mg/kg was not associated with any effects, adverse or not, and was therefore determined to be the no observable effect level (“NOEL”). These studies also demonstrated that CF-301 was well tolerated in dogs for seven consecutive days of once daily two-hour IV infusions of up to 2.5mg/kg. A pilot study has determined that 1.0 mg/kg/day in rats was well tolerated for up to seven consecutive days of once daily two-hour IV infusions or IV boluses. We will need to conduct a definitive dose ranging, repeat dose study in rats prior to initiating any clinical trial with administration of CF-301 over consecutive days.

Dose dependent adverse tissue effects were seen in both species at doses above 25 mg/kg/day for 1 day in the rat and above 2.5 mg/kg/day for seven-consecutive days in the dog. The dose limiting toxicity observed was the development of vascular lesions on the outer wall of the aorta and pulmonary artery. In accordance with industry practice, we intend to study CF-301 in clinical trials at doses much lower than those that caused adverse effects in animals, and we believe these doses to be within the efficacious range of the drug.

Upon first exposure to CF-301, no hypersensitivity reaction was observed in any of our animal studies. Upon administration of a second course of CF-301, given two weeks after completion of the first course, hypersensitivity or hypersensitivity-like findings were observed in mice, rats and dogs. In a dedicated hypersensitivity study in rats, findings of hypersensitivity (Types I and III) were observed after a two week delayed re-challenge with a second course of CF-301 and were not dose dependent. In general, Type I hypersensitivity is an allergic anaphylaxis-like response (e.g., an immediate and potentially life-threatening allergic reaction) and Type III hypersensitivity is a serum sickness-like response (e.g., fever, joint pain, protein in urine, vascular changes). In addition to these findings, we have also considered the risk of hypersensitivity occurring upon first administration of CF-301 due to potential prior exposure to the active protein component of CF-301 from the environment, as it is a naturally occurring protein. As a risk mitigation strategy for hypersensitivity in our clinical trials, we intend to screen patients for anti-CF-301 antibody and exclude them if they test positive for the antibody. In addition, the nature of hypersensitivity reactions in rats may not necessarily be predictive of the nature of any hypersensitivity reactions that may occur in humans.

Clinical Activities

Phase 1. We are commencing a single ascending dose Phase 1 clinical trial in healthy human volunteers. This trial will be a randomized, double-blind, placebo-controlled, dose-ranging trial designed to evaluate the safety, tolerability, immunogenicity and PK of four different intravenous doses of CF-301 alone. In accordance with industry practice and FDA guidance documents, the safe starting CF-301 clinical dose for this trial will be 10 fold below the dose determined in the animal studies to be the highest exposure without effects, the NOEL. Patients will be randomized to receive a single IV dose of CF-301 administered as a two hour infusion or placebo.

Phase 2. If the Phase 1 results are consistent with our expectations of the safety profile of CF-301, we expect to proceed into Phase 2 clinical trials to assess the safety, tolerability, immunogenicity, PK, and efficacy

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of CF-301 in combination with standard-of-care (“SOC”) antibiotics. We expect any Phase 2 clinical trial to be a multicenter, double-blind, randomized study that evaluates the safety and efficacy of multiple doses of CF-301 plus SOC antibiotics and SOC antibiotics alone in patients with Staph bacteremia caused by MSSA or MRSA.

Phase 3. If the Phase 2 results are consistent with our expectations regarding the safety and efficacy profile of CF-301, we expect to enter into Phase 3 clinical trials with a study design acceptable to the FDA and other regulatory authorities. We expect any Phase 3 clinical trial to be a global, multicenter, double-blind, randomized study that evaluates the efficacy and safety of CF-301 plus SOC antibiotics compared to SOC antibiotics alone among patients with bacteremia caused by MSSA or MRSA. Specific parameters for Phase 3 trials will be based on the outcomes of previously completed clinical trials and relevant guidance and precedents from regulatory authorities.

Our Lysin Discovery Platform

We employ bioinformatics and a series of metagenomic-based techniques to clone bacteriophage lysins from bacterial, viral, and environmental sources. The field of metagenomics is based on the bulk extraction of DNA/RNA from environmental samples (e.g., soil, water, etc.) without prior isolation of individual microbial sources. This is useful when one considers that less than 1% of microbes are culturable under standard laboratory conditions. Once extracted, the metagenomic DNA can then be examined using sequence-based methods or by proprietary functional screens. These functional screens for bacteriophage lysin activity form the basis for our lysin discovery work.

For the functional metagenomic work that we perform, environmental genes are expressed in a recombinant format in a standard host organism (i.e., *Escherichia coli*) and cells are monitored for the acquisition of a desired phenotype. We can vary both the source of environmental DNA and the way we monitor for desired phenotypes to focus only on environmental populations enriched for bacteriophage lysins that can actively kill a pathogen of interest. We sample various DNA sources including viral, prophage, and pathogen-amplified viral metagenomics. Multiple methods for both DNA library construction and for functional screening are used in parallel in order to maximize lysin identification.

We have also established additional discovery methodologies, including bioinformatics analysis of the rapidly expanding databases of bacterial genomic sequences. The highly conserved modular structure of lysins, combined with sequence homologies amongst different lysin classes, enable the rapid analysis of putative lysins from DNA databases. Such sequences can be readily synthesized and screened for lytic activity against any pathogen of interest.

The application of these methods enables the large scale identification of lysins, enabling the production of lysin banks specific for any particular pathogen. We believe the ability to rapidly identify lysins specific for any pathogen of interest, either by in vitro or in silico methods, will provide a steady pipeline of novel lysins for consideration as potential antimicrobial therapeutic candidates.

We intend to pursue pre-clinical and clinical development of additional lysins. In addition to the lysins we have licensed from Rockefeller and our in-house lysin discovery program, we have an active collaborative research agreement where we provide funding for the discovery of new lysins with Dr. Vincent Fischetti’s Laboratory of Bacterial Pathogenesis and Immunology at Rockefeller, where we have the first right to negotiate a license to all discoveries concerning lysins through October 2016. The primary focus of our in-house and sponsored research is the discovery of lysins to target gram-negative bacteria.

Monoclonal Antibodies

We are exploring combination therapy with mAbs that block and disarm virulence factors of bacteria and viruses, rendering them vulnerable to the natural immune balance of the body. The strategies of our mAb

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program include: (1) targeting conserved regions of the virus or bacteria which are not prone to mutation and (b) targeting multiple proteins expressed from different genes within a bacteria or virus to prevent therapeutic escape and (c) combining mAbs to cover multiple strains for superior outcomes.

Our antibodies are generated by genetic engineering using phage display libraries, isolated directly from human blood samples or other available technologies, enabling the screening of billions of human mAbs with different binding sites. When these mAbs are generated by genetic engineering, we have the ability to develop antibodies with a common backbone (“isotype”) structure, providing for a similar pharmacokinetic profile (half-life, absorption, distribution, metabolism and excretion); alternatively, we can isolate directly from human blood samples antibodies that naturally possess the same isotype as well. The common properties provide for a unique ability to create a therapeutic combination of mAbs.

Our Lead mAb Program: CF-404

We are developing a combination of three human mAbs against influenza as a treatment for life-threatening seasonal and pandemic influenza infections, a disease that kills as many as 49,000 people annually in the U.S. alone. We expect to complete the required manufacturing and pre-clinical studies to file an IND for CF-404 and enter Phase 1 clinical trials in 2016. Our pre-clinical studies to date have shown that CF-404 has the following attributes:

- **Highly specific.** Through specific targeting of a conserved region on the virus, our mAbs cross-react with all strains of influenza, including the three principal strains (H1, H3 and B).
- **Minimal resistance potential.** Our mAbs react with the principal protein, hemagglutinin, on the surface of influenza at a region referred to as the hemagglutinin stalk, which is genetically stable and does not vary from one season to another.
- **Broad influenza coverage in one combination drug.** Targeting the hemagglutinin stalk bypasses the effects of seasonal change, which allows (1) our mAbs to neutralize many different influenza strains; (2) for the production of a single therapeutic combination of only three mAbs covering all influenza, including Types A H1 and H3, and Type B; and (3) for an immediate effect (through injection) that cannot be obtained by vaccination which typically requires weeks.
- **Minimal competition.** There are only four approved drugs for the treatment of influenza—Tamiflu, Relenza, Symmetrel and Flumadine—although only Tamiflu is widely used in practice. Influenza has demonstrated a strong propensity for developing resistance to Tamiflu, and the clinical benefit of Tamiflu is greatest when antiviral treatment is administered early, especially within 48 hours of influenza illness onset. Based on pre-clinical data, we believe treatment with our mAbs may be effective even when given 96 hours after infection. Additionally, our mAbs have an immediate treatment effect that cannot be obtained by vaccination, which only acts prophylactically and typically requires weeks to become effective.

Influenza Research

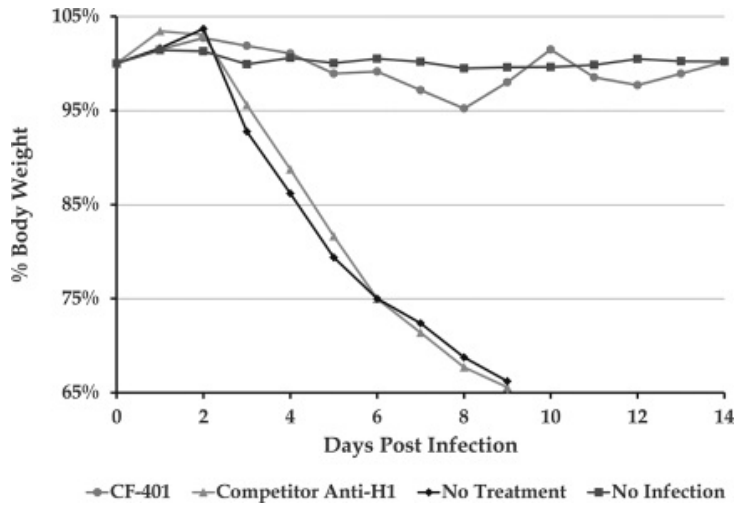
We currently have lead compounds that cross-react with all strains of influenza, including the three principal strains (H1, H3 and B). These mAbs react with the principal protein (hemagglutinin) on the surface of influenza at a region (referred to as the hemagglutinin stalk) which is genetically stable and does not vary from one season to another. We have produced mAbs that are reactive with the stalk region of hemagglutinin for the entire natural history of the H3 influenza (1968-present), H1 influenza (1918-present; seasonal and swine flu), all other strains of type A influenza (including H5), and Type B influenza.

We have tested our mAbs in mouse models to demonstrate protection against lethal infection with influenza in “proof-of-concept” experiments. These data demonstrated that our anti-H1 (CF-401), anti-H3 (CF-402) and anti-B mAbs (CF-403) were able to protect animals from lethal challenge. Importantly, our in vivo animal studies

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show that treatment with our mAbs appears to provide greatly enhanced potency compared to treatment with other mAbs. Figure 7 below shows the results of an experiment using CF-401 in a mouse model of influenza infection, in which body weight loss is used as a proxy of disease progression (and ultimately, death). In this figure, we also demonstrate that at equivalent dosing of 1 mg/kg, CF-401 is far superior to a competitor's mAb currently in clinical development. Control mice treated with buffer (diamonds) succumbed to viral infection within 9 days. Administration of a single treatment, 24 hours post-infection, of a competitor's antibody (triangles) resulted in clinical failure at an identical rate as the no treatment group. When CF-401 (circles) is administered as a single treatment, 24 hours post-infection, the mice appear perfectly healthy, with weight changes identical to animals that do not receive challenge with influenza (squares).

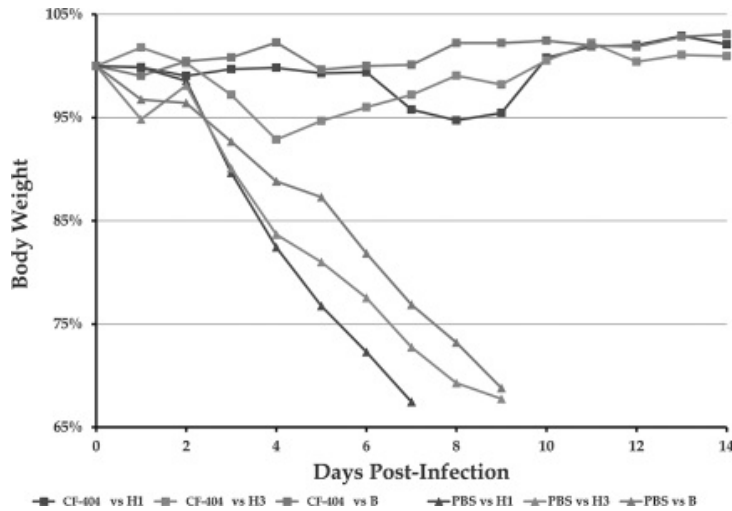
Figure 7: Effectiveness of CF-401 in Mouse Model of Influenza



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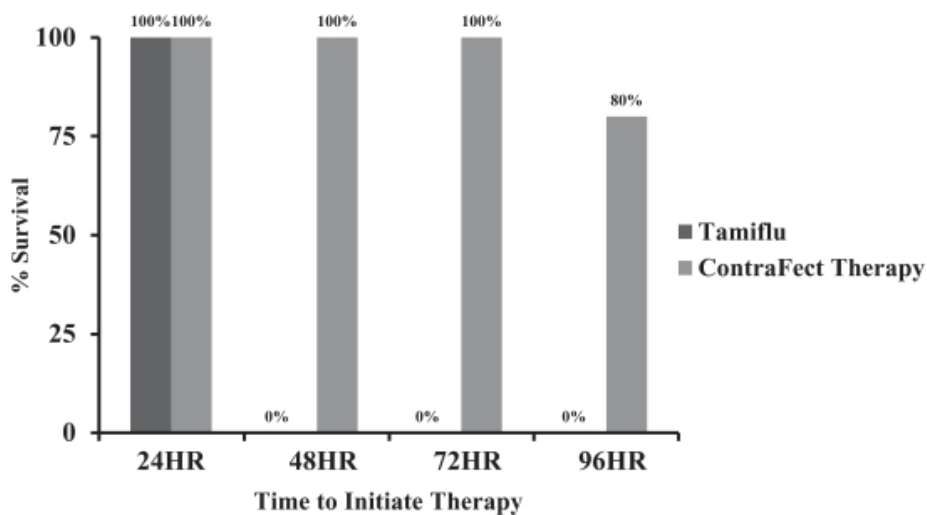
As the goal of our influenza program is a combination of mAbs with efficacy against all strains of the flu, we have formulated a preliminary combination of three mAbs covering all influenza strains and tested it in animal models of disease. Figure 8 below shows how CF-404 cures mice infected with influenza, regardless of the strain (H1N1, H3N2 or B). Control mice treated with buffer (triangles) all succumbed to viral infection within 7-9 days. By contrast, when we administered a single treatment of our anti-Influenza combination (squares) 24 hours post-infection, the mice appeared perfectly healthy, with weight change compared to healthy mice (not pictured).

Figure 8: Effectiveness of CF-404 in Mouse Model



Currently, the SOC treatment for influenza is Tamiflu®. Tamiflu, however, has several limitations, including emerging resistance. In 2009, just prior to the emergence of the pandemic H1N1 swine flu, the CDC cautioned against the use of Tamiflu for the treatment of H1N1 seasonal influenza due to nearly complete drug-resistance of the virus (in 2006 <1% of H1N1 were resistant, by 2008 that figure jumped to >95%). As previously discussed, due to the targeting of conserved regions on the hemagglutinin, we do not anticipate resistance will occur to our mAbs. The second major limitation of Tamiflu is its narrow therapeutic window to treat a patient and still be efficacious. The clinical benefit of Tamiflu is greatest when admitted early, especially within 48 hours of illness onset. To compare the therapeutic window of our mAbs to Tamiflu, influenza-infected mice were treated with either a single administration of our combination or a 5 day course of Tamiflu beginning 24-96 hours post infection (“HPI”). Figure 9 below shows that in mouse models of influenza Tamiflu must be given 24 HPI to cure mice, while treatment at 48, 72 or 96 HPI results in 100% death before day 14. Treatment with CF-401, on the other hand, results in 100% survival when given 24-72 HPI and 80% survival when given 96 HPI.

Figure 9: Our mAbs Provide Greater Therapeutic Window than Tamiflu® in Mouse Model



We believe our combination for the treatment of influenza is a novel approach addressing a high unmet medical need (influenza causes up to 49,000 deaths per year in U.S. alone) and offers competitive advantages to the only product widely used on the market today and those in the pipeline as well.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we will require all of our employees, consultants, and other contractors (including any contractors we may retain for purposes of any of our ad hoc Clinical Advisory Boards) to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Our lysin portfolio consists of approximately 60 United States and international patents and patent applications which we have licensed from Rockefeller and/or developed in-house. The patents and patent applications are directed to compositions and methods for the treatment of infections caused by Group B Streptococci, Staphylococcus aureus, Streptococcus pneumonia, Bacillus anthracis (anthrax), Enterococcus faecalis and Enterococcus faecium. These patents will expire between 2023 and 2029. If patents are granted on our patent applications, which include the patent applications for CF-301, they would expire between April 2032 and May 2033.

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Our influenza patent portfolio consists of four active patent application families, which we have licensed from Trellis and/or developed in-house. The patent applications are directed to compositions relating to influenza antibodies as well as to pharmaceutical compositions for administration to patients and to methods for their use in conferring passive immunity against various influenza strains and clades. If patents are granted on these patent applications they would expire between June 2031 and February 2035.

The U.S. patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by the United States Patent and Trademark Office (“USPTO”), and can issue as a patent once the USPTO determines that the claimed invention meets the various standards for patentability. A provisional patent application is not examined or prosecuted, and automatically expires 12 months after its filing date if a non-provisional application is not filed based on the provisional application within that 12-month period. Provisional applications are often used, among other things, to establish a priority filing date for the subsequently filed non-provisional patent application. The term of individual patents depends upon the legal term for patents in the countries in which they are filed. In most countries in which we file, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent. Alternatively, a patent’s term may be shortened if a patent is terminally disclaimed over another patent.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension (“PTE”), which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical product candidates receive FDA or other regulatory approval, we may be able to apply for or receive the benefit of PTEs on patents covering those products.

License Agreements—The Rockefeller University

We have entered into the following license agreements with Rockefeller:

- On July 12, 2011, we entered into a license agreement for the worldwide, exclusive right to a provisional patent application, upon which a non-provisional patent application has since been filed, covering the composition of matter for the lysin PlySS2 for the treatment and prevention of diseases caused by gram-positive bacteria (the “CF-301 License”). We rebranded PlySS2 as CF-301. This license gives us the right to exclusively develop, make, have made, use, import, lease, sell and offer for sale products that would otherwise infringe a claim of this patent application or patent.
- On June 1, 2011, we entered into a license agreement for the exclusive rights to Rockefeller’s interest in a joint patent application, which is presently pending, covering the method of delivering antibodies through the cell wall of a gram-positive bacteria to the periplasmic space. This intellectual property was developed as a result of the sponsored research agreement between us and Rockefeller, and was jointly discovered and filed by the two parties.
- On September 23, 2010, we entered into a license agreement for the worldwide, exclusive right to develop, make, have made, use, import, lease and sell, and offer for sale products that would otherwise infringe a claim of the suite of patents and patent applications covering the composition of matter for eight individual lysin molecules for the treatment and prevention of diseases caused by gram-positive bacteria. The lysins in this suite have activity against Group B Streptococci, Staphylococcus aureus, Streptococcus pneumoniae, Bacillus anthracis, Enterococcus faecalis and Enterococcus faecium.

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In consideration for each license, we paid Rockefeller a license initiation fee in cash or stock and may be required to pay an annual maintenance fee, milestone payments and royalties on net sales from products to Rockefeller. We are allowed to grant sublicenses to third parties without prior approval, subject to certain conditions and the payment of a certain percentage of all payments we receive from sublicensees.

Each license agreement terminates upon the later of (i) the expiration or abandonment of the last licensed patent under the license agreement to expire or become abandoned, or (ii) 10 years after the first commercial sale of the first licensed product. Rockefeller may terminate any license agreement in the event of a breach of such agreement by us or if we challenge the validity or enforceability of the underlying patent rights. We may terminate any license agreement at any time on 60 days' notice.

License Agreement—Trellis Bioscience LLC

On January 29, 2014, we entered into a license agreement with Trellis that gives us exclusive rights to all Trellis mAbs in the field of influenza discovered from their CellSpot platform. Particularly, the license provides us 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). To date, we have selected our lead mAbs for the H1 and H3 influenzas, and are evaluating multiple lead candidates that have anti-B activity.

In consideration for the license, we paid Trellis licensing fees in cash and stock and may be required to make specified development and regulatory milestone payments and make additional payments upon the achievement of future sales and a royalty on net sales from products to Trellis. We are allowed to grant sublicenses to third parties.

The license agreement terminates upon the earlier of (i) our 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.

On August 14, 2014, we amended the license agreement to include research conducted pursuant to a government grant.

Collaborative Research Agreements—The Rockefeller University

Beginning in October 2009, we entered into a research agreement with Rockefeller where we provided funding for the research. The initial agreement focused on producing and testing monoclonal antibodies against proteins of Staph aureus. On October 24, 2011, we entered into a second research agreement with Rockefeller, where we provide funding for the research primarily to identify lysins, enzymes or small molecules that will kill gram-negative bacteria, and to identify and characterize lysins from Clostridia difficile to be engineered into gut commensal bacteria.

Our current agreement runs through October 31, 2016. Either party may terminate the agreement upon breach of the agreement, following 30 days written notice and failure to cure such breach. Following the expiration or termination of the agreement, each party will have a non-exclusive license to use for internal research purposes all research results, including joint intellectual property. If Rockefeller or joint intellectual property develops from these programs, we will have the right-of-first refusal to negotiate to acquire a royalty-bearing license to utilize such intellectual property for commercial purposes.

Competition

The pharmaceutical and biotechnology industries are intensely competitive. While we believe that our technology and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies and academic and research organizations in developing therapies to treat diseases.

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CF-301 is a first-in-class drug and we believe will be among the first lysins to enter human clinical trials. There is no clinical competitor to CF-301 as it contains at least six attributes that no single antibiotic possesses, including: (1) a novel mechanism of action, (2) specificity for a target bacteria (only *Staph aureus*), (3) rapid speed of action, (4) activity across all drug-sensitive and drug-resistant strains of the target bacteria (including MRSA, VRSA and DRSA), (5) the ability to eradicate biofilms, and (6) synergy with antibiotics. The indication for staph bacteremia currently has two approved standard-of-care drugs: daptomycin and vancomycin. Vancomycin is currently a generic drug and we expect daptomycin to reach the end of its patent life by the time we come to market. We do not see market competition with these drugs, as our strategy is to combine CF-301 with these drugs to aim for superiority over any one of those drugs alone. Additionally, we anticipate similar synergy (and combination approach) with identifiable clinical development molecules, such as Teflaro from Cerexa Inc.

Recently, iNtRon Biotechnology Inc., a biotechnology company located in South Korea, completed the first Phase I human clinical trial for an anti-Staph lysin, SAL-200. While the indication is yet to be disclosed, it has been reported that SAL-200 is to be administered intravenously in a trial that will take place in South Korea. We will continue to monitor the advancements of SAL-200 as data becomes available.

CF-404, for the treatment of life-threatening seasonal and pandemic influenza infections, we believe has competitive advantages in that it potentially addresses the short-comings of currently marketed products (Tamiflu and Peramivir) and other products in development for the following reasons: (1) it may not be prone to drug-resistance due to targeting conserved regions of influenza, (2) it may provide for an increased "time-to-treat" window compared to Tamiflu and Peramivir, which are indicated to be used within 48 hours of symptom onset, and (3) it may provide complete coverage against all seasonal and potential pandemic strains of influenza without the need for annual reformulation, including influenza B.

CF-404 may directly or indirectly compete with other products already in development from F. Hoffmann-La Roche Ltd., Genentech, Inc., Crucell N.V, Vertex Pharmaceuticals Incorporated, Theraclone Sciences, Inc., Toyama Chemical Co., Ltd., Romark Laboratories, L.C., Biota Pharmaceuticals, Inc., Adamas Pharmaceuticals, Inc., Activaero GmbH, Far East Bio-Tec Co. Ltd and others with early stage product candidates.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved medicines than we do. We compete with companies that have products on the market or in development for the same indications as our product candidates. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price and the availability of reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any medicines that we may develop. Our competitors also may obtain FDA or other regulatory approval for their medicines more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for

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pre-clinical and clinical testing, as well as for commercial manufacture of any products that we may commercialize. We employ the services of 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 for CF-301; however, we intend to pursue agreements with Fujifilm UK to do so. We employ the services of CanGene to produce CF-301 in its final vial drug product form. We do not have contracts for the commercial supply of CF-301. We intend to pursue agreements with third party manufacturers regarding commercial supply of vial drug product 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.

We generally expect to rely on third parties for the manufacture of any companion diagnostics we develop.

Sales, Marketing and Distribution

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that any of our other products will be approved.

Research and Development Expenses

We have invested \$8.9 million and \$9.1 million in research and development expenses for the years ended December 31, 2014 and 2013, respectively.

Government Regulation

The production, distribution, and marketing of products employing our research and intellectual property or that we may license from third parties are subject to extensive governmental regulation in the United States and in other countries. In the United States, our products will be regulated as biologics and subject to the Federal Food, Drug, and Cosmetic Act, as amended (the "FDC Act"), the Public Health Service Act, as amended (the "PHSA") and the regulations of the FDA, as well as to other federal, state, and local statutes and regulations. These laws, and similar laws outside the United States, govern the research, development, clinical and pre-clinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, record-keeping, reporting, advertising, and promotion and marketing of our products. Product development and approval within this regulatory framework, if successful, will require the expenditure of substantial resources and take years to achieve. Violations of regulatory requirements at any stage may result in various adverse consequences, including the FDA's and other health authorities' delay in approving or refusal to approve a product and may result in enforcement actions and administrative or judicial sanctions.

The following provides further information on certain legal and regulatory requirements that have the potential to affect our operations and the future marketing of our products.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDC Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to

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regulation under the FDC Act, except the section of the FDC Act which governs the approval of new drug applications (“NDAs”). Biological products are approved for marketing under provisions of PHSa, via a BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves pre-clinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice (“GCP”), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on healthy U.S. volunteers or patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug or biologic into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug or biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic and to provide adequate information for the

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labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all pre-clinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, currently exceeding \$2,169,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding \$104,000 per product and \$554,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Most such applications for standard review drug or biologic products are reviewed within ten to twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for products intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug or biologic products, or drug or biologic products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices (“cGMPs”) is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug or biologic is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy (“REMS”), to help ensure that the benefits of the drug or biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (“ETASU”). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and

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profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or NDA or BLA supplement before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA or BLA supplements as it does in reviewing NDAs or BLAs.

Post-Approval Requirements

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs and biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug and biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs or biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug or biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track drug or biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the drug or biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program and the FDA's accelerated approval regulations, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the

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completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track product's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA or BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The Breakthrough Therapy Designation

The FDA is required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. We intend to apply for breakthrough therapy designation of CF-301 during Phase 1 clinical trials.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

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Biosimilars

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver by the Secretary. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. No biosimilar or interchangeable products have been approved under the BPCIA to date. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation which are still being evaluated by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar’s application has been approved if a patent lawsuit is ongoing within the 42-month period.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Other Domestic Regulatory Requirements

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of the Inspector General), the United States Department of Justice and individual United States Attorneys’ offices within the Department of Justice, and state and local governments. For example, sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provision of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair

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competition, and other laws, and violations of these laws may result in imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption of safe harbor.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Moreover, ContraFect is now, and in the future may become, subject to additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Physician Drug Samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the

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agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations changed or what the effect of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we may become subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacture, product registration and approval, and pharmaceutical sales. Whether or not FDA approval has been obtained, we must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. In addition, under current United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

Pharmaceutical Coverage, Pricing and Reimbursement

Our ability to commercialize our product candidates successfully will depend in part on the extent to which the United States and foreign governmental authorities, private health insurers and other third-party payors establish appropriate coverage and reimbursement levels for our product candidates and related treatments. In many of the markets where we would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms. Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenues and profitability and the future revenues and profitability of our potential customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA") revised the payment methodologies for many drugs, which resulted in reduced reimbursement to providers. Additionally, the MMA created an outpatient prescription drug benefit which became effective on January 1, 2006. This benefit is administered by private pharmacy benefit managers and other managed care organizations and is putting increased pressure on the pharmaceutical industry to reduce prices.

Segment Reporting

We are engaged solely in the discovery and development of therapeutic protein and antibody products for life-threatening, drug-resistant infectious diseases. Accordingly, we have determined that we operate in one operating segment.

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Our Scientific Advisors

We have assembled a world-class scientific advisory board that includes renowned experts in infectious diseases. These advisors work in close collaboration with our scientists to identify new research directions and accelerate our infectious disease programs. Our scientific advisory board is led by Dr. Vincent A. Fischetti, the founder of our lysin technology.

<u>Name</u>	<u>Primary Affiliation</u>
Vincent A. Fischetti, Ph.D.	The Rockefeller University, Laboratory of Bacterial Pathogenesis and Immunology
Daniel Capon, Ph.D.	Blood Systems Research Institute
Adolfo Garcia-Sastre, Ph.D.	Mount Sinai School of Medicine, Department of Microbiology; Global Health & Emerging Pathogens Institute
Peter Palese, Ph.D.	Mount Sinai School of Medicine, Department of Microbiology
Leon G. Smith, M.D., M.A.C.P.	Formerly, Saint Michael's Medical Center, New Jersey

Employees

As of March 19, 2015, we had 21 full-time employees, including 8 employees with M.D. or Ph.D. degrees. Of these full-time employees, 10 employees are engaged in research and development activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in March 2008. Our executive offices are located at 28 Wells Avenue, 3rd Floor, Yonkers, NY 10701, and our telephone number is (914) 207-2300. Our website address is www.contrafect.com. References to our website are inactive textual references only and the content of our website should not be deemed incorporated by reference into this Form 10-K.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website located at www.contrafect.com as soon as reasonably practicable after they are filed with or furnished to the Securities and Exchange Commission (the "SEC"). These reports are also available at the SEC's Internet website at www.sec.gov. The public may also read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics, Whistleblower Policy and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.contrafect.com, under "Corporate Governance" and are available in print to any person who requests copies by contacting us by calling (914) 207-2300 or by writing to ContraFect Corporation, Attn: General Counsel, 28 Wells Avenue, 3rd Floor, Yonkers, NY 10701.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this report, and in our other public filings. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or

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more of which could, directly or indirectly, cause the Company's actual results of operations and financial condition to vary materially from past, or from anticipated future, results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect the Company's business, financial condition, results of operations and common stock price. Other factors may exist that we do not consider significant based on information that is currently available. In addition, new risks may emerge at any time, and we cannot predict those risks or estimate the extent to which they may affect us. Past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

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. To date, we have focused exclusively on developing our product candidates and have funded our operations primarily through public sale of units and private sales of common stock, convertible preferred stock and issuances of convertible debt to our investors. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the pharmaceutical industry, and you should analyze our company in light of such risks and uncertainties.

Since inception, we have incurred significant operating losses. Our net loss was \$30.1 million for the year ended December 31, 2014. We have devoted substantially all of our efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

We anticipate that our expenses will increase substantially 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 could raise substantial doubt regarding our ability to continue as a going concern.

Prior to our initial public offering, our independent registered public accounting firm expressed substantial doubt concerning our ability to continue as a going concern in its report on our financial statements as of and for the year ended December 31, 2013. 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

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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 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

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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

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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, 2014, we had federal and state net operating loss carryforwards of approximately \$68.3 million and \$65.7 million, respectively, and federal research and development credits of approximately \$1.2 million, the use of which could be limited or eliminated by virtue of one or more "ownership changes."

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

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

Our near-term business prospects are substantially dependent on our ability to develop and commercialize CF-301 and CF-404. We cannot market or sell CF-301, CF-404 or any other product candidate in the United

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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. 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

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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.

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

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

Our clinical trials may be suspended at any time for a number of reasons. For example, it is possible that exposure to CF-301 could result in adverse clinical events such as 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.

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.

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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

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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 vial 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.

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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 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;

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- 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

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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

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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 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

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to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

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

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

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;

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- 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

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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

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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 our Chief Executive Officer, Julia P. Gregory, 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

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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 as it progresses CF-301 through phase 1 clinical trials. 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, jeopardize our ability to raise additional funding 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

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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 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

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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

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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.

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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, Class A Warrants to purchase one share of common stock at an exercise price of \$4.80 per share (the "Class A Warrants") and Class B Warrants to purchase one-half share of common stock at an exercise price of \$4.00 per full share (the "Class B Warrants," and together with the Class A Warrants, the "Warrants"). The trading price of our securities is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual 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 SEC;
- changes in investor and financial analyst perceptions of the risks and condition of our business;
- changes in, or our failure to meet, performance expectations of investors or financial analysts (including, without limitation, with respect to the status of development of our lead product candidates);
- changes in market valuations of biotechnology companies;
- changes in key personnel;
- increased competition;
- sales of common stock by us or members of our management team;

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- 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; 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;

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- 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. As of March 19, 2015, 13.3 million shares of our outstanding 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”). Additionally, we have Warrants to purchase 10.3 million shares of common stock outstanding as of March 15, 2015. All shares of common stock underlying the Warrants will be freely tradable upon exercise of the Warrants unless held by our affiliates. The remaining shares of common stock and the shares of common stock underlying our Warrants are, or will be upon exercise of the Warrants, “restricted securities,” as that term is defined in Rule 144 under the Securities Act, and will be freely tradable subject to the applicable holding period, volume, manner of sale and other limitations under Rule 144 or Rule 701 of the Securities Act.

We have registered 3,358,270 shares of our common stock as of December 31, 2014 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 24.8% of our outstanding common stock as of March 15, 2015. 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.

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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 holders of the Warrants acquire shares of our common stock upon exercise of the Warrants, such holders 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 a holder’s Warrants, such holder will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Although we are required to use our best efforts to maintain an effective registration statement covering the issuance of the shares of common stock underlying the Warrants at the time that holders of our Warrants exercise their Warrants, we cannot guarantee that a registration statement will continue to 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 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.

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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.

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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 our 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 certain reduced reporting burdens. We cannot predict whether investors will find our securities less attractive if we rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our common stock or the 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,

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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;
- 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 1B. Unresolved Staff Comments

None

Item 2. Properties

In the second quarter of 2011, we opened our corporate headquarters and laboratory in Yonkers, New York. This 15,000 sq. ft. mixed use office, laboratory space consists of open laboratory and suites for molecular biology, microbiology, tissue culture, microscopy, an animal vivarium, and a robotics suite. This facility is leased through December 31, 2027. We also retain the right to an additional 45,000 sq. ft. of expansion space, which may house up to 200 employees when fully constructed.

Item 3. Legal Proceedings

None

Item 4. Mine Safety Disclosures

None

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been publicly traded on the NASDAQ Capital Market under the symbol “CFRX”. Trading of our common stock commenced on September 12, 2014, the first date that shares of our common stock were publicly traded. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sales prices of our common stock as reported on the NASDAQ Capital Market for each quarter in the year ended December 31, 2014.

2014	High	Low
Third Quarter (Beginning September 12, 2014)	\$5.50	\$3.30
Fourth Quarter	\$4.44	\$2.50

Holders

As of March 19, 2015, there were approximately 1,058 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have not declared or paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends to holders of common stock in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None

Use of Proceeds from Registered Securities

Pursuant to the Registration Statement on Form S-1 (File No. 333-195378), as amended, that was declared effective by the SEC on July 28, 2014, we registered the units to be sold in our initial public offering (the “IPO”) (including 900,000 units with respect to an over-allotment option granted by us to the underwriters in the offering). 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”).

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.

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Item 6. Selected Financial Data

Not applicable

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

Overview

We are 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 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 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 our Units, common stock and convertible preferred stock and issuances of convertible debt to our investors. During the two years ended December 31, 2014, we have received gross proceeds of \$41.3 million from the sale of Units in our IPO and 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. The Units sold in the IPO were separated into freely traded common stock, Class A Warrants and Class B Warrants on September 12, 2014. In connection with the IPO, our Board of Directors and stockholders approved a 1-for-7 reverse stock split of our common stock. The reverse stock split became effective on July 25, 2014. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

We have never been profitable and our net losses from operations were \$30.1 million and \$23.6 million for the years ended December 31, 2014 and 2013, respectively. 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

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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 primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and non-cash share-based compensation expense;
- external research and development expenses incurred under arrangements with third parties such as contract research organizations, 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.

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

CF-301: lead lysin program

CF-301 is a parenteral, potent, bactericidal lysin targeting Staph aureus bacteria, making it a highly specific therapeutic candidate for the treatment of patients with Staph aureus bacteremia. We have completed IND-enabling studies and in December 2014, the FDA approved the initiation of a phase 1 clinical trial for CF-301. We expect to initiate the trial early in 2015. We have worldwide development and commercial rights to CF-301 and expect to fund the future development and commercialization costs related to this program.

CF-404: lead mAb program

CF-404 is a potent combination of three mAbs targeting the conserved regions of the influenza virus. The combination cross-reacts with all strains of influenza, including the three principal strains (H1, H3 and B), making it a highly specific therapeutic candidate for the treatment of patients with life-threatening seasonal and pandemic varieties of influenza. We initiated IND-enabling activities prior to the end of 2014 and expect to initiate phase 1 clinical trials for CF-404 in the second half of 2016. We have worldwide development and commercial rights to CF-404 and expect to fund the future development and commercialization costs related to this program.

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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 years ended December 31, 2014 and 2013, we recorded approximately \$8.9 million and \$9.1 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 and CF-404, as shown below.

The following table summarizes our research and development expenses by category for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
	2014	2013
Personnel related	\$2,747,487	\$3,182,153
Product development	1,311,452	2,044,774
Laboratory costs	1,473,739	1,908,789
External research and licensing costs	1,956,861	1,175,221
Professional fees	663,039	591,609
Share-based compensation	715,475	230,629
	<u>\$8,868,053</u>	<u>\$9,133,175</u>

The following table summarizes our research and development expenses by program for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
	2014	2013
CF-301	\$1,666,016	\$2,567,138
CF-404	1,507,285	—
Other research and development	2,231,790	3,153,255
Personnel related and share-based compensation	3,462,962	3,412,782
	<u>\$8,868,053</u>	<u>\$9,133,175</u>

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.

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A change in the outcome of any of these variables with respect to the development of CF-301, CF-404 or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of CF-301, CF-404 or any 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 and available-for-sale securities.

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.

While our significant accounting policies are described in more detail in the notes to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

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Accrued research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses are related to fees paid to CROs in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to CROs on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepayment expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. Differences between our estimates and amounts actually incurred to date, and any resulting adjustments, have not been material.

Stock-based compensation

We account for stock-based compensation in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation-Stock Compensation*, which we refer to as ASC 718. ASC 718 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.

We account for stock options granted to non-employees, which primarily consist of consultants and members of our scientific advisory board, using the fair value method. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms and stock-based compensation expense may be recognized using an accelerated recognition model.

We use the Black-Scholes option pricing model to estimate the fair value of stock option awards using various assumptions that require management to apply judgment and make estimates, including:

- the expected term of the stock option award, which we calculate using the simplified method, as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, as we have insufficient historical information regarding our stock options to provide a basis for an estimate;
- the expected volatility of the underlying common stock, which we estimate based on the historical volatility of a representative peer group of publicly traded biopharmaceutical companies with similarities to us, including stage of drug development, area of therapeutic focus, number of employees and market capitalization;
- the risk-free interest rate, which we based on the yield curve of U.S. Treasury securities with periods commensurate with the expected term of the options being valued;

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- the expected dividend yield, which we estimate to be zero based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends; and
- the fair value of our common stock on the date of grant.

If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

Determination of the fair value of common stock on grant dates prior to our IPO

Prior to being a public company, we utilized significant estimates and assumptions in determining the fair value of our common stock, due to the absence of an active market for our common stock. We determined the estimated per share fair value of our common stock at various dates using contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, also known as the Practice Aid, for financial reporting purposes. We utilized both the option pricing method and the probability-weighted expected return method as valuation methodologies in accordance with the guidelines in the Practice Aid.

The dates of our contemporaneous valuations have not always coincided with the dates of our stock option grants. In determining the exercise prices of the stock options, our board of directors considered, among other things, the most recent contemporaneous valuations of our common stock and our assessment of additional objective and subjective factors we believed were relevant as of the grant date. The additional factors considered when determining any changes in fair value between the most recent contemporaneous valuation and the grant dates included our stage of research and preclinical development, our operating and financial performance and current business conditions.

Prior to being a public company, there were significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates included assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our share-based compensation expense, net loss and net loss per common share could have been significantly different.

Recent Accounting Pronouncements

See Note 2, Recent Accounting Pronouncements, of the Notes to Financial Statements, for a discussion of the impact of new accounting standards on our Financial Statements.

Results of Operations

Comparison of years ended December 31, 2014 and 2013

The following table summarizes our results of operations for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
	2014	2013
Operating expenses:		
Research and development	\$ 8,868,053	\$ 9,133,175
General and administrative	\$ 8,067,858	\$10,163,259
Other income (expense)	\$(13,213,173)	\$(4,324,268)

Research and Development Expenses

Research and development expense was \$8.9 million for the year ended December 31, 2014, compared with \$9.1 million for the year ended December 31, 2013, a decrease of \$0.2 million. This decrease was primarily

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attributable to a \$0.9 million decrease in our research headcount and related salaries, benefits and laboratory support costs and a \$0.6 million decrease in product development costs associated with our lead product, CF-301, for which we obtained regulatory approval to initiate clinical trials in December 2014. This decrease was partially offset by a \$0.8 million increase in external research and licensing expense as a result of the Trellis license and 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.

General and Administrative Expenses

General and administrative expense was \$8.1 million for the year ended December 31, 2014, compared with \$10.2 million for the year ended December 31, 2013, a decrease of \$2.1 million. This decrease was primarily attributable to the \$3.6 million in severance related charges for the termination of the former CEO in 2013. This decrease was partially offset by an increase of \$1.3 million in legal expenses including the termination of the MorphoSys agreement and a \$0.2 million increase in our insurance and investor relations costs related to being a public company.

Other income (expense)

Other expense was \$13.2 million for the year ended December 31, 2014 compared with \$4.3 million for the year ended December 31, 2013, an increase of \$8.9 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 and a \$2.9 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. These increases were partially offset by a decrease of \$1.4 million in non-cash expense from the change in fair value measurement of our warrant and embedded derivative liabilities.

Liquidity and Capital Resources

Sources of Liquidity

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

For the two years ended December 31, 2014, we have received gross proceeds of \$41.3 million from the sale of Units in our IPO, 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.

Cash flows

The following table provides information regarding our cash flows for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
	2014	2013
Net cash used in operating activities	\$(14,864,762)	\$(14,056,424)
Net cash (used in) provided by investing activities	\$ (1,610,536)	\$ 1,588,570
Net cash provided by financing activities	\$ 38,052,481	\$ 8,726,860
Net increase (decrease) in cash and cash equivalents	\$ 21,577,183	\$ (3,740,994)

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Net cash used in 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 year ended December 31, 2014 increased by \$0.8 million as compared to the same period in 2013. In the year ended December 31, 2014, we were able to substantially reduce our accounts payable and accrued liabilities by approximately \$1.1 million after completing our IPO. This use of cash was partially offset by lower overall cash operating expense and the non-recurring receipt of funds from refundable tax credits.

Net cash (used in) provided by investing activities

Net cash used in investing activities in the year ended December 31, 2014 resulted primarily from the purchases of marketable securities as we initiated the investment of the proceeds of our IPO. Net cash provided by investing activities in the year ended December 31, 2013 resulted primarily from the decrease in our restricted cash balances. As of December 31, 2014, we have no restricted cash balances on our balance sheet.

Net cash provided by financing activities

Net cash provided by financing activities increased in the year ended December 31, 2014 as compared to the same period in 2013 due to the completion of our IPO. In the period ended December 31, 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 December 31, 2013, we issued approximately \$12.0 million of our Convertible Notes due 2015 and repaid approximately \$1.9 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

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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 and debt 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 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable

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Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of December 31, 2014, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are 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 or submit 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. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management’s Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(1) Financial Statements

The following documents are included on pages F-1 through F-26 attached hereto and are filed as part of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Comprehensive Loss	F-5
Statement of Convertible Preferred Stock and Stockholders' Equity (Deficit)	F-6
Statements of Cash Flows	F-7
Notes to Financial Statements	F-8

(2) Financial Statement Schedules

Schedules have been omitted since they are either not required or not applicable or the information is otherwise included herein.

(3) Exhibits

The exhibits filed as part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding such Exhibits, which Exhibit Index is incorporated herein by reference.

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CONTRAFECT CORPORATION

Index to Financial Statements

Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

ContraFect Corporation

We have audited the accompanying balance sheets of ContraFect Corporation as of December 31, 2014 and 2013, and the related statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of ContraFect Corporation at December 31, 2014 and 2013, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Metro Park, New Jersey

March 26, 2015

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CONTRAFECT CORPORATION
Balance Sheets

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,722,453	\$ 4,145,270
Marketable securities	1,670,606	—
Prepaid expenses and other current assets	368,787	198,410
Total current assets	27,761,846	4,343,680
Property and equipment, net	2,148,155	2,735,175
Restricted cash	—	25,000
Other assets	143,621	2,579,980
Total assets	<u>\$ 30,053,622</u>	<u>\$ 9,683,835</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 481,626	\$ 2,124,906
Accrued liabilities	2,711,207	4,095,337
Deferred rent	966,278	896,603
Total current liabilities	4,159,111	7,116,846
Convertible notes payable	—	9,816,365
Warrant liabilities	313,004	3,088,017
Embedded derivatives liabilities	—	2,680,780
Total liabilities	4,472,115	22,702,008
Commitments and contingencies	—	—
Series A convertible preferred stock, \$0.0002 par value, none authorized and outstanding at December 31, 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 December 31, 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 December 31, 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 December 31, 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 December 31, 2014; none authorized and outstanding at December 31, 2013	—	—
Common stock, \$0.0001 par value, 100,000,000 shares authorized, 20,217,263 shares outstanding at December 31, 2014; 28,571,428 shares authorized, 1,011,997 shares outstanding at December 31, 2013	2,021	101
Additional paid-in capital	118,038,560	4,930,310
Accumulated other comprehensive loss	(627)	—
Accumulated deficit	(92,458,447)	(57,840,911)
Total stockholders' equity (deficit)	25,581,507	(52,910,500)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 30,053,622</u>	<u>\$ 9,683,835</u>

See accompanying notes.

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CONTRAFECT CORPORATION
Statements of Operations

	Year Ended December 31,	
	2014	2013
Operating expenses:		
Research and development, including stock-based compensation of \$715,475 and \$230,629, respectively	\$ 8,868,053	\$ 9,133,175
General and administrative, including stock-based compensation of \$1,224,704 and \$2,101,089, respectively	8,067,858	10,163,259
Total operating expenses	<u>16,935,911</u>	<u>19,296,434</u>
Loss from operations	(16,935,911)	(19,296,434)
Other income (expense):		
Interest expense, net	(12,412,620)	(1,712,178)
Refundable state tax credits	424,649	—
Change in fair value of warrant and embedded derivative liabilities	(1,225,202)	(2,612,090)
Total other income (expense)	<u>(13,213,173)</u>	<u>(4,324,268)</u>
Net loss	(30,149,084)	(23,620,702)
Preferred stock dividend in-kind	(4,468,452)	—
Net loss attributable to common stockholders	<u><u>\$(34,617,536)</u></u>	<u><u>\$(23,620,702)</u></u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (3.86)</u>	<u>\$ (23.35)</u>
Basic and diluted weighted average shares outstanding	<u>8,973,599</u>	<u>1,011,789</u>

See accompanying notes.

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CONTRAFECT CORPORATION
Statements of Comprehensive Loss

	Year Ended December 31,	
	2014	2013
Net loss	\$(30,149,084)	\$(23,620,702)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities	(627)	—
Comprehensive loss	<u>\$(30,149,711)</u>	<u>\$(23,620,702)</u>

See accompanying notes.

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CONTRAFECT CORPORATION
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	Loan Receivable - Officer	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2012	2,200,000	\$ 1,964,283	4,651,163	\$ 10,175,750	9,090,909	\$ 27,752,294	—	\$ —	1,006,417	\$ 101	\$ 2,588,592	\$ (600,000)	\$ —	\$ (34,220,209)	\$ (32,231,516)
Issuance of common stock for license	—	—	—	—	—	—	—	—	5,580	—	10,000	—	—	—	10,000
Issuance of warrants for services	—	—	—	—	—	—	—	—	—	—	22,149	—	—	—	22,149
Loan forgiven- officer	—	—	—	—	—	—	—	—	—	—	—	600,000	—	—	600,000
Share-based compensation	—	—	—	—	—	—	—	—	—	—	2,309,569	—	—	—	2,309,569
Net loss for the year ended December 31, 2013	—	—	—	—	—	—	—	—	—	—	—	—	—	(23,620,702)	(23,620,702)
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 warrants for services	—	—	—	—	—	—	—	—	—	—	26,354	—	—	—	26,354
Issuance of securities in IPO, including over-allotment	—	—	—	—	—	—	—	—	6,880,333	688	41,281,310	—	—	—	41,281,998
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
Financing cost of sale of securities in IPO	—	—	—	—	—	—	—	—	—	—	(6,644,713)	—	—	—	(6,644,713)
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
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
Issuance of common stock for license	—	—	—	—	—	—	—	—	132,380	13	499,987	—	—	—	500,000
Share-based compensation	—	—	—	—	—	—	—	—	—	—	979,071	—	—	—	979,071
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	(627)	—	(627)
Net loss for the year ended December 31, 2014	—	—	—	—	—	—	—	—	—	—	—	—	—	(30,149,084)	(30,149,084)
Balance, December 31, 2014	—	\$ —	—	\$ —	—	\$ —	—	\$ —	20,217,263	\$ 2,021	\$ 118,038,560	\$ —	(627)	\$ (92,458,447)	\$ 25,581,507

See accompanying notes

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CONTRAFECT CORPORATION
Statements of Cash Flows

	Year Ended December 31,	
	2014	2013
Cash flows from operating activities		
Net loss	\$(30,149,084)	\$(23,620,702)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	551,323	559,237
Stock-based compensation expense	1,511,509	2,309,569
Issuance of preferred stock in exchange for licensed technology	500,000	—
Issuance of common stock in exchange for licensed technology	500,000	10,000
Issuance of common stock warrants in exchange for services	26,354	22,149
Recognition of beneficial conversion feature	7,428,547	—
Amortization of debt issuance costs	1,240,391	416,075
Amortization of debt discount	3,550,527	738,935
Change in fair value of warrant and embedded derivative liabilities	1,225,202	2,612,090
Increase in deferred rent	69,675	224,367
Other non-cash charges and expenses	—	600,000
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	(170,377)	69,387
Increase in other assets	—	(939,998)
(Decrease) increase in accounts payable and accrued liabilities	(1,148,829)	2,002,469
Net cash used in operating activities	(14,864,762)	(14,056,424)
Cash flows from investing activities		
Decrease in restricted cash	25,000	1,575,000
Purchases of marketable securities	(1,671,233)	—
Proceeds from disposal of property and equipment	35,697	13,570
Net cash (used in) provided by investing activities	(1,610,536)	1,588,570
Cash flows from financing activities		
Proceeds from issuance of convertible notes	3,036,350	11,963,650
Payment of financing costs of convertible notes	(24,850)	(1,336,280)
Proceeds from initial public offering	41,281,998	—
Payment of financing costs of initial public offering	(6,241,017)	—
Repayment of lease and notes payable	—	(1,900,510)
Net cash provided by financing activities	38,052,481	8,726,860
Net increase (decrease) in cash and cash equivalents	21,577,183	(3,740,994)
Cash and cash equivalents at beginning of period	4,145,270	7,886,264
Cash and cash equivalents at end of period	<u>\$ 25,722,453</u>	<u>\$ 4,145,270</u>
Supplemental disclosures of cash flow information and non-cash investing and financing activities		
Cash paid for interest	\$ —	\$ 107,632
Issuance of common and preferred stock for license received	1,000,000	10,000
Cancellation of placement agent warrants	941,541	—

See accompanying notes.

ContraFect Corporation
Notes to Financial Statements
December 31, 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 its therapeutic product candidates from its lysin and monoclonal antibody platforms to target conserved regions of either bacteria or viruses. The Company's most advanced product candidates are CF-301, a lysin for the treatment of Staph aureus bacteremia, and CF-404, a combination of mAbs for the treatment of life-threatening seasonal and pandemic varieties of influenza.

The Company has incurred losses from operations since inception as a research and development organization and has relied on its ability to fund its operations through public and private debt and equity financings. Management 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. There can be no assurances that such financing will be available to the Company on satisfactory terms, or at all. In August 2014, the Company completed its initial public offering of 6,000,000 units and closed on the underwriter's over-allotment option for 880,333 units (the "IPO"), raising total 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 7 "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 December 31, 2014 and 2013 and for the years then ended has been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

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 Annual Report on Form 10-K for additional risks and uncertainties.

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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.

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

Marketable securities at December 31, 2014 consisted of investments in short-term corporate debt securities. The Company did not have any marketable securities as of December 31, 2013. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, *Investments – Debt and Equity Securities*. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit) and a component of total comprehensive loss in the statements of comprehensive loss, until realized. The fair value of these securities is based on quoted prices for identical or similar assets. Realized gains and losses are included in investment income on a specific-identification basis. There were no realized gains or losses on marketable securities for the year ended December 31, 2014.

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

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Marketable securities at December 31, 2014 consist of the following:

<u>Marketable Securities</u>	<u>Amortized Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>
Current:				
Corporate debt	\$ 1,671,233	\$ 159	\$ (786)	\$1,670,606

At December 31, 2014, the Company held only current investments. Investments classified as current have maturities of less than one year. Investments that would be classified as non-current are those that have maturities of greater than one year and management does not intend to liquidate within the next twelve months.

At December 31, 2014, the Company held three debt securities that individually and in total were in an immaterial unrealized loss position for less than one year. The aggregate fair value of debt securities in an unrealized loss position at December 31, 2014 was \$1,222,291. The Company evaluated its securities for other-than-temporary impairment and considered the decline in market value for the securities to be primarily attributable to current economic and market conditions. It is not more likely than not that the Company will be required to sell the securities, and the Company does not intend to do so prior to the recovery of the amortized cost basis. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of December 31, 2014.

Concentrations of Credit Risk

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

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, 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.

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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."

Property, Office Equipment, and Leasehold Improvements

Property and equipment are recorded at cost less accumulated depreciation. Depreciation of property and equipment is provided by the straight-line method over their estimated useful lives, ranging from three to five years.

Leasehold improvements are amortized on a straight line basis over the useful life of the improvement or the initial lease term, whichever is shorter. Costs for normal repair and maintenance are charged to expense as incurred.

Deferred Rent

The Company has an operating lease for office and laboratory space. Rent expense is recorded on a straight-line basis over the initial lease term. The difference between the actual cash paid and the straight-line rent expense is recorded as deferred rent.

Research and Development Costs

Research and development costs are charged to expense as incurred and are typically made up of salaries and benefits, clinical trial activities, drug development and manufacturing costs, and third-party service fees, including for clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued expenses.

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

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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.

Income Taxes

The Company uses the asset and liability method to calculate deferred tax assets and liabilities. Deferred taxes are recognized based on the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates expected to apply to taxable income in the years in which those differences are expected to be recovered or settled. The Company records a valuation allowance against a deferred tax asset when it is more-likely-than-not that the deferred tax asset will not be realized.

The Company is subject to federal, state and local taxes and follows a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company recognizes tax benefits or expenses of uncertain tax positions in the year such determination is made when the position is "more likely than not" to be sustained assuming examination by tax authorities. Management has reviewed the Company's tax positions for all open tax years (tax years ended December 31, 2008 through December 31, 2014) and concluded that no provision for unrecognized tax benefits or expense is required in these financial statements. There are no income tax audits in progress as of December 31, 2014.

Impairment of Long-lived Assets

In accordance with ASC 360, *Property, Plant, and Equipment*, the Company's policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Through December 31, 2014, no impairment of long-lived assets has occurred.

Segment and Geographic Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company and the chief decision maker view the Company's operations and manage its business as one operating segment. The Company operates in only one geographic segment.

Net Loss per Share Applicable to Common Stockholders

Basic net loss per share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Net loss applicable to common stockholders is calculated by adjusting the net loss of the Company for cumulative preferred stock dividends. Diluted net loss per share applicable to common stockholders is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the dilutive net loss per share applicable to common stockholders calculation, stock options and warrant are

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considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share applicable to common stockholders, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

Comprehensive Income (Loss)

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

Recent Accounting Pronouncements

In 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 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.

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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:

Scenarios	Immediately Prior to IPO		December 31, 2013	
	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 10, "Capital Structure"). The warrant will be re-measured at each subsequent reporting period and changes in fair value will be recognized in the statement of operations. The following assumptions were used in a Black-Scholes option-pricing model to determine the fair value of the warrant liability as of December 31, 2014 and at issuance:

	As of December 31, 2014	Issuance of Underwriter's Warrant
Expected volatility	74.8%	75.5%
Remaining contractual term (in years)	4.67	5.00
Risk-free interest rate	1.65%	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 December 31, 2014 and 2013:

	Fair Value Measurement As of December 31, 2014		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 25,628,918	\$ —	\$ —
Marketable securities	1,670,606	—	—
Warrant liability	—	—	313,004
Total	<u>\$ 27,309,524</u>	<u>\$ —</u>	<u>\$ 313,004</u>

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	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	<u>\$ 3,917,876</u>	<u>\$ —</u>	<u>\$ 5,768,797</u>

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 years ended December 31, 2014 and 2013:

Warrant liabilities

	Year Ended December 31,	
	2014	2013
Balance at beginning of period	\$ 3,088,017	\$ —
Issuances of convertible notes	865,635	2,080,722
Cancellation of placement agent warrants (2)	(941,541)	—
Issuance of underwriter's warrants	403,696	—
Increase in fair value (1)	2,563,080	1,007,295
Conversion of convertible notes to common stock	(5,665,883)	—
Balance at end of period	<u>\$ 313,004</u>	<u>\$3,088,017</u>

Embedded derivatives liabilities

	Year Ended December 31,	
	2014	2013
Balance at beginning of period	\$ 2,680,780	\$ —
Issuances of convertible notes	537,607	1,075,985
(Decrease) increase in fair value (1)	(1,337,878)	1,604,795
Conversion of convertible notes to common stock	(1,880,509)	—
Balance at end of period	<u>\$ —</u>	<u>\$2,680,780</u>

- (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.

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4. Property, Equipment, and Leasehold Improvements

Property, equipment, and leasehold improvements, at cost, consist of:

	December 31,	
	2014	2013
Computer equipment	\$ 19,691	\$ 19,691
Furniture	434,697	451,197
Lab equipment	1,631,016	1,708,162
Leasehold improvements	1,813,520	1,813,520
	<u>3,898,924</u>	<u>3,992,570</u>
Less: accumulated depreciation and amortization	<u>(1,750,769)</u>	<u>(1,257,395)</u>
	<u>\$ 2,148,155</u>	<u>\$ 2,735,175</u>

Depreciation expense was \$551,323 and \$559,237 for the years ended December 31, 2014 and 2013, respectively.

5. Other Assets

Other assets consists of the following:

	December 31,	
	2014	2013
Deferred offering costs	\$ —	\$1,245,660
Debt issuance costs	—	1,190,699
Other	143,621	143,621
	<u>\$143,621</u>	<u>\$2,579,980</u>

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 7, "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.

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6. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2014	2013
Accrued compensation costs	\$1,865,778	\$2,162,961
Accrued financing costs	—	1,245,660
Accrued interest charges	—	462,773
Accrued research and development service fees	202,183	100,800
Accrued professional fees	286,443	13,413
Accrued licensing fees	200,000	—
Other	156,803	109,730
	<u>\$2,711,207</u>	<u>\$4,095,337</u>

7. 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

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

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

- (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 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.

8. 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:

	<u>Year Ended December 31,</u>	
	<u>2014</u>	<u>2013</u>
Net loss applicable to common stockholders	\$(34,617,536)	\$(23,620,702)
Weighted average shares of common stock outstanding	8,973,599	1,011,789
Net loss per share of common stock—basic and diluted	<u>\$ (3.86)</u>	<u>\$ (23.35)</u>

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The following potentially dilutive securities outstanding at December 31, 2014 and 2013 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been antidilutive:

	December 31,	
	2014	2013
Preferred stock	—	4,554,874
Stock options	3,089,327	2,221,652
Class A Warrants	6,880,333	—
Class B Warrants	3,440,166	—
Warrants	<u>4,256,862</u>	<u>718,322</u>
	<u>17,666,688</u>	<u>7,494,848</u>

The potential dilutive impact of the Company's Convertible Notes and related warrants are not included as of December 31, 2013 as the number of shares was not determinable at that time and would also have been antidilutive.

9. Commitments and Contingencies

Operating Leases

In December 2010, the Company entered into a non-cancellable operating lease for office space and laboratory facilities in Yonkers, New York expiring in December 2025. In December 2011, the Company entered into an amendment which extended the terms of the lease through December 2027. The lease provides for the option to renew for two additional five-year terms. The premises were occupied in June 2011. Monthly rent payments began the date the office and laboratory facilities were ready for occupancy. A security deposit in the amount of \$54,865 was paid by the Company.

In January 2012, the Company entered into a non-cancellable operating lease for additional office space and laboratory facilities in the same building in Yonkers, New York expiring in December 2027. The lease provides for an option to renew for two additional five-year terms. A security deposit in the amount of \$78,238 was paid by the Company. Future minimum lease payments are as follows:

	Amount
Year ending December 31:	
2015	\$ 835,191
2016	851,895
2017	868,933
2018	886,311
2019	904,038
Thereafter	<u>7,914,514</u>
	<u>\$12,260,882</u>

Rent expense is recognized on the straight-line method over the terms of each lease. Rent expense for the years ended December 31, 2014 and 2013, was approximately \$871,000 and \$870,000, respectively.

Separation Agreement with Former CEO

In June 2010, we entered into an employment agreement with Robert Nowinski, Ph.D., to serve as our Chief Executive Officer and as a member of the board of directors for a period of five (5) years. This agreement was terminated effective December 25, 2013. Consistent with the terms of the June 2010 agreement, we entered into a

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separation agreement and release of claims with Dr. Nowinski in December 2013 which provided for severance payments and the maintenance of health benefits for a period of 24 months following the departure date of Dr. Nowinski. The separation agreement also provided for the modification of existing stock option grants such that all unvested portions of existing stock option grants were immediately vested and all existing stock option grants became exercisable for up to ten years from the date of grant. The estimated fair value of these modifications of \$0.9 million was recognized as non-cash share-based compensation for the year ended December 31, 2013. Dr. Nowinski received an additional, fully vested stock option to purchase 35,714 shares of common stock at an exercise price of \$6.02 per share, resulting in recognition of non-cash share-based compensation expense of \$0.1 million for the year ended December 31, 2013. In addition, the outstanding loans to Dr. Nowinski, in the aggregate amount of \$600,000, plus accrued interest of \$32,650, were forgiven pursuant to the separation agreement. Dr. Nowinski is subject to restrictive covenants, including non-competition and non-solicitation provisions. The total amount of the severance payments of \$2.0 million, share-based compensation of \$1.0 million and loan forgiveness of \$0.6 million was included as part of general and administrative expenses for the year ended December 31, 2013.

10. Capital Structure

Common Stock

As of December 31, 2014, the Company was authorized to issue 100,000,000 shares of common stock at \$0.0001 par value per share.

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 Class A Warrants expire on January 31, 2017 and the Class B Warrants expire on October 31, 2015. 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 (see Note 3, "Fair Value Measurements").

Voting

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

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Dividends

The holders of shares of common stock are entitled to receive dividends, if and when declared by the board of directors. As of December 31, 2014, no dividends have been declared or paid on the Company's common stock since inception.

Reserved for Future Issuance

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

	December 31,	
	2014	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	3,089,327	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
	<u>17,666,688</u>	<u>7,494,848</u>

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.

11. Stock Warrants

During 2014, the Company issued warrants to purchase 10,714 shares of common stock at a strike price of \$5.25 per share for services rendered to the Company. The Company calculated the fair value of these warrants to be \$26,354 which has been recognized as a component of general and administrative expenses in 2014.

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During 2013, the Company issued warrants to purchase 14,285 shares of common stock at a strike price of \$7.00 per share for services rendered to the Company. The Company calculated the fair value of these warrants to be \$22,149 which has been recognized as a component of general and administrative expenses in 2013.

The fair value of each warrant to purchase shares of common stock issued for services rendered to the Company was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	Year Ended December 31,	
	2014	2013
Fair value of underlying common stock	\$ 4.27	\$ 3.50
Expected volatility	75.4%	72.8%
Remaining contractual term (in years)	5.00	5.00
Risk-free interest rate	1.68%	0.65%
Expected dividend yield	— %	— %

As of December 31, 2014 and 2013, the Company had warrants outstanding as shown in the table below.

	December 31,	
	2014	2013
Warrants to purchase common stock	14,577,361	718,322(1)
Weighted-average exercise price per share	\$ 4.32	\$ 6.44

- (1) The warrants issued to purchasers of Company's senior convertible notes were not included as the number of shares was not determinable as of December 31, 2013

The following table summarizes information regarding the Company's warrants outstanding at December 31, 2014:

Exercise Prices	Shares Underlying Outstanding Warrants	Expiry Date
≤ \$3.50	3,656,086	August 31, 2016 – September 1, 2021
\$4.00	3,440,166	October 31, 2015
\$4.80	6,880,333	January 31, 2017
\$5.00 - \$9.99	412,434	August 6, 2015 – June 27, 2021
≥ \$10.00	188,342	August 31, 2016 – January 5, 2022
	<u>14,577,361</u>	

12. 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"). 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, for new awards, to reduce the period that vested awards would 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

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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.

The board of directors also increased the number of shares of common stock available under the Company's Amended Plan on February 24, 2014 and April 29, 2014 to 1,857,142 and 2,357,142, respectively.

As of the closing of 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. Consistent with the provision for an annual increase, an additional 808,690 shares of common stock have been reserved under the 2014 Plan.

The Company recognizes 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 year ended December 31, 2014, is summarized as follows:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Aggregate Intrinsic Value</u>
Options outstanding at December 31, 2012	1,549,390	\$ 9.31		
Granted (1)	1,351,220	3.57		
Exercised	—	—		
Forfeited (1)	(678,948)	10.99		
Options outstanding at December 31, 2013	2,221,652	\$ 5.32		
Granted	983,484	4.00		
Exercised	—	—		
Forfeited	(115,809)	4.50		
Options outstanding at December 31, 2014	<u>3,089,327</u>	4.95	7.57	\$ <u>75,478</u>
Vested and exercisable at December 31, 2014	<u>2,306,769</u>	5.19	4.95	\$ <u>20,529</u>

(1) Includes grants for the purchase of 647,521 shares of common stock that were tendered under the Exchange Offer.

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

The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of options granted during the years ended

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December 31, 2014 and 2013 was \$3.95 and \$3.50, respectively. Total compensation expense recognized amounted to \$1,940,179 and \$2,309,569 for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, the total remaining unrecognized compensation cost related to unvested stock options was \$2,021,465 which will be recognized over a weighted average period of approximately 2.24 years.

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

	Year Ended December 31,	
	2014	2013
Risk free interest rate	1.95%	1.21%
Expected dividend yield	—	—
Expected term (in years)	5.96	6.22
Expected volatility	76.3%	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.

13. 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 shares of common stock in an amount equal to 1.82 times each participant’s Award Amount.

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.

14. 401k Savings Plan

In 2010, the Company established a defined-contribution savings plan under Section 401k of the Internal Revenue Code (the 401k Plan). The 401k Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pre-tax basis. The company has not made any contributions to the 401k Plan.

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15. Income Taxes

The Company has available approximately \$68,283,000 and \$65,724,000 of unused operating loss carryforwards for federal and state tax purposes, respectively, that may be applied against future taxable income. The net operating loss carryforwards will expire through the year 2034 if not utilized prior to that date. No provision for a deferred tax asset has been made for the tax benefits of the net operating loss carryforwards as the entire amount is offset by a valuation allowance. The valuation allowance increased by approximately \$7,494,000 and \$8,685,000 during the years 2014 and 2013, respectively, and was approximately \$30,152,000 and \$22,658,000 at December 31, 2014 and 2013, respectively.

The Internal Revenue Code of 1986, as amended (the Code) provides for a limitation of the annual use of net operating losses and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes (as defined by the Code) that could limit the Company's ability to utilize these carryforwards. At this time, the Company has 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 the Company's formation, due to the costs and complexities associated with such a study. The Company may have experienced various ownership changes, as defined by the Code, as a result of past financing transactions. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, the Company may not be able to take full advantage of these carryforwards for federal or state income tax purposes.

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. For the two years ended December 31, 2014, the Company had no unrecognized tax benefits or related interest and penalties accrued. The Company has not, as yet, conducted a study of research and development (R&D) credit carryforwards. This study may result in an adjustment to the Company's R&D credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's R&D credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment were required. The Company would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company's uncertain tax positions are related to years that remain subject to examination by relevant tax authorities. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

The principal components of the Company's deferred tax assets/liabilities for 2014 and 2013 are as follows:

	December 31,	
	2014	2013
Deferred tax assets/liabilities:		
Net operating loss carryovers	\$ 26,959,701	\$ 19,631,830
R&D tax credits	1,224,288	882,330
Share-based compensation	1,649,073	1,513,809
Accrued compensation and severance	409,234	906,922
Depreciation	(690,981)	(867,325)
Deferred rent	370,376	349,675
Intangible assets	229,836	240,565
	<u>30,151,527</u>	<u>22,657,806</u>
Valuation allowance	<u>(30,151,527)</u>	<u>(22,657,806)</u>
Net deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>

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A reconciliation of the statutory U.S. Federal rate to the company's effective tax rate is as follows:

	Year Ended December 31,	
	2014	2013
Federal income tax benefit at statutory rate	(34.00)%	(34.00)%
State income tax, net of federal benefit	(5.70)	(5.00)
Permanent item—non-deductible interest	14.59	—
Other permanent items	1.83	0.01
Change in valuation allowance	24.89	40.17
R&D tax credits	(1.13)	(1.08)
Other	(0.48)	(0.10)
Effective income tax (benefit) expense rate	<u>0%</u>	<u>0%</u>

16. Significant Agreements

Rockefeller University

License Agreements

The Company has entered into the following license agreements with The Rockefeller University:

- On July 12, 2011, the Company entered into a license agreement for the worldwide, exclusive right to a patent covering the composition of matter for the lysin PlySS2 for the treatment and prevention of diseases caused by gram-positive bacteria (the "CF-301 License"). The Company rebranded PlySS2 as CF-301. The license gives the Company the right to exclusively develop, make, have made, use, import, lease, sell and offer for sale products that would otherwise infringe a claim of this patent application or patent.
- On June 1, 2011, the Company entered into a license agreement for the exclusive rights to The Rockefeller University's interest in a joint patent application covering the method of delivering antibodies through the cell wall of gram-positive bacteria to the periplasmic space. This intellectual property was developed as a result of the sponsored research agreement between the Company and The Rockefeller University, and was jointly discovered and filed by the two parties.
- On September 23, 2010, the Company entered into a license agreement for the worldwide, exclusive right to develop, make, have made, use, import, lease, sell, and offer for sale products that would otherwise infringe a claim of the suite of patents and patent applications covering the composition of matter for eight individual lysin molecules for the treatment and prevention of diseases caused by gram-positive bacteria. The lysins in this suite have activity against Group B Streptococci, Staphylococcus aureus, Streptococcus pneumoniae, Bacillus anthracis, Enterococcus faecalis and Enterococcus faecium.

In consideration for each license, we paid Rockefeller a license initiation fee in cash or stock and may be required to pay an annual maintenance fee, milestone payments and royalties on net sales from products to Rockefeller. We are allowed to grant sublicenses to third parties without prior approval, subject to certain conditions and the payment of a certain percentage of all payments we receive from sublicensees.

Each license agreement terminates upon the later of (i) the expiration or abandonment of the last licensed patent under the license agreement to expire or become abandoned, or (ii) 10 years after the first commercial sale of the first licensed product. The Rockefeller University may terminate any license agreement in the event of a breach of such agreement by the Company or if the Company challenges the validity or enforceability of the underlying patent rights. The Company may terminate any license agreement at any time on 60 days' notice.

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Collaborative Research Agreements

Beginning in October 2009, we entered into a research agreement with Rockefeller where we provided funding for the research. The initial agreement focused on producing and testing monoclonal antibodies against proteins of Staph aureus. On October 24, 2011, we entered into a second research agreement with Rockefeller where we provide funding for the research, to identify lysins, enzymes or small molecules that will kill gram-negative bacteria, and identify and characterize lysins from Clostridia difficile to be engineered into gut commensal bacteria.

Our current agreement runs through October 31, 2016. Either party may terminate the agreement upon breach of the agreement, following 30 days written notice and failure to cure such breach. Following the expiration or termination of the agreement, each party will have a non-exclusive license to use for internal research purposes all research results, including joint intellectual property. If Rockefeller or joint intellectual property develops from these programs, we will have the right-of-first refusal to negotiate to acquire a royalty-bearing license to utilize such intellectual property for commercial purposes.

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. On October 7, 2014, the Company issued 132,380 shares of its common stock in satisfaction of the \$500,000 remaining due in stock as consideration for the license. The Company will also be required to make payments to Trellis upon the achievement of specified development and regulatory milestones and upon the achievement of future sales and for royalty on 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.

Legal Contingencies

From time to time, the Company may be involved in disputes and legal proceedings in the ordinary course of its business. These proceedings may include allegations of infringement of intellectual property, employment or other matters. The Company currently has no legal proceedings ongoing that management estimates could have a material effect on the Company’s Financial Statements.

17. Related-Party Transactions

The Company paid its non-employee directors fees for services as directors and consulting of approximately \$568,000 and \$271,000 for the years ended December 31, 2014 and 2013, respectively, which were included in general and administrative expenses.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CONTRAFECT CORPORATION

By: /s/ JULIA P. GREGORY

Julia P. Gregory
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JULIA P. GREGORY</u> Julia P. Gregory	Chief Executive Officer and Director (Principal Executive Officer) (Principal Financial Officer)	March 26, 2015
<u>/s/ MICHAEL MESSINGER</u> Michael Messinger	Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	March 26, 2015
<u>/s/ SOL BARER</u> Sol Barer, Ph.D.	Chairman of the Board	March 26, 2015
<u>/s/ ISAAC BLECH</u> Isaac Blech	Director	March 26, 2015
<u>/s/ DAVID N. LOW, JR.</u> David N. Low, Jr.	Director	March 26, 2015
<u>/s/ MICHAEL OTTO</u> Michael Otto, Ph.D.	Director	March 26, 2015
<u>/s/ ROGER POMERANTZ</u> Roger Pomerantz, M.D., F.A.C.P.	Vice Chairman of the Board	March 26, 2015
<u>/s/ DAVID SCHEINBERG</u> David Scheinberg, M.D., Ph.D.	Director	March 26, 2015
<u>/s/ CARY SUCOFF</u> Cary Sucoff	Director	March 26, 2015
<u>/s/ SHENGDA ZAN</u> Shengda Zan	Director	March 26, 2015

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Exhibit No.	Description	Form	Incorporated by Reference			Filed Herewith
			File No.	Exhibit	Filing Date	
3.1	Sixth Amended and Restated Certificate of Incorporation	S-1	333-195378	3.3	July 25, 2014	
3.2	Second Amended and Restated Bylaws	S-1	333-195378	3.2	July 3, 2014	
4.1	Form of Common Stock Certificate	S-1	333-195378	4.1	July 3, 2014	
4.2	Form of Class A Warrant Agreement	S-1	333-195378	4.2	July 1, 2014	
4.3	Specimen Class A Warrant Certificate	S-1	333-195378	4.3	July 1, 2014	
4.4	Form of Class B Warrant Agreement	S-1	333-195378	4.4	July 1, 2014	
4.5	Specimen Class B Warrant Certificate	S-1	333-195378	4.5	July 1, 2014	
4.6	Form of Representative's Warrant	S-1	333-195378	4.6	July 25, 2014	
4.7	Form of Noteholder Warrant	S-1	333-195378	4.7	July 3, 2014	
4.8	Specimen Unit Certificate	S-1	333-195378	4.8	July 1, 2014	
10.1	License Agreement, between The Rockefeller University and ContraFect Corporation, dated July 12, 2011	S-1	333-195378	10.1	April 18, 2014	
10.2	Lease Agreement, between Hudson View Building #3 LLC and ContraFect Corporation, dated December 1, 2010	S-1	333-195378	10.2	April 18, 2014	
10.3	Lease Agreement, between Hudson View Building #3 LLC and ContraFect Corporation, dated January 1, 2012	S-1	333-195378	10.3	April 18, 2014	
10.4	Form of Indemnification Agreement	S-1	333-195378	10.4	July 1, 2014	
10.5	Employment Agreement by and between ContraFect Corporation and David Huang, M.D. dated June 30, 2011	S-1	333-195378	10.5	April 18, 2014	
10.6	Employment Agreement by and between ContraFect Corporation and Julia P. Gregory dated April 29, 2014	S-1	333-195378	10.6	July 1, 2014	
10.7	Employment Agreement by and between ContraFect Corporation and Michael Wittekind, Ph.D. dated March 6, 2012	S-1	333-195378	10.7	April 18, 2014	
10.8	Separation Agreement between ContraFect Corporation and Robert Nowinski, M.D. dated December 18, 2013	S-1	333-195378	10.8	April 18, 2014	
10.9	ContraFect Corporation Retention Bonus Plan	S-1	333-195378	10.9	April 18, 2014	

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<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
10.10	ContraFect Corporation Retention Bonus Plan Award Agreement	S-1	333-195378	10.10	April 18, 2014	
10.11	ContraFect Corporation Amended and Restated 2008 Equity Incentive Plan	S-1	333-195378	10.11	April 18, 2014	
10.12	ContraFect Corporation Form of Stock Option Agreement	S-1	333-195378	10.12	April 18, 2014	
10.13	ContraFect Corporation 2008 Equity Incentive Plan	S-1	333-195378	10.13	April 18, 2014	
10.14	ContraFect Corporation 2014 Omnibus Incentive Plan	S-1	333-195378	10.14	July 1, 2014	
10.15	License Agreement, between Trellis Bioscience LLC and ContraFect Corporation, dated January 29, 2014	S-1	333-195378	10.15	July 1, 2014	
10.16	Amendment to the Trellis License Agreement, dated June 15, 2014	S-1	333-195378	10.16	July 1, 2014	
16.1	Letter from EisnerAmper LLP, as to the change in certifying accountant, dated as of April 17, 2014	S-1	333-195378	16.1	April 18, 2014	
23.1	Consent of Ernst & Young LLP					X
24.1	Power of Attorney (see signature page)					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	XBRL Instance Document					X

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<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-199046) pertaining to the ContraFect Corporation Amended and Restated 2008 Equity Incentive Plan and the ContraFect Corporation 2014 Omnibus Incentive Plan of our report dated March 26, 2015, with respect to the financial statements of ContraFect Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2014.

/s/ Ernst & Young LLP

MetroPark, New Jersey
March 26, 2015

CERTIFICATION

I, Julia P. Gregory, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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: March 26, 2015

/s/ Julia P. Gregory

Julia P. Gregory
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Michael Messinger, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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: March 26, 2014

/s/ Michael Messinger

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

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

In connection with this Annual Report on Form 10-K of ContraFect Corporation (the "Company") for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Julia P. Gregory, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

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

Date: March 26, 2014

/s/ Julia P. Gregory

Julia P. Gregory
Chief Executive Officer
(Principal Executive Officer)

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

In connection with this Annual Report on Form 10-K of ContraFect Corporation (the "Company") for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Michael Messinger, Vice President, Finance of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge on the date hereof:

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

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

Date: March 26, 2014

/s/ Michael Messinger

Michael Messinger

Vice President, Finance

(Principal Financial and Accounting Officer)