# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K	
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(Ma	urk One)	
X	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF T	HE SECURITIES EXCHANGE ACT OF 1934
	For the fiscal year ended Dec	ember 31, 2015
	OR	
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) (	OF THE SECURITIES EXCHANGE ACT OF 1934
	Commission File Number	: 001-36577
	ContraFect Co (Exact name of registrant as spec	-
	Delaware (State or other jurisdiction of incorporation or organization)	39-2072586 (IRS Employer Identification No.)
	28 Wells Avenue, 3rd Floor Yonkers, NY	10701
	(Address of principal executive offices)	(Zip Code)
	Registrant's telephone number, in (914) 207-2300	
	Securities registered pursuant to Se	ction 12(b) of the Act:
	Title of Class  Common Stock, Par Value \$0.0001 per share  Class A warrant, exercisable for one share of common stock	Name of Exchange on Which Registered NASDAQ Capital Market NASDAQ Capital Market
	Securities registered pursuant to Section	on 12(g) of the Act: None
	Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in I	Rule 405 of the Securities Act Yes □ No 図
	Indicate by check mark if the registrant is not required to file reports pursuant to Section	
	Indicate by check mark whether the registrant (1) has filed all reports required to be file seeding 12 months (or for such shorter period that the registrant was required to file such rs. Yes ⊠ No □	d by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the
	Indicate by check mark whether the registrant has submitted electronically and posted of	n its cornorate 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

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. 🗵

was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer		Accelerated filer				
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	X			
Indicate by check mar	k whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes □ No ⊠					
As of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$120.0 million, based on the closing price of the registrant's common stock on the NASDAQ Capital Market on June 30, 2015 of \$5.25 per share.						
As of March 9, 2016, there were 27,484,005 shares of Common Stock, \$0.0001 par value per share, outstanding.						
DOCUMENTS INCORPORATED BY REFERENCE						
None			_			

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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.

All brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders.

#### **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", "estimates", "expects", "intends", "targets", "may", "plans", "projects", "potential", "will", "would", "could" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. All such forward-looking statements involve significant risks and uncertainties, including, but not limited to, statements regarding:

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

As more fully described under the heading "Risk Factors" contained elsewhere in this 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.

#### Item 1. Business

We are a clinical-stage biotechnology company focused on discovering and developing therapeutic protein and antibody products for the treatment of life-threatening infectious diseases, including those caused by drug-resistant pathogens, particularly those treated in hospital settings. Drug-resistant infections account for two million illnesses in the United States and 700,000 deaths worldwide each year. We intend to address drug-resistant infections using product candidates from our lysin and monoclonal antibody platforms that target conserved regions of either bacteria or viruses. Lysins are enzymes derived from naturally occurring bacteriophage which are viruses that infect bacteria. When recombinantly produced and then applied to bacteria, lysins cleave a key component of the target bacteria's peptidoglycan cell wall, which results in rapid bacterial cell death. Lysins kill bacteria faster than conventional antibiotics, which typically require bacterial cell division and metabolism in order to kill or stop the growth of bacteria. We believe that the properties of our lysins will make them suitable for targeting antibiotic-resistant organisms, such as Staphylococcus aureus ("Staph aureus") which causes serious infections such as bacteremia, pneumonia and osteomyelitis. In addition, our lysins have demonstrated the ability to clear biofilms in animal models, and we believe they may be useful for the treatment of biofilm-related infections in prosthetic joints, indwelling devices and catheters. Beyond our lysin programs, we are exploring therapies using monoclonal antibodies ("mAbs") designed to bind to viral targets. Our approach to antibody therapy employs a combination of multiple mAbs to either achieve greater efficacy or provide broader coverage across pathogenic strains.

In August 2015, our most advanced lysin product candidate, CF-301, was granted fast track designation for the treatment of *Staph aureus* bacteremia, including endocarditis. CF-301 recently concluded a Phase 1 single ascending dose study in healthy volunteers. The study was designed as a randomized, double-blind, placebo-controlled trial in order to evaluate the safety, tolerability and pharmacokinetics of CF-301 alone, administered as a two hour IV infusion. As specified in the protocol, an independent data safety monitoring board (the "DSMB") reviewed the safety, tolerability, and pharmacokinetic data from healthy volunteers dosed in all of the planned cohorts. The DSMB observed no clinical adverse safety signals associated with CF-301 in the study. We intend to pursue an initial indication for the treatment of *Staph aureus* bacteremia, including endocarditis, caused by methicillin-resistant ("MRSA") or methicillin-susceptible ("MSSA") *Staph aureus*. We believe CF-301 may also be developed for the treatment of *Staph aureus* pneumonia, osteomyelitis, and biofilm-related infections in prosthetic joints, indwelling devices and catheters. Our second product candidate, CF-404, is a combination of three human mAbs for the treatment of life-threatening human influenza, including all seasonal and most pandemic varieties. We are also advancing earlier stage programs that leverage the lysin and monoclonal antibody platforms.

# **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 those caused by 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 our therapy combined with standard-of-care
  ("SOC") drugs over SOC alone for the treatment of Staph aureus bacteremia;
- Advance CF-404 through preclinical 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

In the United States ("U.S.") alone there are approximately 120,000 cases annually of *Staph aureus* bacteremia, a bloodstream infection, which causes approximately 30,000 deaths. *Staph aureus* bacteremia can be further complicated when the infection spreads into the heart muscle, heart valves or lining of the heart, causing endocarditis. Even with current SOC antibiotic therapy, the resulting damage to the heart muscle or heart valves could require surgery to prevent stroke, heart failure or severe organ damage. Of further concern, drug-resistant strains of *Staph aureus* 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 aureus* bacteremia, including endocarditis.

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 U.S., approximately 30 million people will contract influenza, resulting in an average of over 200,000 hospitalizations and up to 49,000 influenza-associated deaths each year in the U.S. alone. Because of reduced vaccine effectiveness against the predominant circulating influenza virus in the 2014-2015 season, approximately 40 million people contracted influenza, resulting in over 970,000 flu-associated hospitalizations. 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 ineffectiveness 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**

With our product candidates, we intend to treat life-threatening infections, including those caused by drug resistant pathogens. Our current pipeline of product candidates and advanced research programs is reflected in Figure 1:

Program	Research	Candidate Selection	IND-Enabling	Phase I	Phase II
Lysin Candidates					
CF-301 - S. aureus - Complicated Bacteremia					
Additional Gram-Pos	sitive Lysins				
CF-303 - S. pneumor	niae				
CF-304 - E. faecalis a	nd E. faecium				
CF-305 - S. agalactia	le				
CF-306 - B. anthracis	;				
Gram-Negative Lysin	ıs				
Antibody Candidates	<b>s</b>				
CF-404 – Seasonal ai	nd Pandemic Infl	uenza			

#### 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 also makes 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.

Lysins are enzymes derived from naturally occurring bacteriophage, which are viruses that infect bacteria. When recombinantly produced and then applied to bacteria, lysins cleave a key component of the target bacteria's peptidoglycan cell wall, resulting in rapid bacterial cell death. We believe lysins are unlike conventional antibiotics, especially regarding their mechanism and speed of action. Conventional antibiotics 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, regardless of bacterial growth and cell division.

Our pipeline of lysins includes internally discovered lysins targeting gram-positive and gram-negative organisms, as well as lysins discovered at The Rockefeller University ("Rockefeller") which are being developed by us. We were granted a world-wide, exclusive license under Rockefeller patent rights to discover, develop, make, have made, use, import, lease, sell and offer for sale lysin products. We acquired worldwide exclusive

license rights to patents for composition of matter for nine lysins from Rockefeller. Each lysin targets a specific species of bacteria, including drugsensitive and drug-resistant forms of *Staph aureus*, pneumococcus, group B streptococcus, enterococcus and anthrax. Significantly, our lysins kill only the specific species 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 pathogenic bacteria.

Table 1: Lysins Licensed from The Rockefeller University

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

<sup>\*</sup> Indicates published data.

#### Our Lead Lysin Program: CF-301

# CF-301: Market Opportunity

We recently concluded a Phase 1 single ascending dose study in healthy volunteers with CF-301. CF-301 represents a first-in-class anti-bacterial therapeutic candidate. CF-301 has been granted fast track designation for the initial indication we intend to pursue for the treatment of *Staph aureus* bacteremia, including endocarditis, caused by MRSA or MSSA. If we are able to obtain regulatory 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 infections in 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 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 microbial infections. 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 associated with high morbidity and mortality. In the U.S. alone, there were approximately 120,000 cases of Staph aureus bacteremia, of which over 80,000 were reported as invasive MRSA infections in 2011. Of further concern, the incidence of infective endocarditis is increasing, with over 47,000 cases in 2011, due to the growth of the at-risk populations, such as adults with heart disease and prosthetic device implants, especially cardiac devices.

# CF-301: Potential Advantages

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

- Highly specific to, yet broadly active against Staph aureus bacteria. CF-301 exhibits broad activity against a wide spectrum of Staph aureus strains, including resistant strains such as MRSA, vancomycin-resistant Staph aureus ("VRSA"), and daptomycin-resistant Staph aureus ("DRSA"). Significantly, CF-301 specifically kills Staph aureus, which we believe will avoid the damaging side effects that often occur when conventional broad spectrum antibiotic treatments kill the body's healthy, desirable bacteria.
- Rapid bactericidal activity. In vitro, CF-301 kills Staph aureus bacteria within seconds after contact. Currently, mortality from Staph aureus 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 expect CF-301, combined with SOC antibiotics, to have 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 to be used in addition to these SOC antibiotics. We believe that the use of CF-301, if approved, in addition to, rather than as a replacement for, SOC antibiotics, may help speed adoption of our product by physicians and provide the best outcome for patients.
- Clears biofilms. In in vitro studies, CF-301 clears 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 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 an impediment to effective treatment using 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 addition to, not as a replacement for, SOC antibiotics.
- **Patent protection.** Our issued composition of matter patent on CF-301 provides protection through 2032 and additional patents, if issued as we expect, could provide further protection beyond 2032.

#### CF-301: Preclinical Data

A key feature of lysins is their ability to target pathogenic antibiotic-resistant bacteria, as well as those that are antibiotic-sensitive. Table 2 sets forth our findings of CF-301's effect on *Staph aureus* isolates, showing that CF-301 killed 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 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 Strains to CF-301

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

Lysins have been shown to kill bacteria upon contact and demonstrate bactericidal activity (defined as 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 (with all drugs being administered at 1X MIC). 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.

9
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Time (Hours) (1xMic)

Growth Dap Van CF-301

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

# 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). In these

<sup>\*</sup> The star symbols indicate the limit of detection in the plating assay.

preclinical tests, when used together, lysins and antibiotics offered a dual attack on pathogenic bacteria that was far greater than the sum of their individual contributions. The result was 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 combined 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 lower survival rates.

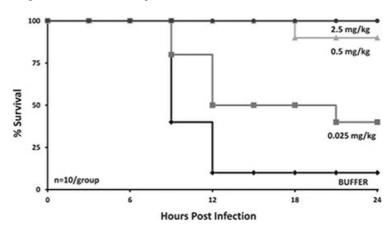
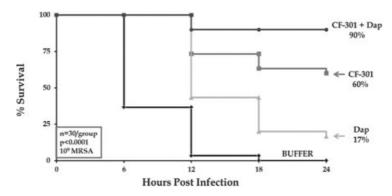


Figure 3: CF-301 Dose Response in Mice in the Standard Bacteremia Model

We also developed the Drug Failure Bacteremia Model, where the bacterial infection burden (one billion CFU) was so high that SOC antibiotics used at their human equivalent doses as monotherapies failed to have significant cure rates. We tested daptomycin, vancomycin and oxacillin in this model (data not shown for vancomycin and oxacillin). We then adjusted the dose of CF-301 so that CF-301 monotherapy would also fail to have significant cure rates under these infection conditions. To test whether the synergy that we had observed in vitro between CF-301 and SOC antibiotics would lead to improved efficacy in vivo, we then treated groups of animals in the Drug Failure Bacteremia Model with the drugs as monotherapies and also in combinations to evaluate if there was an improvement in efficacy.

Figure 4 below presents the results of the combination of CF-301 and daptomycin when used in the Drug Failure Bacteremia Model. All control mice treated with buffer (diamonds) succumbed to bacterial infection within 18 hours. Administration of a clinical dose of daptomycin as a single agent (triangles) resulted in clinical failure, as only 17% of mice survived. When CF-301 (squares) was dosed as a single agent at this chosen dose, only 60% of mice survived. In contrast, when mice received the *combination* of CF-301 plus daptomycin (circles), 90% 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). In each experiment, the combination therapy was shown to be superior to monotherapy 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 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. Prior to running the experiment, management and the investigator agreed that the achievement of 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 considered a good result and the achievement of a 3-log (or 99.9%) reduction would be considered 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.

12 Mean Log CFU/Gram of Tissue 10 8 6 3.05 Logs 2.7 Logs 2 Vegetation Kidney Spleen ■ Buffer **■ CF-301** ■ Dap ■ CF-301+ Dap

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

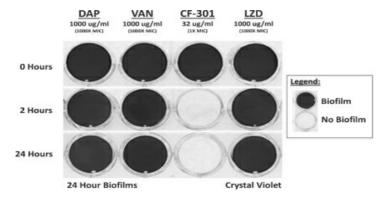
As a result, we believe this additional data supports our human clinical study plan to evaluate the combination of CF-301 and SOC antibiotics for the treatment of patients with invasive *Staph aureus* infections, including endocarditis, caused by MSSA or MRSA.

#### 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. Biofilm bacteria exhibit significant tolerance of various antimicrobial agents, rendering biofilm cells up to 1,000-fold less susceptible than the same bacteria grown in a planktonic, or free-floating, non-biofilm culture. 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. For this reason, novel treatment strategies and antimicrobial agents with activity toward biofilms remain a serious unmet medical need as there is no product currently indicated for the treatment of biofilms.

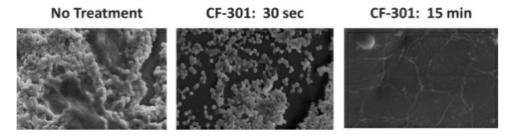
Since CF-301 disrupts the outer wall of *Staph aureus* by enzymatic lysis, we performed studies to determine if CF-301 would also disrupt biofilms. For this purpose, we cultured MRSA for 24 hours within wells of polystyrene dishes typically used for the culture of cells, at which point a dense biofilm 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 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 shown in Figure 6 below). 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 in vitro.

Figure 6: Sensitivity of Staph Aureus (MRSA) Biofilms to CF-301 Versus SOC Antibiotics



To microscopically visualize CF-301's disruption of biofilms, we inoculated MRSA onto 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 7. 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 potentially represents a new therapeutic option against what were previously untreatable biofilms.

Figure 7: 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) preclinical 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, efficacy, safety, tolerability, PK and immunogenicity; and (4) Phase 3 clinical trials, the pivotal trials in patients to confirm 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.

We intend to further optimize the manufacturing process for increased purity and yield. Once completed, we plan to 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 intend to include the results in the biologics license application ("BLA") that we expect to submit 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

Preclinical safety pharmacology and toxicology studies have been completed in connection with our IND application for CF-301. In these studies 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, or "NOAEL") and that a single 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"). CF-301 was also well tolerated in these studies in both rats and dogs for seven consecutive days of once daily two-hour IV infusions of up to 2.5mg/kg. In a non-GLP pilot study in rats, 1.0 mg/kg/day 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 both the rat and the dog. The dose limiting toxicity observed was a localized inflammation surrounding certain blood vessels. 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 studies in rats, findings of Type III hypersensitivity 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). While the nature of hypersensitivity reactions in rats may not necessarily be predictive of hypersensitivity reactions that may occur in humans, 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. Testing for anti-CF-301 antibodies was performed in Phase I subjects. No clinical hypersensitivity related to CF-301 was observed in subjects dosed in our Phase 1 study.

#### Clinical Activities

Phase 1. We recently concluded a Phase 1 single ascending dose study in healthy volunteers. This trial was a randomized, double-blind, placebo-controlled trial designed to evaluate the safety, tolerability and PK of four different intravenous doses of CF-301 alone. Subjects were randomized to receive a single IV dose of CF-301 or placebo, each administered as a two hour infusion. As specified in the protocol, an independent data safety monitoring board (DSMB) reviewed the safety, tolerability, and pharmacokinetic data from healthy volunteers dosed in all of the planned cohorts. The DSMB observed no clinical adverse safety signals associated with CF-301 in the study. No clinical hypersensitivity related to CF-301 was observed in subjects dosed in our Phase 1 study.

Phase 2. We expect to proceed into Phase 2 clinical trials to assess the safety, tolerability, PK, and efficacy of CF-301 plus 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 CF-301 plus 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. 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 preclinical and clinical development of additional lysins. In addition to the lysins we have licensed from Rockefeller and our inhouse 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 gramnegative bacteria.

#### **Monoclonal Antibodies**

We are exploring combination therapy with mAbs that bind to target bacteria or viruses and block certain biological activities or recruit other parts of the immune system to destroy the pathogenic target. The strategies of our mAb 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. Once the best monoclonal antibodies are isolated, we use protein engineering techniques to optimize important antibody attributes such as pharmacokinetic profile, effector function engagement, antibody format (such as Fabs and bispecifics), and manufacturing efficiency. 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 preclinical studies to file an IND for CF-404 in 2016. Our preclinical studies to date have shown that CF-404 may have the following attributes:

- Broad activity against influenza in one combination drug. CF-404 exhibits broad activity against influenza strains, including the three principal strains (H1, H3 and B). By targeting a conserved region on the virus, we believe CF-404 bypasses the effects of seasonal change, which allows (1) our mAbs to cross-react and neutralize many different influenza strains; (2) for the production of a single therapeutic combination of only three mAbs covering all human seasonal and most pandemic influenza strains; and (3) for an immediate therapeutic effect that cannot be obtained by vaccination which typically requires weeks.
- *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. Because the hemagglutinin stalk is genetically stable and therefore represents a conserved region of the virus, it does not vary from one season to another.
- *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 an increasing 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 preclinical data, we believe treatment with our mAbs may be effective even when given 96 hours after infection.

# Influenza Research

In preclinical studies, our combination of mAbs in CF-404 cross-reacts 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), other strains of type A influenza (including H5), and Type B influenza.

We have tested our mAbs in mouse models to evaluate 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 show that treatment with our mAbs appears to provide greatly enhanced potency compared to treatment with other mAbs.

Figure 8 below shows the results of an experiment using CF-401 in a mouse model of HINI 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 was 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) was administered as a single treatment, 24 hours post-infection, the mice appeared perfectly healthy, with weight changes identical to animals that did not receive challenge with influenza (squares).

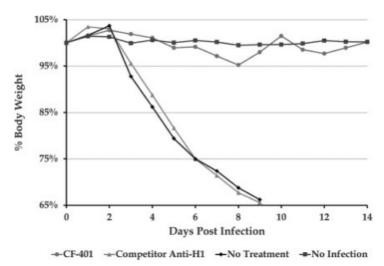


Figure 8: Effectiveness of CF-401 in Mouse Model of Influenza

As the goal of our influenza program is to produce a combination of mAbs with efficacy against all human seasonal strains of influenza, we have formulated a combination of three mAbs ("CF-404") and tested it in animal models of disease. Figure 9 below shows how CF-404 cured mice infected with three different strains of 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 CF-404 (squares) 24 hours post-infection, the infected mice appeared perfectly healthy, with weight changes comparable to healthy mice (not pictured).

105% 95% 95% 85% 0 2 4 6 8 10 12 1 Days Post-Infection

Figure 9: 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 2009 that figure jumped to >98%). 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 time window to treat a patient and still be efficacious. The clinical benefit of Tamiflu is greatest when administered early in a patient's infection, especially within 48 hours of illness onset. To compare the time-to-treat windows of our mAbs to Tamiflu, H1N1 influenza-infected mice were treated with either a single administration of CF-401or a 5 day course of Tamiflu beginning 24-96 hours post infection ("HPI"). Figure 10 below shows the findings of that study, including the finding that Tamiflu treatment had to have been initiated by 24 HPI to cure mice, while treatments beginning at 48, 72 or 96 HPI resulted in 100% death by day 14. In contrast, a single treatment with CF-401 resulted in 100% survival when given any time up to 72 HPI and in 80% survival when given 96 HPI. This result suggests that our mAb treatment may provide effective treatment to influenza patients at later times post-infection when Tamiflu is no longer effective.

→ PBS vs H1 → PBS vs H3 → PBS vs B

-- CF-404 vs H1 -- CF-404 vs H3 -- CF-404 vs B

100%100% 100% 100% 100 75 % Survival **■** Tamiflu 50 **■** ContraFect Therapy 25 0 **24HR** 48HR **72HR** 96HR Time to Initiate Therapy

Figure 10: 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 would offer competitive advantages to the only product widely used on the market today if successfully developed and approved.

#### **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 consultants or 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 eleven (11) U.S. patents, four (4) foreign patents and fifty-seven (57) U.S. and international patent applications that 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 2032 and 2033.

Our influenza patent portfolio consists of forty-one (41) U.S. and foreign patent applications, 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 2031 and 2036.

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 pneumonia, Bacillus anthracis,
  Enterococcus faecalis and Enterococcus faecium.

In consideration for the licenses, we paid Rockefeller license initiation fees in cash and 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 other seasonal or pandemic influenza strains that may arise (including H5N1 and H7N9). We have selected our three lead mAbs for the H1, H3, and B influenzas and are currently producing these antibodies at scale using manufacturing-grade expression systems and performing IND-enabling studies.

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 research 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.

CF-301 is a first-in-class drug candidate and we believe will be among the first lysins to enter human clinical trials. We believe there is no clinical competitor to CF-301 as it was designed with 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. *Staph aureus* bacteremia is typically treated with oxacillin, or for MRSA strains, daptomycin and vancomycin. Vancomycin is currently a generic drug and we expect daptomycin to reach the end of its patent life by the time CF-301 comes to market, if approved. 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 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 SAL-200, an endolysin-based drug candidate for multidrug-resistant *Staph aureus* infections. We will continue to monitor the advancements of SAL-200 as data become available.

CF-404 is intended for the treatment of life-threatening seasonal and pandemic influenza infections. We believe CF-404 has competitive advantages in that it potentially addresses the short-comings of currently marketed products (Tamiflu, Relenza and Rapivab) and other products in development for the following reasons: (1) it may not be prone to drug-resistance due to targeting conserved regions of the influenza virus, (2) it may provide for an increased "time-to-treat" window compared to Tamiflu, Relenza and Rapivab, which are indicated to be used within 48 hours of symptom onset, and (3) it may provide complete coverage against all seasonal and most potential pandemic strains of human 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, Visterra Inc., MedImmune LLC, Ansun Biopharma, Inc. 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 preclinical or clinical manufacturing, testing, as well as for commercial manufacture of any products that we may commercialize. We employ the services of Fujifilm UK to supply the drug substance for CF-301. We do not yet have contracts to produce a commercial supply of the drug substance 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 vialed 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 vialed drug product at an appropriate future time. We may choose to locate second fill finish third party manufacturers to supply other world regions such as the European Union or Asia.

# 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 copromotion 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 \$15.0 million, \$8.9 million and \$9.1 million in research and development expenses for the years ended December 31, 2015, 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 preclinical 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 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 preclinical 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.

Preclinical 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 preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical 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 preclinical 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 healthy volunteers or 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 volunteers or patients in the U.S. 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 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 preclinical, 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 set at \$2,374,200, and the manufacturer and/or sponsor under an approved NDA or BLA are also subject to annual product and establishment user fees, currently set at \$114,450 per product and \$585,200 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 indepth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. The FDA aims to review applications for standard review drug or biologic products within twelve months of the submission of the application, and the goal is to review applications for priority review drugs or biologics in eight months of the date of submission. Priority review can be applied to applications for drugs or biologics that are intended to treat a serious disease or condition and that, if approved, would provide a significant improvement in safety or effectiveness. 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 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 administers a number of programs to facilitate the development, and expedite the review, of drugs or biologics that are intended for the treatment of serious or life-threatening diseases or conditions. For instance, a sponsor may seek the FDA's designation of its product candidate as a "fast track" product. Fast track products are those products intended for the treatment of a serious or life-threatening disease or condition and which demonstrate the potential to address unmet medical needs for such disease or condition. Drugs that qualify as a qualified infectious disease product, or QIDP, under the recently enacted Generating Antibiotic Incentives Now, or GAIN Act, are also eligible for fast track designation.

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. If fast track designation is obtained, the FDA may initiate review of sections of a the marketing application before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. 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. In addition, a product candidate that receives fast track designation is eligible for more frequent meetings with the FDA to discuss the product's development plan and ensure collection of appropriate data needed to support approval and more frequent communications from FDA regarding such things as the design of the proposed clinical trials and use of biomarkers, as applicable. In August 2015, the FDA granted fast track designation to CF-301 for the treatment of *Staph aureus* bacteremia, including endocarditis.

In some cases, a fast track product may be approved under the accelerated approval program, which means that the approval may be made on the basis of either 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 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.

#### 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.

#### **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.

#### **Biosimilars**

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), created 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. In March 2015, the FDA approved the first biosimilar product in the U.S., though no 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.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that company's own preclinical and clinical data from adequate and well-controlled trials to demonstrate the safety, and efficacy of their product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product may also enjoy a period of exclusivity. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

#### 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 and security provisions of the Health Insurance Portability and Accountability Act, or "HIPAA", as amended by the Health Information Technology and Clinical Health Act, or "HITECH", 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 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.

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. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. 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.

HIPAA also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care

and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

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 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.

#### **Healthcare Reform**

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.

In March 2010, the Affordable Care Act was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, subjects biologic products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with

recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, due to subsequent legislative amendments to the statute, and will remain in effect through 2025 unless additional Congressional action is taken.

If additional state and federal healthcare reform measures are adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, we could expect such measures to result in reduced demand for our product candidates or additional pricing pressures.

#### **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.

#### **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.

Name Primary Affiliation

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 9, 2016, we had 31 full-time employees, including 9 employees with M.D. or Ph.D. degrees. Of these full-time employees, 15 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 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 clinical-stage biopharmaceutical company with no approved products, and we have not generated any revenue from product sales to date. To date, we have focused exclusively on developing our product candidates and have funded our operations primarily through public sale of units and private sales of common stock, convertible preferred stock and issuances of convertible debt to our investors. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the pharmaceutical industry, and you should analyze our company in light of such risks and uncertainties.

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

We anticipate that our expenses will increase substantially 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.

We currently operate with limited resources. We believe that our cash, cash equivalents and marketable securities balance of \$32.9 million as of December 31, 2015 will be sufficient to fund our projected operations into the first half of 2017. Depending on the level of cash used in or generated from operations, additional capital may be required to sustain operations. We have incurred significant losses since our inception and have never generated revenue or profit, and it is possible we will never generate revenue or profit. Meaningful revenues will likely not be available until and unless any future product candidates are approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company.

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

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

- successfully complete development activities, including the necessary clinical trials;
- · complete and submit 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 advance the clinical development of CF-301 and commence the clinical development of CF-404, make acquisitions of new products and technologies and, possibly, acquire and develop other product candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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

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

Conducting clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results to obtain marketing approval and achieve product sales. In addition, if approved, CF-301, CF-404 or any other product candidate that we develop may not achieve commercial success. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

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

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise

additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

We were incorporated in 2008 and commenced active research operations in 2010. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital and acquiring and developing CF-301, CF-404 and other potential products. We have not yet demonstrated our ability to successfully complete Phase 2 or Phase 3 clinical trials, obtain marketing approval, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

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

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

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

Under Section 382 and related provisions of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its prechange net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our past transactions, we may have experienced an "ownership change." At this time, we have not completed a study to assess whether an ownership change under Section 382 of the Code has occurred, or whether there have been multiple ownership changes since our formation, due to the costs and complexities associated with such a study. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Thus, our ability to utilize carryforwards of our net operating losses and other tax attributes to reduce future tax liabilities may be substantially restricted. Further, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, we may not be able to take full advantage of these carryforwards for federal or state tax purposes. As of December 31, 2015, we had federal and state net operating loss carryforwards of approximately \$1.6 million, respectively, and federal research and development credits of approximately \$1.5 million, the use of which could be limited or eliminated by virtue of one or more "ownership changes."

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

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

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

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

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

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

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

Before obtaining marketing approval from regulatory authorities for the sale of CF-301, CF-404 or any other product candidate, we must complete preclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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

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

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

• be delayed in obtaining marketing approval or sales revenues for our product candidates;

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

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

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

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

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

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

- imposition of a clinical hold by the FDA or other regulatory authorities;
- · delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- · delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- adverse side effects in patient populations;
- time required to add new sites;

- · delays 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.

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

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

In addition, our CROs are not our employees and we cannot control whether or not they devote sufficient time and resources to our non-clinical, preclinical or clinical programs. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or

successfully commercialize CF-301, CF-404 or any other product candidate that we seek to develop. As a result, our financial results and the commercial prospects for CF-301, CF-404 or any other product candidate that we seek to develop would be harmed, our costs could increase and our ability to generate revenues could be delayed or ended.

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

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

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

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

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

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

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.

We have not yet manufactured all supplies for our contemplated Phase 3 human clinical trials, scaled up the process for manufacture, validated the process, or contractually secured third parties for manufacture and commercial supply.

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

We employ the services of CanGene bioPharma ("CanGene") to produce CF-301 in its final vialed drug product form. We do not have contracts for the commercial supply of CF-301 drug product. We intend to pursue agreements with third-party manufacturers regarding commercial supply at an appropriate future time. We intend to locate second fill finish third-party manufacturers to supply other world regions such as the European Union or Asia.

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

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

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

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

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

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

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

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

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

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

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

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act ("MMA"), changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by those covered by Medicare under a new Part D and introduced a new reimbursement methodology based on average sales prices

for Medicare Part B physician-administered drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies whereby they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and therefore any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), became law in the United States. The goal of the Affordable Care Act is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. The Affordable Care Act, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, required manufacturers to participate in a discount program for certain outpatient drugs under Medicare Part D and promoted programs that increase the federal government's comparative effectiveness research, which will impact existing government healthcare programs and will result in the development of new programs. An expansion in the government's role in the United States healthcare industry may further lower rates of reimbursement for pharmaceutical products.

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

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

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

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

In order to market CF-301, CF-404 or any other products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional

administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in the United States or any foreign country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in the United States or any foreign country and we do not have experience as a company in obtaining regulatory approval in international markets.

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

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

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

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

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

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. If we experience delays in obtaining approvals or if we fail to obtain approval of our product candidates that we develop, our ability to generate revenues will be materially impaired.

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

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

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

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising,

promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

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

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

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

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

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

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

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

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

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

- distraction of our management or other internal resources from pursuing our business strategies;
- · decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- · substantial monetary awards to trial participants or patients;
- · loss of revenue; and
- the inability to commercialize any products that we may develop.

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and wastes, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

# Our product candidates may face competition sooner than anticipated.

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

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

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

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

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or
  entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or
  making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for

executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation:
- the federal transparency requirements under the Affordable Care Act requires certain manufacturers of drugs, devices, biologics and medical
  supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to
  report to the Department of Health and Human Services information related to physician payments and other transfers of value and ownership
  and investment interests held by physicians and their immediate family members and payments or other transfers of value made to such
  physician owners; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

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

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

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

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

# Risks Related to Employee Matters and Managing Growth

### Our future success depends on our ability to attract and retain qualified personnel.

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. 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. The unexpected loss of any 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 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 coll

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to prevent others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of

our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized and such patents may not be able to claim the benefits of any patent term extension laws or regulations. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

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

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

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

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

In addition, while we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, or such agreements may be inadequately drafted at times thereby not ensuring assignment to us of all potential intellectual property rights. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets, nor can we guarantee that such agreements will always be adequately drafted so as to be enforceable. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, because of potential differences in laws in different jurisdictions, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

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

### Risks Related to Our Securities

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

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

Prior to our initial public offering, there was no public market for our common stock and Class A Warrants to purchase one share of common stock at an exercise price of \$4.80 per share (the "Class A Warrants"). The trading price of our securities is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond are 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 preclinical, clinical and other development or operational plans;
- · adverse regulatory decisions;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- · new laws or regulations, or new interpretations of existing laws or regulations, applicable to our business;
- · actual or anticipated fluctuations in our financial condition or annual or quarterly results of operations;
- · our cash position;

- · public reaction to our press releases, other public announcements and filings with the SEC;
- · changes in investor and financial analyst perceptions of the risks and condition of our business;
- changes in, or our failure to meet, performance expectations of investors or financial analysts (including, without limitation, with respect to the status of development of our lead product candidates);
- · changes in market valuations of biotechnology companies;
- · changes in key personnel;
- increased competition;
- · sales of common stock by us or members of our management team;
- · trading volume of our common stock and Class A Warrants;
- · issuances of debt or equity securities;
- the granting or exercise of employee stock options or other equity awards;
- · changes in accounting standards, policies, guidance, interpretations or principles;
- ineffectiveness of our internal controls;
- · actions by institutional or other large shareholders;
- significant lawsuits, including patent or stockholder litigation;
- general political, market and economic conditions; and
- · other events or factors, many of which are beyond our control.

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

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

We are required to meet the continued listing requirements of the NASDAQ Capital Market and other NASDAQ rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of \$1.00 per share. If we do not meet these continued listing requirements, our common stock and the Class A Warrants could be delisted. Delisting from the NASDAQ Capital Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, or on the "pink sheets." In such case, our stockholders' ability to trade, or obtain quotations of the market value of our common stock and the Class A Warrants would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our securities, if delisted from the NASDAQ Capital Market in the future, would be listed on a national securities exchange, a

national quotation service, the over-the-counter markets or the pink sheets. Delisting from the NASDAQ Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

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

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

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

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

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

Sales of substantial amounts of shares of our common stock or warrants in the public market, or the perception that these sales may occur, could adversely affect the price of our securities and impair our ability to raise capital through the sale of additional equity securities. We have 27.5 million shares of common stock outstanding. As of March 9, 2016, 22.8 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 Class A Warrants to purchase 6.9 million shares of common stock outstanding as of March 9, 2016. All shares of common stock underlying the Class A Warrants will be freely tradable upon exercise of the Class A Warrants unless held by our affiliates. The remaining shares of common stock and the shares of common stock underlying our Class A Warrants are, or will be upon exercise of the Class A Warrants, "restricted securities," as that term is defined in Rule 144 under the Securities Act, and will be freely tradable subject to the applicable holding period, volume, manner of sale and other limitations under Rule 144 or Rule 701 of the Securities Act.

We have registered 3,358,270 shares of our common stock as of December 31, 2015 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 14.7% of our outstanding common stock as of March 9, 2016. Accordingly, they collectively have the ability to significantly influence or determine the election of all of our directors or the outcome of most corporate actions requiring stockholder approval such as: (i) a merger or a sale of our Company, (ii) a sale of all or substantially all of our assets and (iii) amendments to our certificate of incorporation or bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those individuals. These individuals also have significant control over our business as officers and directors of our Company. There is a risk that they may exercise this ability in a manner that advances their best interests and not necessarily those of our other stockholders.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our management has broad discretion in the application of the net proceeds from our initial public offering and private placement and could spend the proceeds in ways that do not enhance the value of our common stock. Because of the number and variability of factors that will determine our use of the net proceeds from our completed offerings, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could delay the development of our product candidates or have a material adverse effect on our business. Pending their use, we may invest the net proceeds from the 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:

· not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

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

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

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

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

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, a vivarium, and a robotics suite. This facility is leased through December 31, 2027.

# 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 years ended December 31, 2015 and December 31, 2014.

Fiscal Year Ended December 31, 2014	High	Low
Third Quarter (Beginning September 12, 2014)	\$5.50	\$3.30
Fourth Quarter	\$4.44	\$2.50
Fiscal Year Ended December 31, 2015		
First Quarter	\$6.13	\$3.50
Second Quarter	\$6.24	\$3.92
Third Quarter	\$5.80	\$3.90
Fourth Quarter	\$5.35	\$3.00

#### Holders

As of March 9, 2016, there were approximately 1,613 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.

# **Recent Sales of Unregistered Securities**

During the quarter ended December 31, 2015, we issued 469,492 shares of common stock upon exercise of Class B Warrants. We received aggregate gross proceeds of \$1,878,368 from the exercise of the Class B Warrants.

# Use of Proceeds from Registered Securities

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

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

### Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", the financial statements and the notes thereto and other financial information included elsewhere in this Annual Report on Form 10-K.

We derived the financial data for the years ended December 31, 2015, 2014 and 2013 and as of December 31, 2015 and 2014 from our audited financial statements, which are included elsewhere in this Annual Report on Form 10-K. We derived the financial data for the year ended December 31, 2012 and as of December 31, 2013 and 2012 from our audited financial statements that are not included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our financial statements and related notes. Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,			
Statement of Operations Data	2015	2014	2013	2012
Loss from operations	\$ (25,065,336)	\$ (16,935,911)	\$ (19,296,434)	\$ (19,154,173)
Net loss attributable to common stockholders	\$ (25,120,964)	\$ (34,617,536)	\$ (23,620,702)	\$ (19,283,454)
Net loss per share of common stock, basic and diluted	\$ (1.08)	\$ (3.86)	\$ (23.35)	\$ (19.16)

	As of December 31,			
Balance Sheet Data	2015	2014	2013	2012
Cash, cash equivalents and marketable securities	\$32,921,653	\$27,393,059	\$ 4,145,270	\$ 7,886,264
Total assets	35,861,137	30,053,622	9,683,835	13,205,664
Long-term liabilities	1,416,443	1,249,046	16,481,765	1,502,946
Total stockholders' equity (deficit)	30,675,510	25,581,507	(52,910,500)	(32,231,516)

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

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

We have not generated any revenues and, to date, have funded our operations primarily through the issuance and sale of our Units, which consisted of one share of common stock, one Class A Warrant to purchase one share of common stock at an exercise price of \$4.80 per share and one Class B Warrant to purchase one-half share of common stock at an exercise price of \$4.00 per full share ("Units"), common stock, convertible preferred stock and convertible debt to our investors. As of November 2, 2015, the date of expiration of the Class B Warrants, holders of the Class B Warrants had exercised 4,812,328 Class B Warrants, resulting in the issuance of 2,406,164 shares of the Company's common stock and the receipt by the Company of approximately \$9.6 million in gross proceeds. In June 2015, the Company completed a private placement of securities to institutional investors whereby the investors received an aggregate of 4,728,128 shares of the Company's common stock and warrants to purchase an additional 2,364,066 shares of common stock at an exercise price of \$8.00 per share. The Company received net proceeds of \$18.3 million, net of expenses. In August 2014, we completed our IPO, raising net proceeds of \$35.0 million, net of an underwriting discount, commissions and offering expenses. In connection with the IPO, our Board of Directors and stockholders approved a 1-for-7 reverse stock split of our common stock. The reverse stock split became effective on July 25, 2014. 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 \$25.1 million, \$30.1 million and \$23.6 million for the years ended December 31, 2015, 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 preclinical activities and clinical trials to seek regulatory approval and, if approved, commercialize such product candidates. Additionally, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We expect to seek to fund our operations through public or private equity, debt financings, equity-linked financings, collaborations, strategic alliances, licensing arrangements, research grants or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

# **Financial Operations Overview**

### Revenue

We have not generated any revenues to date. In the future, we may generate revenues from product sales. In addition, to the extent we enter into licensing or collaboration arrangements, we may have additional sources of revenue. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of payments that we may recognize upon the sale of our products, to the extent that any products are successfully commercialized, and the amount and timing of fees, reimbursements, milestone and other payments received under any future licensing or collaboration arrangements. If we fail to complete the development of our product candidates in a timely manner 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 recently concluded a Phase 1 single ascending dose study in healthy volunteers. This trial was a randomized, double-blind, placebo-controlled, dose-escalation trial designed to evaluate the safety, tolerability and PK of four different intravenous doses of CF-301 alone. Subjects were randomized to receive a single IV dose of CF-301 or placebo, each administered as a two hour infusion. We have worldwide development and commercial rights to CF-301 and expect to fund the future development and commercialization costs related to this program.

# CF-404: lead mAb program

CF-404 is a potent combination of three mAbs targeting the conserved regions of the influenza virus. CF-404 cross-reacts with all human seasonal strains of influenza, making it a highly specific therapeutic candidate for the treatment of patients with life-threatening varieties of influenza. We initiated IND-enabling activities prior to the end of 2014 and expect to file our IND 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.

To date, a large portion of our research and development work has related to the establishment of both our lysin and antibody platform technologies, the advancement of our research projects to discovery of clinical candidates, manufacturing and preclinical testing of our clinical candidates and Phase 1 clinical testing of CF-301, the first lysin to enter clinical trials in the U.S. In the future, we intend to continue using our employee and infrastructure resources across multiple development programs well as research projects. In the years ended December 31, 2015, 2014 and 2013, we recorded approximately \$15.0 million, \$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 categories, 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, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015	2014	2013
Personnel related	\$ 3,178,451	\$ 2,747,487	\$ 3,182,153
Product development	7,457,384	1,311,452	2,044,774
Laboratory costs	1,929,799	1,473,739	1,908,789
External research and licensing costs	1,324,425	1,956,861	1,175,221
Professional fees	724,486	663,039	591,609
Share-based compensation	389,967	715,475	230,629
Total research and development expense	\$ 15,004,512	\$ 8,868,053	\$ 9,133,175

The following table summarizes our research and development expenses by program for the years ended December 31, 2015, 2014 and 2013:

	Yes	Year Ended December 31,		
	2015	2014	2013	
CF-301	\$ 4,847,190	\$ 1,666,016	\$ 2,567,138	
CF-404	3,315,797	1,507,285	_	
Other research and development	3,273,107	2,231,790	3,153,255	
Personnel related and share-based compensation	3,568,418	3,462,962	3,412,782	
Total research and development expense	\$ 15,004,512	\$ 8,868,053	\$ 9,133,175	

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

- the scope, rate of progress and expense of our research and development activities;
- · clinical trial results;
- the terms and timing of regulatory approvals;
- · our ability to market, commercialize and achieve market acceptance for our product candidates in the future; and
- · the expense, filing, prosecuting, defending and enforcing of patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of CF-301, 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.

# Fair Value of Warrant Liability

In accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 820, Fair Value Measurements and Disclosures ("ASC 820"), we classify and account for our warrant liability as a level 3 financial instrument. The valuation of a level 3 financial instrument requires inputs that reflect our own assumptions that are both significant to the fair value measurement and unobservable. We calculate the fair value estimate of our warrant liability on a recurring basis at each measurement date, based on relevant market information.

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

- the expected term of the warrant, which we estimate to be the remaining contractual life;
- 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; and
- 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.

These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. If factors change and different assumptions are used, our warrant liability could be materially different in the future.

#### 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;
- 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.

### **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, 2015 and 2014

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014:

	Year Ended December 31,			
	2015	2014	Dollar Change	% Change
Operating expenses:				
Research and development	\$15,004,512	\$ 8,868,053	\$ 6,136,459	69%
General and administrative	\$10,060,825	\$ 8,067,858	\$ 1,992,967	25%
Other income (expense)	\$ (55,627)	\$(13,213,173)	\$13,157,546	(100)%

# Research and Development Expenses

Research and development expense was \$15.0 million for the year ended December 31, 2015, compared with \$8.9 million for the year ended December 31, 2014, an increase of \$6.1 million. This increase was primarily attributable to a \$4.7 million increase in expenditures on our product candidates as we initiated and concluded our Phase 1 clinical study of CF-301 and continued to progress CF-404 through IND-enabling studies and manufacturing activities. The increase was also due to a \$1.4 million increase in our research headcount and related salaries, benefits and laboratory costs in support of the discovery and study of additional product candidates.

# General and Administrative Expenses

General and administrative expense was \$10.1 million for the year ended December 31, 2015, compared with \$8.1 million for the year ended December 31, 2014, an increase of \$2.0 million. This increase was primarily attributable to an increase in our administrative and Board of Directors headcount, resulting in an \$1.0 million increase in expenses, a \$0.7 million increase in costs related to being a public company, including listing fees, filing fees, insurance and investor relations expenses, \$0.6 million in severance costs that did not occur in 2014, and a \$0.2 million increase in expenses related to business development activities. These increases were partially offset by a \$0.5 million decrease in our legal expenses.

# Other income (expense)

Other expense was \$0.1 million for the year ended December 31, 2015 compared with \$13.2 million for the year ended December 31, 2014, a decrease of \$13.1 million. In 2015, we had non-cash expense of more than \$0.1 million related to the change in fair value of our warrant liability, which was partially offset by interest income of less than \$0.1 million from our marketable securities. In 2014, we had non-cash interest charges of \$12.4 million related to our Convertible Notes and non-cash expense of \$1.2 million related to the change in fair value of our warrant and embedded derivatives liabilities, which were partially offset by \$0.4 million of income from the receipt of refundable state tax credits.

# Comparison of years ended December 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	Dollar Change	% Change
Operating expenses:				
Research and development	\$ 8,868,053	\$ 9,133,175	\$ (265,122)	(3)%
General and administrative	\$ 8,067,858	\$10,163,259	\$ (2,095,401)	(21)%
Other income (expense)	\$(13,213,173)	\$ (4,324,268)	\$ (8,888,905)	206%

# 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 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 convertible debt. To date, we have not generated any revenue from the sale of products. We have incurred losses and generated negative cash flows from operations since inception.

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

As of December 31, 2015, we had approximately \$32.9 million in cash, cash equivalents and marketable securities. We primarily invest our cash and cash equivalents in commercial money market accounts and our marketable securities in highly rated corporate debt securities.

In January 2016, we entered into a Sales Agreement with Cowen and Company, LLC ("Cowen") to sell shares of our common stock, with aggregate gross sales proceeds of up to \$30 million, through an "at the market" equity offering program under which Cowen will act as sales agent. As of the date of this report, we have not sold any shares under the program.

#### Cash flows

The following table shows a summary of our cash flows for the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015	2014	2013
Net cash provided by (used in):			
Operating activities	\$ (22,182,601)	\$ (14,864,762)	\$ (14,056,424)
Investing activities	\$ (21,600,084)	\$ (1,610,536)	\$ 1,588,570
Financing activities	\$ 28,033,013	\$ 38,052,481	\$ 8,726,860

#### 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, 2015 increased by \$7.3 million and \$8.1 million as compared to the comparable periods in 2014 and 2013, respectively. This is attributable to the increase in our loss from operations in 2015 as we advanced our product candidates and expanded our research and administrative headcount.

# Net cash (used in) provided by investing activities

Net cash used in investing activities in the years ended December 31, 2015 and 2014 resulted from the investment of our cash balances into marketable securities. Net cash provided by investing activities in the year ended December 31, 2013 resulted from the reduction of our restricted cash balances. As of December 31, 2015 and 2014, we had no restricted cash balances on our balance sheet.

#### Net cash provided by financing activities

Net cash provided by financing activities in the year ended December 31, 2015 resulted primarily from the completion of a private placement of our securities to institutional investors in June 2015, resulting in net proceeds of \$18.3 million and the exercise of the Class B Warrants issued as part of the Units sold in our IPO,

resulting in net proceeds of \$9.7 million. Net cash provided by financing activities in the year ended December 31, 2014 resulted from the issuance of approximately 6.9 million Units on the completion of our IPO, resulting in net proceeds of \$35.0 million and the issuance of approximately \$3.0 million of our Convertible Notes, which were converted into common stock on the closing of our IPO. In the year ended December 31, 2013, we received net proceeds of \$10.6 million from the issuance of Convertible Notes, which were converted into common stock on the closing of our IPO, and repaid approximately \$1.9 million of commercial debt.

#### **Funding requirements**

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

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

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

- the progress and results of the clinical trials of our lead product candidates;
- the scope, progress, results and costs of compound discovery, preclinical 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

#### 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**

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

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period

covered by this Annual Report on Form 10-K of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2015.

## Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2015, our internal control over financial reporting was effective.

This annual report does not include an attestation report of our registered public accounting firm on internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies".

#### **Changes in Internal Control Over Financial Reporting**

As required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of our internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded that there were no changes during the quarter ended December 31, 2015 that materially affected, or are 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

#### Director Biographical Information

Biographical information concerning each of our directors is set forth below:

Name	Age	Position
Steven C. Gilman, Ph.D.	63	Director, Chairman of the Board
Roger Pomerantz, M.D., F.A.C.P.	59	Director, Vice Chairman of the Board
Sol Barer, Ph.D.	68	Director, Lead Independent Director
Isaac Blech	66	Director
Julia P. Gregory, M.B.A	63	Director and Chief Executive Officer
David N. Low, Jr.	57	Director
Michael J. Otto, Ph.D.	67	Director
David A. Scheinberg, M.D., Ph.D.	59	Director
Cary W. Sucoff, J.D.	64	Director
Lawrence Yuan Tian, Ph.D.	61	Director

Steven C. Gilman, Ph.D. Dr. Gilman has served as Chairman of our board of directors since May 2015. Until 2015, he served as the Executive Vice President, Research & Development and Chief Scientific Officer at Cubist Pharmaceuticals, a biopharmaceutical company, until its acquisition by Merck & Co. Prior to joining Cubist in 2008, he served as Chairman of the Board of Directors and Chief Executive Officer of ActivBiotics, a privately held biopharmaceutical company. Previously, he worked at Millennium Pharmaceuticals, Inc., where he held a number of senior leadership roles including Vice President and General Manager of the Inflammation franchise, responsible for all aspects of the Inflammation business from early gene discovery to product commercialization. Prior to Millennium, he was Group Director at Pfizer Global Research and Development, where he was responsible for drug discovery of novel antibacterial agents as well as several other therapeutic areas. Dr. Gilman has also held scientific, business, and academic appointments at Wyeth, Cytogen Corporation, Temple Medical School, and Connecticut College. He currently serves on the board of directors of publicly traded companies Vericel Corporation and SCYNEXIS Inc., the Massachusetts Biotechnology Association and the Penn State University Biotechnology Advisory Board. Dr. Gilman received his Ph.D. and M.S. degrees in microbiology from Pennsylvania State University, his post-doctoral training at Scripps Clinic and Research Foundation, and received a B.A. in microbiology from Miami University of Ohio. He has authored over 60 publications and is an inventor on 7 patents. We believe that Dr. Gilman's significant scientific, executive and board leadership experience in the pharmaceutical and biotechnology industries qualifies him to serve as a member of our board of directors.

Roger J. Pomerantz, M.D., F.A.C.P. Dr. Pomerantz has served as a member of our board of directors since April 2014 and was appointed Vice Chairman in May 2014. Since 2014, Dr. Pomerantz has served as President and Chief Executive Officer of Seres Therapeutics, Inc., a biotechnology company. He has also served as Chairman of the board of directors of Seres since 2013. From 2011 to 2013, he was formerly Worldwide Head of Licensing & Acquisitions, Senior Vice President at Merck & Co., Inc. where he oversaw all licensing and acquisitions at Merck Research Laboratories. Previously, he served as Senior Vice President and Global Franchise Head of Infectious Diseases at Merck. Prior to joining Merck, Dr. Pomerantz was Global Head of Infectious Diseases for Johnson & Johnson Pharmaceuticals. He joined Johnson & Johnson in 2005 as President of Tibotec Pharmaceuticals, Inc. Dr. Pomerantz received his B.A. in Biochemistry at the Johns Hopkins University and his M.D. at the Johns Hopkins School of Medicine. He received post-graduate training at the Massachusetts General Hospital, Harvard Medical School and M.I.T. Dr. Pomerantz is Board Certified in both Internal Medicine and Infectious Diseases. He was Professor of Medicine, Biochemistry and Molecular Pharmacology, Chief of Infectious Diseases, and the Founding Director and Chair of the Institute for Human Virology and Biodefense at the Thomas Jefferson University and Medical School. He has developed nine drugs

approved world-wide in important diseases, including HIV, HCV, and tuberculosis. We believe that Dr. Pomerantz's significant scientific, executive and board leadership experience in drug development and in the pharmaceutical industry qualifies him to serve as a member of our board of directors.

Sol Barer, Ph.D. Dr. Barer has served as a member of our board of directors since April 2011. Dr. Barer served as our Chairman of the board of directors from February 2012 to May 2015. He was appointed Lead Independent Director in May 2015. Dr. Barer spent most of his professional career with the Celgene Corporation. He was Chairman from January 2011 until June 2011, Executive Chairman from June 2010 until Jan 2011 and Chairman and Chief Executive Officer from May 2006 until June 2010. Dr. Barer was the founder of the biotechnology group at the Celanese Research Company which was subsequently spun out to form Celgene. Dr. Barer serves as Chairman of the board of directors of the public companies Edge Therapeutics, InspireMD, and Medgenics, and the private company Centrexion and is on the board of directors of the public companies Aegerion Pharmaceuticals, Amicus Therapeutics and Teva Pharmaceutical Industries. He is an advisor to biopharmaceutical companies and not for profit organizations. He also serves as an investment advisor to the Israel Biotechnology Fund. In 2011 Dr. Barer was Chairman of the University of Medicine and Dentistry of New Jersey Governor's Advisory Committee which resulted in sweeping changes in the structure of New Jersey's medical schools and public research universities. He previously served as a Commissioner of the NJ Commission on Science and Technology. He was a member of the Board of Trustees of Rutgers University and served two terms as Chair of the Board of Trustees of BioNJ, the New Jersey biotechnology organization. We believe that Dr. Barer's significant scientific, executive and board leadership experience in the pharmaceutical and biotechnology industries qualifies him to serve as a member of our board of directors.

Isaac Blech. Mr. Blech has served as a member of our board of directors since August 2010. Mr. Blech is currently Vice Chairman of the board of directors of the public companies Cerecor, Inc., Edge Therapeutics, Inc., WaveGuide Corporation, root9B Technologies, Inc. and SpendSmart Payments Company and the private companies Centrexian Corporation, Regenovation, Inc. and X-4 Pharmaceuticals and Sapience Therapeutics. He is also on the board of directors of the public company Medgenics, Inc. Over the past 35 years, Mr. Blech has helped found some of the world's leading biotechnology companies, including Celgene Corporation, ICOS Corporation, Pathogenesis Corporation, Nova Pharmaceutical Corporation and Genetic Systems Corporation. These companies are responsible for major advances in oncology, infectious disease and cystic fibrosis. Mr. Blech earned a B.A. degree from Baruch College in 1975. We believe that Mr. Blech's broad experience as a founder, director and major investor in numerous biotechnology companies qualifies him to serve as a member of our board of directors.

Julia P. Gregory. Ms. Gregory has been our Chief Executive Officer since November 2013 and a director since April 2014, previously serving as Executive Vice President and Chief Financial Officer since July 2012. Prior to joining ContraFect, Ms. Gregory was President and Chief Executive Officer of Five Prime Therapeutics, Inc. ("Five Prime"), a clinical-stage, biotechnology company discovering and developing innovative protein and antibody therapeutics in the fields of oncology and immunology since 2009. Prior to Five Prime, Ms. Gregory was Executive Vice President, Corporate Development and Chief Financial Officer of Lexicon Pharmaceuticals, Inc. ("Lexicon"). While at Five Prime and Lexicon, she led transactions for several strategic partnerships including those with GlaxoSmithKline, Human Genome Sciences, Genentech, Inc., The Bristol-Myers Squibb Company and Takeda Pharmaceutical Company Limited. She was the Chief Financial Officer of Lexicon during its \$220 million initial public offering and was involved in the creation of Lexicon's \$500 million private equity investment plan with Invus, LLP. Prior to joining Lexicon, Ms. Gregory served as the head of investment banking for Punk, Ziegel & Company, a specialty technology and healthcare investment banking firm, and was an investment banker with Dillon, Read & Co., Inc. She has served as a director on the board of Clinipace, Inc. on behalf of and as Special Advisor to Morgan Stanley Expansion Capital and on the board of The Global TB Alliance for Drug Development, primarily funded by the Bill & Melinda Gates Foundation. Ms. Gregory received her B.A. from George Washington University's Elliott School of International Affairs, where she was elected to Phi Beta Kappa, and her M.B.A. from the Wharton School of the University of Pennsylvania. We

believe that Ms. Gregory's significant financial, executive leadership and board experience qualify her to serve as a member of our board of directors.

David N. Low, Jr. Mr. Low has served as a member of our board of directors since April 2014. Mr. Low has worked as an investment banker since 1987, with broad investment and advisory experience in the life sciences, biotechnology and medical technology sectors. Since 2013, Mr. Low has served as a Senior Advisor at Lazard Freres & Company, an investment bank. From 2002 to 2013, Mr. Low was a member of Lazard's Life Sciences Group as a Managing Director. Mr. Low has advised on major M&A transactions in the life sciences, biotechnology and medical technology sectors, and has worked with private and public companies to raise capital, including emerging growth companies. Prior to joining Lazard, Mr. Low was a Managing Director at JP Morgan Chase & Co. and a Senior Vice President at Lehman Brothers. Mr. Low serves on the board of directors of the We Teach Science Foundation (as Chairman), the Philharmonia Baroque Orchestra, and the French International School. Mr. Low holds an A.B. from Harvard College, where he graduated cum laude, an M.A. from the Johns Hopkins University School of Advanced International Studies and an M.B.A. from Yale University. We believe that Mr. Low's significant investment and financial advisory experience qualifies him to serve as a member of our board of directors.

Michael J. Otto, Ph.D. Dr. Otto has served as a member of our board of directors since April 2014. Dr. Otto served as Chief Scientific Officer of Pharmasset from October 1999 until February 2012, when the company was acquired by Gilead Sciences. He led the research team responsible for the discovery of sofosbuvir for the treatment of HCV infections. In previous capacities he has served as Associate Director of Anti-Infectives Clinical Research at Rhône-Poulenc Rorer, Vice President for Research and Development at Avid Therapeutics, Inc., Research Manager at DuPont Pharmaceuticals and Dupont Merck Pharmaceuticals and as Group Leader in the Virology Dept. at Sterling Drug in Rensselaer, NY. Prior to joining Sterling Drug, Dr. Otto was Research Assistant Professor at Yale University School of Medicine, Dept. of Pharmacology. Dr. Otto also served as the US editor for Antiviral Chemistry & Chemotherapy from 1989 until 2012. Dr. Otto holds a B.S. degree from Loyola University of Chicago and a Ph.D. degree in medical microbiology from The Medical College of Wisconsin. He is the author or coauthor of over 100 research papers and book chapters and named inventor on several patents and patent applications. We believe that Dr. Otto's substantial scientific and executive leadership experience in the pharmaceutical industry qualifies him to serve as a member of our board of directors.

David A. Scheinberg, M.D., Ph.D. Dr. Scheinberg has served as a member of our board of directors since June 2010. Since 2003, Dr. Scheinberg has been the Chairman, of the Molecular Pharmacology and Chemistry Program, Sloan-Kettering Institute. He also founded and chairs the Experimental Therapeutics Center at Memorial Sloan-Kettering Cancer Center, co-chairs the Pharmacology Graduate Program at the Weill-Cornell University Medical College, and is a professor in the Gerstner-Sloan Kettering Graduate School at MSKCC as well as at Weill Cornell Medical College. From 1992 until 2003 he was Chief of Leukemia Service at Memorial Hospital. In 2013 he was Interim Director of Sloan-Kettering Institute. A physician-scientist, Dr. Scheinberg specializes in the care of patients with leukemia. He investigates new therapeutic approaches to cancer, both in the hospital and in the laboratory. The focus of his research is the discovery and development of novel, specific immunotherapeutic agents. Eight therapeutic agents developed by Dr. Scheinberg-which include the first humanized antibodies to treat acute leukemia, the first targeted alpha particle therapies and alpha generators, and the first tumor-specific fusion oncogene product vaccines-have reached human clinical trials. He has published more than 200 peer-reviewed papers, chapters and books. In the private sector, Dr. Scheinberg was Founder and Chairman of the Board of Active Biotherapeutics, Inc., which was acquired by Progenics Pharmaceuticals. He is currently a Director of Progenics Pharmaceuticals, a public company, and a member of the scientific advisory boards of Oncopep and Ensysce pharmaceuticals. Dr. Scheinberg founded and is a Director of the Therapeutics Discovery Institute, a non-profit drug discovery corporation serving Rockefeller University, Weil Cornell Medical College and Memorial Sloan Kettering Cancer Center. He advises charitable foundations, cancer centers, and biotech companies and sits on several journal editorial boards. Dr. Scheinberg received his A.B., cum laude, distinction in all subjects, from the College of Arts and Sciences, Cornell University, in 1977. He earned his M.D. from Johns Hopkins University in 1983, and his Ph.D. from Johns Hopkins University School of

Medicine, Department of Pharmacology and Experimental Therapeutics, in 1983. We believe that Dr. Scheinberg's significant scientific, executive and board leadership experience in drug and biologic therapy development and in the pharmaceutical industry qualifies him to serve as a member of our board of directors.

Cary W. Sucoff. Mr. Sucoff has served on our board of directors since May 2010. Mr. Sucoff has more than 30 years of securities industry experience encompassing supervisory, banking and sales responsibilities. He has participated in the financing of more than 100 public and private companies, raising approximately \$500 million of equity capital and playing a role in securing financing for biotech companies including Amgen, Centecor, Genzyme, Genentech, Icos, PathoGenesis, Vaxgen and Biotime. Since 2011, Mr. Sucoff has owned and operated Equity Source Partners LLC, an advisory and consulting firm. In addition to ContraFect, Mr. Sucoff currently serves on the board of directors of The SpendSmart Payments Company, root9B Technologies, and Legacy Education Alliance, Inc. In addition, Mr. Sucoff currently serves as a consultant to Sapience Therapeutics. Mr. Sucoff is the President of New England Law/Boston, has been a member of the Board of Trustees for over 25 years and is the current Chairman of the Endowment Committee. Mr. Sucoff received a B.A. from SUNY Binghamton in 1974 and a J.D. from New England School of Law in 1977, where he was managing editor of the Law Review and graduated magna cum laude. He has been a member of the Bar of the State of New York since 1978. We believe that Mr. Sucoff's broad financial and legal experience qualifies him to serve as a member of our board of directors.

Lawrence Yuan Tian. Dr. Tian has served on our board of directors since May 2015. He has been the Chairman and Chief Executive Officer of CIFCO International Group since 2007. From 1992 to 2007, he was Chairman of the China International Futures Company, Ltd. Since 2010, Dr. Tian has been Chairman of the US-China Business Leaders Roundtable. In 2001, Dr. Tian founded and was elected Chairman of the China Entrepreneurs Forum. Dr. Tian has published numerous articles on economic policies, market reform and business development. Dr. Tian received his B.A., M.A. and Ph.D. in Economics from Wuhan University. We believe that Dr. Tian's significant international business experience and financial expertise qualifies him to serve as a member of our board of directors.

#### Executive Officers of the Registrant

Biographical information concerning each of our executive officers is set forth below. Information concerning Julia P. Gregory, our Chief Executive Officer, may be found above in the section entitled "Director Biographical Information."

Michael Wittekind, Ph.D. Dr. Wittekind, age 61, has served as our Senior Vice President and Chief Scientific Officer since August 2012. Prior to joining ContraFect, Dr. Wittekind served as the Executive Director of Research for Amgen Inc. ("Amgen"), a biopharmaceutical company, since 2003, where he directed the Protein Science Department at the Amgen-Seattle site. While at Amgen, he was involved in the discovery efforts for multiple protein therapeutics currently undergoing clinical trials, including antibodies, antibody-drug conjugates, and protein fusions. Previously, Dr. Wittekind was the Director of Process Development for Phylos Inc., where he played a key role in the development of alternate scaffold therapeutic discovery, design, and production. Dr. Wittekind has also served as the Associate Director of the Gene Expression and Protein Biochemistry Department of the Bristol-Myers Squibb Pharmaceutical Research Institute, directing groups in both the Lawrenceville and Hopewell, New Jersey sites leading structural biology research as well as protein and small molecule therapeutic efforts. Dr. Wittekind received his Ph.D. from the University of Wisconsin-Madison in Biochemistry and pursued his postdoctoral studies at the University of Washington. Dr. Wittekind's research interests have encompassed genetics, molecular biology, structural biology, and engineering of novel antibodies and proteins, resulting in over 40 publications and patents.

Cara Cassino, M.D. Dr. Cassino, age 54, has served as our Chief Medical Officer since September 2015. Dr. Cassino has over 20 years of experience as a clinician and executive in healthcare, including over 14 years of experience in pharmaceutical product development and over 20 successful regulatory submissions in the United

States and globally. Prior to joining ContraFect, Dr. Cassino served as Senior Vice President at Forest Laboratories, Inc., a biopharmaceutical company (acquired by Actavis plc, now Allergan plc), where she oversaw Global Clinical Development, since 2014. While at Forest, she was responsible for preand post-marketing clinical activities for a portfolio of 35 compounds, and also clinical due diligence for M&A activity including the \$2.9 billion acquisition of Aptalis Pharma and the \$1.1 billion acquisition of Furiex Pharmaceuticals. Previously, Dr. Cassino held a number of senior positions at Pfizer, including Global Medical Team Leader of Pfizer's antibacterial franchise which included Zyvox (linezolid) and Medicines Development Group VP for Pulmonary Vascular Disease and Rare Diseases. Dr. Cassino also served as Executive Medical Director for the late stage U.S. respiratory franchise at Boehringer-Ingelheim Pharmaceuticals, Inc, and was a member of the academic faculty of the Division of Pulmonary and Critical Care Medicine at New York University School of Medicine. Dr. Cassino received her BA, summa cum laude, in Chemistry and Fine Arts from New York University (NYU) where she was elected Phi Beta Kappa, followed by an M.D. from NYU School of Medicine. She completed her internship and residency in Internal Medicine at NYU/Bellevue Hospital and a fellowship in Pulmonary/Critical Care Medicine at NYU and Mount Sinai Medical Centers. Dr. Cassino is Board Certified in both internal medicine and pulmonary medicine.

Daniel Couto. Mr. Couto, age 44, currently serves as our Senior Vice President, Manufacturing & Facilities Operations. He has over 20 years of experience in Operations Management. Prior to joining ContraFect in 2011, he served as Vice President of Commercial Manufacturing Operations for Merck Sharp & Dohme Biologics UK Ltd. for three years. Previously, he was Director of Manufacturing for Nuvelo Inc. for three years, where he was responsible for seven worldwide contract manufacturing sites. Mr. Couto also served in similar director and senior management positions at Genzyme Transgenics Corp., Advanced Biosystems Corp., ImmuCell Corp. and Sepracor Corp. Mr. Couto holds patents for several novel separation technologies such as Bulk Protein Crystallization, High Performance Tangential Flow Filtration, and Simulated Moving Bed. Mr. Couto received his B.S. Degree in Chemical Engineering from Rensselaer Polytechnic Institute.

Josh Muntner. Mr. Muntner, age 47, has served as the Senior Vice President of Business Development since 2015. Mr. Muntner has more than 15 years of transaction experience assisting life sciences companies with financing and M&A advisory transactions. Prior to joining ContraFect, he served as Managing Director and Co-Head of Healthcare Investment Banking at Janney Montgomery Scott, a financial services firm from 2012 to 2015. Mr. Muntner was also a Managing Director at ThinkEquity, an investment bank from 2009 to 2012. Previously, Mr. Muntner spent nine years at Oppenheimer & Co. and its U.S. predecessor, CIBC World Markets, in positions of increasing responsibility. Mr. Muntner also served as an investment banker at Prudential Securities. Mr. Muntner received his B.F.A. degree from Carnegie Mellon and his M.B.A. degree from The Anderson School at UCLA.

Michael Messinger, CPA. Mr. Messinger, age 41, currently serves as our Vice President, Finance. He has more than 15 years of experience in finance, accounting and forecasting for clinical development. Prior to joining ContraFect in November 2012, he served as Director of Finance at Lexicon Pharmaceuticals, Inc. ("Lexicon") for eight years and also held the position of Controller for three years. Prior to working at Lexicon, Mr. Messinger served as Controller of Coelacanth Corporation (which was acquired by Lexicon) for two years. While at Lexicon, Mr. Messinger was responsible for the financial management of Lexicon's partnership with Symphony Capital, LLC, in addition to coordinating fiscal and program management concerning Lexicon's development programs. Mr. Messinger received his B.B.A. degree in accounting from the University of Michigan. He started his career as an auditor at Ernst & Young LLP.

Natalie Bogdanos, J.D. Ms. Bogdanos, age 47, currently serves as our General Counsel and Corporate Secretary. She has over 17 years of experience in the legal field. Prior to joining ContraFect in 2014, Ms. Bogdanos served as Associate General Counsel at Memorial Sloan-Kettering Cancer Center ("MSKCC") where she held a joint appointment with the Office of the General Counsel and the Office of Technology Development ("OTD"). At MSKCC, she provided legal counsel and guidance to various departments throughout the institution while having sole responsibility for the legal oversight of the OTD. She led the contracts group,

managed the institution's patent portfolio, provided regulatory guidance and compliance, and advised on litigation strategy. Prior to MSKCC, she was General Counsel at Enzo Biochem, Inc. ("Enzo"), a publicly-traded biotechnology company, from 2003 to 2012. At Enzo, she was responsible for leading the legal department, handling contracts and complex business development agreements, ensuring SEC and regulatory compliance, overseeing litigation and managing Enzo's portfolio of 500+ patents and patent applications. Previously, Ms. Bogdanos was an associate at Amster, Rothstein & Ebenstein from 1999 to 2003 where her practice focused on patent litigation and patent prosecution. Ms. Bogdanos has also served as a legal consultant to pharmaceutical companies and was a faculty member at the Practising Law Institute. Prior to attending law school, she was a research technician at the Public Health Research Institute where her work focused on Staphylococcus aureus. Ms. Bogdanos is an attorney licensed to practice before the United States Patent and Trademark Office. She is admitted to practice law in New York, the United States District Court, Southern and Eastern District of New York and the United States Court of Appeals for the Federal Circuit. Ms. Bogdanos received her Juris Doctor from New York Law School and her Bachelor of Arts in Biology, with honors, from Queens College of the City University of New York.

Nancy Dong. Ms. Dong, age 51, has served as Vice President and Controller of the Company since 2010. She has more than 20 years of experience in accounting, strategic planning, budgeting and forecasting, organizational development, financial systems and controls. She served as controller at XL Marketing, a direct marketing firm, from 2009 to 2010 and at Alley Corp, a company that provides strategic advice to companies within its network, from 2007 to 2009. She also served as Vice President of Finance and Administration at DCM, a tele-services firm supporting the performing arts, from 2002 to 2007. Ms. Dong also held the positions of COO/CFO at Semaphore, a project management software development firm. Ms. Dong received her B.A. degree from Yale University and a MPPM degree from The Wharton School at the University of Pennsylvania. She started her career as a management consultant at Ernst & Young LLP.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's executive officers and directors, and persons who own more than 10% common stock, to file reports of ownership and changes in ownership with the Securities and Exchange Commission ("SEC") and The NASDAQ Stock Market, LLC ("NASDAQ"). Executive officers, directors and greater than 10% stockholders are required by SEC regulations to furnish us with all copies of Section 16(a) forms they file. Specific due dates for these reports have been established and we are required to identify in this proxy statement those persons who failed to timely file these reports. Based solely on our review of these forms and written representations from the officers and directors received by us, we believe that during the fiscal year ended December 31, 2015, all Section 16(a) filing requirements were complied with in a timely fashion.

#### Code of Ethics

Our board of directors has adopted a Code of Ethics and Business Conduct applicable to all officers, directors and employees, which is available on our website at http://ir.contrafect.com/governance-docs. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Ethics and Business Conduct, as well as NASDAQ's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address specified above.

## Audit Committee

The members of our Audit Committee are Mr. Low, Dr. Pomerantz, and Mr. Sucoff. Our board of directors has determined that Mr. Low qualifies as an Audit Committee financial expert within the meaning of SEC regulations based on his formal education and the nature and scope of his previous experience. Our Audit Committee assists our board of directors in its oversight of our accounting and financial reporting process and the audits of our financial statements.

## **Item 11. Executive Compensation**

#### **Executive and Director Compensation**

We have elected to provide compensation disclosure pursuant to the reduced disclosure requirements applicable to emerging growth companies, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act.

Our executive compensation program, consisting of a three-part compensation strategy that includes base salary, annual performance-based cash bonuses and long-term equity incentive compensation, is designed to (i) pay for performance to encourage both Company and individual achievement; (ii) encourage efficient use of Company resources; and (iii) provide market competitive compensation to attract and retain highly qualified individuals who are capable of making significant contributions to the long-term success of the Company.

The Company does not adopt express formulae for weighting different elements of compensation or for allocating between long-term and short-term compensation but strives to develop comprehensive packages that are competitive with those offered by other companies with which the Company competes to attract and retain talented executives. Under the Company's compensation practices, cash compensation consists of an annual base salary and performance-based bonuses and equity-based compensation primarily consists of grants of stock options.

#### Named Executive Officers

Our named executive officers for 2015 set forth in this proxy statement (the "Named Executive Officers") are:

- Julia P. Gregory, M.B.A., Chief Executive Officer
- · Michael Wittekind, Ph.D., Chief Scientific Officer
- Daniel Couto, Senior Vice President, Manufacturing and Facilities Operations
- Barry Kappel, Ph.D., M.B.A., Senior Vice President, Business Development

#### 2015 Summary Compensation Table

We are an emerging growth company and have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined under the Securities Exchange Act of 1934, which require compensation disclosure for our principal executive officer and the two most highly-compensated executive officers other than our principal executive officer. The table below sets forth the annual compensation earned during fiscal years 2015 and 2014 by our Named Executive Officers.

Name and Principal Position		Salary (\$)	Bonus (\$) (1)	Stock Awards (\$)	Opt	tion Awards (\$) (2)	All Other pensation (\$)	Total (\$)
Julia P. Gregory, M.B.A.  Chief Executive Officer	2015	\$489,250	\$171,238	\$ —	\$	909,651	\$ 39,973(3)	\$1,610,112
	2014	\$475,000	\$237,500	\$331,504	\$	981,415	\$ 31,564	\$2,056,983
Michael Wittekind, Ph.D.  Chief Scientific Officer	2015	\$330,215	\$ 79,053	\$ —	\$	344,792	\$ 39,973(3)	\$ 794,033
	2014	\$313,000	\$114,808	\$142,415	\$	136,976	\$ 31,564	\$ 738,764
Daniel Couto Sr. Vice President, Manufacturing and Facilities Operations	2015	\$300,000	\$ 69,030	\$ —	\$	149,910	\$ 32,023(4)	\$ 550,963
Barry Kappel, Ph.D (5) Sr. Vice President, Business Development	2015	\$ 78,750	\$ —	\$ —	\$	309,758	\$ 521,733(6)	\$ 910,241
	2014	\$270,000	\$110,860	\$ 98,280	\$	130,200	\$ 31,564	\$ 640,905

- (1) Represents annual bonuses earned under our performance-based bonus program.
- (2) The amounts reported in the "Option Awards" column reflect the aggregate grant date fair value of stock options awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standard Codification, or ASC, Topic 718, disregarding estimated forfeitures. See Note 11 to our financial statements included with this Annual Report on Form 10-K regarding assumptions underlying the valuation of these equity awards. For Dr. Kappel, the amount reported also includes \$99,090 of share-based compensation expense representing the incremental fair value, determined in accordance with ASC, Topic 718, with respect to the modification of options to purchase an aggregate of 42,678 shares of our common stock. Refer to the description of Dr. Kappel's separation and consulting agreement under the heading "Employment Agreements" for additional information.
- (3) The amounts reported in the "All Other Compensation" column include the sum of the incremental cost to us of all perquisites and other personal benefits, which are comprised of \$32,023 for medical and life insurance costs paid by us and \$7,950 of employer 401(k) contributions made by us on behalf of each Named Executive Officer.
- (4) The amount reported in the "All Other Compensation" column includes the sum of the incremental cost to us of all perquisites and other personal benefits, which is comprised of \$32,023 for medical and life insurance costs paid by us for the Named Executive Officer.
- (5) Dr. Kappel resigned from his position as Senior Vice President of Business Development on April 15, 2015 and served as a consultant to us until December 31, 2015.
- (6) Includes \$513,783 in severance payments pursuant to the terms of a separation and consulting agreement that we entered into with Dr. Kappel in connection with his resignation as our Senior Vice President of Business Development. Refer to the description of Dr. Kappel's separation and consulting agreement under the heading "Employment Agreements" for additional information.

# Outstanding Equity Awards at 2015 Fiscal Year-End

The following table sets forth information regarding outstanding stock options held by our Named Executive Officers as of December 31, 2015:

		Option Awards		
Name and Principal Position	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Option exercise price (\$/share)	Option expiration date
Julia P. Gregory  Chief Executive Officer	67,142 43,927 199,999 75,850	14,644(1) 142,858(2) 227,550(3)	3.50 3.50 4.27 4.61	8/10/2022 2/26/2023 4/28/2024 2/6/2025
Michael Wittekind, Ph.D.  Chief Scientific Officer	20,571 8,571 9,642 10,714 20,000 28,750	3,215(1) 10,714(4) 20,000(5) 86,250(3)	3.50 3.50 3.50 4.27 2.91 4.61	3/31/2022 8/10/2022 2/26/2023 4/28/2024 10/28/2024 2/6/2025
Daniel Couto Senior Vice President, Manufacturing and Facility Operations	14,285 7,142 476 7,142 12,321 7,143 7,143 12,500	4,107(1) 7,142(6) 7,142(4) 37,500(3)	3.50 3.50 3.50 3.50 3.50 4.27 4.27 4.61	3/6/2021 9/2/2021 11/28/2021 3/6/2022 2/26/2023 3/20/2024 4/28/2024 2/6/2025
Barry Kappel, Ph.D., M.B.A Senior Vice President, Business Development	9,285 3,571 2,857 7,142 11,428 1,894 5,714 4,017 10,714 13,392 15,000 21,875 35,550	       	3.50 3.50 3.50 3.50 3.50 3.50 3.50 4.27 4.27 2.89 4.61 5.89	4/15/2020 9/1/2020 12/31/2017 12/31/2017 12/31/2017 12/31/2017 12/31/2017 12/31/2017 12/31/2017 12/31/2017 3/30/2016 3/30/2016 3/30/2016

- (1) 25% of the shares underlying the option vested on January 1, 2013 and the remaining shares vest over three years with 25% of the shares underlying the option vesting annually thereafter.
- (2) The shares underlying the option vest over three years beginning on April 1, 2014, with 8.33% of the shares underlying the option vesting at the end of each calendar quarter thereafter.
- (3) The shares underlying the option vest over four years beginning on January 1, 2015, with 6.25% of the shares underlying the option vesting at the end of each calendar quarter thereafter.
- (4) 25% of the shares underlying the option vested on April 29, 2014 and the remaining shares vest over three years with 25% of the shares underlying the option vesting annually thereafter.
- (5) 25% of the shares underlying the option vested on October 28, 2014 and the remaining shares vest over three years with 25% of the shares underlying the option vesting annually thereafter.
- (6) 25% of the shares underlying the option vested on February 24, 2014 and the remaining shares vest over three years with 25% of the shares underlying the option vesting annually thereafter.

#### **Employment Agreements**

#### Julia P. Gregory

On April 29, 2014, we entered into an employment agreement with Julia Gregory, our current Chief Executive Officer, for a period of one year beginning on April 1, 2014, and amended the CEO Agreement on August 10, 2015 (together, the "CEO Agreement"). The CEO Agreement automatically renews for an additional one-year term unless we or Ms. Gregory elect to terminate the CEO Agreement at the expiration of the then-current one-year term. During the term of the CEO Agreement, Ms. Gregory is paid an annual base salary of \$489,250, subject to an increase by us, and is eligible to earn an annual performance bonus in an amount up to 50% of her base salary for each calendar year. In connection with the execution of the CEO Agreement, Ms. Gregory was granted a stock option covering 342,857 shares, which vests in equal quarterly installments over a period of three years. In the event that Ms. Gregory ceases to serve as Chief Executive Officer but remains employed by us in another capacity, she will forfeit any unvested portion of the options granted to her in connection with the execution of the CEO Agreement, after giving effect to accelerated vesting of a prorated portion of the option that would have become vested at the end of the then-current quarter.

In the event that Ms. Gregory is terminated without cause or resigns for good reason during the term of the CEO Agreement other than in connection with a change in control, then, subject to the execution and non-revocation of a release of claims, she is eligible to receive severance consisting of: (i) an amount equal to two times Ms. Gregory's base salary, paid over 18 months following the date of termination; (ii) deemed vesting of 100% of options granted to Ms. Gregory during the period she was serving as our Chief Financial Officer; (iii) accelerated vesting of the portion of the options granted to Ms. Gregory in connection with the execution of the CEO Agreement that would have vested through March 31 of the year following the year in which termination occurs; and (iv) applicable premiums pursuant to COBRA for 12 months from the date of termination for Ms. Gregory and her dependents.

If a change in control occurs during Ms. Gregory's term of employment, the term of the CEO Agreement will expire no earlier than one year from the date of the change in control. If Ms. Gregory's employment is terminated without cause or she resigns for good reason within twelve months following a change of control (and, in certain circumstances, if she is terminated without cause prior to the consummation of a change in control but following the execution of an agreement or approval by our board of directors that would result in a change in control), she will receive the following benefits, subject to the execution and non-revocation of a release of claims: (1) an amount equal to 2.25 times Ms. Gregory's base salary, paid over 18 months; (2) accelerated vesting of 100% of unvested equity awards; and (3) payment of COBRA premiums for 18 months. Ms. Gregory's estate will receive these benefits should her death occur: (1) during the term of her employment; and (2) during the time period commencing three months prior to the consummation of a change in control and ending 12 months following the consummation thereof.

Ms. Gregory is subject to non-competition and non-solicitation provisions during the term and for one year following any termination of employment.

#### Michael Wittekind, Ph.D.

In March 2012, we entered into a three-year employment agreement with Dr. Wittekind, to serve, at will, as Chief Scientific Officer. After the three-year period, the agreement renews for successive one-year terms unless terminated by either party. For 2015, Dr. Wittekind received an annual base salary of \$330,215 and was eligible to receive an annual bonus equivalent to 35% of his annual salary, payable in cash and subject to performance against mutually agreed-upon goals. Effective January 1, 2016, Dr. Wittekind's annual base salary was increased to \$338,000.

Effective November 12, 2015, we entered into an amendment to Dr. Wittekind's employment agreement. In the event that Dr. Wittekind is terminated without cause or resigns for good reason, he is eligible for (i) severance

payments equal to 12 months of base salary continuation; (ii) a payment equal to twelve (12) months of bonus; and (iii) payments of COBRA premiums for 12 months. If there is a change of control and, within 12 months of such change in control, Dr. Wittekind is terminated without cause or resigns for good reason, he will receive the severance payments outlined above and, in addition, any then-outstanding stock options and equity awards will become immediately fully vested and exercisable. Any severance payment is subject to Dr. Wittekind's executing and not revoking a release of claims. Dr. Wittekind is subject to non-competition and non-solicitation provisions during the term of his agreement and for one year following termination.

#### **Daniel Couto**

In March 2011, we entered into a three-year employment agreement with Mr. Couto, to serve, at will, as Vice President of Product Development. After the three-year period, the agreement renews for successive one year terms unless terminated by either party. In February 2014, Mr. Couto's title changed to Senior Vice President, Manufacturing and Facilities Operations. For 2015, Mr. Couto received an annual base salary of \$300,000 and was eligible to receive an annual bonus equivalent to 30% of his annual salary payable in cash. Effective January 1, 2016, Mr. Couto's base salary was increased to \$309,300.

On November 2, 2015, we entered into an amendment to Mr. Couto's employment agreement. In the event that Mr. Couto is terminated without cause or resigns for good reason, he is eligible for (i) severance payments equal to 12 months of base salary continuation; (ii) a payment equal to twelve (12) months of bonus; and (iii) payments of COBRA premiums for 12 months. If there is a change of control and, within 12 months of such change in control, Mr. Couto is terminated without cause or resigns for good reason, he will receive the severance payments outlined above and any then-outstanding stock options and equity awards will become immediately fully vested and exercisable. Any severance payment is subject to Mr. Couto's executing and not revoking a release of claims. Mr. Couto is subject to non-competition and non-solicitation provisions during the term of his agreement and for one year following termination.

#### Barry Kappel, Ph.D., M.B.A.

In October 2009, we entered into a three-year employment agreement with Dr. Kappel, to serve, at will, as Head, Business Development. After the three-year period, the agreement renews for successive one year terms unless terminated by either party. In February 2014, Dr. Kappel's title changed to Senior Vice President, Business Development. For 2015, Dr. Kappel received an annual base salary of \$270,000 and was eligible to receive an annual bonus equivalent to 30% of his annual salary payable in cash. Dr. Kappel resigned from his position on April 15, 2015.

In connection with Dr. Kappel's resignation, we entered into a separation and consulting agreement with him whereby he agreed to provide consulting services to us until December 31, 2015 and we agreed to provide Dr. Kappel (i) a cash payment of \$465,750, of which \$135,000 was paid in a lump sum, with the remainder paid in twenty-four monthly installments beginning in May 2015, (ii) a fully vested stock option covering 35,550 shares that remains exercisable until March 30, 2016, (iii) payments of COBRA premiums for 18 months, and (iv) payment accrued but unused vacation days. In exchange for Dr. Kappel's consulting services, we also agreed to provide accelerated vesting of all of Dr. Kappel's outstanding, unvested stock options.

#### 2015 Cash Bonuses

Each Named Executive Officer is eligible to receive an annual performance-based cash bonus based on achievement of individual performance goals and Company goals, determined by our Compensation Committee at the beginning of each year. Each Named Executive Officer has a target annual bonus award amount, expressed as a percentage of the Named Executive Officer's base salary. For 2015, each Named Executive Officer other than Dr. Kappel was eligible to earn a cash bonus of up to \$244,625 for Ms. Gregory, \$118,300 for Dr. Wittekind, and\$92,790 for Mr. Couto. Dr. Kappel did not receive a 2015 bonus.

As soon as practical after the year is completed, our Compensation Committee reviews actual performance against the stated Company goals and individual goals and determines subjectively what it believes to be the appropriate level of cash bonus, if any, for the Named Executive Officers. For 2015, the Company goals and objectives primarily related to research, clinical and financing activities. Individual goals were based on each person's specific expertise and experience.

In February 2016, our Compensation Committee reviewed the performance of the Company and of each individual executive against the 2015 Company and individual goals and objectives and elected to pay bonuses to the Named Executive Officers. The amounts awarded to each Named Executive Officer for 2015 performance are set forth in the Summary Compensation Table in the column entitled "Bonus."

#### **Equity and Other Compensation Plans**

We generally offer stock options to our employees, including our Named Executive Officers, as the long- term incentive component of our compensation program. Our stock options generally allow employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant and may be intended to qualify as "incentive stock options" under the Internal Revenue Code. As of March 9, 2016, a total of 4,761,372 shares of our common stock were reserved for issuance under our equity incentive plans, with 4,290,542 subject to outstanding awards and 470,831 shares available for the issuance of future awards.

Our stock options typically vest either (a) as to 25% of the shares subject to the option on the first anniversary of the date of grant and in equal quarterly installments over the ensuing 36 months or (b) as to all of the shares subject to the option, ratably on a quarterly basis over a four-year period following the date of grant, in either case subject to the holder's continued employment with us as of each applicable vesting date. From time to time, our board of directors may also construct alternate vesting schedules as it determines are appropriate to motivate particular employees.

We awarded stock options to our Named Executive Officers during 2015 in the following amounts:

Named Executive Officer	2015 Options Granted
Julia P. Gregory	303,400
Michael Wittekind, Ph.D	115,000
Daniel Couto	50,000
Barry Kappel, Ph.D., M.B.A	85,550

These options were granted with exercise prices equal to the fair market of our common stock on the date of grant, as determined by our board of directors. The shares granted to Ms. Gregory and Messrs. Wittekind and Couto vest over four years, with 6.25% of the shares underlying the option vesting at the end of each calendar quarter. The shares granted to Dr. Kappel vested in accordance with the terms of his separation and consulting agreement.

#### 401(k) Retirement Plan

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code. In general, all of our employees are eligible to participate beginning on the first day of their employment. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit, generally equal to \$18,000 for 2015, and have the amount of the reduction contributed to the 401(k) plan. In 2015, the Company implemented a cash matching program whereby it contributes, on a dollar-for-dollar basis, an amount equal to 50% of employee contributions up to 3% of an employee's salary.

#### 2015 Director Compensation

Our non-employee directors are compensated on annual basis for their services on the board of directors as follows:

- each non-employee director receives an annual cash retainer of \$40,000;
- each non-employee director receives an annual stock option grant to purchase 15,000 shares of our common stock, generally granted on or about the Annual Meeting Date;
- the Chairman of the board of directors, each Chairman of a committee of the board of directors or a member of a committee of the board of directors, receives additional cash compensation as follows:
  - Chairman of the board of directors receives an additional annual retainer of \$160,000;
  - Lead Director of the board of directors receives an additional annual retainer of \$20,000;
  - Vice Chairman of the board of directors receives an additional annual retainer of \$10,000;
  - Chairman of the Audit Committee receives an additional annual retainer of \$15,000;
  - Chairman of the Compensation Committee receives and additional annual retainer of \$10,000;
  - Chairman of each of the Science and Technology Committee and the Nominating and Corporate Governance Committee receives an additional annual retainer of \$7,500; and
  - member of the Compensation Committee, Science and Technology Committee or the Nominating and Corporate Governance Committee —with respect to each such membership, an additional annual retainer of \$5,000; member of the Audit Committee receives an additional annual retainer of \$7,500.
- each non-employee director receives an initial stock option grant to purchase 30,000 shares of our common stock upon being appointed to the board, granted as soon as reasonably practicable following the director's appointment.

We generally grant stock options to our non-employee directors as soon as reasonably practical after the Annual Meeting as compensation for their service on our board of directors in the coming year. These stock options have an exercise price equal to the fair market value of our common stock on the date of grant and have a term of ten years from the date of grant, subject to the director's continued service on our board of directors. The stock options vest as to 25% of the original number of shares underlying such options at the end of each calendar quarter following the date of grant.

The initial stock options granted to non-employee directors upon joining the board have an exercise price equal to fair market value on the date of grant and have a term of ten years from the date of grant, subject to the director's continued service. The initial option grant vests 25% on the date of grant and 25% on each of the first three anniversaries of the date of grant.

Each member of our board of directors is also entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of the board of directors and any committee on which he serves.

In May 2015, Dr. Steven Gilman was elected to the board of directors. In addition to the cash and equity compensation paid under our non-employee director compensation program described above, Dr. Gilman received an option to purchase 170,000 shares of our common stock that vests ratably over a three-year period.

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2015 to each of our non-employee directors:

	Fees Earned or Paid in	Option Awards	Other	
Name	Cash (\$)	(\$) (2)(4)	Compensation (\$)	Total (\$)
Steven Gilman, Ph.D.	\$ 150,000	\$598,664	\$ —	\$748,664
Sol Barer, Ph.D.	\$ 75,000	\$ 49,357	\$ —	\$124,357
Roger Pomerantz, M.D., F.A.C.P.	\$ 65,000	\$ 49,357	\$ —	\$114,357
Isaac Blech.	\$ 54,375	\$ 49,357	\$ —	\$103,732
David N. Low, Jr.	\$ 55,000	\$ 49,357	\$ —	\$104,357
Michael J. Otto, Ph.D.	\$ 45,000	\$ 49,357	\$ —	\$ 94,357
David Scheinberg, M.D., Ph.D.	\$ 55,000	\$ 49,357	\$ —	\$104,357
Cary Sucoff.	\$ 45,625	\$ 49,357	\$ —	\$ 94,982
Lawrence Yuan Tian, Ph.D	\$ 30,000	\$100,740	\$ 100,000(3)	\$230,740
Shengda Zan (1)	\$ 10,000(1)	\$ —	\$ —	\$ 10,000

- (1) Resigned from the position of director on May 4, 2015. All unvested portions of outstanding stock option grants were immediately forfeited.
- (2) The amounts reported in the "Option Awards" column reflect the aggregate grant date fair value of stock options compensation awarded during the year computed in accordance with the provisions of ASC, Topic 718. See Note 11 to our financial statements included with this Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.
- (3) Represents compensation received under a consulting agreement we entered into with CIFCO International Group in April of 2013.
- (4) The following table shows the number of outstanding option awards held by each non-employee director as of December 31, 2015. None of our non-employee directors held unvested stock awards as of December 31, 2015.

Name	Option Awards (#)
Steven Gilman, Ph.D.	200,000
Sol Barer, Ph.D.	162,854
Roger Pomerantz, M.D., F.A.C.P.	68,571
Isaac Blech	162,853
David N. Low, Jr.	48,571
Michael J. Otto, Ph.D.	48,571
David Scheinberg, M.D., Ph.D.	102,853
Cary Sucoff	119,995
Lawrence Yuan Tian, Ph.D.	30,000
Shengda Zan	51,246

#### Compensation Risk

The Compensation Committee, in consultation with management, has reviewed the design and operation of the Company's compensation arrangements and evaluated the relationship between the Company's risk management policies and practices and these arrangements. As a result of this review, the Compensation Committee has determined that the Company's compensation policies and practices are not reasonably likely to have a material adverse effect on the Company.

# Compensation Committee Interlocks and Insider Participation

The compensation committee currently consists of David A. Scheinberg, M.D., Ph.D., who serves as chairman, Sol Barer, Ph.D. and Isaac Blech.

During 2015, none of our executive officers served as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the members of our compensation committee has ever been an employee of the Company.

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

## Security Ownership Of Certain Beneficial Owners And Management

The following table sets forth information as of March 9, 2016 as to the shares of our common stock beneficially owned by:

- · each of our directors;
- · each of our Named Executive Officers;
- all of our directors and executive officers as a group; and
- · each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our outstanding shares of common stock.

Ownership information is based upon information furnished by the respective individuals or entities, as the case may be. Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. The percentage of common stock beneficially owned is based on 27,484,005 shares outstanding as of March 9, 2016. Shares of our common stock subject to options or warrants that are currently exercisable or exercisable within 60 days of March 9, 2016 are considered outstanding and beneficially owned by the person holding the options or warrants for the purposes of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as disclosed in the footnotes to this table and subject to applicable community property laws, we believe that each person or entity identified in the table possesses sole voting and investment power over all shares of common stock shown as beneficially owned by such person or entity. Except as otherwise set forth below, the address of the beneficial owner is c/o ContraFect Corporation, 28 Wells Avenue, 3rd Floor, Yonkers, New York 10701.

	Number of Shares of Common Stock Beneficially Owned	Percentage of Shares Beneficially Owned (%)
5% Stockholders:		
Broadfin Capital, LLC. (1)	2,127,659	7.5
Jack W. Schuler (2)	2,127,659	7.5
Ernest W. Moody Revocable Trust (3)	2,000,000	7.0
Oracle Associates, LLC (4)	1,773,048	6.3
Shengda Zan (5)	1,571,240	5.7
Adage Capital Partners, L.P. (6)	1,500,000	5.5
Directors and Named Executive Officers:		
Steven Gilman, Ph.D. (7)	50,000	*
Sol Barer, Ph.D. (8)	1,381,924	4.9
Roger J. Pomerantz, M.D. F.A.C.P. (9)	61,428	*
Isaac Blech (10)	1,443,657	5.2
David N. Low, Jr. (11)	91,835	*
Michael J. Otto, Ph.D. (12)	41,428	*
David Scheinberg, M.D., Ph.D. (13)	124,337	*
Cary Sucoff (14)	189,992	*
Lawrence Yuan Tian, Ph.D. (15)	23,571	*
Julia P. Gregory (16)	517,416	1.9
Michael Wittekind, Ph.D. (17)	136,899	*
Daniel Couto (18)	85,026	*
Barry Kappel, Ph.D. (19)	158,721	*
All current directors and executive officers as a group (17 persons) (20)	4,368,547	14.7

- \* Represents beneficial ownership of less than one percent of our outstanding common stock.
- (1) Based solely on a Schedule 13G filed with the SEC on February 16, 2016 by Broadfin Capital, LLC, Broadfin Healthcare Master Fund, Ltd. and Kevin Kotler (the "Broadfin Reporting Persons"). The address for Broadfin Capital, LLC and Kevin Holter is 300 Park Avenue, 25th Floor, New York, New York 10022. The address for Broadfin Healthcare Master Fund, Ltd. is 20 Genesis Close, Ansbacher House, P.O. Box 1344, Grand Cayman KY1-1108, Cayman Islands. Consists of (a) 1,418,439 shares of common stock and (b) 709,220 shares of common stock underlying warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date. Each of the Broadfin Reporting Persons has shared voting and dispositive power over all such shares.
- (2) The address for Jack W. Schuler is c/o Crabtree Partners, 100 W. Field Drive, Suite 360, Lake Forest, IL 60045. Consists of (a) 1,418,439 shares of common stock and (b) 709,220 shares of common stock underlying warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.

- (3) The address for the Ernest W. Moody Revocable Trust (the "Trust") is 2116 Redbird Drive, Las Vegas, NV 89134. Consists of shares of common stock and shares of common stock underlying warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date. The Trust has sole voting and dispositive power over all such shares.
- (4) Based solely on a Schedule 13G filed with the SEC on June 26, 2015 by Oracle Associates, LLC, Oracle Partners, L.P., Oracle Institutional Partners, L.P. and Larry Feinberg (the "Oracle Reporting Persons"). The address for each of the Oracle Reporting Persons is 200 Greenwich Avenue, 3<sup>rd</sup> Floor, Greenwich, Connecticut 06830. Consists of (a) 1,182,032 shares of common stock and (b) 591,016 shares of common stock underlying warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date. Oracle Associates, LLC and Larry Feinberg have shared voting and dispositive power over all such shares. Oracle Partners, L.P. has shared voting and dispositive power over 1,418,439 shares. Oracle Institutional Partners, L.P. has shared voting and dispositive power over 354,609 shares.
- (5) Shengda Zan, a former member of our board of directors, is the sole director of Alpha Spring Limited. The address for Alpha Spring Limited is P.O. Box 957, Offshore Incorporations Centre, Road Town, Tortola, British Virgin Islands. Consists of (a) 1,337,036 shares of common stock and (b) 234,204 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (6) Based solely on a Schedule 13G filed with the SEC on January 28, 2016 by Adage Capital Partners, L.P., Adage Capital Partners GP, L.L.C., Adage Capital Advisors, L.L.C., Robert Atchinson and Phillip Gross (the "Adage Reporting Persons"). The address for each of the Adage Reporting Persons is 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116. Consists of shares of common stock as of March 9, 2016. Each of the Adage Reporting Persons has shared voting and dispositive power over all such shares.
- (7) Consists of 50,000 shares of common stock underlying options that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (8) Consists of (a) 775,932 shares of common stock and (b) 605,992 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (9) Consists of 61,428 shares of common stock underlying options that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (10) Consists of (a) 1,280,804 shares of common stock and (b) 162,853 shares of common stock underlying options that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (11) Consists of (a) 30,550 shares of common stock and (b) 61,285 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (12) Consists of 41,428 shares of common stock underlying options that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (13) Consists of (a) 15,770 shares of common stock and (b) 108,567 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (14) Consists of 189,992 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (15) Consists of 23,571 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (16) Consists of (a) 50,282 shares of common stock and (b) 467,134 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (17) Consists of (a) 17,893 shares of common stock and (b) 119,006 shares of common stock underlying options that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (18) Consists of 85,026 shares of common stock underlying options that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.
- (19) Consists of (a) 14,032 shares of common stock and (b) 144,689 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.

(20) Consists of (a) 2,203,008 shares of common stock and (b) 2,165,539 shares of common stock underlying options and warrants that are exercisable as of March 9, 2016 or will become exercisable within 60 days after such date.

#### **Equity Compensation Plan Information**

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (3)	Weighted- average exercise price of outstanding options, warrants and rights (3)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)  (3)(4)
Equity compensation plans approved by security holders (1)	1,613,053	\$ 4.47	16,179
Equity compensation plans not approved by security holders (2)	2,032,833	\$ 4.10	<u> </u>

- (1) Consists of the 2014 Omnibus Incentive Plan (the "2014 Plan").
- (2) Consists of the Amended and Restated 2008 Equity Incentive Plan.
- (3) As of December 31, 2015.
- (4) 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 December 31 immediately preceding such date or (ii) a lesser amount determined by the Company's board of directors.

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

#### Certain Relationships and Related Transactions

#### **Indemnification Agreements**

We have entered into indemnification agreements with each of our directors and executive officers in which we agree to indemnify, defend and hold harmless, and also advance expenses as incurred, to the fullest extent permitted under applicable law, from damage arising from the fact that such person is or was an officer or director of the Company or any of its subsidiaries. We maintain insurance policies for director and officer liability providing for maximum coverage in the amount of \$20 million.

#### Policies and Procedures for Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which we are a participant, the amount involved exceeds \$120,000 and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person", has a direct or indirect material interest.

Company management is responsible for determining whether a transaction meets the requirements of a related person transaction requiring review under the related person transaction policy. If review is deemed to be required under the policy, it is the responsibility of the Audit Committee to review related person transactions and approve, ratify, revise or reject related person transactions. The Audit Committee will consider all relevant facts and circumstances and will only ratify those transactions that are in our best interests. If a related party transaction involves a related person who is a director or immediate family member of a director, such director may not participate in the deliberations or vote respecting such transaction; provided, however, that such director may be counted in determining the presence of a quorum at a meeting of the Audit Committee which considers such transaction. If management determines it is impractical or undesirable to wait until an Audit Committee meeting to consummate a transaction with a related person, the chairperson of the Audit Committee may approve

the transaction with the related person. Any such approval must be reported to the Audit Committee at the next regularly scheduled meeting.

The following transactions involving related persons are pre-approved under the related party transaction policy:

- any employment by us of an executive officer, if: (i) the related compensation is required to be reported in our proxy statement under Item 402 of the SEC's compensation disclosure requirements (generally applicable to "named executive officers"); or (ii) the executive officer is not an immediate family member of another executive officer or director, the related compensation would be reported in our proxy statement under Item 402 of the SEC's compensation disclosure requirements if the executive officer was a "named executive officer," and the Compensation Committee approved (or recommended that the Board approve) such compensation;
- any compensation or benefits paid to a director for service as a director, as long as the Board has approved such compensation or benefits;
- any transaction with another company at which a related person's only relationship is as an employee (other than an executive officer), director
  or beneficial owner of less than 10% of that company's shares, if the aggregate amount involved does not exceed the greater of \$1,000,000 or 2
  percent of that company's total annual revenues;
- any charitable contribution, grant or endowment by us to a charitable organization, foundation or university in which a related person's only relationship is as an employee (other than an executive officer), or a director or trustee, if the aggregate amount involved does not exceed the greater of \$250,000 or 2 percent of the charitable organization's total annual receipts;
- any transaction where the related person's interest arises solely from the ownership of a class of our equity securities and all holders of that class of equity securities received the same benefit on a pro rata basis (e.g., dividends);
- any transaction with a related person involving the rendering of services as a common or contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; and
- any transaction with a related person involving services as a bank depositary of funds, transfer agent, registrar, trustee under a trust indenture, or similar services.

# **Director Independence**

Except as may otherwise be permitted by the applicable listing standards of NASDAQ, a majority of the members of the board of directors shall be independent directors. The board of directors has determined that Dr. Gilman, Dr. Barer, Mr. Blech, Mr. Low, Dr. Otto, Dr. Pomerantz, Dr. Scheinberg and Mr. Sucoff qualify as independent directors under the applicable listing standards of NASDAQ. The board of directors has also determined that each director who currently serves on the Audit Committee is independent under the applicable listing standards of NASDAQ and Rule 10A-3 under the Exchange Act, that each director who currently serves on the Compensation Committee meets NASDAQ's heightened standard of independence applicable to compensation committee members, and that each director who currently serves on the Nominating and Corporate Governance Committee is independent under the applicable listing standards of NASDAQ. The board of directors has determined that Ms. Gregory and Dr. Tian are not independent as defined by the applicable listing standards of NASDAQ.

# Item 14. Principal Accounting Fees and Services Principal Accountant Fees and Services

The following table presents aggregate fees billed to us for services rendered by Ernst & Young LLP during the years ended December 31, 2015 and 2014.

	Fiscal Year Ended l	Fiscal Year Ended December 31,		
	2015		2014	
Audit Fees (1)	\$ 305,000	\$	511,000	
Audit-Related Fees	_		_	
Tax Fees	<del>-</del>		_	
All Other Fees (2)			22,000	
Total	\$ 305,000	\$	533,000	

- (1) Audit fees consisted of fees paid for our annual audits, review of our quarterly reports on Form 10-Q and our SEC filings related to our initial public offering and S-8 registration.
- (2) All other fees related to services with respect our employee incentive plans.

## **Preapproval Policies and Procedures**

It is our policy that the Audit Committee shall preapprove all audit services to be provided to the Company, whether provided by the principal auditor or other firms, and all other services (review, attest and non-audit) to be provided to the Company by the independent auditor; *provided, however*, that de minimis non-audit services may instead be approved in accordance with applicable SEC rules. The Audit Committee may form and delegate authority to one or more subcommittees, as it deems appropriate from time to time under the circumstances (including a subcommittee consisting of a single member), any preapproval decisions relating to audit, review, attest or non-audit services, provided that such decisions shall be presented to the full Audit Committee at its next scheduled meeting. During 2015, the Audit Committee pre-approved all audit and non-audit services in accordance with this policy.

# PART IV

## Item 15. Exhibits and Financial Statement Schedules

## (1) Financial Statements

The following documents are included on pages F-1 through F-27 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-8
Notes to Financial Statements	F-9

#### (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.

# CONTRAFECT CORPORATION

# **Index to Financial Statements**

Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Comprehensive Loss	F-5
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	F-6
Statements of Cash Flows	F-8
Notes to Financial Statements	F-9

## 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, 2015 and 2014, and the related statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2015. 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, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Metro Park, New Jersey

March 15, 2016

# CONTRAFECT CORPORATION Balance Sheets

	Decem	ber 31,
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,972,781	\$ 25,722,453
Marketable securities	22,948,872	1,670,606
Prepaid expenses and other current assets	1,176,895	368,787
Total current assets	34,098,548	27,761,846
Property and equipment, net	1,618,968	2,148,155
Other assets	143,621	143,621
Total assets	\$ 35,861,137	\$ 30,053,622
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,517,417	\$ 481,626
Accrued liabilities	2,251,767	2,741,443
Total current liabilities	3,769,184	3,223,069
Deferred rent	972,119	936,042
Warrant liabilities	444,324	313,004
Total liabilities	5,185,627	4,472,115
Commitments and contingencies (Note 8)	_	_
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 25,000,000 shares authorized and none outstanding at December 31, 2015 and 2014	_	
Common stock, \$0.0001 par value, 100,000,000 shares authorized, 27,482,692 shares outstanding at		
December 31, 2015; 100,000,000 shares authorized, 20,217,263 shares outstanding at December 31, 2014	2,748	2,021
Additional paid-in capital	148,282,546	118,038,560
Accumulated other comprehensive loss	(30,373)	(627)
Accumulated deficit	(117,579,411)	(92,458,447)
Total stockholders' equity	30,675,510	25,581,507
Total liabilities and stockholders' equity	\$ 35,861,137	\$ 30,053,622

# CONTRAFECT CORPORATION Statements of Operations

	Year Ended December 31,				
	2015	2014	2013		
Operating expenses:					
Research and development, including stock-based compensation of \$389,967, \$715,475 and \$230,629, respectively	\$ 15,004,512	\$ 8,868,053	\$ 9,133,175		
General and administrative, including stock-based compensation of \$1,599,895, \$1,224,704 and \$2,101,089, respectively	10,060,825	8,067,858	10,163,259		
Total operating expenses	25,065,337	16,935,911	19,296,434		
Loss from operations	(25,065,337)	(16,935,911)	(19,296,434)		
Other income (expense):					
Interest income (expense), net	75,693	(12,412,620)	(1,712,178)		
Refundable state tax credits	_	424,649			
Change in fair value of warrant and embedded derivative liabilities	(131,320)	(1,225,202)	(2,612,090)		
Total other income (expense)	(55,627)	(13,213,173)	(4,324,268)		
Net loss	(25,120,964)	(30,149,084)	(23,620,702)		
Preferred stock dividend in-kind		(4,468,452)			
Net loss attributable to common stockholders	\$ (25,120,964)	\$ (34,617,536)	\$ (23,620,702)		
Per share information:					
Net loss per share of common stock, basic and diluted	\$ (1.08)	\$ (3.86)	\$ (23.35)		
Basic and diluted weighted average shares outstanding	23,328,922	8,973,599	1,011,789		

# **CONTRAFECT CORPORATION Statements of Comprehensive Loss**

	Y	Year Ended December 31,			
	2015	2014	2013		
Net loss	\$ (25,120,964)	\$ (30,149,084)	\$ (23,620,702)		
Other comprehensive loss:					
Unrealized loss on available-for-sale securities	(29,746)	(627)			
Comprehensive loss	\$ (25,150,710)	\$ (30,149,711)	\$ (23,620,702)		

# CONTRAFECT CORPORATION Statement of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Conv	ies A ertible ed Stock Amount	Conv	ries B vertible red Stock Amount	Conv	ies C ertible ed Stock Amount	Conv	es C-1 ertible ed Stock Amount	Common Shares	Stock Amount	Additional Paid-In Capital	Loan Receivable - Officer	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity (Deficit)
Balance, December 31, 2012	2 200 000	\$ 1 964 283	4 651 163	\$ 10,175,750	9 090 909	\$ 27,752,294	_	s —	1 006 417	<b>\$</b> 101	\$ 2,588,592	\$ (600,000)	s –	\$ (34,220,209)	\$ (32 231 516)
Issuance of	_,,	.,,	,,,,,,,,,,	<b>4</b> 14,174,744	-,,	· · · · · · · · · · · · · · · · · ·		-	-,,		-,,	. (000,000)	-	¥ (c 1,==0,=02)	(==,===,===)
common stock									5.500		10.000				10.000
for license Issuance of	_	_	_	_	_	_		_	5,580	_	10,000	_	_		10,000
warrants for															
services	_	_	_	_	_	_	_	_	_	_	22,149	_	_	_	22,149
Loan forgiven- officer	_	_	_	_	_	_	_	_	_	_		600,000	_	_	600,000
Share-based												,			,
compensation	_	_	_	_	_	_	_	_	_	_	2,309,569	_	_	(22,620,702)	2,309,569
Net loss														(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	_	s —	1,011,997	s 101	\$ 4,930,310	s –	s —	\$ (57,840,911)	\$ (52.910.500)
Issuance of	2,200,000	0 1,701,203	1,051,105	\$ 10,175,750	,,0,0,,,0)	<i>\$ 21,102,231</i>		Ψ	1,011,007	0 101	ų 1,750,510	Ψ	•	\$ (57,610,511)	(52,510,500)
preferred stock								#00.000							
for license Issuance of	_	_	_	_	_	_	151,515	500,000	_	_	_	_	_	_	_
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	(2.200.000)	(1.064.202)	(4.651.162)	(10,175,750)	(0.000.000)	(27.752.204)	(151 515)	(500,000)	6,861,968	696	44.960.002			(4.469.453)	40,392,327
closing of IPO Financing cost	(2,200,000)	(1,904,283)	(4,031,103)	(10,175,750)	(9,090,909)	(27,732,294)	(131,313)	(300,000)	0,801,908	686	44,860,093	_	_	(4,468,452)	40,392,327
of sale of															
securities in IPO											(6 (44 712)				(6 644 712)
Issuance of	_	_	_	_	_	_	_	_	_	_	(6,644,713)	_	_		(6,644,713)
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 Cancellation of	_	_	_	_	_	_	_	_	5,197,476	520	30,632,169	_	_	_	30,632,689
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									122 200	12	400.007				500.000
for license Share-based	_	_	_	_	_	_	_	_	132,380	13	499,987	_	_	_	500,000
compensation	_	_	_	_	_	_	_	_	_	_	979,071	_	_	_	979,071
Unrealized loss															
on marketable securities	_	_	_	_	_	_	_	_	_	_	_	_	(627)	_	(627)
Net loss														(30,149,084)	(30,149,084)
Balance,															
December 31, 2014	_	s —	_	s —	_	s —	_	s —	20,217,263	\$ 2,021	\$118,038,560	\$ —	(627)	\$ (92,458,447)	\$ 25,581,507

		Conv	ries A vertible red Stock	Conv	ries B vertible red Stock	Conv	ries C vertible red Stock	Con	ies C-1 vertible red 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					
	Net shares issued in relation to															
	vesting of performance grant	_	_	_	_	_	_	_	_	11,778	1	54,300	_	_	_	54,301
	Issuance of common stock for services	_	_	_	_	_	_	_	_	28,445	3	167,535	_	_	_	167,538
	Issuance of securities in private															
	placement	_	_	_	_	_	_	_	_	4,728,128	474	19,999,526	_	_	_	20,000,000
	Financing cost of sale of securities	_	_	_	_	_	_	_	_	_	_	(1,665,554)	_	_	_	(1,665,554)
	Issuance of common stock for															
	exercise of options	_	_	_	_	_	_	_	_	23,235	2	_	_	_	_	2
	Issuance of common stock for															
	exercise of warrants	_	_	_	_	_	_	_	_	2,473,793	247	9,698,317	_	_	_	9,698,564
	Share-based compensation	_	_	_	_	_	_	_	_	_	_	1,989,862	_	_	_	1,989,862
	Unrealized loss on marketable															
	securities	_	_	_	_	_	_	_	_	_	_	_	_	(29,746)	_	(29,746)
	Net loss	_	_	_	_	_	_	_	_	_	_	_	_	· · · · · ·	(25,120,964)	(25,120,964)
Ba	ance, December 31, 2015		s —		\$ —		\$ <u> </u>	_	s —	27,482,642	\$ 2,748	\$148,282,546	s —	\$ (30,373)	\$(117,579,411)	\$ 30,675,510

# CONTRAFECT CORPORATION Statements of Cash Flows

Cash flows from operating activities           Net loss         \$ (25,120,964)         \$ (30,149,084)         \$ (23,620,702)           Adjustments to reconcile net loss to net cash used in operating activities:           Depreciation         537,344         551,323         559,237           Stock-based compensation expense         1,989,862         1,511,509         2,309,569           Issuance of preferred stock and other costs in exchange for licensed technology         —         1,000,000         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 dissount         —         1,240,391         416,075           Amortization of debt discount         —         3,550,527         738,935           Change in fair value of warrant and embedded derivative liabilities         131,320         1,225,202         2,612,090           Increase in deferred rent         —         —         —         —         600,000           Net amortization of premium paid on marketable securities         283,915         —         —         — </th <th></th> <th></th> <th>Year Ended December 3</th> <th>,</th>			Year Ended December 3	,
Net loss         \$ (25,120,964)         \$ (30,149,084)         \$ (23,620,702)           Adjustments to reconcile net loss to net cash used in operating activities:         537,344         551,323         559,237           Stock-based compensation expense         1,989,862         1,511,509         2,309,569           Issuance of preferred stock and other costs in exchange for licensed technology         —         1,000,000         10,000           Issuance of common stock 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         131,320         1,225,202         2,612,090           Increase in deferred rent         36,077         69,675         224,367           Other non-cash charges and expenses         —         —         600,000           Net amortization of premium paid on marketable securities         283,915         —         —           Changes in operating assets and liabilities:         —         —         —         —	Cash flows from anarating activities	2015	2014	2013
Adjustments to reconcile net loss to net cash used in operating activities:  Depreciation 537,344 551,323 559,237 Stock-based compensation expense 1,989,862 1,511,509 2,309,569 Issuance of preferred stock and other costs in exchange for licensed technology — 1,000,000 10,000 Issuance of common stock in exchange for services 167,538 — —  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 131,320 1,225,202 2,612,090 Increase in deferred rent 36,077 69,675 224,367 Other non-cash charges and expenses — — 600,000 Net amortization of premium paid on marketable securities 283,915 — —  Changes in operating assets and liabilities:	•	\$ (25,120,964)	\$ (30 149 084)	\$ (23,620,702)
Depreciation         537,344         551,323         559,237           Stock-based compensation expense         1,989,862         1,511,509         2,309,569           Issuance of preferred stock and other costs in exchange for licensed technology         —         1,000,000         10,000           Issuance of common stock in exchange for services         167,538         —         —           Issuance of common stock warrants in exchange for services         —         26,354         22,149           Recognition of beneficial conversion feature         —         7,428,547         —           Amortization of debt discount         —         1,240,391         416,075           Amortization of debt discount         —         3,550,527         738,935           Change in fair value of warrant and embedded derivative liabilities         131,320         1,225,202         2,612,090           Increase in deferred rent         36,077         69,675         224,367           Other non-cash charges and expenses         —         —         600,000           Net amortization of premium paid on marketable securities         283,915         —         —           Changes in operating assets and liabilities:         —         —         —		\$ (23,120,704)	\$ (30,142,004)	\$ (23,020,702)
Stock-based compensation expense1,989,8621,511,5092,309,569Issuance of preferred stock and other costs in exchange for licensed technology—1,000,00010,000Issuance of common stock in exchange for services167,538——Issuance of common stock warrants in exchange for services—26,35422,149Recognition of beneficial conversion feature—7,428,547—Amortization of debt issuance costs—1,240,391416,075Amortization of debt discount—3,550,527738,935Change in fair value of warrant and embedded derivative liabilities131,3201,225,2022,612,090Increase in deferred rent36,07769,675224,367Other non-cash charges and expenses——600,000Net amortization of premium paid on marketable securities283,915——Changes in operating assets and liabilities:		537 344	551 323	559 237
Issuance of preferred stock and other costs in exchange for licensed technology—1,000,00010,000Issuance of common stock in exchange for services167,538——Issuance of common stock warrants in exchange for services—26,35422,149Recognition of beneficial conversion feature—7,428,547—Amortization of debt issuance costs—1,240,391416,075Amortization of debt discount—3,550,527738,935Change in fair value of warrant and embedded derivative liabilities131,3201,225,2022,612,090Increase in deferred rent36,07769,675224,367Other non-cash charges and expenses——600,000Net amortization of premium paid on marketable securities283,915——Changes in operating assets and liabilities:				
Issuance of common stock in exchange for services167,538——Issuance of common stock warrants in exchange for services—26,35422,149Recognition of beneficial conversion feature—7,428,547—Amortization of debt issuance costs—1,240,391416,075Amortization of debt discount—3,550,527738,935Change in fair value of warrant and embedded derivative liabilities131,3201,225,2022,612,090Increase in deferred rent36,07769,675224,367Other non-cash charges and expenses——600,000Net amortization of premium paid on marketable securities283,915——Changes in operating assets and liabilities:				
Issuance of common stock warrants in exchange for services—26,35422,149Recognition of beneficial conversion feature—7,428,547—Amortization of debt issuance costs—1,240,391416,075Amortization of debt discount—3,550,527738,935Change in fair value of warrant and embedded derivative liabilities131,3201,225,2022,612,090Increase in deferred rent36,07769,675224,367Other non-cash charges and expenses——600,000Net amortization of premium paid on marketable securities283,915——Changes in operating assets and liabilities:		167.538		_
Recognition of beneficial conversion feature—7,428,547—Amortization of debt issuance costs—1,240,391416,075Amortization of debt discount—3,550,527738,935Change in fair value of warrant and embedded derivative liabilities131,3201,225,2022,612,090Increase in deferred rent36,07769,675224,367Other non-cash charges and expenses——600,000Net amortization of premium paid on marketable securities283,915——Changes in operating assets and liabilities:		_	26,354	22,149
Amortization of debt discount  Change in fair value of warrant and embedded derivative liabilities  131,320 1,225,202 2,612,090 Increase in deferred rent 36,077 69,675 224,367 Other non-cash charges and expenses		_	,	_
Amortization of debt discount  Change in fair value of warrant and embedded derivative liabilities  131,320 1,225,202 2,612,090 Increase in deferred rent 36,077 69,675 224,367 Other non-cash charges and expenses	Amortization of debt issuance costs	_	1,240,391	416,075
Increase in deferred rent  Other non-cash charges and expenses  Net amortization of premium paid on marketable securities  Changes in operating assets and liabilities:  36,077  69,675  224,367  600,000  8283,915  — —  Changes in operating assets and liabilities:	Amortization of debt discount	_		
Other non-cash charges and expenses — — 600,000  Net amortization of premium paid on marketable securities 283,915 — —  Changes in operating assets and liabilities:	Change in fair value of warrant and embedded derivative liabilities	131,320	1,225,202	2,612,090
Net amortization of premium paid on marketable securities 283,915 — — — Changes in operating assets and liabilities:	Increase in deferred rent	36,077	69,675	224,367
Changes in operating assets and liabilities:		_	_	600,000
	Net amortization of premium paid on marketable securities	283,915	_	_
Decrease (increase) in prepaid expenses and other current assets (808,108) (170,377) 69,387	Changes in operating assets and liabilities:			
	Decrease (increase) in prepaid expenses and other current assets	(808,108)	(170,377)	69,387
(Decrease) increase in accounts payable and accrued liabilities 600,415 (1,148,829) 2,002,469	(Decrease) increase in accounts payable and accrued liabilities	600,415	(1,148,829)	2,002,469
Net cash used in operating activities (22,182,601) (14,864,762) (14,056,424)	Net cash used in operating activities	(22,182,601)	(14,864,762)	(14,056,424)
	Cash flows from investing activities			, , , ,
Decrease in restricted cash — 25,000 1,575,000	Decrease in restricted cash	_	25,000	1,575,000
Purchases of marketable securities (33,524,927) (1,671,233) —	Purchases of marketable securities	(33,524,927)	(1,671,233)	_
Proceeds from maturities of marketable securities 11,933,000 — — —	Proceeds from maturities of marketable securities	11,933,000		_
Purchases of property and equipment (8,157) — —	Purchases of property and equipment	(8,157)	_	_
Proceeds from disposal of property and equipment 35,697 13,570	Proceeds from disposal of property and equipment		35,697	13,570
Net cash (used in) provided by investing activities (21,600,084) (1,610,536) 1,588,570	Net cash (used in) provided by investing activities	(21,600,084)	(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)	Payment of financing costs of convertible notes	_	(24,850)	(1,336,280)
Proceeds from issuance of equity securities 20,000,000 41,281,998 —	Proceeds from issuance of equity securities	20,000,000	41,281,998	_
Payment of financing costs of securities sold (1,665,554) (6,241,017) —	Payment of financing costs of securities sold	(1,665,554)	(6,241,017)	_
Repayment of lease and notes payable — (1,900,510)	Repayment of lease and notes payable	_	_	(1,900,510)
Proceeds from exercise of warrants 9,698,567	Proceeds from exercise of warrants	9,698,567		
Net cash provided by financing activities         28,033,013         38,052,481         8,726,860	Net cash provided by financing activities	28,033,013	38,052,481	8,726,860
Net increase (decrease) in cash and cash equivalents (15,749,672) 21,577,183 (3,740,994)	Net increase (decrease) in cash and cash equivalents	(15,749,672)	21,577,183	(3,740,994)
	Cash and cash equivalents at beginning of period			
	Cash and cash equivalents at end of period	\$ 9,972,781	\$ 25,722,453	\$ 4,145,270
	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	_		*,
Issuance of common stock for services 167,538 — —		167,538	_	_
Cancellation of placement agent warrants — 941,541 —	Cancellation of placement agent warrants		941,541	_

### ContraFect Corporation Notes to Financial Statements December 31, 2015

#### 1. Organization and Description of Business

### Organization and Business

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

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

In August 2014, the Company completed its initial public offering of 6,000,000 units, consisting of one share of common stock, one Class A Warrant to purchase one share of common stock at an exercise price of \$4.80 per share and one Class B Warrant to purchase one-half share of common stock at an exercise price of \$4.00 per full share (the "Units") and closed on the underwriter's over-allotment option for an additional 880,333 Units (the "IPO"), raising total net proceeds of \$35.0 million, net of underwriting discount, commissions and offering expenses.

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

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

The significant increase in common stock outstanding in August 2014 and June 2015 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 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.

#### Reclassifications

The Company concluded it was appropriate to classify its deferred rent as a non-current liability. Prior period financial statement amounts have been reclassified to conform to current period presentation. These reclassifications had no effect on reported results of operations or cash flow from operations.

#### **Use of Estimates**

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

#### Cash and Cash Equivalents

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

#### **Marketable Securities**

Marketable securities at December 31, 2015 and December 31, 2014 consisted of investments in short-term corporate debt securities. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, *Investments—Debt and Equity Securities*. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit) and a component of total comprehensive loss in the statements of comprehensive loss, until realized. The fair value of these securities is based on quoted prices for identical or similar assets. Realized gains and losses are included in investment income on a specific-identification basis. There were no realized gains or losses on marketable securities for the year ended December 31, 2015.

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of

investments are recognized in the statements of operations if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

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

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

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

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

At December 31, 2015 and 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, 2015 and December 31, 2014, the Company held 28 and three debt securities, respectively, that individually and in total were in an immaterial unrealized loss position for less than one year. The aggregate fair value of debt securities in an unrealized loss position at December 31, 2015 and December 31, 2014 was \$21,137,424 and \$1,222,291, respectively. The Company evaluated its securities for other-than-temporary impairment and considered the decline in market value for the securities to be primarily attributable to current economic and market conditions. It is not more likely than not that the Company will be required to sell the securities, and the Company does not intend to do so prior to the recovery of the amortized cost basis. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of December 31, 2015 and 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.

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 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.

#### **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, 2015) 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, 2015.

#### 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, 2015, 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 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 August 2014, the FASB issued a new Accounting Standards Update, *Presentation of Financial Statements—Going Concern (Subtopic 205-40):*Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15). ASU 2014-15 provides guidance on management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern within one year of the date the financial statements are issued, and, if such conditions exist, to provide related footnote disclosures. The guidance is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its financial statements and related disclosures.

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

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

In February 2016, the FASB issued a new Accounting Standards Update, *Leases (ASU 2016-02)*, ASU 2016-02 is aimed at making leasing activities more transparent and comparable and requires most leases be

recognized by lessees on the balance sheets as a right-of-use asset and corresponding lease liability, regardless of whether they are classified as finance or operating leases. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the impact of the new pronouncement on the Company's financial statements and related disclosures.

#### 3. Fair Value Measurements

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2015 and December 31, 2014:

	Fair Value	Fair Value Measurement As of December 31, 2015		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Cash equivalents	\$ 9,607,134	\$ —	\$	
Marketable securities	22,948,872	_	_	
Warrant liability	<del>-</del>	_	444,324	
Total	\$ 32,556,006	\$	\$ 444,324	
	·	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	<u> </u>	_	313,004	
Total	\$ 27,299,524	\$ —	\$ 313,004	

The Company issued a warrant to the representative of the underwriters of its IPO (the "Representative's Warrant") to purchase 206,410 shares of common stock at an exercise price of \$7.50 per share (see Note 9, "Capital Structure"). The Company evaluated the Representative's Warrants against current accounting guidance and determined that these warrants should be classified as a liability and considers it as a Level 3 financial instrument. 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, 2015 and 2014:

	As of	As of
	December 31, 2015	December 31, 2014
Expected volatility	78.1%	74.8%
Remaining contractual term (in years)	3.67	4.67
Risk-free interest rate	1.54%	1.65%
Expected dividend yield	— %	— %

The following tables present a reconciliation of the Company's financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2015, 2014 and 2013:

Warrant liabilities (1)

	Year Ended December 31,					
		2015		2014		2013
Balance at beginning of period	\$	313,004	\$	3,088,017	\$	
Issuances of convertible notes		_		865,635	2	,080,722
Cancellation of placement agent warrants (2)		_		(941,541)		_
Issuance of Representative's Warrant		_		403,696		_
Increase in fair value (3)		131,320		2,563,080	1	,007,295
Conversion of convertible notes to common stock				(5,665,883)		
Balance at end of period	\$	444,324	\$	313,004	\$ 3	,088,017

Embedded derivatives liabilities (1)

	Year Ended December 31,			
	2	015	2014	2013
Balance at beginning of period	\$		\$ 2,680,780	\$ —
Issuances of convertible notes		_	537,607	1,075,985
(Decrease) increase in fair value (3)		_	(1,337,878)	1,604,795
Conversion of convertible notes to common stock			(1,880,509)	
Balance at end of period	\$		<u>\$</u>	\$ 2,680,780

- (1) Prior to the closing of the Company's IPO on August 1, 2014, the Company considered its convertible note related warrant liabilities and embedded derivatives liabilities as Level 3 financial instruments. The Company determined the fair value of these liabilities immediately prior to the Company's IPO and then reclassified the balances to additional paid-in capital on the closing of the IPO.
- (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.
- (3) The change in the fair values of the warrant and embedded derivatives liabilities are recorded in other expenses in the statement of operations.

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

#### 4. Property, Equipment, and Leasehold Improvements

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

	December 31,		
	2015	2014	
Computer equipment	\$ 19,691	\$ 19,691	
Furniture	434,697	434,697	
Lab equipment	1,631,016	1,631,016	
Leasehold improvements	1,821,677	1,813,520	
	3,907,081	3,898,924	
Less: accumulated depreciation and amortization	(2,288,113)	(1,750,769)	
	\$ 1,618,968	\$ 2,148,155	

Depreciation expense was \$537,344, \$551,323 and \$559,237 for the years ended December 31, 2015, 2014 and 2013, respectively.

#### 5. Accrued Expenses

Accrued expenses consist of the following:

	Dece	December 31,		
	2015	2014		
Accrued compensation costs	\$1,133,742	\$ 1,865,778		
Accrued research and development service fees	590,307	202,183		
Accrued professional fees	317,796	286,443		
Accrued licensing fees	_	200,000		
Other	209,922	187,039		
	\$ 2,251,767	\$ 2,741,443		

#### 6. Senior Convertible Notes

The Company issued approximately \$15.0 million aggregate principal amount of its 8.00% Convertible Notes due May 31, 2015 (the "Convertible Notes") from June 2013 through June 2014. 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.

The Company recorded the costs directly related to the issuance of its Convertible Notes as debt issuance costs and amortized these costs to interest expense 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.

Each purchaser of the Convertible Notes also received a warrant which included an exercise price "cap" that was analogous to "down round protection" which precluded the Company from classifying the warrants in equity (the "Note Warrants"). The Convertible Notes also included embedded derivatives (i.e. penalty provisions) that required bifurcation. As such, the Company reflected both the values of the Note Warrants and the embedded derivatives as liabilities which 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. Upon the closing of the IPO, the Company reclassified the balances of the Note Warrant and embedded derivative liabilities to additional paid-in capital as the terms of the Note Warrants, including any penalty warrants, became fixed and the interest penalties were paid in the Company's common stock, and therefore both the Note Warrants and penalties were no longer considered a liability (see Note 3, "Fair Value Measurements").

Upon the closing of the IPO and based on the terms of the Note Warrants, the Company determined the total number of shares of the Company's common stock underlying the Note Warrants to be 3,321,416 at an exercise price of \$3.00 per share. The number of shares of common stock underlying the outstanding Note Warrants as of December 31, 2015 and 2014 was 3,315,878 and 3,321,416, respectively. The Note Warrants expire five years from the date of issuance.

## 7. Net Loss Per Share of Common Stock

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

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

	Ye	Year Ended December 31,		
	2015	2014	2013	
Net loss applicable to common stockholders	\$ (25,120,964)	\$ (34,617,536)	\$ (23,620,702)	
Weighted average shares of common stock outstanding	23,328,922	8,973,599	1,011,789	
Net loss per share of common stock—basic and diluted	<u>\$</u> (1.08)	\$ (3.86)	\$ (23.35)	

The following potentially dilutive securities outstanding at December 31, 2015 and 2014 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been antidilutive given the Company's net loss:

		December 31,		
	2015	2014	2013	
Preferred stock			4,554,874	
Options to purchase common stock	4,313,755	3,089,327	2,221,652	
Warrants to purchase common stock (1)	13,503,107	14,577,361	718,322	
	17,816,862	17,666,688	7,494,848	

(1) The potential dilutive impact of the Company's Note Warrants (see Note 6 "Senior Convertible Notes") were not included as of December 31, 2013 as the underlying number of shares was not determinable at that time and would also have been antidilutive.

#### 8. 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:	
2016	\$ 851,895
2017	868,933
2018	886,311
2019	904,038
2020	922,118
Thereafter	6,992,396
	\$ 11,425,691

Rent expense is recognized on the straight-line method over the terms of each lease. Rent expense for the years ended December 31, 2015, 2014 and 2013, was approximately \$873,000, \$871,000 and \$870,000, respectively.

#### 9. Capital Structure

#### Common Stock

As of December 31, 2015, the Company was authorized to issue 100,000,000 shares of common stock at \$0.0001 par value per share.

#### Private Placement

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

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

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

#### Initial Public Offering

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.

On August 1, 2014, the Company closed its 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 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. Following the IPO, the units separated and the shares of common stock, Class A Warrants and Class B Warrants began to trade separately. The common stock and accompanying Class A and Class B warrants were classified to stockholders' equity in the Company's balance sheet.

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

#### Representative's Warrant

The Maxim Group, LLC, the representative of the underwriters in the IPO, received the Representative's Warrant to purchase 3% of the total number of shares of common stock sold in the IPO, including those shares sold upon the exercise of the over-allotment, for a total of 206,410 shares of common stock underlying the

Representative's Warrant. The Representative's Warrant became exercisable at an exercise price of \$7.50 per share beginning 180 days after the effective date of the Company's registration statement (January 24, 2015) and expires on August 27, 2019. The Company classified the Representative's Warrant as a liability since it did not meet the requirements to be included in equity. The fair value of the Representative's Warrant will be re-measured at each reporting period and changes in fair value will be recognized in the statement of operations (see Note 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.

#### 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, 2015, 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, 2015 and 2014:

	Decem	December 31,		
	2015	2014		
Options to purchase common stock	4,313,755	3,089,327		
Warrants to purchase common stock	13,503,107	14,577,361		
	17,816,862	17,666,688		

#### **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.

## 10. Stock Warrants

As of December 31, 2015 and 2014, the Company had warrants outstanding as shown in the table below.

		December 31,
	2015	2014
Note Warrants	3,315,878	3,321,416
Class A Warrants	6,880,333	6,880,333
Class B Warrants (1)	_	3,440,166
PIPE Warrants	2,364,066	_
Representative's Warrant	206,410	206,410
Placement Agent Warrants	189,126	_
Other warrants (2)	547,294	729,036
Warrants to purchase common stock	13,503,107	14,577,361
Weighted-average exercise price per share	\$ 5.02	\$ 4.32

- (1) The Class B Warrants expired pursuant to their terms on November 2, 2015.
- (2) Other warrants are comprised of warrants issued prior to the Company's IPO, generally in exchange for services rendered to the Company.

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	— %	— %

During 2015, the Company did not issue any warrants to purchase shares of common stock for services rendered to the Company.

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.

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 following table summarizes information regarding the Company's warrants outstanding and the corresponding exercise price at December 31, 2015:

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

#### 11. 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 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.

Upon the original adoption of the Plan, the number of shares of common stock reserved pursuant to the Plan was 214,285. On December 12, 2011, the Plan was amended to increase the number of shares of common stock available under the Plan to 900,000. 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, there will be no further grants 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 December 31 immediately preceding such date or (ii) a lesser 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, 2015, is summarized as follows:

	Number of Options	Av	eighted verage cise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2014	3,089,327	\$	4.95		
Granted	1,353,750		4.64		
Exercised	(75,197)		3.50		
Expired	(25,605)		6.59		
Forfeited	(28,520)		3.61		
Options outstanding at December 31, 2015	4,313,755	\$	4.87	7.34	\$ 2,544,493
Vested and exercisable at December 31, 2015	2,864,799	\$	5.05	6.55	\$ 2,014,233

Of the option grants outstanding to purchase 4,313,755 shares of common stock, grants to purchase 667,870 shares of common stock were issued and are outstanding outside the Company's incentive plans.

The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of options granted during the years ended December 31, 2015, 2014 and 2013 was \$4.64, \$3.95 and \$3.50, respectively. Total compensation expense recognized amounted to \$1,929,112, \$1,940,179 and \$2,309,569 for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, the total remaining unrecognized compensation cost related to unvested stock options was \$3,596,629 which will be recognized over a weighted average period of approximately 2.52 years.

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

	Year Ei	nded December	r 31,
	2015	2014	2013
Risk free interest rate	1.62%	1.95%	1.21%
Expected dividend yield	_	_	
Expected term (in years)	5.75	5.96	6.22
Expected volatility	74.36%	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.

#### 12. Retention Bonus Plan

On February 24, 2014, the Company adopted the ContraFect Corporation Retention Bonus Plan (the "Retention Plan"). Under the Retention Plan, participants vested in and became 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 were then employed by the Company were 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.

There are no outstanding Award Amounts as of December 31, 2015 or December 31, 2014 and the Company does not anticipate any further grants under the Retention Plan.

#### 13. 401k Savings Plan

In 2010, the Company established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (the 401(k) Plan). The 401(k) 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 did not make any contributions to the 401(k) Plan through December 31, 2014. During 2015, the Company established an employer matching program for participants in the 401(k) Plan. The Company incurred approximately \$88,000 of expense for matching contributions to the 401(k) Plan during the year ended December 31, 2015.

#### 14. Income Taxes

The Company has available approximately \$91,586,000 and \$96,074,000 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 2035 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 \$9,937,000 and \$7,494,000 during the years 2015 and 2014, respectively, and was approximately \$40,089,000 and \$30,152,000 at December 31, 2015 and 2014, 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 three years ended December 31, 2015, 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 2015 and 2014 are as follows:

	Decem	ber 31,
	2015	2014
Deferred tax assets/liabilities:		
Net operating loss carryovers	\$ 36,414,890	\$ 26,959,701
R&D tax credits	1,469,756	1,224,288
Share-based compensation	1,922,680	1,649,073
Accrued compensation and severance	147,175	409,234
Depreciation	(496,327)	(690,981)
Deferred rent	404,885	370,376
Intangible assets	225,702	229,836
	40,088,761	30,151,527
Valuation allowance	<u>(40,088,761</u> )	(30,151,527)
Net deferred tax assets (liabilities)	<u> </u>	<u>\$</u>

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

	Year	Ended December 3	1,
	2015	2014	2013
Federal income tax benefit at statutory rate	(34.00)%	(34.00)%	(34.00)%
State income tax, net of federal benefit	(5.49)	(5.70)	(5.00)
Permanent item—non-deductible interest	_	14.59	_
Other permanent items	1.99	1.83	0.01
Change in valuation allowance	39.70	24.89	40.17
R&D tax credits	(.99)	(1.13)	(1.08)
Other	(1.21)	(0.48)	(0.10)
Effective income tax (benefit) expense rate	0%	0%	0%

#### 15. 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 pneumonia, Bacillus anthracis, Enterococcus faecalis and Enterococcus faecium.

In consideration for the licenses, we paid Rockefeller license initiation fees in cash and 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.

#### 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 epsilon1,000,000 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 records a liability in its financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in a liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss to the extent necessary to make the financial statements not misleading. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in the Company's financial statements. The Company currently has no legal proceedings ongoing that management estimates could have a material effect on the Company's financial statements.

#### 16. Related-Party Transactions

The Company paid its non-employee directors fees for services as directors and consulting of approximately \$630,000, \$568,000 and \$271,000 for the years ended December 31, 2015, 2014 and 2013, respectively, which were included in general and administrative expenses.

#### 17. Subsequent Events

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

# **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: <u>/s/ JULIA P. GREGORY</u> 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.

Signature	<u>Title</u>	Date
/S/ JULIA P. GREGORY Julia P. Gregory	Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2016
/s/ MICHAEL MESSINGER Michael Messinger	Vice President, Finance and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	March 15, 2016
/s/ Sol Barer	Lead Independent Director	March 15, 2016
Sol Barer, Ph.D.		
/s/ Isaac Blech	Director	March 15, 2016
Isaac Blech		
/s/ Steve Gilman	Chairman of the Board	March 15, 2016
Steve Gilman, Ph.D.		
/S/ DAVID N. LOW, JR.	Director	March 15, 2016
David N. Low, Jr.		
/s/ MICHAEL OTTO	Director	March 15, 2016
Michael Otto, Ph.D.		
/s/ Roger Pomerantz	Vice Chairman of the Board	March 15, 2016
Roger Pomerantz, M.D., F.A.C.P.	<del></del>	
/S/ DAVID SCHEINBERG	Director	March 15, 2016
David Scheinberg, M.D., Ph.D.		
/s/ Cary Sucoff	Director	March 15, 2016
Cary Sucoff		
/s/ Lawrence Tian	Director	March 15, 2016
Lawrence Tian		

# EXHIBIT INDEX

Exhibit		Incorporated by Reference					
No.	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith	
3.1	Amended and Restated Certificate of Incorporation					*	
3.2	Second Amended and Restated Bylaws	8-K	001-36577	3.2	October 29, 2015		
4.1	Form of Common Stock Certificate	S-1/A	333-195378	4.1	July 3, 2014		
4.2	Class A Warrant Agreement, dated as of July 28, 2014, by and between the Company and American Stock Transfer & Trust Company, LLC	8-K	001-36577	4.5.1	October 29, 2015		
4.3	Specimen Class A Warrant Certificate	8-K	001-36577	4.12	October 29, 2015		
4.4	Representative's Warrant, dated August 27, 2014	8-K	001-36577	4.14	October 29, 2015		
4.5	Form of Noteholder Warrant	S-1/A	333-195378	4.7	July 3, 2014		
4.6	Specimen Unit Certificate	S-1	333-195378	4.8	July 1, 2014		
4.7	Form of Indenture	S-3	333-206786	4.1	September 4, 2015		
4.8	Form of Investor Warrant	8-K	001-36577	4.1	June 12, 2015		
4.9	Form of Placement Agent Warrant	8-K	001-36577	4.2	June 12, 2015		
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/A	333-195378	10.4	July 1, 2014		
10.5#	Employment Agreement by and between ContraFect Corporation and Julia P. Gregory dated April 29, 2014	S-1/A	333-195378	10.6	July 1, 2014		

Exhibit		Incorporated by Reference					
No.	Description	<u>Form</u>	File No.	Exhibit	Filing Date	Filed/Furnished Herewith	
10.6#	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		
10.7#	Employment Agreement by and between ContraFect Corporation and Daniel E. Couto, dated March 21, 2011					*	
10.8#	Separation and Consulting Agreement by and between ContraFect Corporation and Dr. Barry Kappel, dated April 15, 2015					*	
10.9#	ContraFect Corporation Retention Bonus Plan	S-1	333-195378	10.9	April 18, 2014		
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/A	333-195378	10.14	July 1, 2014		
10.15	License Agreement, between Trellis Bioscience LLC and ContraFect Corporation, dated January 29, 2014	S-1/A	333-195378	10.15	July 1, 2014		
10.16	Amendment to the Trellis License Agreement, dated June 15, 2014	S-1/A	333-195378	10.16	July 1, 2014		
10.17	Form of Securities Purchase Agreement between the Company and Benjamin Small, Birchview Fund, LLC, Broadfin Healthcare Master Fund, Ltd., Cormorant Global Healthcare Master Fund, LP, Jack W. Schuler, Matthew W. Strobeck, Oracle Institutional Partners, LP, Oracle Partners, LP, and Richard B. McCormick, dated June 11, 2015	8-K	001-36577	10.1	June 12, 2015		

Exhibit		Incorporated by Reference					
No.	Description	<u>Form</u>	File No.	Exhibit	Filing Date	Filed/Furnished Herewith	
10.18	Form of Registration Rights Agreement among the Company, Benjamin Small, Birchview Fund, LLC, Broadfin Healthcare Master Fund, Ltd., Cormorant Global Healthcare Master Fund, LP, Jack W. Schuler, Matthew W. Strobeck, Oracle Institutional Partners, LP, Oracle Partners, LP, and Richard B. McCormick and Brookline Group LLC, dated June 11, 2015	8-K	001-36577	10.2	June 12, 2015		
10.19#	First Amendment to the Employment Agreement by and between ContraFect Corporation and Julia P. Gregory, dated August 10, 2015	8-K	001-36577	10.1	August 13, 2015		
10.20#	First Amendment to Employment Agreement by and between the Company and Michael Wittekind, PhD., dated November 12, 2015	10-Q	001-36577	10.2	November 12, 2015		
10.21#	First Amendment to Employment Agreement by and between the Company and Daniel E. Couto, dated November 2, 2015					*	
23.1	Consent of Ernst & Young LLP					*	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes- Oxley Act of 2002					*	
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes- Oxley Act of 2002					*	
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					**	
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**	
101.INS	XBRL Instance Document					*	

Incorporated by Reference			
	Incorno	rated by	v Reference

Exhibit No.	<b>Description</b>	<u>Form</u>	File No.	<u>Exhibi</u> t	Filing Date	Filed/Furnished Herewith
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

<sup>\*</sup> Filed herewith.

<sup>\*\*</sup> Furnished herewith.

<sup>#</sup> Indicates management contract or compensatory plan.

# AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF CONTRAFECT CORPORATION

(originally incorporated on March 5, 2008)

ContraFect Corporation (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the Delaware General Corporation Law (the "DGCL"), does hereby certify as follows:

- A. The current name of the Corporation is ContraFect Corporation. The Corporation was originally incorporated under the name CONTRAFECT, INC. on March 5, 2008. The original Certificate of Incorporation of the Corporation was amended, supplemented and restated by (a) that certain Certificate of Amendment of Certificate of Incorporation filed on March 17, 2008, (b) that certain Certificate of Designation of Series "A" Preferred Shares filed on July 1, 2009, (c) that certain Amended and Restated Certificate of Incorporation filed on August 2, 2010, (e) that certain Certificate of Amendment of Second Amended and Restated Certificate of Incorporation filed on September 10, 2010, (f) that certain Third Amended and Restated Certificate of Incorporation filed on August 25, 2011, (g) that certain Certificate of Amendment of Third Amended and Restated Certificate of Incorporation filed on June 13, 2012, (h) that certain Fourth Amended and Restated Certificate of Incorporation filed on June 11, 2013 and (i) that certain Fifth Amended and Restated Certificate of Incorporation filed on July 25, 2014.
- B. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Sections 242 and 245 of the DGCL proposing this Amended and Restated Certificate of Incorporation (this "Certificate of Incorporation") and declaring its advisability. The stockholders of the Corporation duly approved and adopted this Certificate of Incorporation by written consent in accordance with Sections 228, 242 and 245 of the DGCL.
  - C. This Certificate of Incorporation shall become effective upon its filing with the Secretary of State of the State of Delaware.
- D. Accordingly, the Corporation's certificate of incorporation, as previously amended and restated, is hereby further amended and restated in its entirety to read as follows:

FIRST: The name of the Corporation is ContraFect Corporation.

SECOND: The address of the registered office of the Corporation in the State of Delaware is located at 2711 Centerville Road, Suite 400, in the City of Wilmington, County of New Castle, 19808, and its registered agent is Corporation Service Company.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is 125,000,000 shares, consisting of (i) 100,000,000 shares of Common Stock, \$0.0001 par value per share ("Common Stock"), and (ii) 25,000,000 shares of Preferred Stock, \$0.0001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

#### A. COMMON STOCK.

- 1. <u>General</u>. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors of the Corporation (the "Board of Directors") upon any issuance of the Preferred Stock of any series.
- 2. <u>Voting</u>. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; <u>provided</u>, <u>however</u>, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

- 3. <u>Dividends</u>. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.
- 4. <u>Liquidation</u>. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

#### B. PREFERRED STOCK.

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

FIFTH: Except as otherwise provided herein, the Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

SIXTH: In furtherance and not in limitation of the powers conferred upon it by the General Corporation Law of the State of Delaware, and subject to the terms of any series of Preferred Stock, the Board of Directors shall have the power to adopt, amend, alter or repeal the By laws of the Corporation by the affirmative vote of a majority of the directors present at any regular or special meeting of the Board of Directors at which a quorum is present. The stockholders may not adopt, amend, alter or repeal the By laws of the Corporation, or adopt any provision inconsistent therewith, unless such action is approved, in addition to any other vote required by this Certificate of Incorporation, by the affirmative vote of the holders of at least seventy five percent (75%) of the votes that all the stockholders would be entitled to cast in any annual election of directors or class of directors. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article SIXTH.

SEVENTH: Except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal. If the General Corporation Law of the State of Delaware is amended to permit further elimination or limitation of the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

EIGHTH: The Corporation shall provide indemnification as follows:

- 1. Actions, Suits and Proceedings Other than by or in the Right of the Corporation. The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974), and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.
- 2. Actions or Suits by or in the Right of the Corporation. The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request

of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including attorneys' fees) which the Court of Chancery of Delaware or such other court shall deem proper.

- 3. <u>Indemnification for Expenses of Successful Party.</u> Notwithstanding any other provisions of this Article EIGHTH, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 1 and 2 of this Article EIGHTH, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified against all expenses (including attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith. Without limiting the foregoing, if any action, suit or proceeding is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to Indemnitee, (ii) an adjudication that Indemnitee was liable to the Corporation, (iii) a plea of guilty or <u>nolo contendere</u> by Indemnitee, (iv) an adjudication that Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Corporation, and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe his or her conduct was unlawful, Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect thereto.
- 4. Notification and Defense of Claim. As a condition precedent to an Indemnitee's right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (i) the employment of counsel by Indemnitee has been authorized by the Corporation, (ii) counsel to Indemnitee shall have reasonably concluded that there may be a

conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article EIGHTH. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Corporation shall not be required to indemnify Indemnitee under this Article EIGHTH for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

- 5. Advance of Expenses. Subject to the provisions of Section 6 of this Article EIGHTH, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article EIGHTH, any expenses (including attorneys' fees) incurred by or on behalf of an Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter; provided, however, that the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article EIGHTH; and provided further that no such advancement of expenses shall be made under this Article EIGHTH if it is determined (in the manner described in Section 6 of this Article EIGHTH) that (i) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.
- 6. Procedure for Indemnification and Advancement of Expenses. In order to obtain indemnification or advancement of expenses pursuant to Section 1, 2, 3 or 5 of this Article EIGHTH, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (i) the Corporation has assumed the defense pursuant to Section 4 of this Article EIGHTH (and none of the circumstances described in Section 4 of this Article EIGHTH that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (ii) the Corporation determines within such 60 day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 1, 2 or 5 of this Article EIGHTH, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 1 or 2 of this Article EIGHTH only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because

Indemnitee has met the applicable standard of conduct set forth in Section 1 or 2 of this Article EIGHTH, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

- 7. Remedies. The right to indemnification or advancement of expenses as granted by this Article EIGHTH shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 6 of this Article EIGHTH that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article EIGHTH. Indemnitee's expenses (including attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification, in whole or in part, in any such proceeding shall also be indemnified by the Corporation. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the General Corporation Law of the State of Delaware.
- 8. <u>Limitations</u>. Notwithstanding anything to the contrary in this Article EIGHTH, except as set forth in Section 7 of this Article EIGHTH, the Corporation shall not indemnify an Indemnitee pursuant to this Article EIGHTH in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors of the Corporation. Notwithstanding anything to the contrary in this Article EIGHTH, the Corporation shall not indemnify an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification payments to the Corporation to the extent of such insurance reimbursement.
- 9. <u>Subsequent Amendment</u>. No amendment, termination or repeal of this Article EIGHTH or of the relevant provisions of the General Corporation Law of the State of Delaware or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

- 10. Other Rights. The indemnification and advancement of expenses provided by this Article EIGHTH shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article EIGHTH shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification rights and procedures different from those set forth in this Article EIGHTH. In addition, the Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article EIGHTH.
- 11. <u>Partial Indemnification</u>. If an Indemnitee is entitled under any provision of this Article EIGHTH to indemnification by the Corporation for some or a portion of the expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement to which Indemnitee is entitled.
- 12. <u>Insurance</u>. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of the State of Delaware.
- 13. <u>Savings Clause</u>. If this Article EIGHTH or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article EIGHTH that shall not have been invalidated and to the fullest extent permitted by applicable law.

14. <u>Definitions</u>. Terms used herein and defined in Section 145(h) and Section 145(i) of the General Corporation Law of the State of Delaware shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

NINTH: This Article NINTH is inserted for the management of the business and for the conduct of the affairs of the Corporation.

- 1. <u>General Powers</u>. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.
- 2. <u>Number of Directors</u>; <u>Election of Directors</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Corporation shall be established by the Board of Directors. Election of directors need not be by written ballot, except as and to the extent provided in the By laws of the Corporation.
- 3. <u>Terms of Office</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the first annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; <u>provided</u> that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.
- 4. Quorum. The greater of (a) a majority of the directors at any time in office and (b) one third of the number of directors fixed pursuant to Section 2 of this Article NINTH shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.
- 5. Action at Meeting. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors unless a greater number is required by law or by this Certificate of Incorporation.
- 6. <u>Removal</u>. Subject to the rights of holders of any series of Preferred Stock, directors of the Corporation may be removed only for cause and only by the affirmative vote of the holders of at least seventy five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors.
- 7. <u>Vacancies</u>. Subject to the rights of holders of any series of Preferred Stock, any vacancy or newly created directorship in the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor and to such director's earlier death, resignation or removal.

- 8. <u>Stockholder Nominations and Introduction of Business, Etc.</u> Advance notice of stockholder nominations for election of directors and other business to be brought by stockholders before a meeting of stockholders shall be given in the manner provided by the By laws of the Corporation.
- 9. <u>Amendments to Article</u>. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article NINTH.

TENTH: Stockholders of the Corporation may not take any action by written consent in lieu of a meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article TENTH.

ELEVENTH: Special meetings of stockholders for any purpose or purposes may be called at any time by only the Board of Directors, the Chairman of the Board of Directors or the Chief Executive Officer of the Corporation, and may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article ELEVENTH.

IN WITNESS WHEREOF, this Certificate of Incorporation, which restates, integrates and amends all previous certificates of incorporation of the Corporation, and which has been duly adopted in accordance with Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware, has been executed by a duly authorized officer this 1st day of August, 2014.

#### CONTRAFECT CORPORATION

By: /s/ Julia Gregory

Name: Julia Gregory

Title: Chief Executive Officer

#### **EMPLOYMENT AGREEMENT**

#### by and between

## CONTRAFECT CORPORATION

#### and

#### DANIEL E. COUTO

THIS EMPLOYMENT AGREEMENT (the "Agreement") is entered into on the latest date set forth on the signature pages hereto, by and between ContraFect Corporation, a Delaware corporation ("Employer") and Daniel E. Couto, a resident of Massachusetts ("Employee").

WHEREAS, Employer is a biotech company engaged in the business of developing products for approval and sale;

WHEREAS, Employee is a research scientist with knowledge and experience in the area of developing products in the biotech field for approval and sale;

WHEREAS, Employer believes that the future services of Employee will be of substantial benefit to Employer and desires to assure itself of the continued availability of such services; and

WHEREAS, Employee desires to accept employment with Employer on the terms and subject to the conditions hereinafter stated.

NOW, THEREFORE, for and in consideration of the premises above and the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

#### 1. Employment and Duties of Employee.

(a) Employer hereby employs Employee to serve Employer in the capacity of Vice President of Product Development. Employer shall have the power to determine the precise duties of Employee as they may change over time and as Employer's needs shall warrant. Employee agrees to devote Employee's full working time, attention, ability, skill and energies to the performance of Employee's duties

hereunder. Employee shall provide professional services on behalf of Employer in a manner and to an extent consistent with that established by Employer. Employee shall work at all locations/offices of Employer as requested by Employer, and upon Employer's request shall travel as needed to carry out his duties. Employee shall not provide like services for any other entity or person, whether for compensation or not, except as an employee of Employer.

- (b) Employee shall comply with all bylaws, policies, procedures, standards and regulations of Employer now or hereafter promulgated. Employee shall participate in such continuing education as may be required under applicable ethical or licensing standards, laws, rules and regulations applying to Employee's profession or as may otherwise be required by Employer. Employee shall obtain and maintain all required licenses, credentials, approvals or other certifications to perform Employee's duties and services hereunder.
- (c) Employee shall disclose in writing to Employer on the date hereof all financial interests or compensation arrangements of Employee (other than this Employment Agreement) and any member of Employee's Immediate Family (as hereinafter defined), including without limitation, any financial interests or compensation arrangements (as owner, employee, lessor, lessee, independent contractor, or otherwise) in any Biotech Venture (as hereinafter defined) (such financial interests and compensation arrangements hereinafter collectively referred to as "Arrangements").
- (i) Biotech Venture shall mean and include without limitation, any entity or person that develops or sells, researches, or licenses scientific information or products for the therapy of human diseases.
  - (ii) Immediate Family shall mean Employee's spouse, parent, child, sibling, grandparent, and grandchild.

Employee shall not enter into any Arrangements with any Biotech Venture without the prior written consent of Employer. In the event that there is a change in any Arrangement, or if any member of Employee's Immediate Family enters into an Arrangement during the term of this Agreement, Employee shall immediately disclose such Arrangement to Employer.

2. <u>Hours and Place of Employment</u>. Employee is expected to maintain a regular work week as assigned by the Employer for employees at his level performing such duties. Until such time as Employee moves to New York City, without the Employer's instruction to do so he shall work no less than three days per week at the Employer's offices in New York unless otherwise instructed by Employer. Employee, as a condition of his continued employment, shall relocate to New York on or by April 15, 2011 so that he can be a full time employee working at Employer's offices.

3. Term of Employment. The initial term of employment (the "Initial Term") of Employee's employment by Employer under this Agreement shall commence on March 5, 2011 (the "Commencement Date") and shall end three (3) years thereafter, unless earlier terminated as hereinafter provided. Unless either party elects to terminate this Agreement at the end of the Initial Term or any renewal term by giving the other party notice of such election at least ninety (90) days before the expiration of the Initial Term, this Agreement shall be deemed to have been renewed for an additional term of one (1) year commencing on the day after the expiration of the then current term and so on from year to year. Notwithstanding the foregoing, either party shall have the right to terminate this Agreement at any time for any reason or no reason upon thirty (30) days' prior written notice. In the event that Employer or Employee gives notice to terminate pursuant to the foregoing sentence, Employer may elect to have Employee cease working immediately so long as Employer continues to pay Employee his base salary in accordance with the provisions of Section (4)(a) hereof for the entire thirty (30) day notice period. In the event Employer elects to have Employee immediately cease working during the thirty (30) days notice period as provided in the foregoing sentence and Employee finds alternative employment that is not in violation of any provision herein, Employee may accept and engage in the alternative employment and upon Employee's first date of employment with the alternative employer, Employer shall terminate the payment of Employee's base salary as provided in subsection 4(a). In the event that Employee is terminated by Employer without cause then in such event Employee shall be given a severance payment in the amount that is equal to twelve (12) months of his then base salary provided that Employee first signs a Severance and Release Agreement in a form prescribed by Employer. The aforesaid severance payment shall be paid over twelve (12) months and shall be subject to mitigation by Employee.

## 4. Compensation of Employee.

(a) As compensation for all services to be performed by Employee from and after the Commencement Date, Employer agrees to pay to Employee a base salary of Two Hundred Ten Thousand Dollars (\$210,000.00) per annum. All such payments shall be prorated for any partial month or year and shall be payable in accordance with Employer's customary payroll practices for Employees. Federal income taxes, social security taxes and other customary employee payroll deductions shall be deducted from all amounts paid to Employee as compensation under this Employment Agreement. The Employer shall review Employee's performance after he has worked on a full time basis for six months at which time it will consider increasing his base salary to thereafter be \$220,000. Employer will review Employee's performance annually at which time Employee's base salary may subsequently be changed.

- (b) Effective as of the Commencement Date Employer shall give Employee stock options for 100,000 shares of common stock under its stock option plan which will provide, among other things, for vesting in three near equal annual increments at a \$1.29 per share strike price. Such options shall have a duration of 10 years. The stock option plan provides, inter alia, that unvested options shall be forfeited in the event that Employee is no longer an employee as of the vesting date.
- (c) The Employee also may qualify for a bonus based on the following criteria. During the first sixteen (16) months of this Agreement, (i) a bonus in the amount of 15% of the then base salary upon an IND application that is approved of by the CEO being filed with the FDA; and (ii) a bonus in the amount of 5% of the then base salary upon the delivery of material for toxicology. Each bonus, if any, shall be paid 50% in cash and 50% as options derived from The Company's Incentive stock option plan. Such options shall have a duration of 10 years and vest over a period of 3 years as described in 4(b) with an exercise price at the fair market value on the date of approval by the Board of Directors. Employer shall review Employee's performance annually with a view towards setting criteria for possible additional bonus arrangements.
- (d) Employee shall be entitled to participate in such fringe benefit programs as Employer may offer to its senior employees generally, including family health and life insurance, at Employer's expense. The Employer's current health insurance plan is with Empire Blue Cross/Blue Shield and also includes optical and dental coverage. However, Employer may amend, decrease or discontinue any benefit program at any time without advance notice to or consent of the Employee, consistent with the manner in which Employer changes the benefit programs for other similarly situated employees of Employer.
- 5. <u>Absences and Vacation</u>. Paid time off for vacations and sick days shall be limited to an aggregate of seventeen (17 days) per annum during the term of this Agreement, which shall be in addition to legal holidays. Except as to sick days, time off shall be taken at a time reasonably convenient to Employer. In the event Employee's employment terminates prior to the end of the term hereof, such entitlement shall be prorated. Any unused time off at the end of any annual term of this Agreement shall not entitle Employee to payment therefor and may not be carried forward into any subsequent period of employment.

#### 6. Expenses.

(a) In addition to the compensation payable to Employee under Section 4, Employer agrees to reimburse Employee for up to Twenty-Five Thousand Dollars (\$25,000.00) of actual expenses incurred by Employee to transfer his household to New York City (permitted expenses hereunder include, but are not limited to, costs such as: contractual obligations for Employee's children's school term through June 2011, temporary housing needs for the time between Employee's home in Boston (March 31) and when Employee can occupy his new home in New York State, health care premium charges for Employee's Boston based health insurance plan for the period of March 15 to April 15, 2011) and an additional amount, up to \$6,000 for Employee to take his family on up to three trips to New York in search of housing including the rental of a car. Such payments will be made subject to the submission of receipts for expenses. The amount of unused expenses, if any, will not be paid to Employee and may not be carried forward for use in future years. Such reimbursement shall be made upon presentation of receipts satisfactory to Employer for expenses actually incurred in connection with the foregoing.

#### 7. Termination Other Than For Cause.

- (a) In the event of Employee's death, Employee's employment shall terminate immediately and Employee's estate shall be paid Employee's base salary and accrued bonus, if any, through the date on which such death occurred.
- (b) If Employee becomes unable to perform the essential functions of Employee's duties (with reasonable accommodation, if requested) due to partial or total disability or incapacity resulting from a mental or physical illness or injury or any similar cause, Employer will continue the payment of Employee's base salary pursuant to Section 4(a) for a period of two (2) weeks or for the duration of any accrued and unused vacation, whichever is longer, following the work day that Employee first is unable to perform the essential functions of Employee's duties due to such disability or incapacity. Thereafter, Employer shall have no obligation for the payment of Employee's base salary pursuant to Section 4(a) to Employee during the continuance of such disability or incapacity. Notwithstanding anything to the contrary contained herein, Employee shall not be entitled to receive base salary pursuant to this subsection 8(b) for more than thirty (30) days, or such additional days if the Employee shall have accrued and unused vacation, in any consecutive twenty-four (24) month period. If Employee is unable to perform the essential functions of Employee's duties (with reasonable accommodation, if requested) due to partial or total disability or incapacity resulting from a mental or physical illness or any similar cause for the longer of a period of sixty (60) consecutive days or for a cumulative period of sixty (60) days during any twelve (12) month period or the maximum period of time required under the federal Family Medical Leave Act ("FMLA") or other applicable law, Employer shall have the right to terminate this Agreement immediately after the expiration of the later of the sixtieth (60th) day of disability or exhaustion of available unpaid leave under FMLA or other applicable law, without the requirement of any further notice, in which event Employer shall have no further obligations or liabilities hereunder after the date of such termination.

### 8. Termination For Cause.

- (a) Employee's employment under this Agreement shall be deemed to be terminated upon the occurrence of any of the following, at Employer's election, immediately upon Employer giving written notice of such termination to Employee:
  - (i) Employee's conviction of any felony or a crime involving moral turpitude.
- (ii) Employee's failure or refusal to follow, in any material respect, the instructions of Employer or the bylaws, policies, standards or regulations of Employer, which from time to time may be established or changed, and such failure or refusal is not cured within fifteen (15) days of receiving written notice of such violation from Employer.
- (iii) Employee's continued failure or refusal to faithfully and diligently perform, in any material respect, the usual and customary duties of Employee's employment hereunder, and such failure or refusal is not cured within fifteen (15) days of receiving written notice of such violation from Employer.
- (iv) Employee's conduct is unprofessional, unethical, immoral or fraudulent and such conduct is not cured within fifteen (15) days of receiving written notice to cure such conduct from Employer.
  - (v) Employee's conduct is detrimental to the reputation, character or standing of Employer.
- (vi) Unlawful use by Employee of narcotics or other controlled substances, or use of alcohol or other drugs in a manner Employer reasonably determines interferes with the performance of the essential functions of Employee's duties hereunder.
- (xxii) Employee's failure or refusal to behave in a courteous, respectful and helpful manner toward third parties or coworkers and such behavior is not cured within ten (10) days of receiving notice to cure such behavior from Employer.
- (xiii) Any written notice under this Section 9(a) shall specify the alleged violations in sufficient detail as to apprise Employee of the default or failure.

(b) In the event that Employer fails to pay Employee any installment of the base salary owed to Employee under Section 4(a) or (b) when it is due and such non-payment is not cured within fifteen (15) days after Employee shall have notified Employer in writing of such non-payment, then Employee, provided that Employee is not in default with respect to any of Employee's obligations under this Agreement, shall have the option to terminate Employee's employment under this Agreement immediately upon Employee giving written notice of such termination to Employer.

# 9. Proprietary and Confidential Information.

a. Confidential Information. Employee acknowledges that, during the course of his service with Employer, he will have access to Confidential Information and materials not generally known outside Employer. For all purposes of this Agreement, "Confidential Information" means all information and materials (whether conceived or developed by Employee or others), marketing and other business plans, customers and customer information, data strategies, research, reports, copyrights and patents related to Employer. During the Term of this Agreement, Employee shall not, without the prior consent of Employer, communicate or divulge any Confidential Information or materials to anyone other than Employer and its partners, affiliates, employees, consultants and those designated by it except in the course of carrying out his duties or as required by law. Employee acknowledges that Confidential Information is and shall remain the property of Employer. The confidentiality obligations hereunder shall not apply to Confidential Information which: (i) is, or later becomes, public knowledge other than by breach of this Agreement; or (ii) is in the possession of Employee with the full right to disclose same prior to his receipt of it from Employer; or (iii) is independently received by Employee from a third party, with no restrictions of disclosure. Furthermore, Employee agrees not to use Confidential Information for any purposes other than to perform duties for Employer hereunder. Employee shall also execute Employer's standard Confidentiality Agreement.

b. Ownership of Patents and Intellectual Property. Employee agrees that any work prepared for Employer from the date of this Agreement until the expiration of his employment with Employer, which is eligible for copyright and patent protection under the laws of the United States or any other country and any proprietary know-how developed by Employee while rendering services for Employer, will vest in Employer. Employee hereby grants, transfers and assigns all right, title and interest in such work and all copyrights and patents in such work and all renewals and extensions thereof to Employer, and agrees to provide all assistance reasonably requested by Employer in the establishment, preservation and enforcement of Employer's copyright and patents in such work, such assistance to be provided at Employer's expense but without any additional

compensation to Employee if Employee is employed by Employer and for reasonable compensation and subject to his reasonable availability if he is not. If Employer cannot, after reasonable effort, secure Employee's signature on any documents needed do apply for or prosecute any patent, copyright or other right or protection relating to an invention, whether because of his physical or mental incapacity or for any other reason whatsoever, Employee hereby irrevocably designates and appoints Employer and its duly authorized officers and agents as his agent and attorney-in-fact, to act for and on his behalf and in his name and stead for the purpose of executing and filing any such application or applications and taking all other lawfully permitted actions to further the prosecution and issuance of patents, copyrights, or similar protections thereon, with the same legal force and effect as if executed by him.

c. Litigation. Employee agrees to render assistance and cooperation to Employer at its request regarding any matter, dispute or controversy with which Employer may become involved and of which Employee has useful knowledge, information or expertise. Such services will be without additional compensation if Employee is then employed by Employer and for reasonable compensation and subject to his reasonable availability if he is not. Following his employment, Employee shall not be required to cooperate other than as a fact witness. Employer agrees to pay all expenses reasonably incurred or to be incurred by Employee in connection with his cooperation.

### 10. Covenants not to Compete.

- a. Non-competition. Employee acknowledges that his duties hereunder and the services he will provide to Employer are of a special, unique, unusual and extraordinary character, which gives this Agreement particular value to Employer, and that the knowledge he will learn while working for Employer is such that it will necessarily be valuable to a competitor and almost impossible to keep confidential if Employee were to work for a competitor. Therefore, during the Term and for a period of one year after termination of his service to Employer, Employee will not, directly or indirectly, enter into, organize, control, engage in, be employed by, serve as a consultant to, be an officer or director of, or have any direct investment of more than 5% of the outstanding shares in, any business, person, partnership, association, firm, corporation, or other entity engaged in any business activity (including, but not limited to, research, development, manufacturing, selling, leasing, licensing or providing services) which is competitive with the business of Employer.
- b. Non-diversion. During the Term, and for a period of one year after the date of termination of Employee's employment with Employer, Employee will not divert or attempt to divert or take advantage of or attempt to take advantage of any actual or potential business or opportunities of Employer.

c. Non-recruitment. Employee agrees that Employer has or will invest substantial time and effort in assembling its workforce. Accordingly, Employee agrees that during the Term and for a period of one year after the date of termination of Employee's employment with Employer Employee will not directly or indirectly (a) hire away any individuals who were employed by Employer during the one-year period prior to the date of termination of Employee's service with Employer, or (b) directly or indirectly, entice, solicit or seek to induce or influence any such employees to leave their service with Employer.

### 11. Remedies.

- a. Employee acknowledges that the restrictions contained in Sections 9 and 10, in view of the nature of the business of Employer, are reasonable and necessary in order to protect the legitimate interests of Employer. Employee acknowledges that any violation of such restrictions would likely result in irreparable injuries to Employer, and Employee therefore acknowledges that, in the event of Employee's violation of any of these restrictions, Employer shall be entitled to seek from any court of competent jurisdiction preliminary and permanent injunctive relief without proving actual damage or immediate or irreparable harm and without posting any bond. In addition, Employer shall be entitled to seek damages and an equitable accounting of all earnings, profits and other benefits arising from such violation, which rights shall be cumulative and in addition to any other rights or remedies to which Employer may be entitled.
- b. If the time, geographic, or other limitations specified in Sections 9 and 10 above should be adjudged to exceed limitations permitted by applicable law in any proceeding, then the affected provisions shall be deemed reformed in such jurisdiction to the maximum time, geographic, product or service or other limitations permitted by applicable law. If Employee violates any of the restrictions contained in the foregoing Sections 9 and 10, the restrictive period shall be tolled, and shall not run, during the time of any said breach.
- c. In view of the difficulty of determining the amount of damages that may result to the parties hereto from the breach of the provision of Section 9 or 10, it is the intent of the parties hereto that, in addition to monetary damages, any non-breaching party shall have the right to prevent any such breach in equity or otherwise, including without limitation prevention by means of injunctive relief. The prevailing party in any such action shall be entitled to an award of its reasonable attorney's fees and costs.
- 12. Non-disparagement. Employee and Employer mutually agree that, during the Term and for a period of five years thereafter, neither will directly or indirectly disparage the other.

- 13. Entire Agreement; Amendments. This Agreement constitutes the entire agreement and understanding between Employer and Employee relating to the subject matter hereof, and shall not be amended or changed except by written instrument signed by each of the undersigned parties. There are no prior or contemporaneous oral or written understandings or agreements between the parties regarding Employee's employment by Employer or any other matter.
- 14. <u>No Waiver</u>. Neither Employee nor Employer shall by any act, delay, indulgence, omission or otherwise be deemed to have waived any right or remedy hereunder or to have acquiesced in any default in or breach of any of the terms and conditions hereof. No failure to exercise, nor any delay in exercising, on the part of Employee or Employer, any right, power or privilege hereunder shall operate as a waiver thereof. No single or partial exercise of any right, power or privilege hereunder shall preclude any other or further exercise thereof or the exercise of any other right, power or privilege.
- 15. Waiver of jury trial. The parties hereto waive any and all rights to a trial by jury with respect to any action arising hereunder.
- 16. <u>Governing Law, Venue. Interpretation of Language</u>. The parties agree that this Agreement shall be governed by the laws of the State of New York and that venue for an action between the parties that arises out of this Agreement shall be in New York county, State of New York. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any of the provisions of this Agreement.
- 17. <u>Resignation as Officer and Director</u>. In the event that Employee's employment with Employer is terminated for any reason whatsoever, Employee agrees to immediately resign from any position Employee may hold as an officer or director of, or on behalf of, Employer.
- 18. <u>Limitation on Authority</u>. Without the express written consent of Employer, the Employee shall have no apparent or implied authority to:
  - (a) pledge the credit of Employer or any of its employees;

- (b) bind the Employer under any contract, agreement, note, mortgage or otherwise; or
- (c) sell, mortgage, transfer or otherwise dispose of any assets of Employer.
- 19. <u>Notices</u>. Any notices under this Agreement shall be given in writing in person or by registered or certified U.S. mail, postage prepaid, return receipt requested, or by facsimile with confirmation, to the parties at their respective addresses set forth below, and such notices shall be deemed given when received or three (3) days after placed in the mail in the manner provided above. Either party may change such party's address for notice by giving notice as provided herein.

(a) If to Employer: With a copy to:
Dr. Robert Nowinski Seth I. Rubin, Esq.
ContraFect, Corp. East Tower, 15th Floor
28 Wells Avenue 1425 Rxr Plaza

Yonkers, NY 110701 Uniondale, NY 11556-1425

(b) If to Employee:
Daniel Couto
70 Somerstown Rd.
Ossining, NY 10562

20. <u>Prior Agreements</u>. Employee represents to Employer that (a) there are no restrictions, agreements or understandings to which Employee is a party that would prevent or make unlawful Employee's execution of this Agreement or Employee's employment hereunder, (b) Employee's execution of this Agreement and Employee's employment hereunder shall not constitute a breach of any contract, agreement or understanding, oral or written, to which Employee is a party or by which Employee is bound, (c) Employee is free and able to execute this Agreement and to enter into employment by Employer, and (d) Employee shall not divulge to Employer any trade secrets or proprietary information that belongs to any other person or entity.

21. No Assignment. This Agreement and the rights and obligations of both parties hereunder are personal in nature, and shall not be assignable by either party hereto, except by operation of law. Notwithstanding the foregoing, Employer may assign some or all of its rights hereunder to a successor in interest.

22. <u>Headings</u>. Headings used in this Agreement are solely for the convenience of the parties and shall be given no effect in the construction or interpretation of this Agreement.

### 23 Miscellaneous.

- (a) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original as against any party whose signature appears thereon, and all of which shall together constitute one and the same instrument. This Agreement shall become binding when one or more counterparts hereof, individually or taken together, shall bear the signatures of all of the parties reflected hereon as the signatories.
- (b) Provisions Separable. The provisions of this Agreement are independent of and separable from each other, and no provision shall be affected or rendered invalid or unenforceable by virtue of the fact that for any reason any other or others of them may be invalid or unenforceable in whole or in part.
- (c) Survival. Any provisions of this Agreement which, by their terms, are intended to survive the expiration or termination of this Agreement, including but not limited to the restrictive covenant and the provisions relating to non-solicitation, confidentiality, and both parties agree to forever waive any claim or defense, at law or in equity, asserting that such provision(s) terminated or otherwise became unenforceable as a result of the expiration or termination of this Agreement.
- (d) <u>Section 409A Compliance.</u> Any payments under this Agreement that are deemed to be deferred compensation subject to the requirements of Section 409A of the Internal Revenue Code are intended to comply with the requirements of section 409A. To this end, if at any time during the term of this Agreement, or upon its termination, the deferral of any payments or benefits otherwise payable is necessary to prevent any additional tax under Section 409A, then Employer will defer such payments (without reduction in the amount ultimately paid or provided to Employee) until the earliest date that is permitted under Section 409A. Any amounts so deferred will be paid promptly to Employee at the end of such deferral period.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed and delivered as of the day and year set forth below.

# CONTRAFECT CORPORATION

By: /s/ Robert Nowinski

Robert Nowinski, CEO

Dated: March 21, 2011

/s/ Daniel E. Couto

Daniel E. Couto

Dated: March 21, 2011

### SEPARATION AND CONSULTING AGREEMENT

This Separation and Consulting Agreement (the "Agreement") is entered into by and between ContraFect Corporation (the "Company") and Dr. Barry Kappel ("Kappel"), effective as of April 15, 2015.

1. Resignation from Employment. Effective as of April 15, 2015, Kappel resigned from his employment with the Company, and thereby terminated his service in any position or office that he held as a consequence of his employment with the Company. For the avoidance of doubt, Kappel's last day of employment with the Company shall be April 15, 2015 (the "Employment Termination Date"). The parties agree that they (in the Company's case, including its officers and directors) will refer to Kappel's termination of employment only in the manner set forth on Exhibit A, which shall be reflected in a Form 8-K. The Company agrees that no grounds exist to terminate Kappel for "Cause" as defined in the Employment Agreement (as defined below).

### 2. Severance Compensation

- a. <u>Cash Compensation</u>. Subject to Kappel's execution of this Agreement, the Company will provide Kappel with (i) a cash separation payment of \$135,000, paid as a lump sum within ten business days following execution of this Agreement, and (ii) \$330,750 in cash compensation, payable in twenty-four (24) substantially equal installments consistent with the Company's customary payroll practices, commencing on May 15, 2015.
- b. <u>Equity Compensation</u>. Effective as of April 15, 2015 ("date of grant"), Kappel will receive, a grant of fully vested and exercisable options to purchase shares of the Company's common stock with a grant date fair market value of \$60,750, as determined by the Company in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, or any successor promulgation, and which shall have a stated exercise price equal to the closing per share price of the Company's common stock on the date of grant. These options shall remain exercisable until March 30, 2016, after which date they shall expire to the extent unexercised. Such grant will be made on the same terms as previous grants, including the ability to cashless exercise.
- c. <u>Benefit Continuation</u>. If Kappel elects to receive continued healthcare coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA") in connection with the termination of Kappel's employment with the Company, the Company will pay the full premiums for such coverage (for Kappel and his eligible dependents) until the earlier of (i) the eighteen (18) month anniversary of the Employment Termination Date, or (ii) the date that Kappel and his covered dependents become eligible for healthcare coverage under a plan of Kappel's successor employer's plan(s).
- 3. <u>Payment of Earned but Unpaid Salary and Paid Time Off.</u> In connection with the termination of Kappel's employment with the Company, the Company will pay Kappel any earned but unpaid base salary in a lump sum on the payroll date that falls on the Employment Termination Date. The Company will also pay Kappel salary for three (3) accrued but unused vacation days in a lump sum on the next payroll date following that which occurs on the Employment Termination Date. In lieu of payment for a fourth accrued but unused vacation day, Kappel will be entitled to retain his Company-issued iPad.

- 4. <u>Consulting Services</u>. Kappel agrees, for the period from April 15, 2015 to December 31, 2015 (the "Consulting Period"), to perform consulting services for the Company and its affiliates as reasonably requested by the Company. Kappel's services shall be of an advisory nature and the Company shall not have any obligation to follow Kappel's advice. Kappel agrees to provide such services as reasonably requested by the Company but in no event for more than seventeen business days during the Consulting Period at such times and at such locations as may be reasonably requested by the Company's Chief Executive Officer and agreed to by Kappel, whose consent will not be unreasonably withheld. It is anticipated by the parties that Kappel's services shall be limited to no more than four days per month (two days in December). In connection with the provision of such consulting services, the Company will reimburse Kappel for any expenses reasonably incurred by him.
- 5. <u>Consulting Compensation</u>. In exchange for Kappel's agreement to provide the consulting services contemplated hereunder, the Company will provide Kappel with the following treatment with regard to equity awards:
- a. The vesting of Kappel's outstanding unvested options held as of the Employment Termination Date will accelerate in accordance with Exhibit B attached hereto. For the avoidance of doubt, such accelerated vesting will apply to each individual option grant until the earlier of (i) the date on which the entire grant is vested or (ii) December 31, 2015. Such accelerated vesting is not intended to create entitlement to any options beyond those initially awarded in connection with each grant of options. Any options remaining unvested after December 31, 2015 will be forfeited. Options granted prior to the consummation of the Company's initial public offering (specifically, those granted on April 15, 2010, September 1, 2010, November 1, 2010, February 8, 2011, October 3, 2011, February 27, 2013, March 21, 2014, and April 29, 2014) will expire (to the extent vested on or prior to December 31, 2015 after giving effect to this Agreement) on December 31, 2017, with the exception of the options granted on April 15, 2010 and September 1, 2010, which will expire on April 15, 2020 and September 1, 2020, respectively. Options granted after the consummation of the Company's initial public offering (specifically, those granted on December 4, 2014, February 6, 2015, and those granted pursuant to Section 2(b) above) will expire (to the extent vested on or prior to December 31, 2015 after giving effect to this Agreement) on March 30, 2016.
- b. With respect to the consulting services contemplated hereunder, the Company will indemnify Kappel in respect of any liability he may incur, unless such liability is incurred due to Kappel's gross negligence or willful misconduct, as a result of his provision of the consulting services (including, without limitation, the payment of any reasonable attorneys' fees and costs incurred by him). Kappel will be covered by the Company's applicable insurance policies with respect to the performance of any such services.
- 6. <u>Independent Contractor</u>. During the Consulting Period, Kappel will not be an employee of the Company, but will have the relationship of an independent contractor to the Company. As an independent contractor, Kappel shall have no authority to represent, act on behalf of or bind

the Company. The parties agree that all income recognized by Kappel in respect of stock options vesting following the date hereof shall be self-employment income reportable on Form 1099. Kappel shall have the sole responsibility and obligation to report such self-employment income on Kappel's tax returns and to pay such taxes as are required by law, and, solely with respect to the income relating to such stock options, the Company shall have no right, responsibility or obligation to withhold income or payroll taxes under the United States Insurance Contributions Act or under state unemployment, disability or other laws or to pay employer payroll taxes thereon under such laws or to withhold special or general funds, assessments, or taxes generally collected by employers for the use and benefit of employees.

- 7. Cooperation. Kappel agrees to render assistance and cooperation to the Company as the Company reasonably requests regarding any matter, dispute or controversy with which the Company may become involved and of which Kappel has or may have reason to have relevant knowledge, information or expertise. Such services will be without additional compensation if during the Consulting Period, and for reasonable compensation (including, without limitation, a per diem fee no less than the ratable base salary amount as was in effect prior to the Employment Termination Date) and subject to Kappel's reasonable availability if after the Consulting Period, provided, that in any event the Company will reimburse Kappel for any expenses reasonably incurred by him in connection with such cooperation. In no event will (i) Kappel have any obligation to cooperate if the Company is in breach of this Agreement (or any other agreement to which he is a party with the Company or its affiliates) and (ii) Kappel have an obligation to cooperate in any matter, dispute or controversy involving Kappel as an adverse party to the Company or its affiliates.
- 8. Confidentiality. Kappel acknowledges that, during the Consulting Period he may have, and during his employment with the Company he has had, access to Confidential Information and materials not generally known outside the Company. For the purposes of this Agreement, "Confidential Information" shall mean all confidential and proprietary information and materials (whether conceived or developed by Kappel or others) of the Company, and Company marketing and other business plans, customers and customer information, data strategies, research, reports, copyrights and patents related to the Company. During the Consulting Period and thereafter, Kappel shall not, without the prior consent of the Company, communicate or divulge any Confidential Information or materials to anyone other than the Company and its partners or affiliates and those designated by the Company unless required by law. Kappel acknowledges that Confidential Information is and shall remain the property of the Company. The confidentiality obligations hereunder shall not apply to Company information that would be Confidential Information but which: (i) is, or later becomes, public knowledge other than by breach of this Agreement; (ii) is in the possession of Kappel with the full right to disclose prior to his receipt of such Confidential Information from the Company, as evidenced by written records; or (iii) is independently received by Kappel from a third party with no restrictions on disclosure. Furthermore, Kappel agrees not to use, without the Company's approval, Confidential Information for any purposes other than to perform duties for the Company under this Agreement. Kappel also hereby reaffirms his obligations under the Company's standard confidentiality agreement, executed by Kappel on February 27, 2013.

- 9. Ownership of Copyrights, Patents, and Intellectual Property. Kappel agrees that any work prepared for the Company during his employment therewith and during the Consulting Period which is eligible for copyright and patent protection under the laws of the United States or any other country, and any proprietary know how developed by Kappel while rendering services for the Company in any capacity, will vest in the Company. Kappel hereby grants, transfers, and assigns all rights, titles, interests, copyrights and patents in such work, and all renewals and extensions thereof, to the Company, and agrees to provide all assistance reasonably requested by the Company in the establishment, preservation and enforcement of the Company's copyrights and patents in such work. Such assistance will be provided at the Company's expense, but without any additional compensation to Kappel if during the Consulting Period, and for reasonable compensation (including, without limitation, a per diem fee no less than the ratable base salary amount as was in effect prior to the Employment Termination Date) and subject to Kappel's reasonable availability if after the Consulting Period. If the Company cannot, after reasonable effort, secure Kappel's signature on any documents needed to apply for or to prosecute any patent, copyright, or other right or protection relating to an invention, whether because of his physical or mental incapacity or for any other reason, Kappel hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as his agent and attorney-in-fact, to act for and on his behalf and in his name and stead for the purpose of executing and filing any such application or applications and taking all other lawfully permitted actions to further the prosecution and issuance of patents, copyrights, or similar protections thereon with the same legal force and effect as if executed by him.
- 10. Non-Competition. Kappel agrees that, during the Consulting Period and for a period of one year thereafter, he will not, directly or indirectly, enter into, organize, control, engage in, be employed by, serve as a consultant to, be an officer or director of, or have any direct or indirect investment in any business, person, partnership, association, firm, corporation, or other entity engaged in any business activity (including, but not limited to, research, development, manufacturing, selling, leasing, licensing or providing services) which is competitive with the business of the Company. For the sake of clarity, a business competitive with the Company's business is one that uses bacteriophages, bacteriophage lysins, endolysins or a derivative thereof for the treatment of human infections or the use of antibodies for the treatment of influenza.
- 11. <u>Non-Solicitation</u>. Kappel agrees that, for a period of fifteen months after the Employment Termination Date, he will not divert, attempt to divert, take advantage of or attempt to take advantage of any actual or potential business or opportunities of the Company which Kappel became aware of as a result of his employment or consulting with the Company. Kappel further agrees that, during the Consulting Period and for a period of one year thereafter, he will not hire away any critical individuals who were employed by the Company during the Consulting Period or the one-year period thereafter, nor will Kappel directly or indirectly entice, solicit, or seek to induce or influence any such employees to leave their positions at the Company.
- 12. Non-Disparagement. Kappel and the Company agree that, during the Consulting Period and for a period of five years thereafter, neither will directly or indirectly disparage the other.

- 13. <u>Non-Disclosure</u>. Kappel agrees that, during the Consulting Period and perpetually thereafter, he will not disclose, to any party, (i) the terms of this Agreement, including but not limited to the payments made to Kappel hereunder, or (ii) any information pertaining to the negotiation of this Agreement, provided that it will not be a breach of this Agreement if Kappel discloses the terms of this Agreement and information pertaining to its negotiation to his personal legal, financial and tax advisors and his family members.
- 14. Remedies for Breach. In the event that Kappel willfully and materially breaches obligations under this Agreement, which have not been cured after a remedial period provided to Kappel by the Company of at least ten (10) business days, in addition to whatever other rights the Company may have, Kappel shall forfeit his right to receive any payments or benefits under this Agreement except with respect to the severance benefits described in Section 2 hereof (which shall be provided in all instances other than willful and material breaches of any of Sections 8 through 13 hereof). In the event that the Company willfully and materially breaches obligations under this Agreement, which have not been cured after a remedial period provided to the Company by Kappel of at least ten (10) business days, Kappel may cease providing consulting services to the Company, although compensation therefor as described in the Agreement will be deemed earned in full and payable and no such breach will relieve the Company from any obligation under the Agreement.
- 15. Non-Waiver of Breach. Either party may waive any breach of this Agreement by the other party, but no such waiver shall be deemed to have been given unless such waiver be in writing, signed by the waiving party and specifically designate the breach waived, nor shall any such waiver constitute a continuing waiver of similar or other breaches.
  - 16. Non-Assignment. Neither party may assign its obligations hereunder without the prior written consent of the other party.

### 17. Release.

a. General Release. In consideration of the payments and benefits provided to Kappel under this Agreement, Kappel and each of his heirs, executors, administrators, representatives, agents, successors and assigns (collectively, the "Releasors") hereby irrevocably and unconditionally waive, release and forever discharge the Company and its subsidiaries and affiliates and each of their respective current and former officers, employees, directors, partners, members, shareholders, representatives, attorneys and agents (collectively, the "Released Parties") from any and all claims, demands, actions, causes of action, rights, judgments, obligations, damages, demands, accountings or liabilities of whatever kind or character, whether known or unknown, suspected or unsuspected (collectively, "Claims"), that the Releasors have or may have against the Released Parties that arise out of or are connected to (i) Kappel's relationship with the Company up to and including the dates of the execution of this Agreement, (ii) the Employment Agreement, dated as of October 20, 2009, between the Company and Kappel (the "Employment Agreement"), or (iii) any event, condition, circumstance, conduct, occurrence, omission, transaction or obligation that occurred, existed or arose on or prior to the date hereof, including, with respect to both clauses (i) and (ii) of this Section 17(a), without limitation: (1) any Claims under all federal, state and local statutes that employees or service

providers could bring employment or service-related claims under, including, without limitation, any antidiscrimination statute, wage and hour statute, leave statute, equal pay statute, whistleblower statute and any other federal, state, local or foreign law, rule or regulation, in each case that may legally be waived and released, and (2) any tort or contract Claims, including, without limitation, wrongful discharge, breach of contract, defamation, slander, libel, emotional distress, tortious conduct, invasion of privacy, wrongful or retaliatory discharge, violation of public policy, implied covenant of good faith and fair dealing, negligence, fraud, personal injury or sickness or any other harm. Kappel does not release, discharge or waive (A) any right Kappel may have to enforce this Agreement, (B) any Claims made under state workers' compensation or unemployment laws, (C) Claims that cannot be waived by law, (D) Claims for vested benefits under the Company's employee benefit plans including equity compensation plans and grants thereunder to the extent vested or to be vested, or (E) Claims to indemnification, contribution, exculpation, directors and officers insurance or other insurance (e.g., executives and officers).

### b. Proceedings.

- i. <u>General Agreement Relating to Proceedings</u>. Kappel has not filed, and except as provided in Section 17(b)(ii) hereof, Kappel agrees not to initiate or cause to be initiated on his behalf, any complaint, charge, claim or proceeding against the Released Parties before any local, state or federal agency, court or other body relating to matters released pursuant to Section 17 (each, individually, a "Proceeding"), and agrees not to participate voluntarily in any Proceeding. Kappel waives any right he may have to benefit in any manner from any relief (whether monetary or otherwise) arising out of any Proceeding.
- ii. <u>Certain Administrative Proceedings</u>. Section 17(b)(i) hereof shall not preclude Kappel from filing a charge with or participating in any administrative investigation or proceeding by the Equal Employment Opportunity Commission or another Fair Employment Practices agency. Kappel is, however, waiving his right to recover money in connection with any such charge or investigation. Kappel is also waiving his right to recover money in connection with a charge filed by any other entity or individual, or by any federal, state or local agency.
- 18. Section 409A. This Agreement is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments and benefits provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by Kappel on account of non-compliance with Section 409A. The parties agree that the treatment of equity compensation outstanding hereunder is not a material modification to

any such equity compensation. The parties further agree that the payment schedule for severance compensation payable hereunder would not result in a violation of Section 409A (including the requirement that any compensation be subject to any six-month delay for specified employees), and the Company agrees to report such treatment consistent therewith.

- 19. <u>Severability</u>. Provisions of this Agreement are severable. If any provision is held to be invalid or unenforceable it shall not affect the validity or enforceability of any other provision.
- 20. <u>Entire Agreement</u>. This Agreement (and the applicable equity compensation arrangements referenced herein) represents the sole and entire agreement between the parties and, except as expressly stated herein, supersedes the Employment Agreement and all prior agreements, negotiations and discussions between Kappel and the Company, with respect to the subject matters contained herein.
- 21. <u>Governing Law</u>. This Agreement shall be construed as a whole in accordance with its fair meaning and in accordance with the laws of the State of New York. The language in the Agreement shall not be construed for or against any particular party.
  - 22. Headings. The headings used herein are for reference only and shall not affect the construction of this Agreement.
- 23. <u>Disputes</u>. The parties agree that any and all disputes, controversies or claims arising out of or relating to this Agreement, or breach thereof, shall be submitted to final and binding arbitration pursuant to the employment arbitration rules of the American Arbitration Association. The arbitration shall take place in the State of New York.
- 24. <u>Miscellaneous</u>. Payments and benefits under this Agreement are not subject to mitigation or offset, except as expressly stated herein with respect to COBRA. This Agreement will be binding upon and inure to the benefit of the parties' successors and heirs. This Agreement can be executed in counterparts, which together will constitute the binding agreement of the parties, and electronic copies shall have the effect of originals.

[The remainder of this page is intentionally left blank.]

below.	IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed as of the day and year written					
	THE COMPANY					
/s/ Barry Kappel	By: /s/ Julia P Gregory					
Dr. Barry Kappel	Name: Julia P Gregory Title: Chief Executive Officer					
Date: April 15, 2	015 Date: April 15, 2015					

## Exhibit A: Joint Statement

On April 15, 2015, Barry Kappel resigned from his position as Senior Vice President of Business Development of ContraFect Corporation to pursue other opportunities. He will serve as a consultant to ContraFect until December 31, 2015.

Exhibit B: Schedule of Options

25% on 1-1-13; 25% annually over next	4,285/75%	0		12-31-15	Agreement
three			1,429/25% on 7-1-15	5,714/100%	0
25% on 2-24-14; 25% annually over next three years	7,143/50%	0	3,571/25% on 8-24-15	10,714/75%	3,571/25%
25% on 4-29-14; 25% annually over next three years	4,464/25%	4,464/25% on 4-29-15	4,464/25% on 4-29-15 4,464/25% on 10-29-15	13,392/75%	4,465/25%
25% on 12-4-14; 25% annually over next three	5,000/25%	5,000/25% on 12-4-15	5,000/25% on 6-4-15 5,000/25% on 12-4-15	15,000/75%	5,000/25%
1/16 on each calendar quarter end through 2018	3,125/6.25%	3,125/6.25% on 6-30-15 3,125/6.25% on 9-30-15 3,125/6.25% on 12-31-15	on 5-15-15  3,125/6.25% on 6-30-15  3,125/6.25% on 8-15-15  3,125/6.25% on 9-30-15  3,125/6.25% on 11-15-15  3,125/6.25%	21,875/43.75%	28,125/56.25%
	years 25% on 2-24-14; 25% annually over next three years 25% on 4-29-14; 25% annually over next three years 25% on 12-4-14; 25% annually over next three years 1/16 on each calendar quarter end through	years 25% on 7,143/50% 2-24-14; 25% annually over next three years 25% on 4,464/25% 4-29-14; 25% annually over next three years 25% on 5,000/25% 12-4-14; 25% annually over next three years 1/16 on 3,125/6.25% calendar quarter end through	years 25% on 2-24-14; 25% annually over next three years 25% on 4-29-14; 25% annually over next three years 25% on 4-29-15 25% annually over next three years 25% on 12-4-14; 25% annually over next three years 25% on 12-4-15 25% annually over next three years 1/16 on each calendar quarter quarter end through 2018 3,125/6.25% on 9-30-15	years 25% on 2-24-14; 25% annually over next three years 25% on 4.29-14; 25% annually over next three years 25% on 4.29-15; 25% annually over next three years 25% on 12-25% annually over next three years 25% on 12-4-14; 25% annually over next three years 25% on 12-4-14; 25% annually over next three years 25% on 12-4-15; 5,000/25% on 12-4-15 6-4-15 25% annually over next three years 1/16 on 3,125/6.25% on each calendar quarter end quarter end 9-30-15  12-31-15  3,125/6.25% on 9-30-15  3,125/6.25% on 9-30-15	years 25% on 7,143/50% 0 3,571/25% on 10,714/75% 2-24-14; 25% annually over next three years 25% on 4,464/25% 4,464/25% on 4,464/25% on 13,392/75% 4-29-14; 25% annually over next three years 25% on 4,464/25% 4-29-15 4-29-15 25% annually over next three years 25% on 5,000/25% 5,000/25% on 5,000/25% on 10-29-15 three years 25% on 5,000/25% 5,000/25% on 5,000/25% on 12-4-15 25% annually over next three years 1/16 on 3,125/6.25% 3,125/6.25% on 12-4-15 three years 1/16 on 3,125/6.25% 3,125/6.25% on 3,125/6.25% calendar quarter quarter and quarter and

### Amendment No. 1 to Employment Agreement with Daniel E. Couto

This Amendment No. 1 (the "Amendment") is entered into by and between ContraFect Corporation (the "Employer"), and Daniel E. Couto, (the "Employee"), as of November 2, 2015.

WHEREAS, pursuant to Section 15 of the Employment Agreement, the Employer and the Employee desire to amend the Employment Agreement in accordance with the terms of this Amendment, as more fully set forth herein.

THEREFORE, in consideration of the mutual agreements set forth below, the Employer and the Employee agree to amend the Employment Agreement as follows:

1. Section 4 of the Employment Agreement is amended by adding the following:

"You will be eligible for an annual incentive bonus of 30% of your annual base salary, subject to performance against mutually agreed-upon goals (effective January 1, 2016, 70% corporate/30% individual). You will also be eligible for stock option grants on an annual basis.

2. Section 7d of the Employment Agreement is amended to include:

"In the event that you are terminated by the Company without Cause, or in the event that you resign with Good Reason, as defined below, you will be given (i) a severance payment in the amount that is equal to twelve (12) months of your then-current base salary, (ii) a payment equal to twelve (12) months of applicable health insurance premiums (inclusive of dental and vision insurance) due under COBRA, provided that you first sign a Severance and Release Agreement in a form prescribed by the Company. These severance payments shall be paid over twelve (12) months as any regular paycheck.

"Good Reason" shall mean the occurrence of any of the events or conditions as described here: (i) a material diminution of your authority, duties and responsibilities; (ii) a material reduction in your then-effective base salary, or (iii) the relocation of your principal place of employment to a location that is more than fifty (50) miles "as the crow flies" from Yonkers, New York. Employee must provide written notice ("Notice of Good Reason") to Employer of the existence of a condition described in subsections (i) through (iii) above within 30 days of Employee's knowledge of the initial existence of the condition or such right is waived. The Notice of Good Reason shall fully set forth the facts comprising the event(s) or circumstance(s) giving rise to Good Reason.

Employer shall have a period (the "Good Reason Notice Period") of 30 days during which it may remedy the condition so that it shall not constitute Good Reason or inform Employee that it does not believe Good Reason exists. If Employee believes that the condition has not been cured, or that Good Reason exists notwithstanding Employer's belief that it does not, then Employee shall either abandon the contention that Good Reason exists or terminate employment within 30 days. If Employee continues to work beyond the 30<sup>th</sup> day without resigning, Employee shall be deemed to have waived Good Reason for the event(s) or circumstance(s) set forth in the Notice of Good Reason. "If there is a Change of Control Event and, within twelve (12) months of such Change of Control Event, you resign for Good Reason or you are terminated without Cause, you will receive the severance benefits as outlined above, and, in addition, your thenoutstanding stock options and other equity awards, if any, will become immediately fully vested and exercisable. All such benefits are conditioned upon the execution of a Severance and Release Agreement in a form prescribed by the Company or its successors.

"A "Change of Control Event" means any of the following: (i) any person, or persons acting as a group, or entity (except for a current stockholder) becomes the beneficial owner of greater than 50% of the then-outstanding voting power of the Company; (ii) a change in the composition of the Board of Directors, as a result of which fewer than a majority of the directors are Incumbent Directors. "Incumbent Directors" shall mean directors who either (a) are directors of the Company as of the date hereof, or (a) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of those directors whose election or nomination was not in connection with any transaction described in subsections (i), (iii) or (iv) or in connection with an actual or threatened proxy contest relating to the election of directors of the Company; (iii) a merger or consolidation with another entity where the voting securities of the Company outstanding immediately before the transaction constitute less than a majority of the voting power of the voting securities of the surviving entity outstanding immediately after the transaction, or (iv) the sale or disposition of all or substantially all of the Company's assets."

Section 409A. The Company and you intend, and this Amendment No. 1 to the Employment Agreement shall be construed, that any amounts or benefits payable or provided under this Amendment and the Company's and your exercise of authority or discretion hereunder shall either be exempt from or comply with the provisions of Section 409A of the Internal Revenue Code of 1986, as amended ("the Code") and the treasury regulations relating thereto so as not to subject you to the payment of the tax, interest and any tax penalty which may be imposed under Code Section 409A. The provisions of this Amendment shall be

interpreted and construed in a manner consistent with such intent. In the event that any provision of this Amendment would otherwise fail to satisfy the requirements of Section 409A and the treasury regulations relating thereto, the Company and you agree to further amend this Amendment to maintain to the maximum extent practicable the original intent of the provision without violating the requirements of Code Section 409A. Notwithstanding anything in this Amendment, you acknowledge and agree that the Company has not made any representations to you as to the tax treatment of any payments or benefits under this Amendment, and the Company does not guarantee the tax treatment of any payments or benefits under this Agreement, including without limitation pursuant to Section 409A of the Code, federal, state, or local tax laws or regulations.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed and delivered as of the date first written above.

# EMPLOYER:

By: /s/ Julia P Gregory

Name: Julia P Gregory

Title: CEO

EMPLOYEE:

By: /s/ Daniel E. Couto

Daniel E. Couto

# **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 15, 2016, with respect to the financial statements of ContraFect Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2015.

/s/ Ernst & Young LLP

MetroPark, New Jersey March 15, 2016

#### 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2016

/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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2016

/s/ Michael Messinger

Michael Messinger Vice President, Finance (Principal Financial Officer)

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

In connection with this Annual Report on Form 10-K of ContraFect Corporation (the "Company") for the year ended December 31, 2015, 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 15, 2016

/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, 2015, 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 15, 2016

/s/ Michael Messinger

Michael Messinger Vice President, Finance (Principal Financial Officer)