Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

Commission File Number: 001-36577

ContraFect Corporation

(Exact name of registrant as specified in its charter)

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

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

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

Title of Class	Name of Exchange on Which Registered
Common Stock, Par Value $0.0001 per share	**Nasdaq Capital Market**

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

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☒

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

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

As of June 29, 2018, 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 $157.8 million, based on the closing price of the registrant's common stock on the Nasdaq Capital Market on June 29, 2018 of $2.21 per share.

As of March 7, 2019, there were 79,409,556 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

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

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

As more fully described under the heading "Risk Factors" contained elsewhere in this 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 novel, differentiated biologic therapeutics and developing them for the treatment of life-threatening infectious diseases, including those caused by drug-resistant pathogens. Drug-resistant infections account for 2,000,000 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 platform. 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. Conventional antibiotics require bacterial cell division and metabolism to occur in order to exert their intended effect (i.e., cell death or cessation of growth). Based on *in vitro* tests, lysins, however, are fundamentally different in that they kill bacteria rapidly by enzymatic cleavage of the bacterial cell wall without need for bacterial growth and cell division. In addition to the speed of action and potent cidality, we believe lysins are differentiated by their other hallmark features, which include the demonstrated ability to eradicate biofilms and synergistically boost the efficacy of conventional antibiotics in animal models. Importantly, lysins also have a "narrow spectrum," meaning they kill only specific species of bacteria or closely related bacteria. As such, we believe that lysins targeting gram-positive pathogens will not have negative effects on the beneficial, normal human gastrointestinal ("GI") microbiome, in contrast to conventional "broad spectrum" antibiotics which can kill the body's normal, beneficial bacteria. We believe that the therapeutic profile of lysins is complementary to that of conventional antibiotics. As such, our approach includes the use of lysins in addition to conventional antibiotics for the treatment of serious, drug-resistant bacterial infections, including biofilm-associated infections, to achieve greater efficacy and improve clinical outcomes, as well as potentially protecting against antibiotic resistance.

We believe that the properties of our lysins will make them suitable for targeting antibiotic-resistant organisms, such as *Staphylococcus aureus* ("*Staph aureus")* and *Pseudomonas aeruginosa* ("*P. aeruginosa"*), which can cause serious infections such as bacteremia, pneumonia and osteomyelitis. Beyond lysins, we continue to seek and identify novel antibacterial product candidates. We recently discovered a new class of novel lytic agents, called amurin peptides. Our preliminary characterization studies indicate that amurin peptides have potency across a wide range of resistant gram-negative pathogens, including species that are part of the ESKAPE pathogens (*Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa,* and *Enterobacter species*), which are the leading causes of hospital acquired infections throughout the world. These pathogens are considered to be urgent or serious threats to global health by the U.S. Center for Disease Control ("CDC") and critical priorities by the World Health Organization ("WHO"). We believe that the amurin peptides will be highly complementary to our pathogen-specific lysin platform in addressing these infections. We aim to improve outcomes in patient with these life-threatening bacterial infections through use of our differentiated biologic candidates developed from our novel lysin and amurin platforms.

Our most advanced program, CF-301 ("exebacase"), is an investigational novel lysin that targets *Staph aureus*, including methicillin-resistant ("MRSA") strains, which causes serious infections such as bacteremia, pneumonia and osteomyelitis. *Staph aureus* is also a common cause of biofilm-associated infections of heart valves (endocarditis), prosthetic joints, indwelling devices and catheters. These infections result in significant morbidity and mortality despite currently available antibiotic therapies. Exebacase is being studied in a Phase 2 superiority study to evaluate its safety, tolerability, efficacy and pharmacokinetics ("PK") when used in addition to background standard of care ("SOC") antibiotics compared to antibiotics alone for the treatment of *Staph aureus* bacteremia, including endocarditis in adult patients.

We recently announced positive topline results from this first-in-patient Phase 2 superiority study of exebacase, which showed clinically meaningful improvement in clinical responder rates among patients treated with exebacase in addition to SOC antibiotics compared to SOC antibiotics alone. In the primary efficacy analysis population of 116 patients with documented *Staph aureus* bacteremia, including endocarditis, who received a single intravenous (IV) infusion of blinded study drug, the clinical responder rate was 70.4% for

patients treated with exebacase and 60.0% for patients dosed with SOC antibiotics alone. In a pre-specified analysis of MRSA-infected patients, the clinical responder rate in patients treated with exebacase was 42.8% higher than the clinical responder rate in patients treated with SOC antibiotics alone (74.1% for patients treated with exebacase compared to 31.3% for patients treated with SOC antibiotics alone (p=0.010)). The clinical responder rate in the subset of patients with bacteremia including right-sided endocarditis was 80.0% for patients treated with exebacase compared to 59.5% for patients treated with SOC antibiotics alone, an increase of 20.5% (p=0.028). In the subset of patients with bacteremia alone, the clinical responder rate was 81.8% for patients treated with exebacase compared to 61.5% for patients treated with SOC antibiotics alone, an increase of 20.3% (p=0.035). Exebacase was well-tolerated and treatment emergent adverse events, including serious treatment-emergent serious adverse events (SAEs) were balanced between the treatment groups. There were no SAEs that we determined to be related to exebacase, there were no reports of hypersensitivity related to exebacase and no patients discontinued treatment with study drug in either treatment group. We believe these data establish proof of concept for exebacase, and for the lysin class as therapeutic agents, and will inform the design of Phase 3 for exebacase.

We also continue to advance our preclinical portfolio of novel lysin programs. We have developed a novel, engineered variant of exebacase, known as CF-296, which we believe provides the opportunity for extension of our agents targeting *Staph aureus* through alternative dosing paradigms or drug product presentations. We are evaluating the potential to develop CF-296 as a targeted therapy for deep-seated, invasive biofilm-associated *Staph aureus* infections such as prosthetic joint infections. We are conducting further *in vitro* and *in vivo* characterization of CF-296 to determine the profile and potential place in therapy for this compound. Our lysin research efforts are focused on a broad-based gram-negative discovery program which aims to identify, optimize and develop lysins that target deadly gram-negative pathogens. We have discovered and engineered lysins with potent activity against drug-resistant *P. aeruginosa* bacteria, a major cause of morbidity and mortality in patients with hospital acquired pneumonia and a major medical challenge for patients with cystic fibrosis. We are initiating animal studies of our most promising anti-pseudomonal lysins with the goal of moving this program to the clinic as soon as possible. We were awarded $1.0 million in funding from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) in 2017 to support these efforts and we announced in January 2019 that CARB-X awarded us an additional $2.3 million in the amount of funding to be received over the next two years.

Beyond our lysin programs, we continue our proprietary research to expand our pipeline of complementary, nontraditional antimicrobials to address high unmet medical needs. We have discovered a novel class of phage-derived lytic agents, known as amurin peptides, which have displayed potent activity against a wide range of gram-negative pathogens in preclinical studies, including deadly, drug-resistant *P. aeruginosa, Klebsiella pneumoniae, Escherichia coli, Acinetobacter baumannii and Enterobacter cloacae* bacteria species. We are currently evaluating the *in vitro* profiles of the amurins as we continue to advance the program. We recently announced an award from CARB-X of up to $6.9 million of funding to support these efforts.

Our Strategy

Our strategy is to use our novel, highly differentiated therapeutic products, if approved, 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, exebacase, through Phase 3 clinical development and demonstrate superiority of our therapeutic candidate used in addition to SOC antibiotics over SOC antibiotics alone for the treatment of *Staph aureus* bacteremia, including endocarditis. If our Phase 3 clinical program confirms the results of the Phase 2 study, demonstrating the superiority of exebacase, used in addition to SOC antibiotics as compared to antibiotics alone, we would seek marketing authorization with a superiority claim which, if exebacase is approved, we believe would be highly differentiated from

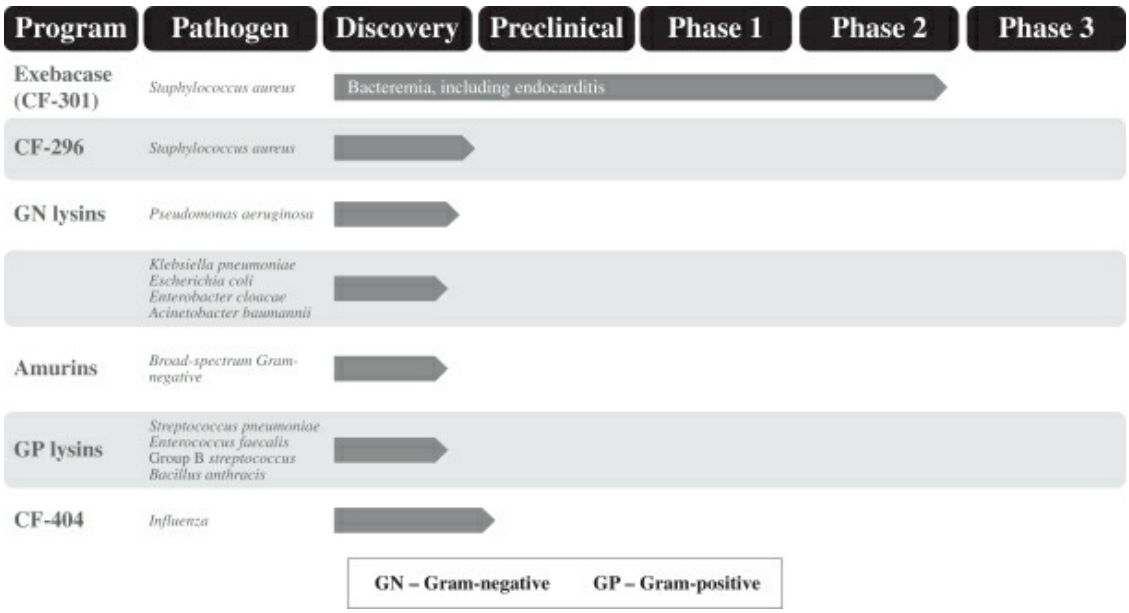
conventional antibiotics and would lead to rapid uptake by providers, favorable reimbursements from payors and potential reductions in health care utilization and the overall cost of treatment per patient;

- Advance additional product candidates from our portfolio, including lysins targeting gram-negative bacteria, to clinical development as rapidly as possible, and further advance our next-generation gram-positive lysins and amurin antimicrobial peptides;
- Acquire additional foundation technologies that enable the efficient discovery of anti-infective agents;
- Acquire clinical stage therapies that treat infectious diseases through unique mechanisms of action; and
- Establish collaborations to further develop and commercialize our product candidates.

Our Portfolio

We intend to develop and commercialize novel therapeutic agents to treat life-threatening infections, including those caused by drug-resistant pathogens. The increasing prevalence of antibiotic resistance among bacterial pathogens has been widely recognized as an urgent public health threat by the CDC, the WHO and the Infectious Disease Society of America ("IDSA"). Antibiotic resistance has limited the effectiveness of many conventional antibiotics and the discovery and development of new therapeutics to address resistance has not kept pace with the increasing incidence of these difficult-to-treat microbial infections. According to the IDSA, 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 necessary to treat these patients.

We have focused our research and discovery efforts on those pathogens that are considered to be urgent or serious threats to global health by the CDC or considered critical priority by the WHO. Our current portfolio of programs is reflected below:



Our Lead Program: Exebacase (CF-301)

Medical Opportunity

Staph aureus bacteremia is a serious bacterial infection associated with high morbidity and mortality. In the U.S. alone, there are approximately 200,000 hospitalizations for *Staph aureus* bacteremia annually. Mortality rates from this bloodstream infection have been reported as ranging from 20-40% despite conventional antibiotics. The last new agent for *Staph aureus* bacteremia and endocarditis, daptomycin, was approved over 13 years ago based on clinical cure rates of less than 50% in the Phase 3 study that led to its approval.

Staph aureus bacteremia can lead to infectious endocarditis, a serious infection affecting the heart valves. The incidence of infective endocarditis in the U.S. has increased over the past decade, with over 47,000 cases in 2011, and is likely due to the growth of the at-risk populations, such as older, diabetic and hemodialysis patients. *Staph aureus* endocarditis remains difficult to treat with current standard of care antibiotics. One reason for this is biofilm formation which prevents antibiotics from eradicating the bacteria, leading to the need for long courses of antibiotic therapy, which are often unsuccessful and necessitate surgery to eradicate bacteria from infected heart valves. Mortality attributed to *Staph aureus* bacteremia is higher when the infection is caused by MRSA as compared to methicillin-susceptible ("MSSA") *Staph aureus*. MRSA is considered a serious threat to global health by the CDC and a high priority threat by the WHO. Emerging resistance to conventional antibiotics such as vancomycin and daptomycin, which are used to treat MSSA and MRSA, represents an additional serious threat which may have serious consequences in terms of increasing morbidity, mortality and health care utilization.

Exebacase Development

Exebacase is the first lysin to enter U.S. clinical trials and represents a first-in-class anti-bacterial therapeutic candidate. Exebacase has been granted Fast Track designation by the U.S. Food and Drug Administration ("FDA") for the development of a parenteral formulation for the treatment of *Staph aureus* bacteremia, including endocarditis, caused by MRSA or MSSA. If we are able to obtain regulatory approval of exebacase for this initial indication, we believe exebacase, and/or engineered variants, may be further developed for the treatment of other serious diseases caused by *Staph aureus* including biofilm-related infections in prosthetic joints and indwelling devices, as well as pneumonia and osteomyelitis.

Clinical Studies

Phase 2 Clinical Study

We are conducting a multi-center, multi-national Phase 2 clinical study of exebacase for the treatment of *Staph aureus* bacteremia, including endocarditis, caused by MRSA or MSSA. This randomized, double-blind, placebo-controlled study compares the efficacy, safety and tolerability of exebacase used in addition to SOC antibiotics to SOC antibiotics alone. The study enrolled 121 patients randomized 3:2 to receive either a single dose of exebacase (0.25 mg/kg) administered as a 2 hour IV infusion in addition to SOC antibiotics or placebo plus SOC antibiotics. The primary efficacy analysis population (also known as the microbiological intent-to-treat population, or "mITT") consisted of 116 patients with confirmed *Staph aureus* infection based on blood culture who received study drug, of which 71 patients received exebacase and 45 patients received placebo. All patients were treated with SOC antibiotics as prescribed by the study investigators, consisting of vancomycin or daptomycin for MRSA and a semi-synthetic penicillin or first-generation cephalosporin for MSSA, prescribed in accordance with treatment guidelines, accepted medical practice and the study protocol. The majority of patients were enrolled in the U.S. (79.3%) with the remainder of patient enrolled from sites in Europe, Latin America, Russia and Israel. A total of 38.8% of exebacase-treated and 35.5% of placebo patients, respectively, had a MRSA infection. The majority of patients in both treatment groups had bacteremia, 77.5% of the exebacase-treated group and 86.7% of the placebo group. Final diagnosis was determined by an independent, blinded clinical adjudication committee.

The primary efficacy endpoint of the study was clinical response at day 14. Clinical response was defined by objective clinical response criteria including (1) improvement or complete resolution of all attributable signs

and symptoms of *Staph aureus* bacteremia that were present at baseline, (2) no new, worsening or persistent signs and symptoms attributable to *Staph aureus* bacteremia, (3) no development of a new foci of *Staph aureus* infection after Day 7, (4) no further anti-staphylococcal therapy was needed, (5) no surgery or further medical intervention for the *Staph aureus* infection was necessary and (6) the patient is alive. Clinical response was also determined by the independent, blinded clinical adjudication committee.

Recently announced topline efficacy results from the core study demonstrated the clinical responder rate was 70.4% for patients treated with exebacase and 60.0% for patients treated with SOC antibiotics alone (p=0.314). In a pre-specified analysis of MRSA-infected patients, the clinical responder rate was 42.8% higher in the exebacase group compared to the SOC antibiotics alone group (74.1% for patients treated with exebacase compared to 31.3% for patients dosed with SOC antibiotics alone (p=0.010)). The clinical responder rate in the subset of patients with bacteremia, including right-sided endocarditis was 80.0% for patients treated with exebacase compared to 59.5% for patients treated with SOC antibiotics alone, an increase of 20.5% (p=0.028). Similarly, in the subset of patients with bacteremia alone, the clinical responder rate was 81.8% for patients treated with exebacase compared to 61.5% for patients treated with SOC antibiotics alone, an increase of 20.3% (p=0.035).

Based on these efficacy data, summarized in Table 1 below, treatment with exebacase in addition to SOC antibiotics resulted in clinically meaningful improvements in outcomes compared to antibiotic therapy alone.

Table 1

Clinical response at Day 14	exebacase*	antibiotics alone	p-value
Overall mITT population	70.4%	60.0%	0.314
MRSA infection	74.1%	31.3%	0.010
MSSA infection	68.2%	73.3%	0.796
Bacteremia + right-sided endocarditis	80.0%	59.5%	0.028
Bacteremia only	81.8%	61.5%	0.035

* used in addition to antibiotics

Another primary objective of the study was to describe the safety and tolerability of exebacase used in addition to SOC antibacterial therapy compared to SOC antibiotics alone in hospitalized patients with *Staph aureus* bacteremia, including endocarditis. An independent Data Safety Monitoring Board (DSMB) reviewed unblinded safety and pharmacokinetic data during the study. Treatment emergent adverse events (TEAEs) were defined as an untoward medical event reported from the study drug administration until 28 days after last dose of standard of care antibiotics, regardless of whether or not the event was considered related to study drug. The incidence of TEAEs was balanced between the treatment groups (88.9% and 85.1% of the exebacase and SOC antibiotics alone groups, respectively), with incidence rates as expected for this population, given the severity of the disease under study and that patients had multiple co-morbidities. The incidence rates of TEAEs reported within approximately one week after administration of the single dose of study drug were also balanced between the treatment groups (66.7% and 66.0% in the exebacase and SOC antibiotics alone groups, respectively). The overall rate of serious treatment-emergent SAEs was also similar between the treatment groups (47.2% for the exebacase group and 51.1% for the SOC antibiotics alone group). Among all patients who received study drug, 19.4% of exebacase patients and 14.9% of placebo patients died. There were no SAEs that we determined to be related to study drug. Exebacase was well-tolerated and there were no reports of hypersensitivity related to exebacase and no patients discontinued study drug in either treatment group.

Based on these safety and tolerability data, summarized in Table 2 below, we concluded that exebacase was well-tolerated in this study.

Table 2

	exebacase* N=72 n (%)	antibiotics alone N=47 n (%)
TEAE	64 (88.9)	40 (85.1)
TEAE through day 7	48 (66.7)	31 (66.0)
TEAE leading to study drug interruption	1 (1.4)	0
TEAE leading to study drug withdrawal	0	0
TEAE related to study drug	8 (11.1)	4 (8.5)
Serious TEAE	34 (47.2)	24 (51.1)
Total deaths	14 (19.4)	7 (14.9)

* used in addition to antibiotics

The Phase 2 study is still ongoing as patients are followed up to 180 days after administration of study drug. We expect to complete the study and have the complete data set in the second quarter of 2019. We also expect to have additional data from the 180 day long-term follow-up visit including additional safety, immunogenicity and PK data being assessed in the trial.

We expect to progress exebacase into Phase 3 of clinical development. Based on previous feedback from the FDA, we believe that a single confirmatory Phase 3 clinical trial evaluating the superiority of exebacase used in addition to SOC antibiotics compared to SOC antibiotics alone for the treatment of *Staph aureus* bacteremia, including right-sided endocarditis, together with the full package of Phase 1 and Phase 2 clinical data, along with a robust non-clinical and PK/PD data package will be sufficient to support the biologics license application ("BLA") submission. As such, the planned Phase 3 study is expected to be a multi-center, multi-national, randomized, double-blind, placebo-controlled superiority study comparing clinical responder rates of exebacase used in addition to SOC antibiotics to SOC antibiotics alone for the treatment of *Staph aureus* bacteremia, including right-sided endocarditis. Specific parameters for Phase 3 will be informed by data from the Phase 2 study once it is completed, and relevant guidance from regulatory authorities. If the Phase 3 study confirms superiority of exebacase, used in addition to SOC antibiotics as compared to antibiotics alone, we would seek marketing authorization with a superiority claim, which we believe would be highly differentiated from conventional antibiotics and would lead to rapid uptake by providers and favorable reimbursements from payors.

Phase 1 Clinical Study

In 2015, we 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 exebacase. Healthy normal subjects were randomized to receive a single IV dose of exebacase or placebo, each administered as a 2 hour IV infusion.

In this Phase 1 study, exebacase was generally well tolerated and there were no clinical adverse safety signals. No SAEs or hypersensitivity AEs related to exebacase were reported, and no study stopping rules were met. A total of five non-serious AEs were reporting during the study as follows: two subjects who received exebacase reported a total of three non-serious AEs (headache, contact dermatitis, and allergic rhinitis); two subjects who received placebo reported a total of two non-serious AEs (viral upper respiratory tract infection and

viral infection). All of these events were mild in intensity and resolved. No patients withdrew from the study due to an AE. There were no clinically relevant changes in inflammatory markers (e.g., erythrocyte sedimentation rate, high sensitivity c-reactive protein, or complement factors including total hemolytic complement (CH50) associated with exebacase dosing.

Nine out of 13 subjects dosed with exebacase developed anti-drug antibodies ("ADAs") in the study. These ADAs were waning or absent by day 180, and were not correlated with mediators of allergic immune response. Exposure was generally linear, dose dependent and intra-subject variability was low. A pharmacometric analysis of the relationship between exebacase exposure and heart rate ("HR"), blood pressure and QT interval parameters showed no significant changes in systolic or diastolic blood pressure, HR or HR-corrected QT intervals with increases in exebacase plasma concentration at the doses tested in the Phase 1 study.

Estimated effective exposure of exebacase, based on in vivo pharmacology, PK/PD exposure target attainment analysis and PK/PD modeling was attained at the 0.25mg/kg dose in healthy subjects. The Phase 1 Clinical Study Report, as well as reports of the animal studies, PK/PD modeling and in vitro clinical microbiology studies were submitted to the regulatory authorities and an End of Phase 1 Meeting with FDA was conducted prior to advancing into Phase 2.

In vitro Microbiologic Studies and Animal Models Demonstrate the Therapeutic Potential of Exebacase

We believe exebacase is well differentiated from conventional antibiotics by it spectrum of activity, including:

- ***Eradication of biofilms.*** Exebacase has been shown to clear biofilms *in vitro* studies and in animal models. Biofilm matrices associated with serious *Staph aureus* infections form on human tissues (e.g., valve in endocarditis or bone in osteomyelitis) and/or on the abiotic surfaces (e.g., prosthetic joints, catheters and other devices) and protect bacteria from immune defenses. Biofilms pose significant therapeutic challenges by increasing antibiotic tolerance up to 1,000-fold because conventional antibiotics are generally unable to clear or penetrate biofilms and kill dormant *Staph aureus* bacteria harbored within the biofilms. Hence, surgical removal of infected tissue, catheters, prosthetic joints and other indwelling devices containing *Staph aureus* biofilms is generally required to eradicate the infections.
- ***Rapid, potent and selective bactericidal activity***. *In vitro*, exebacase kills *Staph aureus* bacteria within seconds, thereby exerting a bactericidal effect, defined as a 3-log (99.9%) drop in colony forming units ("CFU") per mL, within about 30 minutes. Exebacase has exhibited potent antibacterial activity against *Staph aureus* strains that are sensitive to methicillin as well as strains resistant to methicillin, vancomycin, daptomycin, or linezolid. Exebacase is highly targeted against *staphylococcal* and some *streptococcal* species, with no demonstrable activity against gram negative organisms. We believe that this targeted effect will reduce the possible negative effects of exebacase on normal, healthy human bacterial flora, known as the microbiome, in the GI tract, in contrast to broad spectrum antibiotics which are widely known to have deleterious effects on the human GI microbiome.
- ***Potentiation of the efficacy of conventional anti-staphylococcal antibiotics.*** We have demonstrated strong synergy between exebacase and a wide range of antibiotics in preclinical studies, which we believe may enable exebacase to potentiate the efficacy of current standards of care for the treatment of *Staph aureus* bacteremia, including daptomycin, vancomycin and oxacillin. Because of this and the aforementioned features of exebacase which are also complementary to antibiotics, we believe the use of exebacase, in addition to conventional anti-staphylococcal antibiotics will provide significantly improved clinical cure rates, compared to antibiotics alone.
- ***Low propensity for the development of resistance.*** *In vitro* models designed to induce the emergence of antibiotic resistance, such as 26 day serial passage studies, have shown a low propensity for bacteria to develop resistance to exebacase. In comparison, resistance to standard of care antibiotics such as

daptomycin can readily be induced in the same model. Importantly, the addition of exebacase to daptomycin or other antibiotics in the same model was observed to suppress the emergence of resistance to conventional antibiotics.

We believe exebacase has other competitive advantages as well, including:

- ***No direct competition.*** Vancomycin and daptomycin are the only two antibiotics with label indications in the U.S. for the treatment of *Staph aureus* bacteremia, including endocarditis due to MSSA and MRSA. Daptomycin, the most recently FDA approved drug for this indication, was approved in 2005. Clinical cure rates at the test of cure visit in the Phase 3 non-inferiority study which led to daptomycin's approval were less than 50% for both daptomycin and the standard of care comparator. Exebacase has been shown to act synergistically with both daptomycin and vancomycin to improve eradication of *Staph aureus* in animal studies of *Staph aureus* endocarditis conducted in different species. As such exebacase is intended to be used in addition to, not as a replacement for, SOC antibiotics. No other agents have been shown to provide improved outcomes over SOC antibiotics.
- ***Patent protection.*** Our issued patent with composition of matter claims and issued patent with method claims for killing *Staph aureus* stains both provide protection through 2032, our issued patent with method claims for disrupting or treating biofilm provides protection until 2033 and additional patents, if issued as we expect, could provide further protection beyond 2033.

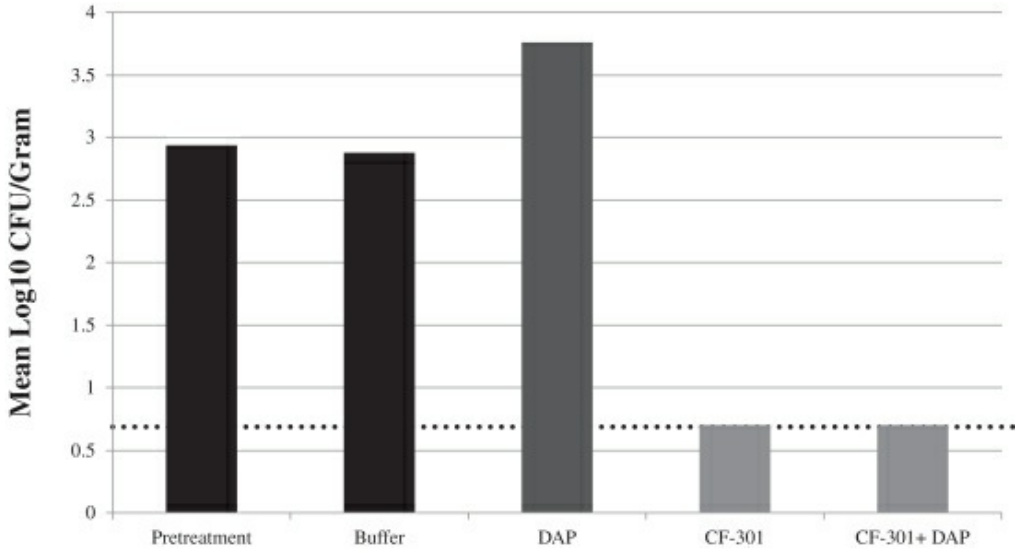
Eradication of Antibiotic-Resistant Biofilms

Biofilm formation is a common characteristic of certain pathogenic bacteria such as *Staph aureus* and *P. aeruginosa* and represents a major therapeutic challenge. 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. Bacteria harbored within biofilms exhibit significant tolerance to conventional antibiotics, and can be up to 1,000-fold less susceptible than planktonic (or, free-floating) bacteria. Infected human tissues, such as the heart valve in endocarditis or bone in osteomyelitis, and the abiotic surfaces of indwelling medical devices, such as central venous catheters, prosthetic joints and cardiac devices are common sites for biofilm formation in the setting of systemic *Staph aureus* infections. Because conventional antibiotics are relatively ineffective at penetrating biofilms, long courses of antibiotics are generally required and are often unsuccessful, necessitating surgery (e.g., heart valve or prosthetic joint removal and replacement to eradicate the infection). There is a significant unmet medical need for novel treatment strategies to eradicate biofilms, as there are no medical products currently indicated for, or effective in, the eradication of biofilms.

Because exebacase disrupts the cell wall of *Staph aureus* bacteria by enzymatic lysis, we expected exebacase to be highly active against biofilms and we have performed an extensive battery of studies to profile exebacase's activity against *Staph aureus* biofilms. These studies tested exebacase against biofilms formed on a range of surfaces, including polystyrene (i.e., microtiter plates), glass (i.e., chamber slides), and PVC (i.e., catheter tubing), as well as in human serum, plasma, blood and synovial fluid. The results of these studies as detailed and recently published in Antimicrobial Agents and Chemotherapy (Schuch, et al, AAC, July 2017), provide evidence that exebacase is a potent anti-staphylococcal biofilm agent.

We recently conducted a pilot study evaluating exebacase's ability to eradicate *Staph aureus* biofilm from the inside of a hemodialysis catheter removed from an infected patient. The endpoint of the model was a reduction in the amount of bacteria (measured in CFUs). Segments of the catheter were assigned to one of three different treatment groups: exebacase, daptomycin (DAP) or exebacase + DAP at the clinically relevant concentration of 1 µg/mL. As shown in Figure 1 below, exebacase eradicated the biofilm at 1 µg/mL whereas daptomycin alone did not clear biofilm at 1 µg/mL. The addition of exebacase with daptomycin resulted in the same clearance of biofilm as exebacase alone. The catheter biofilm contained MRSA as well as other *Staph* species. We believe these data provide important translation of the previously reported potent efficacy of exebacase against biofilms formed in vitro and in animal models, to biofilms formed in the setting of human disease.

Figure 1: Sensitivity of MRSA Biofilms on Explanted Human Catheter to Exebacase (CF-301)



*** The dotted line indicates the limit of detection of CFUs/Gram.

In view of the lack of efficacy of conventional antibiotics against biofilms, we believe exebacase, if approved, may provide an important new therapeutic option to address the biofilm components of invasive *Staph aureus* infections and potentially forestall or eliminate the need for surgical intervention.

Rapid, potent and selective bactericidal activity

Lysins have demonstrated rapid bactericidal activity. We have performed timekill assays comparing the time it has taken exebacase to kill bacteria *in vitro* and exert a bactericidal effect to the time required for daptomycin or vancomycin to do the same. All drugs were administered at a concentration of 1x minimal inhibitory concentration ("MIC"). Exebacase reduced the number of *Staph aureus* bacteria in tests on 62 strains (20 MSSA and 42 MRSA strains) by 3-logs within 30 minutes. In contrast, daptomycin required six hours to achieve the same level of cell killing, while vancomycin failed to achieve a 2-log, or 99%, cell kill during the same six-hour test period. The rapid bactericidal activity of exebacase is one of the important reasons that we believe it could be a highly desirable therapeutic option, if approved, for the treatment of *Staph aureus* infections.

Exebacase has been bactericidal against all *Staph aureus* isolates tested to date, regardless of their antibiotic-resistance profile. We have tested over 250 different drug sensitive and resistant isolates of *Staph aureus*. The isolates tested can be classified by the particular drugs to which they are sensitive or resistant, including MSSA, MRSA, VRSA, linezolid-resistant ("LRSA") and daptomycin-resistant ("DRSA") *Staph aureus*. Exebacase was shown to be active against all the strains tested. Our Standard Bacteremia Model utilizes animals infected with 10 million (10^7) CFU of MRSA and treated 3 hours later with various doses of therapy or buffer. In this model, exebacase produced a dose-dependent increase in survival rates, with mice receiving at least 0.5 mg/kg of exebacase demonstrated at least 90% survival, whereas doses below 0.5 mg/kg resulted in lower survival.

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 identified a strong synergy between lysins and a wide range of anti-staphylococcal antibiotics, including daptomycin, vancomycin and oxacillin through *in vitro* synergy assays. In

these tests, synergy was assessed by checkerboard assay using the fractional inhibitory concentration index ("FICI") for each combination. An FICI mean was derived from each checkerboard based on two consecutive FIC values along the growth/no growth interface. Synergy was defined as an FICI of £0.5; strongly additive was >0.5-<1; indifference was 1 to <2; and antagonism was ³2.

To test and demonstrate this synergy *in vivo*, we developed the Drug Failure Bacteremia Model where exebacase could be tested in combination with a SOC antibiotic. The Drug Failure Bacteremia Model utilizes an extremely high infection burden of one billion (10^9) CFU. This produces such an overwhelming infection in the animals such that SOC antibiotics used as monotherapies at their human equivalent doses failed to produce significant cure rates. We tested daptomycin, vancomycin and oxacillin in this model. We then adjusted the dose of exebacase so that monotherapy with exebacase would also fail to have significant cure rates under these intense infection conditions. To test and demonstrate whether the synergy that we had observed *in vitro* between exebacase 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 combination to evaluate if there was an improvement in efficacy.

In the Drug Failure Bacteremia Model, all control mice treated with buffer succumbed to bacterial infection within 12 hours. Administration of a clinical dose of daptomycin as a single agent resulted in clinical failure, as only 31% of mice survived. Similarly, when exebacase was dosed as a single agent at this chosen dose, only 18% of mice survived. In contrast, when mice received the exebacase *in addition to* daptomycin, 82% survived the bacterial challenge, demonstrating superiority of the combination therapy over either of the single-drug regimens, with a significantly higher survival rate than the sum of the results from the two monotherapies.

We have tested the combination of exebacase with daptomycin, vancomycin and oxacillin in multiple experiments with the Drug Failure Bacteremia Model. In each experiment, the combination therapy was shown to be superior to monotherapy with a single drug alone. We have also studied the combination of exebacase with other anti-staphylococcal agents, including linezolid, televancin, nafcillin, cefazolin, clindamycin and azithromycin, *in vitro* and found exebacase to be synergistic or strongly additive with each agent against both MSSA and MRSA strains.

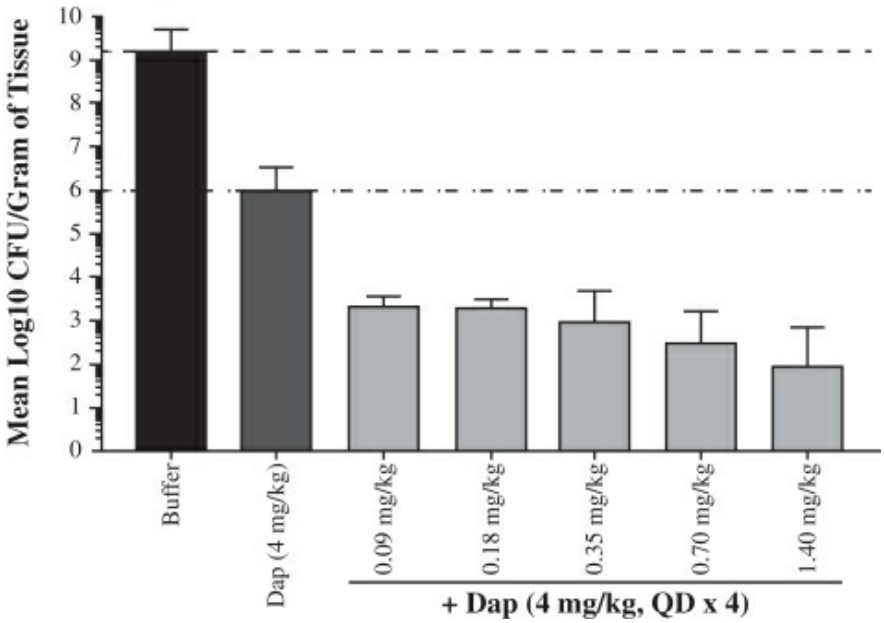
To further explore the activity of exebacase in combination with SOC antibiotics for the treatment of life-threatening, drug-resistant infections, we engaged the LA Biomed Research Institute at Harbor-UCLA Medical Center ("UCLA") to perform studies in their standard, well characterized rat and rabbit infective endocarditis models. The endpoint of the model is a reduction in the amount of bacteria (measured as CFUs) on the heart valve, in the kidney and in the spleen. The studies examined the activity of exebacase in combination with daptomycin, in UCLA's prototypical high-burden biofilm-based model.

In this study, a single dose of exebacase used in addition to daptomycin resulted in an additional substantial reduction in CFUs, on top of the reduction in CFUs by daptomycin alone. This study is highly relevant to our understanding of the therapeutic potential of exebacase and the intended clinical application in a difficult to treat biofilm-based infection. This study demonstrated that a single dose of exebacase, 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, four out of nine animals treated with exebacase and daptomycin were found to have sterilized kidney, spleen and heart valve vegetations, whereas none of the animals treated with daptomycin alone had tissues that were sterilized.

We have subsequently conducted additional experiments at UCLA in the rabbit infective endocarditis model in order to both replicate the results of the rat study, but also to examine a range of exebacase doses used in addition to daptomycin as compared to both buffer and daptomycin alone. The results of a dose-ranging study, where a range of single doses of exebacase was assessed when administered in addition to four days of daptomycin treatment are shown in Figure 2 below. As seen in the rat studies, administration of daptomycin alone resulted in a 3-log reduction in CFUs in the heart valve vegetations in these animals infected with MRSA.

The addition of a single dose of exebacase, resulted in an additional ~3-log reduction in CFUs in the cardiac vegetations compared to daptomycin alone at all doses of exebacase tested ($p \leq 0.002$). Using conventional allometric scaling, the 0.7 mg/kg dose of exebacase approximates the human clinical dose of 0.25mg/kg, which is the dose being studied in our Phase 2 clinical trial. This dose together with daptomycin resulted in a 6-log reduction in CFUs compared to buffer ($p \leq 0.001$). Of note, efficacy was maintained even at the lowest dose of exebacase tested (0.09 mg/kg) in this study ($p \leq 0.001$).

Figure 2: Dose Ranging Study of Exebacase (CF-301) with Daptomycin in Rabbit Infective Endocarditis Model



Collectively, we believe these preclinical data provided significant support to the design of our ongoing Phase 2 study to evaluate the use of exebacase in addition to SOC antibiotics for the treatment of *Staph aureus* bacteremia, including endocarditis.

Non-Clinical Activities

Chemistry, Manufacturing and Controls ("CMC")

Exebacase is manufactured using 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 exebacase per liter of fermentation broth. After fermentation, the broth containing exebacase is separated and purified through a process containing two chromatographic columns. The resulting product has greater than 99% purity.

We recently achieved concurrence with the FDA on our CMC plans for Phase 3 and BLA submission. 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 up from the current 100 liter fermentation and 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 BLA that we

expect to submit to the FDA. Following submission, we expect that 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

We conducted non-clinical safety pharmacology and toxicology studies in connection with our Investigational New Drug application ("IND") for exebacase. In these studies exebacase 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 2.5 mg/kg was not associated with any effects, adverse or not, and was therefore determined to be the no observable effect level ("NOEL"). Exebacase was well tolerated in these studies in both rats and dogs for seven consecutive days of once daily two-hour IV infusions of up to 2.5 mg/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.

Dose-dependent adverse 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 microscopic histopathological change surrounding certain blood vessels. In accordance with industry practice, we intend to study exebacase 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 exebacase, no hypersensitivity reaction was observed in any of our animal studies. Upon administration of a second course of exebacase, given two weeks after completion of the first course, including multiple-day courses, hypersensitivity or hypersensitivity-like findings were observed in mice, rats and dogs. In a dedicated hypersensitivity study in rats, using a model intended to elicit hypersensitivity, findings consistent with hypersensitivity were observed after a two week delayed re-challenge with a second course of exebacase and were not dose-dependent. In general, in humans, 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 exebacase due to potential prior exposure to the active protein component of exebacase from the environment, as it is a naturally occurring protein. Testing for anti-drug antibodies was performed in Phase 1 subjects. No clinical hypersensitivity related to exebacase was observed in subjects dosed in our Phase 1 or Phase 2 study. We are collecting additional information about the development of ADAs after dosing with exebacase in the Phase 2 study.

CF-296: An Engineered Approach for Invasive *Staph aureus* Infections

We have engineered a lysin variant of exebacase which we believe may suitable for the potential treatment of the most challenging invasive infections caused by *Staph aureus* including biofilm-related infections in prosthetic joints and indwelling devices and osteomyelitis. Based on the safety pharmacology and toxicology profile of exebacase described above, our objectives for the program were to maintain the spectrum of activity of an anti-staphylococcal lysin while improving the non-clinical safety profile.

Lysin Discovery Platform

The main objective of our lysin discovery platform has been to bring forth a portfolio of lysins that selectively target the largest threats of resistant bacteria, commonly referred to as the ESKAPE pathogens (*Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter species*), which are the leading causes of hospital acquired infections throughout the world.

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. 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 rapidly by enzymatic cleavage of the bacterial cell wall without need for bacterial growth and cell division. In addition to the speed of action and potent cidality, we believe lysins are differentiated by their other hallmark features which include the demonstrated ability to eradicate biofilms and synergistically boost the efficacy of conventional antibiotics in animal models. Importantly, lysins also have a "narrow spectrum" meaning they kill only specific species of bacteria or closely related bacteria. As such, we believe that lysins targeting gram-positive pathogens will not have negative effects on the beneficial, normal human GI microbiome in contrast to conventional "broad spectrum" antibiotics which can kill the body's normal, beneficial bacteria. We believe that the potential therapeutic profile of lysins is complementary to that of conventional antibiotics. As such, our approach includes the use of lysins in addition to conventional antibiotics for the treatment of serious, drug-resistant bacterial infections, including biofilm-associated infections, in an effort to achieve greater efficacy and improve clinical outcomes, as well as potentially protect against antibiotic resistance.

We employ bioinformatics and a series of metagenomic-based techniques to identify and 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 major component of our lysin discovery work. Once cloned, our scientists also employ a variety of techniques to further optimize and 'engineer' changes to the lysins to introduce specific characteristics which we believe may be favorable for potential therapeutic use.

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.

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. Using this methodology, we have discovered lysins targeting gram-negative pathogens as part of our proprietary discovery program. These lysins were further characterized with funding from CARB-X and will be further developed and tested in *in vivo* models as part of this program.

In addition to our proprietary lysin discovery program, we have an active collaborative research agreement through which we provide funding for the discovery of new lysins to Dr. Vincent Fischetti's Laboratory of Bacterial Pathogenesis and Immunology at The Rockefeller University ("Rockefeller"). We have the first right to negotiate a license to all discoveries concerning lysins through October 2019. We hold worldwide exclusive license rights to patents for composition of matter for nine lysins from Rockefeller. Each lysin targets a specific species of gram-positive bacteria, including drug-sensitive and drug-resistant forms as shown in Table 3 below.

Table 3: Lysins Licensed From The Rockefeller University

Pathogen	CDC Threat Level	WHO Priority Level	Lysins
Staphylococcus aureus	Serious	High	CF-301, CF-302
Streptococcus pneumoniae	Serious	Medium	CF-303, CF-309
Enterococcus faecalis	Serious	High	CF-304
Group B *streptococcus*	Concerning	—	CF-307
Bacillus anthracis	—	—	CF-306, CF-308

The focus of our research and discovery efforts is on identifying lysins which selectively kill specific species of gram-negative bacteria that are considered to be urgent or serious threats to global health by the CDC or critical priorities by the WHO. Emerging strains of multi-drug resistant gram-negative pathogens that are resistant to all or nearly all available antibiotics are considered to be a major global health threat. We believe that lysins targeting gram-negative pathogens have the potential to be important therapeutics to combat antimicrobial resistance due to their novel mechanism of action and therapeutic profile, which is complementary to conventional antibiotics.

P. aeruginosa is the initial target of our gram-negative lysin discovery efforts.

P. aeruginosa is a gram-negative pathogen which is common in the environment and is an important and much-feared potential pathogen in hospitals. *P. aeruginosa* readily develops resistance to conventional antibiotics resulting in the emergence of multidrug resistant ("MDR") strains, which have become common in some hospitals and regions. *P. aeruginosa* is a major cause of hospital-acquired infections and is a particularly important cause of infections in immunocompromised hosts, and is also a major pathogen in burn and surgical wound infections. P. aeruginosa is also the most common pathogen isolated from adults with cystic fibrosis, the most common cause of respiratory failure in cystic fibrosis and responsible for the deaths of the majority of these patients.

Invasive *P. aeruginosa* infections, including ventilator associated pneumonia, blood stream infections, complicated urinary tract infections, and infections following surgery carry some of the highest risks of mortality among hospital acquired infections. An estimated 51,000 healthcare-associated P. aeruginosa infections occur in the United States each year. More than 6,000 (13%) of these are multidrug-resistant, with roughly 400 deaths per year attributed to these infections. Infections caused by multidrug resistant *P. aeruginosa* are associated with high all-cause mortality, hospital mortality and higher health-care related costs compared to infections caused by susceptible strains.

The discovery and development of lysins that target *P. aeruginosa* is a focus of our research efforts. We developed a strategy for large scale cloning of lysins with potential specificity for the target pathogen. We then conducted functional screening in the context of both media and human serum to identify lysins with potent antimicrobial activity against *P. aeruginosa,* including resistant strains. For all highly active clones, additional modifications were introduced to generate second and third generation molecules for further *in vitro* screening. We have identified several lysins that *in vitro* exhibit the hallmark features which differentiate the lysin class, including rapid and potent bactericidal activity, synergy with a broad range of standard of care agents and the eradication of biofilms.

Based on the results of these assays and the additional data we continue to generate *in vitro*, our gram-negative lysins represent a potential new therapeutic class of bactericidal agents to combat resistant *P. aeruginosa*. In 2017, we were awarded a grant from CARB-X in support of this program. In January 2019, we announced an additional $2.3 million in the amount of funding to be received in further support of this effort as we move into *in vivo* models of disease to further characterize these candidates.

Enterobacteriaceae

The *Enterobacteriaceae* family of gram-negative bacteria includes *Klebsiella pneumoniae* ("*K. pneumoniae*"), *Enterobacter species* ("*Enterobacter"* e.g. Enterobacter cloacae) and *Escherichia coli* ("*E. coli*"), all of which can cause serious, life-threatening infections, and have demonstrated concerning resistance patterns.

- *K. pneumoniae* are common causes of serious, potentially life-threatening invasive infections (e.g. pneumonia, complicated urinary tract, intra-abdominal infections) in hospital settings, particularly in intensive care units and among vulnerable patients with impaired immune systems, diabetes or alcohol-use disorders. The mortality rates for hospital-acquired pneumonia due to *K. pneumonia*e can exceed 50% in vulnerable patients.
- *Enterobacter cloacae* can cause a wide range of invasive infections, and potentially contaminate intravenous fluids and medical devices as the source of deadly outbreaks in the hospital.
- *E. coli* is the most frequent cause of community and hospital acquired urinary tract infections and a frequent cause of bloodstream infection. Patients in hospitals, nursing homes, and other healthcare settings whose care requires devices like ventilators (breathing machines), urinary (bladder) catheters, or intravenous (vein) catheters, and patients who are taking long courses of certain antibiotics are most at risk for infection.

The emergence and spread of antimicrobial resistance among *Enterobacteriaceae* are recognized public health threats which complicate the treatment of serious nosocomial infections.

Enterobacteriaceae can produce enzymes (e.g., "extended-spectrum beta-lactamases ("ESBL")) that confer resistance to most beta-lactam antibiotics, including penicillins, cephalosporins, and the monobactam aztreonam. Infections with ESBL-producing organisms have been associated with poor outcomes. Approximately 20% of *K. pneumoniae* infections and 31% of *Enterobacter* infections in intensive care units in the United States now involve strains which are not susceptible to third-generation cephalosporins. Community and hospital-acquired ESBL-producing *Enterobacteriaceae* are prevalent worldwide, and their prevalence may be underestimated because reliable identification of ESBL-producing organisms in clinical laboratories can be challenging.

Carbapenem antibiotics are considered to be the best currently available antimicrobial agent to treat infections caused by ESBL-producing Enterobacteriaceae. However, resistance to carbapenems is becoming increasingly prevalent, and the resulting Carbapenem-resistant *Enterobacteriaceae* ("CRE"), have high levels of resistance to antibiotics. *K. pneumoniae* and *E. coli* are a normal part of the human gut bacteria that can become carbapenem-resistant due to enzymes that breakdown carbapenem antibiotics and make them ineffective. *Klebsiella pneumoniae* carbapenemase ("KPC") and New Delhi Metallo-beta-lactamase ("NDM") are two such enzymes that break down carbapenems and make them ineffective. Both of these enzymes have also been reported in *P. aeruginosa*. CRE infections typically occur in hospitals, nursing homes, and other healthcare settings. Patients who require devices like ventilators (breathing machines), urinary (bladder) catheters, or intravenous (vein) catheters, and/or patients who are taking long courses of certain antibiotics are most at risk for CRE infections. Some CRE bacteria have become resistant to most available antibiotics, are very difficult to treat, and can lead to death in up to 50% of patients who become infected.

We believe that lysins which target *K. pneumoniae*, *Enterobacter* and *E. coli* may be important therapeutic options for the treatment of serious, potentially life-threatening invasive infections caused by multidrug resistant pathogens. Because of the novel mechanism by which lysins kill bacterial, no cross resistance to conventional antibiotics, and as such, KPC, NDM and similar enzymes are not expected to have any effect on the activity of lysins. We believe that lysins may help to improve clinical outcomes of infections caused by these pathogens and thus we are also focusing research efforts to identify and develop lysins which target them.

Amurin Discovery Program

Amurin peptides are a class of novel, phage-derived lytic agents discovered in our laboratories. In preclinical studies, amurin peptides have shown some features common to lysins, including potent

bacteriocidality, including antibiotic-resistant strains, the ability to clear biofilms and synergize with conventional antibiotics. However, amurin peptides are further differentiated in their potential ability to exert these actions on the full range of gram-negative ESKAPE pathogens, as well as a range of additional, serious and difficult to treat gram-negative bacteria, including *Burkholdaria* and *Stenotrophomonas*, in the context of human serum, without apparent 'off target' effects against gram-negatives. As such, amurin peptides have shown a highly differentiated spectrum of action, and we believe, if successfully developed, would be extremely well suited as potential treatments for patients suffering from polymicrobial gram-negative infections, such as cystic fibrosis, ventilator-associated pneumonia, intra-abdominal infections, and serious burns or certain chronic wound infections. Given their powerful *in vitro* activity against a broad range of resistant pathogens, we believe that amurin peptides have the potential to become a powerful addition to our armamentarium against strains of gram-negative pathogens which have extreme- or pan- drug resistance to all or almost all currently available antibiotics.

We plan to progress our amurin peptide program as quickly as possible through preclinical profiling and into the clinic. We are currently evaluating the *in vitro* profiles of the amurins as we continue to advance the program. We recently announced an award from CARB-X of up to $6.9 million of funding to support the development of amurin peptides as potential therapeutics to treat serious and potentially life-threatening infections, including those caused by antibiotic-resistant gram-negative ESKAPE pathogens.

CF-404: An Antibody Approach for Influenza

We intend to develop CF-404, a combination of three human mAbs against influenza, as a potential treatment for seasonal and pandemic influenza infections, which kill as many as 49,000 people annually in the U.S. alone. Our preclinical studies to date have shown that CF-404 may have the following attributes:

- ***Broad activity against influenza in one formulation.*** CF-404 exhibits broad activity against influenza strains, including the three principal strains (H1, H3 and B). By targeting conserved regions on the virus, which are not subject to seasonal mutation, we believe that the efficacy of CF-404 will be robust from season to season. The unique triple mAb formulation, allows (1) our mAbs to neutralize many different influenza strains; (2) for a single therapeutic covering all human seasonal and most pandemic influenza strains; and (3) for an immediate therapeutic effect.
- ***Minimal resistance potential.*** Our mAbs target the principal hemagglutinin stalk on the surface of influenza which is a genetically conserved region of the virus, and hence, does not vary from one season to another.
- ***Novel inhaled delivery.*** We intend to develop CF-404 as an inhaled therapy. Inhaled therapy has demonstrated enhanced efficacy at lower doses than systemic administration in animal models. We believe that this delivery route will enable CF-404 to more directly target influenza potentially allowing for increased efficacy, even at low doses.

Preclinical studies

In preclinical studies, CF-404 was active against all seasonal 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 tested our mAbs in standard mouse models which use weight changes to evaluate protection against lethal infection with different strains of influenza (H1N1, H3N2 or B). Control mice treated with buffer all succumbed to viral infection within 7-9 days. By contrast, when we administered a single treatment of CF-404 24 hours post-infection, the infected mice appeared healthy, with weight changes comparable to healthy mice.

We are developing CF-404 as an inhaled therapy. We believe that this novel delivery route allows CF-404 to target the influenza virus more directly where it resides, in the respiratory system. We have demonstrated efficacy in animal models even when using low doses of our antibodies administered in an aerosolized form. In

our inhalation model, control mice treated with buffer all succumbed to viral infection within 10 days. By contrast, when we administered a single inhaled treatment of CF-404 over a range of low doses 24 hours post-infection, the infected mice were protected and fared better with increasing dose (up to 0.82mg/kg) as compared to the 5mg/kg with a systemic dose.

We are continuing to develop a formulation of CF-404 that would be suitable for human use. Our *in vivo* data has shown that our anti-H1 (CF-401), anti-H3 (CF-402) and anti-B (CF-403) mAbs have been able to protect animals from lethal challenge. Importantly, our studies also show that treatment with our mAbs appears to provide greatly enhanced potency compared to treatment with other mAbs. We believe our combination for the treatment of influenza is a novel approach addressing a high unmet medical need 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 fifteen (15) U.S. patents, thirty-one (31) foreign patents and one hundred seventeen (117) U.S. and international patent applications that we have licensed from Rockefeller and/or developed in-house. These patents will expire between 2024 and 2033. The patents and patent applications are directed to compositions and methods for the treatment of infections caused by gram-positive bacteria (Group B *Streptococci, Staph aureus, Streptococcus pneumonia, Bacillus anthracis (anthrax), Enterococcus faecalis and Enterococcus faecium*) and infections caused by gram-negative bacteria (*P. aeruginosa, K. pneumoniae*, Enterobacter cloacae and *E. coli)*. If patents are granted on our patent applications, which include the patent applications related to exebacase, CF-296 and the gram-negative lysins, they would expire between 2029 and 2039.

Our influenza patent portfolio consists of one (1) U.S. patent, eleven (11) foreign patents, and fifty-one (51) 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 or exebacase. 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*, *Staph 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*, which is now expired On October 24, 2011, we entered into a second research agreement with Rockefeller, where we provided 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. This agreement expired on October 25, 2016. On October 25, 2016, we entered into a third research agreement with Rockefeller, where we provide funding for the identification of novel lysin therapeutic candidates that target gram-negative pathogens. The research collaboration will focus on gram-negative pathogens such as *P. aeruginosa, E. coli,* and *K. pneumoniae*, including antibiotic-resistant strains.

Our current agreement runs through October 24, 2019. 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.

Exebacase is a potential first-in-class drug candidate and we believe it is the first lysin to enter human clinical trials in the U.S. We believe there is currently no clinical competitor to exebacase, which is highly

differentiated from conventional antibiotics by 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 other semi-synthetic penicillin or first-generation cephalosporin, or for MRSA strains, daptomycin or vancomycin. We do not see market competition with these drugs, as our strategy is to administer exebacase in addition to these drugs with the goal of achieving clinical superiority over any one of those SOC antibiotics alone. We are aware of several other clinical trials currently being conducted or recently concluded in patients with *Staph aureus* bacteremia. Depending on the outcomes of those and future trials, exebacase may compete with products in development from Genentech, Inc., iNtRon Biotechnology, Inc., ("iNtRon") and XBiotech, Inc. We believe that exebacase has demonstrated synergy in vitro with a broad range of anti-staphylococcal agents of different classes and we believe that exebacase will also be synergistic and non-competitive with newer conventional antibiotics in these classes.

We are not aware of any other lysins in clinical development under an IND in the United States. We believe iNtRon, a biotechnology company located in South Korea, is currently conducting a human clinical trial for SAL-200, an endolysin-based drug candidate to evaluate it as a treatment for *Staph aureus* bacteremia. Additionally, iNtRon recently announced a licensing arrangement with Roivant Sciences with a stated purpose to pursue the global development and commercialization of its endolysin products, including SAL-200. We will continue to monitor the advancement of SAL-200 as data and information become available.

CF-404 is intended for the treatment of potentially life-threatening seasonal and pandemic influenza infections. We believe CF-404 has competitive advantages in that it potentially addresses the short-comings of neuraminidase inhibitors 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 neuraminidase inhibitors, 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., Johnson & Johnson, Inc., Theraclone Sciences, Inc., Toyama Chemical Co., Ltd., Romark Laboratories, L.C., Aviragen, Inc., Vectura Group plc, 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 exebacase. We do not yet have contracts to produce a commercial supply of the drug substance for exebacase; however, we intend to pursue agreements with Fujifilm UK to do so. We employ the services of various vendors to produce exebacase in its final vialed drug product form. We do not have contracts for the commercial supply of exebacase. 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 (the "EU") 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 co-promotion agreements with strategic partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that any of our other products will be approved.

Research and Development Expenses

We have invested $22.4 million, $17.3 million, and $22.1 million in research and development expenses for the years ended December 31, 2018, 2017 and 2016, 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. In addition to regulation under the FDC Act, biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under provisions of the PHSA, and FDA reviews applications for approval of a biologic pursuant to a BLA. FDA review applications for approval of drug products pursuant to a new drug application ("NDA"). 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") regulations 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 typically 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 some 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. For fiscal year 2019, the application user fee is $2,588,478. The manufacturer and/or sponsor under an approved NDA or BLA are also subject to annual program user fees, currently set at $309,915 per program. These fees are typically adjusted annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. The FDA aims to review applications for standard review drugs containing new molecular entities or original biologic products within ten months of the date the application was accepted for filing, and the goal is to review applications for priority review drugs or biologics in six months of the date the application was accepted for filing. Priority review can be applied to applications for drugs containing new molecular entities 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 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 BLA contains data that provide substantial evidence that the proposed biologic is safe, pure and potent for its intended use, and has an acceptable purity profile. In the case of an NDA, whether the drug is safe and effective for its intended use.

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 Generating Antibiotic Incentives Now, or GAIN Act, are also eligible for fast track designation. Biologics, such as lysins, are not currently eligible for QIDP 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 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 exebacase for the treatment of *Staph aureus* bacteremia, including endocarditis.

In some cases, a product may be eligible for accelerated approval. Drug or biological products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on 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. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Guidance for Industry: "Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases" – Potential for Streamlined Development

The FDA issued guidance for the industry in August 2017, which among other things, discusses the potential for antibacterial drug candidates intended to treat serious bacterial infections in patients who have few or no available therapies to be candidates for a streamlined development pathway. According to the guidance, candidates for a streamlined process would be likely to have (1) a new mechanism of action that preserves antibacterial activity against bacteria that have mechanisms of resistance to other available antibacterial drugs; (2) an added inhibitor that neutralizes a mechanism of resistance; (3) an alteration in the structure of the molecule that makes the drug candidate no longer susceptible to the mechanisms of resistance to existing drugs; or (4) some other characteristic that has a potential to lead to enhanced effectiveness.

Draft Guidance for Industry: "Limited Population Pathway for Antibacterial and Antifungal Drugs" (LPAD)

As part of the 21st Century Cures Act of 2016, LPAD is intended to permit the approval of new antibiotics on the basis of relatively small clinical data sets studying patients with rare, serious, or life-threatening infections in whom large-scale trials would be infeasible. The FDA issued draft guidance for the industry regarding LPAD in June 2018 which defines the potential for antibacterial and antifungal drug candidates to be approved under a limited population development pathway. According to the draft guidance, candidates for this pathway are agents intended to treat a serious or life-threatening infection in a limited population with unmet needs, have substantial evidence of effectiveness for the drug's intended use and sufficient information to conclude that the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling which is expected to define the limited population for intended use. The FDA's determination of safety and effectiveness must reflect the benefit-risk profile of the antibiotic in the limited population and must take into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatments for that limited population.

Breakthrough Therapy Designation

The Food and Drug Administration Safety and Innovation Act established a category of drugs and biologics referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. 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 designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug. The FDA may also rescind breakthrough therapy designation for a product candidate if the FDA determines the product candidate no longer meets the criteria for breakthrough therapy designation.

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. To date, few biosimilars have been licensed under the BPCIA, and 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 $165,786 per year (or up to an aggregate of $1,105,241 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, impose 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.

For example, in December 2016, the 21st Century Cures act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation, but its ultimate implementation remains unclear. Among other things, the Cures Act provides a new "limited population" approval pathway for antibacterial and antifungal drugs intended to treat serious or life-threatening infections.

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.

European Medicines Agency (EMA) – Small and Medium Enterprise (SME) Designation

The SME designation was established by EMA to promote innovation and the development of new medicinal products by smaller companies. Companies with SME status are eligible to receive financial incentives as well as administrative and regulatory support through national and regional level programs. These benefits include access to dedicated EMA personnel during the clinical development process as well as reductions in fees associated with regulatory procedures such as Scientific Advice, Marketing Authorizations, and inspections. Companies with SME status are also eligible for early application (prior to proof of concept) to the priority medicines (PRIME) scheme. PRIME provides enhanced support for the development of medicines that target an unmet medical need. In August 2016, the EMA granted SME designation to ContraFect. We continue to meet the requirements for the designation and have maintained our SME status.

Data Privacy and Security Laws

We are also subject to data privacy and security laws in jurisdictions outside of the U.S. For example, in the European Union ("E.U.") and the European Economic Area ("E.E.A.") we are subject to Regulation (EU) 2016/679 (General Data Protection Regulation or GDPR) in relation to our collection, control, processing, sharing, disclosure and other use of personal data (i.e. data relating to an identifiable living individual). The GDPR is directly applicable in each E.U. and E.E.A. Member State, however, it provides that E.U. and E.E.A. Member States may introduce further conditions, including limitations, which could limit our ability to collect, control, process, share, disclose and otherwise use personal data (including health and medical information), and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes a strict data protection compliance regime including: providing detailed disclosures about how personal data is collected and processed (in a concise, intelligible and easily accessible form); demonstrating that valid consent or another an appropriate legal basis is in place or otherwise exists to justify data processing activities; appointing data protection officers in certain circumstances; granting new rights for data subjects in regard to their personal data (including the right to be "forgotten" and the right to data portability), as well as enhancing current rights (e.g., data subject access requests); introducing the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches; imposing limitations on retention of personal data; maintaining a record of data processing; defining for the first time pseudonymized (i.e., key-coded) data; and complying with principal of accountability and complying with the obligation to demonstrate compliance through policies, procedures, training and audit.

We are also subject to E.U. rules with respect to cross-border transfers of personal data out of the E.U. and E.E.A. These rules are under scrutiny from time to time. For example, there is ongoing litigation challenging the EU Commission approved model clauses (also called standard contractual clauses), which is a commonly used transfer mechanism under the GDPR. It is uncertain whether the model clauses will be invalidated by the European courts. In addition, Brexit will mean that at some point that the United Kingdom ("U.K.") will become a "third party" for the purposes of data transfers under the GDPR.

We depend on a number of third parties in relation to the operation of our business (including clinical research organizations), a number of which process personal data on our behalf. There is no assurance that our own privacy and security-related safeguards and/or any contractual measures that we enter into with these providers will protect us from the risks associated with the third-party processing, storage and transmission of such information. Any violation of data or security laws by our third party processors could have a material adverse effect on our business and result in the fines and penalties outlined below.

We are subject to the supervision of local data protection authorities in those E.U. and E.E.A. jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of EUR 20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/ change our processing of our data, enforcement notices, assessment notices (for a compulsory audit), as well potential civil claims including class action type litigation where individuals suffer harm.

We are also subject to evolving E.U. privacy laws on cookies, and e-marketing. The E.U. is in the process of replacing the e-Privacy Directive with a new set of rules taking the form of a regulation. The draft e-Privacy Regulation imposes strict opt-in marketing rules with limited exceptions for business-to-business communications, alters rules on third-party cookies, web beacons and similar technology and significantly increases fining powers to the same levels as the GDPR (i.e. the greater of 20 million Euros or 4% of total global annual revenue). While the e-Privacy Regulation was originally intended to be adopted on May 25 2018 (alongside the GDPR), it is still going through the European legislative process and commentators now expect it to be adopted during the second half of 2020 or during 2021 following a transition period. We are likely to be required to expend further capital and other resources to ensure compliance with these changing laws and regulations.

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.

The current presidential administration and U.S. Congress have attempted to repeal or "repeal and replace" the Affordable Care Act. Although those efforts did not succeed, the presidential administration may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. There is still uncertainty with respect to the impact the President's administration and the U.S. Congress may have, if any, on the Affordable Care Act, and any changes will likely take time to unfold. Additionally, since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire Affordable Care Act is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the Affordable Care Act, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate". While the Texas District Court Judge, as well as the current presidential administration and the Centers for Medicare and Medicaid Services, have stated that this ruling will have no immediate effect, it is unclear how this decision and subsequent appeals will impact the law and the effect such impact could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 among other things, resulted in 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 2027 unless additional Congressional action is taken. Further, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. For example, the Cures Act changes the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain drugs.

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.

Employees

As of March 7, 2019, we had 20 full-time employees, including 10 employees with advanced degrees. Of these full-time employees, 11 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.

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 important 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 the sale of common stock and warrants, 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 losses were $37.7 million, $15.5 million and $28.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. We have devoted substantially all of our efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

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

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

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

We currently operate with limited resources. 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. Based on our current operating plans, and without additional funding, we believe we will not have sufficient funds to meet our

obligations within the next twelve months from the issuance of our audited consolidated financial statements that are included elsewhere in this Annual Report on Form 10-K. These factors raise substantial doubt about our ability to continue as a going concern. We have relied on our ability to fund our operations primarily through public and private debt and equity financings, but there can be no assurances that such financing will continue to be available to us on satisfactory terms, or at all.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize exebacase or any of our other product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to obtain funding, we would be forced to delay, reduce or eliminate our research and development programs, which would adversely affect our business prospects. In addition, if we are unable to raise capital, we will also need to implement cost reductions, and any failure to effectively do so will harm our business, results of operations and future prospects.

The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company.

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

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

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

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

Even if we are able to generate revenues from the sale of our products, we may not become profitable. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our

failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital to expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

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

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

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

Conducting clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results to obtain marketing approval and achieve product sales. In addition, if approved, exebacase 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 exebacase and other potential product candidates. We have not yet demonstrated our ability to successfully complete Phase 2 or Phase 3 clinical trials, obtain marketing approval, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

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

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

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

Under Section 382 and related provisions of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our past transactions, we may have experienced an "ownership change." At this time, we have not completed a study to assess whether an ownership change under Section 382 of the Code has occurred, or whether there have been multiple ownership changes since our formation, due to the costs and complexities associated with such a study. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Thus, our ability to utilize carryforwards of our net operating losses and other tax attributes to reduce future tax liabilities may be substantially restricted. Further, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, we may not be able to take full advantage of these carryforwards for federal or state tax purposes. As of December 31, 2018, we had federal and state net operating loss carryforwards of approximately $175.4 million and $189.0 million, respectively, and federal research and development credits of approximately $2.5 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 candidate, exebacase. 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 exebacase 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 exebacase. We cannot market or sell exebacase 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 exebacase or any other product candidate outside of the United States, we will need applicable foreign regulatory approvals. The clinical development of exebacase 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 exebacase 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 exebacase 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 exebacase 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 exebacase or any other product candidate, which would significantly harm our business.

If clinical trials of exebacase 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 exebacase or any other product candidate.

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

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

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

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

- delays in completing, or as a result of findings from, preclinical studies; or
- delays in developing adequate processes for manufacture of, or formulations for, sufficient supplies of clinical trial materials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues.

We are significantly dependent on our license agreements with Rockefeller that relate to exebacase.

Under our various license agreements with Rockefeller, we are obligated to use our diligent efforts to develop and commercialize licensed products, including exebacase. 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 exebacase, 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 exebacase 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 exebacase 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 exebacase 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 exebacase or any other product candidate that we seek to develop. As a result, our financial results and the commercial prospects for exebacase 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 exebacase 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 exebacase or any other product candidate, generating revenues and achieving and sustaining profitability.

Even if the FDA approves exebacase or any other product candidate, adverse effects discovered after approval could adversely affect our markets.

If we obtain regulatory approval for exebacase 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 process or formulation development, scaling up or reproducing manufacturing processes and lack of timely availability of raw materials.

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture exebacase or any other product candidates.

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

We employ the services of other vendors to produce exebacase in its final vialed drug product form. We do not have contracts for the commercial supply of exebacase 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 EU 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 scale up from the current clinical process and then be repeated under protocol successfully three times for validation.

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

If Fujifilm UK, or any alternate supplier of active pharmaceutical ingredient, or any supplier of 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. For example, a lot of the exebacase investigational drug product did not meet manufacturing release specifications, resulting in the delay of our Phase 2 study.

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 exebacase and our other product candidates.

The level of commercial success of exebacase or any other product candidates that we develop will depend upon attaining significant market acceptance of these products among physicians and payors.

Even if exebacase 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 exebacase or any other product candidate that we develop by physicians, patients and payors will depend on a number of factors, many of which are beyond our control, including:

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

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

Coverage and reimbursement may not be available for exebacase 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 exebacase 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 exebacase 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 exebacase 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 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.

The current presidential administration and U.S. Congress attempted to repeal or "repeal and replace" the Affordable Care Act. Although those efforts did not succeed, the presidential administration may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have on the Affordable Care Act, if any, and any changes will likely take time to unfold. Additionally, since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire Affordable Care Act is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the Affordable Care Act, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate". While the Texas District Court Judge, as well as the current presidential administration and the Centers for Medicare and Medicaid Services, have stated that this ruling will have no immediate effect, it is unclear how this decision and subsequent appeals will impact the law and the effect such impact could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, resulted in 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 2027 unless additional Congressional action is taken. Further, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, or the ATRA, which, among other things, further reduced Medicare payments to several providers. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. For example, the Cures Act changes the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain drugs.

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 exebacase or any future products.

We expect to experience pricing pressures in connection with the sale of exebacase or 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 exebacase 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 exebacase 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 exebacase 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 exebacase 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 exebacase 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 exebacase or 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 alliances and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic collaboration or other alternative arrangements for exebacase 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 exebacase or any future product candidate as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic collaboration agreements could delay the development and commercialization of exebacase or 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, exebacase and any future product candidate, and our ability to generate revenue will be materially impaired.

Exebacase 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. Exebacase 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.

We 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.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current presidential administration may impact our business and industry. Namely, the administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the current Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If foreign approval for exebacase 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 exebacase 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 exebacase 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 Affordable Care Act 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.

We may be subject, directly or indirectly, to federal and state healthcare laws, including 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 business operations and current and future arrangements with third-party payors, healthcare providers 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 research, develop, 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;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency 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 and pricing information; and

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain personal data, including the General Data Protection Regulation ("GDPR"), which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the E.U. and E.E.A. (including with regard to health data).

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, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, imprisonment and the curtailment or restructuring of our operations. Further, defending against any such actions, even if successful, can be costly, time-consuming and may require significant personnel resources. 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 unfavorable consequences of any plaintiff attorney investigation or the adverse outcome of litigation or arbitration proceedings commenced by or against us could materially harm our business.

The unfavorable consequences of any investigations by a plaintiff attorney could damage our reputation and disrupt 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.

The United Kingdom's planned exit from the European Union may adversely impact our business.

In a non-binding referendum on the United Kingdom of Great Britain and Northern Ireland's membership in the European Union in June 2016, a majority of the United Kingdom's electorate voted for the United Kingdom's withdrawal from the European Union ("Brexit"). A process of negotiation will determine the future terms of the United Kingdom's relationship with the European Union and its members. While Article 50 of the Lisbon Treaty was invoked by the United Kingdom on March 29, 2017, substantial uncertainty remains regarding the outcome of the negotiations, as well as the scope and duration of a transitionary period, if any, following the expiration of the Article 50 period on March 29, 2019. This uncertainty was exacerbated by the lack of a decisive majority following the United Kingdom general election in June 2017 and, following months of negotiation, the rejection by United Kingdom's Parliament in January 2019 of a withdrawal agreement and related statement on future relations negotiated by representatives of the United Kingdom and the European Union.

Depending on the terms of Brexit, the United Kingdom could lose its present rights or terms of access to the single EU market and EU customs areas and to the global trade deals negotiated by the European Union on

behalf of its members. The uncertainty regarding new or modified arrangements, or initially the absence of such arrangements, between the United Kingdom and other countries following Brexit may have a material adverse effect on the movement of goods between the United Kingdom and members of the European Union and the United States, including the interruption of or delays in imports into the United Kingdom of goods originating within the European Union and exports from the United Kingdom of goods originating there. For example, shipments into the United Kingdom of drug substance manufactured for the Company in the European Union may be interrupted or delayed and thereby prevent or delay the manufacture in the United Kingdom of drug product. Similarly, shipments out of the United Kingdom of drug product to the United States or the European Union may be interrupted or delayed and thereby prevent or delay the delivery of drug product to clinical sites. Such a situation could hinder our ability to conduct current and planned clinical trials and have an adverse effect on our business.

Risks Related to Employee Matters and Managing Growth

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

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

Recruiting and retaining qualified scientific and clinical personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also compete for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

For our Company to successfully develop and commercialize our product candidates, we may need 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.

In order to successfully develop and commercialize our product candidate, we may need to increase the number of our employees and expand 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 would need 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 growth, we may not be able to effectively manage a significant expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products or technology or products that may have been licensed to us. Similar to our licensors, we seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. This process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of either our or their research and development output before it is too late to obtain patent protection. Moreover, if we license technology or product candidates from third parties in the future, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering this intellectual property. These agreements could also give our licensors the right to enforce the licensed patents without our involvement, or to decide not to enforce the patents without our consent. Therefore, in these circumstances, we could not be certain that these patents and applications would be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights and any patent rights we may license from a third party are highly uncertain. Our or our licensors' pending and future patent applications may not result in issued patents that protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our or our licensors' patents or narrow the scope of such patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Assuming the other requirements for patentability are met, historically, in the United States, the first to make the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. The United States currently uses a first-inventor-to-file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, litigation, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our or our licensors' patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us

with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

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

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

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

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 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. The trading price of our securities has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Annual Report, these factors include:

- our ability to implement our 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 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;
- 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, 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, which could make it more difficult for us to sell securities in a future financing or for you to sell our common stock.

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 could be delisted. On February 20, 2019, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial period of 180 calendar days, or until

August 19, 2019, to regain compliance. The letter states that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5550(a)(2) if at any time before August 19, 2019, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. The letter has no immediate effect on the listing or trading of our common stock. 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 would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our securities, if delisted from the Nasdaq Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the over-the-counter markets or the pink sheets. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

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

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

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

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

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

Sales of substantial amounts of shares of our common stock or warrants in the public market, or the perception that these sales may occur, could adversely affect the price of our securities and impair our ability to raise capital through the sale of additional equity securities. As of March 7, 2019, we have approximately 79.4 million shares of common stock outstanding, of which approximately 77.1 million shares of our outstanding common stock are freely tradable, or may become freely tradable, without restriction, in the public market unless held by our "affiliates," as defined under Rule 144 of the Securities Act of 1933, as amended (the "Securities Act"). Additionally, we have warrants to purchase approximately 31.3 million shares of our common stock outstanding as of March 7, 2019. Approximately 30.9 million shares of common stock underlying the Warrants will be freely tradable upon exercise unless held by our affiliates.

We have registered 9,878,747 shares of our common stock as of March 7, 2019 that we may issue under our employee benefit plans. These shares can be freely sold in the public market upon issuance, unless pursuant to their terms these stock awards have transfer restrictions attached to them. Additionally, pursuant to the 2014 Omnibus Incentive Plan (the "2014 Plan"), our management is authorized to grant stock options and other equity linked award to our employees, directors and consultants. The 2014 Plan provides that 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.

If shares of our common stock 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 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.

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 costs as a result of operating as a 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 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 to decline. Our executive officers and other personnel also need to devote substantial time and financial resources to comply with these rules, regulations and requirements.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and made 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 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.

Any failure to maintain effective internal control over financial reporting could have a significant adverse effect on our business and the price of our common stock.

Our management is required to report annually on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In the future, we may identify material weaknesses or significant deficiencies in our internal control over financial reporting, and we may not be able to remediate them in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation report from our independent registered public accounting firm, if such a report is required. We will be unable to issue securities in the public markets through the use of a shelf registration statement if we are not in compliance with Section 404. Furthermore, failure to achieve and maintain an effective internal control environment could materially adversely affect our business, reduce the market's confidence in our common stock, adversely affect the price of our common stock and limit our ability to report our financial results accurately and timely.

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.

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 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 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 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 public offerings and private placement and may not use them effectively.

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

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

We are an "emerging growth company," as defined in the JOBS Act, and will remain an emerging growth company through the year ended December 31, 2018. 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, 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;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a shareholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding

voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Risks Related to Cybersecurity, Data Protection and Privacy

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we store sensitive data, including intellectual property, proprietary business information and personally identifiable information, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in significant costs to address and remediate the incident, lead to legal claims or proceedings, disrupt our operations, and damage our reputation.

We maintain cyber risk insurance, but this insurance may not be sufficient to cover all of our losses from any future breaches of our systems.

Our collection, control, processing, sharing, disclosure and otherwise use of personal data could give rise to liabilities as a result of governmental regulation, conflicting legal requirements, and evolving laws concerning data privacy in the E.U. and E.E.A.

The regulatory environment with regard to privacy and data protection issues is increasingly challenging. For example, the GDPR repealed the Data Protection Directive (95/46/EC) and is directly applicable in all E.U. and E.E.A. Member States since its effective date of May 25, 2018. The GDPR applies to companies established in the E.U. or E.E.A., as well as companies that are not established in the E.U. or E.E.A. and which collect and use personal data in relation to offering goods or services to, or monitoring the behavior of, individuals located in the E.U. or E.E.A., including, for example, through the conduct of clinical trials (whether the trials are conducted directly by the company itself or through a clinical vendor or collaborators). The GDPR permits E.U. and E.E.A. Member State derogations for certain matters and, accordingly, we are also subject to EU national laws relating to the processing of certain data such as genetic data, biometric data and health data. It imposes a strict data protection compliance regime including: providing detailed disclosures about how personal data is collected and processed (in a concise, intelligible and easily accessible form); demonstrating that valid consent or another an appropriate legal basis is in place or otherwise exists to justify data processing activities; appointing data protection officers in certain circumstances; granting new rights for data subjects in regard to their personal data (including the right to be “forgotten” and the right to data portability), as well as enhancing current rights (e.g., data subject access requests); introducing the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches; imposing limitations on retention of personal data; maintaining a record of data processing; defining for the first time pseudonymized (i.e., key-coded) data; and complying with principal of accountability and complying with the obligation to demonstrate compliance through policies, procedures, training and audit.

We are also subject to E.U. rules with respect to cross-border transfers of personal data out of the E.U. and E.E.A. These rules are under scrutiny from time to time. For example, there is ongoing litigation challenging the EU Commission approved model clauses (also called standard contractual clauses), which is a commonly used transfer mechanism under the GDPR. It is uncertain whether the model clauses will be invalidated by the European courts. In addition, Brexit will mean that at some point that the United Kingdom (“U.K.”) will become a “third party” for the purposes of data transfers under the GDPR.

We depend on a number of third parties in relation to the operation of our business (including clinical research organizations), a number of which process personal data on our behalf. There is no assurance that our own privacy and security-related safeguards and/or any contractual measures that we enter into with these providers will protect us from the risks associated with the third-party processing, storage and transmission of such information. Any violation of data or security laws by our third party processors could have a material adverse effect on our business and result in the fines and penalties outlined below.

Fines for certain breaches of the GDPR are significant: up to the greater of 4% of total worldwide turnover, or €20 million. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/ change our processing of our data, enforcement notices, assessment notices (for a compulsory audit), as well potential civil claims including class action type litigation where individuals suffer harm. Our actual or alleged failure to comply with the GDPR could result in enforcement actions and significant penalties against us (as outlined above), which could result in negative publicity, increase our operating, business and/or legal costs, subject us to claims or other remedies and have a material adverse effect on our clinical trials, business, financial condition, and operations.

We are also subject to evolving E.U. privacy laws on cookies, and e-marketing. The E.U. is in the process of replacing the e-Privacy Directive with a new set of rules taking the form of a regulation. The draft E-Privacy Regulation imposes strict opt-in marketing rules with limited exceptions for business-to-business communications, alters rules on third-party cookies, web beacons and similar technology and significantly increases fining powers to the same levels as the GDPR (i.e. the greater of 20 million Euros or 4% of total global annual revenue). While the e-Privacy Regulation was originally intended to be adopted on May 25 2018 (alongside the GDPR), it is still going through the European legislative process and commentators now expect it to be adopted during the second half of 2020 or during 2021 following a transition period. We are likely to be required to expend further capital and other resources to ensure compliance with these changing laws and regulations.

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 is publicly traded on the Nasdaq Capital Market under the symbol "CFRX".

Holders

On March 7, 2019, the last reported sale price for our common stock on the Nasdaq Capital Market was $0.40 per share. As of March 7, 2019, 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; Purchases of Equity Securities by the Issuer or Affiliated Purchaser

We did not repurchase any of our equity securities or issue any securities that were not registered under Securities Act during the quarter ended December 31, 2018.

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, 2018, 2017 and 2016 and as of December 31, 2018 and 2017 from our audited financial statements, which are included elsewhere in this Annual Report on Form 10-K. We derived the financial data for the years ended December 31, 2015 and 2014 and as of December 31, 2016, 2015 and 2014 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	**2018**	**2017**	**2016**	**2015**	**2014**
Loss from operations	$(31,124,425)	$(26,563,757)	$(33,532,246)	$(25,065,336)	$(16,935,911)
Net loss attributable to common stockholders	$(37,668,424)	$(15,517,658)	$(28,538,399)	$(25,120,964)	$(34,617,536)
Net loss per share of common stock, basic and diluted	$ (0.50)	$ (0.28)	$ (0.85)	$ (1.08)	$ (3.86)

	As of December 31,				
Balance Sheet Data	**2018**	**2017**	**2016**	**2015**	**2014**
Cash, cash equivalents and marketable securities	$ 30,452,253	$ 46,853,910	$ 35,161,154	$ 32,921,653	$ 27,393,059
Total assets	32,872,571	50,189,479	37,624,470	35,861,137	30,053,622
Long-term liabilities	21,533,592	14,575,366	13,693,419	1,416,443	1,249,046
Total stockholders' equity	5,541,960	31,193,445	19,512,854	30,675,510	25,581,507

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 novel, differentiated biologic therapeutics and developing them for the treatment of life-threatening infectious diseases, including those caused by drug-resistant pathogens. Drug-resistant infections account for 2,000,000 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 platform. 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. Conventional antibiotics require bacterial cell division and metabolism to occur in order to exert their intended effect (i.e., cell death or cessation of growth). Based on *in vitro* tests, lysins, however, are fundamentally different in that they kill bacteria rapidly by enzymatic cleavage of the bacterial cell wall without need for bacterial growth and cell division. In addition to the speed of action and potent cidality, we believe lysins are differentiated by their other hallmark features, which include the demonstrated ability to eradicate biofilms and synergistically boost the efficacy of conventional antibiotics in animal models. Importantly, lysins also have a "narrow spectrum," meaning they kill only specific species of bacteria or closely related bacteria. As such, we believe that lysins targeting gram-positive pathogens will not have negative effects on the beneficial, normal human GI microbiome, in contrast to conventional "broad spectrum" antibiotics which can kill the body's normal, beneficial bacteria. We believe that the therapeutic profile of lysins is complimentary to that of conventional antibiotics. As such, our approach includes the use of lysins in addition to conventional antibiotics for the treatment of serious, drug-resistant bacterial infections, including biofilm-associated infections, to achieve greater efficacy and improve clinical outcomes, as well as potentially protecting against antibiotic resistance.

We believe that the properties of our lysins will make them suitable for targeting antibiotic-resistant organisms, such as *Staphylococcus aureus* ("*Staph aureus")* and *Pseudomonas aeruginosa* ("*P.aeruginosa"*), which cause serious infections such as bacteremia, pneumonia and osteomyelitis. Beyond lysins, we continue to seek and identify novel antibacterial product candidates. We recently discovered a new class of novel lytic agents, called amurin peptides. Our preliminary characterization studies indicate that amurin peptides have potency across a wide range of resistant gram-negative pathogens, including species that are part of the ESKAPE pathogens (*Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa,* and *Enterobacter species*), which are the leading causes of hospital acquired infections throughout the world. These pathogens are considered to be urgent or serious threats to global health by the U.S. Center for Disease Control ("CDC") and critical priorities by the World Health Organization ("WHO"). We believe that the amurin peptides will be highly complementary to our pathogen-specific lysin platform in addressing these infections. We aim to improve outcomes in patient with these life-threatening bacterial infections through use of our differentiated biologic candidates developed from our new classes of molecules.

We have not generated any revenues and, to date, have funded our operations primarily through our IPO, our follow-on public offerings, private placements of convertible preferred stock and convertible debt to our investors, and grant funding received. In our most recent financing in July and August 2018, we sold an

aggregate of 5,750,000 shares of our common stock, including shares sold pursuant to the fully exercised overallotment option granted to the underwriters in connection with the offering, at a public offering price of $2.00 per share in an underwritten follow-on offering, generating net proceeds of approximately $10.4 million after underwriting discounts, commissions and offering expenses payable by us.

We have never been profitable and our net losses were $37.7 million, $15.5 million and $28.5 million for the years ended December 31, 2018, 2017 and 2016, 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. 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.

Exebacase

Exebacase is an investigational novel lysin that targets *Staph aureus*, including MRSA strains, which causes serious infections such as bacteremia, pneumonia and osteomyelitis. *Staph aureus* is also a frequent source of

biofilm-dependent infections of heart valves (endocarditis), prosthetic joints, indwelling devices and catheters. These infections result in significant morbidity and mortality despite currently available antibiotic therapies. Exebacase is being studied in a Phase 2 superiority study to evaluate its safety, tolerability, efficacy and PK when used in addition to background SOC antibacterial therapy for the treatment of *Staph aureus* bacteremia, including endocarditis in adult patients.

We recently announced positive topline results from this first-in-patient Phase 2 superiority study of exebacase which showed clinically meaningful improvement in clinical responder rates among patients treated with exebacase in addition to SOC antibiotics compared to SOC antibiotics alone. In the primary efficacy analysis population of 116 patients with documented *Staph aureus* bacteremia, including endocarditis, who received a single intravenous (IV) infusion of blinded study drug, the clinical responder rate was 70.4% for patients treated with exebacase and 60.0% for patients dosed with SOC antibiotics alone. In a pre-specified analysis of MRSA-infected patients, the clinical responder rate in patients treated with exebacase was 42.8% higher than the clinical responder rate in patients treated with SOC antibiotics alone (74.1% for patients treated with exebacase compared to 31.3% for patients treated with SOC antibiotics alone ($p=0.010$)). The clinical responder rate in the subset of patients with bacteremia including right-sided endocarditis was 80.0% for patients treated with exebacase compared to 59.5% for patients treated with SOC antibiotics alone, an increase of 20.5% ($p=0.028$). In the subset of patients with bacteremia alone, the clinical responder rate was 81.8% for patients treated with exebacase compared to 61.5% for patients treated with SOC antibiotics alone, an increase of 20.3% ($p=0.035$). Exebacase was well-tolerated and treatment emergent adverse events, including treatment-emergent SAEs were balanced between the treatment groups. There were no SAEs that we determined to be related to exebacase, there were no reports of hypersensitivity related to exebacase and no patients discontinued treatment with study drug in either treatment group. We believe these data establish proof of concept for exebacase, and for the lysin class as therapeutic agents, and will inform the design of Phase 3 for exebacase.

Other programs

We continue to explore variants of exebacase to expand our portfolio of lysins targeting biofilm-dependent *Staph aureus* infections. We have engineered a novel mutant variant, CF-296, which we believe has properties which may make it particularly useful for the treatment of prosthetic joint infections. We are evaluating CF-296 in animal models to further characterize this compound.

Our lysin research efforts are focused on a broad-based gram-negative discovery program which aims to identify, optimize and develop lysins that target deadly gram-negative pathogens. We have discovered and engineered lysins with potent activity against drug-resistant *P. aeruginosa* bacteria in preclinical studies, a major cause of morbidity and mortality, often related to hospital acquired pneumonia and a major medical challenge, particularly for patients with cystic fibrosis. We are initiating animal studies of our most promising anti-pseudomonal lysins with the goal of moving this program to the clinic as soon as possible.

Beyond our lysin programs, we continue our proprietary research to expand our pipeline of complimentary, nontraditional antimicrobials to address unmet medical needs. We are continuing to progress CF-404, which is an aerosolized treatment for life-threatening human influenza composed of three human mAbs which target all seasonal and most pandemic strains of influenza. We have discovered a novel class of phage-derived lytic agents, known as amurin peptides, which display potent bacteriocidal activity against a wide range of gram-negative pathogens in preclinical studies, including deadly, drug-resistant *P. aeruginosa, Klebsiella pneumoniae, Escherichia coli, Acinetobacter baumannii and Enterobacter cloacae* bacteria species. We are currently evaluating the *in vitro* and *in vivo* profiles of the amurin peptides as we continue to advance the program.

To date, a large portion of our research and development work has related to the establishment of our lysin platform technologies, the advancement of our research projects to discovery of clinical candidates, manufacturing and preclinical testing of our clinical candidates and clinical testing of exebacase. We currently expect to focus the majority of our resources on the exebacase program. In the future, we intend to further

leverage our employee and infrastructure resources across multiple development programs well as research projects. In the years ended December 31, 2018, 2017 and 2016, we recorded approximately $22.4 million, $17.3 million and $22.1 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 exebacase and CF-404, as shown below.

The following table summarizes our research and development expenses by category for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018	2017	2016
Product development	$14,307,715	$10,219,826	$10,331,021
Personnel related	3,064,872	3,387,749	4,357,177
Professional fees	2,467,000	1,760,608	3,170,364
Laboratory costs	1,266,780	1,011,766	2,065,064
External research and licensing costs	684,281	482,803	1,590,668
Share-based compensation	626,003	451,334	587,426
Total research and development expense	$22,416,651	$17,314,086	$22,101,720

The following table summarizes our research and development expenses by program for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018	2017	2016
Exebacase	$16,218,315	$10,974,804	$ 8,092,280
CF-404	5,600	797,726	5,639,474
Other research and development	2,501,861	1,707,473	3,425,363
Personnel related and share-based compensation	3,690,875	3,839,083	4,944,603
Total research and development expense	$22,416,651	$17,314,086	$22,101,720

We anticipate that our research and development expenses will increase substantially in connection with the commencement of additional 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 exebacase or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of exebacase 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 exebacase or if we experience significant delays in enrollment in any clinical trials of exebacase, we could be required to expend significant additional financial resources and time on the completion of the clinical development of exebacase.

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.

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 consists of consultants, 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 for non-employees we use the remaining contractual term, but for employees 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, depending on the related expected term, we estimate based on either (i) 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 or (ii) the historical volatility of our own common shares;
- 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—Summary of Significant Accounting Policies, 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, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017:

	Year Ended December 31,			
	2018	2017	Dollar Change	% Change
Operating expenses:				
Research and development	$22,416,651	$17,314,086	$ 5,102,565	29%
General and administrative	$ 8,707,774	$ 9,249,671	$ (541,897)	(6)%
Other (expense) income	$ (6,559,999)	$11,046,099	$(17,606,098)	(163)%

Research and Development Expenses

Research and development expense was $22.4 million for the year ended December 31, 2018, compared with $17.3 million for the year ended December 31, 2017, an increase of $5.1 million. This increase was primarily attributable to a $4.5 million increase in expenditures on our product candidates as we completed enrollment in and delivery of topline data for the Phase 2 clinical trial of exebacase, partially offset by a continued reduction in expenditures on CF-404 activities. The increase was also due to an overall $0.6 million increase primarily in other research and development expenses, including laboratory and external research costs in support of the discovery and study of additional product candidates.

General and Administrative Expenses

General and administrative expense was $8.7 million for the year ended December 31, 2018, compared with $9.2 million for the year ended December 31, 2017, a decrease of $0.5 million. This decrease was primarily attributable to decreased compensation costs, including severance costs of $0.8 million, which were partially offset by a $0.5 million increase in payroll taxes due to a refundable payroll tax credit realized in the year ended December 31, 2017.

Other (expense) income

Other expense was $6.6 million for the year ended December 31, 2018 compared with other income of $11.0 million for the year ended December 31, 2017, a decrease of $17.6 million. In 2018, we had non-cash expense of $7.2 million related to the change in fair value of our warrant liability, which was partially offset by interest income of $0.6 million. In 2017, we had non-cash income of $11.5 million related to the change in fair value of our warrant liability and $0.4 million of interest income. These income items were partially offset by expense of $0.9 million for issuance costs allocated to the warrants issued with the offering of our securities in July 2017.

Comparison of years ended December 31, 2017 and 2016

The following table summarizes our results of operations for the years ended December 31, 2017 and 2016:

	Year Ended December 31,			
	2017	2016	Dollar Change	% Change
Operating expenses:				
Research and development	$17,314,086	$22,101,720	$ (4,787,634)	(22)%
General and administrative	$ 9,249,671	$11,430,526	$ (2,180,855)	(19)%
Other income	$11,046,099	$ 4,993,847	$ 6,052,252	121%

Research and Development Expenses

Research and development expense was $17.3 million for the year ended December 31, 2017, compared with $22.1 million for the year ended December 31, 2016, a decrease of $4.8 million. This decrease was primarily attributable to a $3.3 million decrease in expenses related to our research headcount, which included a reduction in research and development expense of $1.2 million reflecting grant funding received for salaries, benefits and laboratory costs in support of the discovery and study of additional product candidates and a $1.5 million decrease in external professional and consulting fees.

General and Administrative Expenses

General and administrative expense was $9.2 million for the year ended December 31, 2017, compared with $11.4 million for the year ended December 31, 2016, a decrease of $2.2 million. This decrease was primarily attributable to decreases in severance related costs of $1.1 million, a decrease in external professional, consulting and legal fees of $0.5 million, a decrease of $0.4 million in expenses related to our administrative personnel and a $0.2 million decrease in the administrative portion of the expenditure on our office and laboratory facility and related operating expenses from the reduction of the square footage of our leased premises.

Other income

Other income was $11.0 million for the year ended December 31, 2017 compared with $5.0 million for the year ended December 31, 2016, an increase of $6.0 million. This increase was primarily attributable to an increase in non-cash income of $5.2 million related to the change in fair value of our warrant liability, a decrease of $0.6 million in issuance costs allocated to warrants issued in our follow-on offerings and an increase in interest income of $0.2 million.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations to date primarily through proceeds from sales of common stock, common stock and warrants, convertible preferred stock and convertible debt and, to a lesser extent, grant funding. 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 funded our operations through the sale of registered securities for gross proceeds of $127.8 million, $9.6 million from the exercise of the Class B Warrants issued in our IPO and $20.0 million from the sale of securities in a private placement.

As of December 31, 2018, we had approximately $30.5 million in cash, cash equivalents and marketable securities which will not be sufficient to meet our obligations within the next twelve months from the date of issuance of our audited consolidated financial statements that are included elsewhere in this Annual Report on Form 10-K. Combined with our accumulated deficit and our forecasted cash expenditures, these factors raise substantial doubt about our ability to continue as a going concern. We have relied on our ability to fund our operations primarily through public and private debt and equity financings, but there can be no assurances that such financing will continue to be available to us on satisfactory terms, or at all. As such, under the requirements of ASC 205-40, we may not consider the potential for future capital raises in our assessment of our ability to meet our obligations for the next twelve months. If we are unable to obtain funding, we would be forced to delay, reduce or eliminate our research and development programs, which could adversely affect our business prospects, or we may be unable to continue operations. In accordance with the requirements of ASC 205-40, we have concluded that substantial doubt exists about our ability to continue as a going concern for twelve months from the date of issuance of our audited consolidated financial statements that are included elsewhere in this Annual Report on Form 10-K.

Cash flows

The following table shows a summary of our cash flows for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018	**2017**	**2016**
Net cash provided by (used in):			
Operating activities	$(26,258,849)	$(24,528,993)	$(29,300,340)
Investing activities	$ 17,151,224	$ (9,359,641)	$ (8,968,567)
Financing activities	$ 10,432,896	$ 37,076,696	$ 32,103,109

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 increased $1.7 million in the year ended December 31, 2018 as compared to the comparable period in 2017. This increase was primarily attributable to the increased expenditure on exebacase as we continued to execute the Phase 2 study to completion of enrollment and delivery of topline data. Net cash used in operating activities in the year ended December 31, 2017 decreased by $4.8 million as compared to the comparable period in 2016. This was primarily attributable to our decrease in expenditures of CF-404 as we completed drug substance manufacturing in 2016 and focused our development efforts on advancing exebacase into a Phase 2 clinical study.

Net cash provided by (used in) investing activities

Net cash provided by investing activities in the year ended December 31, 2018 resulted from the excess of the proceeds from the maturities of marketable securities compared to the purchases of marketable securities. Net cash used in investing activities in the years ended December 31, 2017 and 2016 resulted from the investment of our cash balances into marketable securities less proceeds from any maturities of those securities.

Net cash provided by financing activities

Net cash provided by financing activities in the year ended December 31, 2018 resulted primarily from the completion of an offering of our common stock to institutional investors in August 2018, resulting in net proceeds of $10.4 million. Net cash provided by financing activities in the year ended December 31, 2017

resulted from the completion of a registered offering of our securities to institutional investors in July 2017, resulting in net proceeds of $37.1 million. Net cash provided by financing activities in the year ended December 31, 2016 resulted primarily from the completion of a registered offering of our securities to institutional investors in July 2016, resulting in net proceeds of $32.0 million.

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.

Without additional funding, we believe we will not have sufficient funds to meet our obligations within the next twelve months from the date of issuance of our audited consolidated financial statements that are included elsewhere in this Annual Report on Form 10-K. 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. We plan to continue to fund our operations through public or private debt and equity financings, but there can be no assurances that such financing will be available to us on satisfactory terms, or at all. 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 costs as a public company, including, but not limited to, increased personnel costs, increased directors fees, increased directors and officers insurance premiums, audit and legal fees, investor relations and external communications fees, expenses for compliance with the Sarbanes-Oxley Act and rules implemented by the SEC and Nasdaq and various other costs and expenses.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2018 and the effect such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period				
Contractual obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**4 - 5 years**	**More than 5 years**
Operating lease commitments(1)	$6,372,936	$ 653,324	$1,346,110	$1,400,492	$2,973,010
License and sponsored research agreements(2)	1,449,750	449,749	400,000	400,000	200,000
Total contractual obligations	$7,822,686	$1,103,073	$1,746,110	$1,800,492	$3,173,010

(1) Represents future minimum lease payments under non-cancelable operating leases for our principal facilities in Yonkers, New York which expire in 2027. The minimum lease payments above do not include certain utility costs, common area maintenance charges or real estate taxes.

(2) Represents certain amounts payable under our licenses and sponsored research agreements with The Rockefeller University and Trellis Bioscience LLC.

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

The contractual obligations table also does not include any potential contingent payments upon the achievement by us of specified clinical, regulatory and commercial events, as applicable, or royalty payments we may be required to make under license agreements we have entered into with The Rockefeller University and Trellis Bioscience LLC. The occurrence and timing of these events are difficult to predict and subject to significant uncertainty. Since we are unable to reliably estimate the timing and amounts of such milestone and royalty payments, or whether they will occur at all, these contingent payments have been excluded from the table above. See “Note 8—Commitments and Contingencies” on Page F-18 of this Annual Report for additional information.

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

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2018, we had cash, cash equivalents and marketable securities of $30.5 million. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the fair value of our cash equivalents or marketable securities. If a 10% change in interest rates were to have immediately occurred on December 31, 2018, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

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

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

Item 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

Limitations on Effectiveness of 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.

Evaluation of Disclosure Controls and Procedures

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

covered by this 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, 2018.

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, 2018, 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, 2018 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, 2018 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.	66	President, Chief Executive Officer, Director, Chairman of the Board
Roger J. Pomerantz, M.D., F.A.C.P.	62	Director, Vice Chairman of the Board
Sol J. Barer, Ph.D.	71	Director, Lead Independent Director
Isaac Blech	69	Director
David N. Low, Jr.	60	Director
Michael J. Otto, Ph.D.	70	Director
Cary W. Sucoff, J.D.	67	Director

Steven C. Gilman, Ph.D. Dr. Gilman has served as Chairman of our board of directors since May 2015. In March 2016, he was appointed Interim Chief Executive Officer of the Company and in July 2016 he was appointed Chief Executive Officer of the Company. 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 Keryx Biopharmaceuticals, Inc., Momenta Pharmaceuticals, Inc., SCYNEXIS Inc., and Vericel Corporation. 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 November 2013, Dr. Pomerantz has served as Chairman of the board of directors of Seres, a biotechnology company, and as its President and Chief Executive Officer of Seres since June 2014. 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 J. 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 January 2011, and Chairman and Chief Executive Officer from May 2006 until June 2010. Before assuming the CEO position, he was appointed Chief Operating Officer in 1994 and President in 1993. 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 Aevi Genomic Medicine, and Teva Pharmaceutical Industries, and the private company Centrexion. He is an advisor to biotechnology/medical companies, the Israel Biotech Fund and not for profit organizations. 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. Dr. Barer received a Ph.D. in Organic Chemistry in 1974 from Rutgers University where he was an NDEA Graduate Fellow and a B.S. in 1968 from Brooklyn College (City University of New York) where he was an NSF Undergraduate Fellow and Regents Scholar. He received an LL.D. (Honorary) from the Rabbinical College of America in 2018. 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 was the co-founder and has served as Vice Chairman of Sapience Therapeutics Inc. since November 2015. Mr. Blech was the co-founder and Vice Chairman of Elucida Oncology Inc. since 2013. Mr. Blech was the co-founder and Vice Chairman of Centrexion Therapeutics Corp. since 2011. Mr. Blech was also the co-founder and Vice Chairman of Cerecor Inc. since 2011. Mr. Blech is the Vice Chairman of Aridis Pharmaceuticals since December 2015. Mr. Blech currently serves as a Director for Adheara Therapeutics, Inc., Edge Therapeutics Inc., SpendSmart Networks Inc., X4 Pharmaceuticals Inc., and X-VAX Technology, Inc. Mr. Blech is a successful founder and investor in the biotechnology industry. Over the past 35 years, he has established multiple successful biotechnology companies. These include Celgene Corporation, ICOS Corporation, Nova Pharmaceutical Corporation, Pathogenesis Corporation and Genetics Systems Corporation. Mr. Blech earned a B.A. from Baruch College in 1975. We believe that Mr. Blech's business experience and ties to the investment community qualify him 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 June 2017, Mr. Low has served as a partner at MTS Health Partners, a healthcare investment banking boutique. From 2002 to April 2017, Mr. Low was a member of Lazard's Life Sciences Group as a Managing Director and Senior Advisor. 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 Philharmonia Baroque Orchestra. 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.

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 biotech companies. 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, Legacy Education Alliance and First Wave Technologies, Inc. In addition, Mr. Sucoff currently serves as a consultant to Sapience Therapeutics and Galimedix Pharmaceuticals Inc. Mr. Sucoff is the past 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.

Executive Officers of the Registrant

Biographical information concerning each of our executive officers is set forth below. Information concerning Steven C. Gilman, Ph.D., our Chief Executive Officer, may be found above in the section entitled "Director Biographical Information."

Natalie Bogdanos, J.D. Ms. Bogdanos, age 50, has served as our General Counsel and Corporate Secretary since August 2014, and served as a member of the Interim Office of the Chief Executive Officer from March 2017 to June 2017. Ms. Bogdanos has also served as our Data Protection Officer since July 2018. She has over 20 years of experience in the legal field, almost 14 of which were serving as the chief legal officer of a publicly traded biotechnology company. Prior to joining ContraFect in 2014, Ms. Bogdanos served as a full time legal consultant for Ferring Pharmaceuticals, Inc. from January 2014 to August 2014. Prior to that, Ms. Bogdanos served as Associate General Counsel at Memorial Sloan-Kettering Cancer Center ("MSKCC"), a cancer treatment and research institution, where she held a joint appointment with the Office of the General Counsel and the Office of Technology Development ("OTD") from 2012 to 2013. 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. Prior to MSKCC, she was General Counsel at Enzo Biochem, Inc. ("Enzo"), a publicly traded international biotechnology and life science company, from 2003 to 2012. At Enzo, she was responsible for leading the legal department, ensuring SEC and regulatory compliance, overseeing litigation and managing Enzo's portfolio of 500+ patents and patent applications and negotiating complex business development agreements as well as other contracts. Previously, Ms. Bogdanos was an associate at Amster, Rothstein & Ebenstein from 1999 to 2003 where her practice focused on all intellectual property matters including related litigation. Ms. Bogdanos 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 and 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. She is also licensed to practice before the United States Patent and Trademark Office. Ms. Bogdanos received her J.D.

from New York Law School and her Bachelor of Arts in Biology, with honors, from Queens College of the City University of New York.

Cara Cassino, M.D. Dr. Cassino, age 57, has served as our Chief Medical Officer since September 2015, also as Executive Vice President of Research and Development since August 2016, and served as a member of the Interim Office of the Chief Executive Officer from March 2017 to June 2017. Dr. Cassino has over 20 years of experience as a clinician and executive in healthcare, including over 15 years of experience in pharmaceutical product development with over 20 successful regulatory submissions in the United States and globally. Prior to joining ContraFect, Dr. Cassino served as an independent consultant to various pharmaceutical and biotechnology companies, including Scynexis, from December 2014 to September 2015. Prior to that, she 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 from 2013 to 2014. While at Forest, she was responsible for pre- and 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. From 2008 to 2013, 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. Prior to joining Pfizer, 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 (NYU) School of Medicine for eight years prior to joining industry. Dr. Cassino received her B.A., summa cum laude, in Chemistry and Fine Arts from 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.

Michael Messinger, CPA. Mr. Messinger, age 44, has served as our Chief Financial Officer since November 2018. He has more than 18 years of experience in finance, accounting and forecasting for clinical development. Prior to joining ContraFect in November 2012 as our Vice President, Finance, and later serving as our Senior Vice President, Finance beginning in August 2016, 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.

Nancy Dong. Ms. Dong, age 53, has served as our Vice President, Finance and Administration since March 2017 She has more than 20 years of experience in accounting, strategic planning, budgeting and forecasting, organizational development, financial systems and controls and human resources. Prior to joining ContraFect in 2010 as Vice President, Controller, 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 and 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.

Our board of directors has adopted a Code of Business Conduct and Ethics 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 Business Conduct and Ethics, 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 and location specified above.

The remaining information required by this Item 10 will be contained under the headings "Section 16(a) Beneficial Ownership Reporting Compliance," and "Corporate Governance – Committees of the Board of Directors" in our definitive proxy statement to be filed with the SEC with respect to our 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be contained under the heading "Executive Compensation" in our definitive proxy statement to be filed with the SEC with respect to our 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be contained under the headings "Executive Compensation – Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management" in our definitive proxy statement to be filed with the SEC with respect to our 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be contained under the headings "Certain Relationships and Related Transactions" and "Corporate Governance – Director Independence" in our definitive proxy statement to be filed with the SEC with respect to our 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be contained under the heading "Ratification of Appointment of Independent Registered Public Accounting Firm" in our definitive proxy statement to be filed with the SEC with respect to our 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Index list to Consolidated 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.

(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

Exhibit Index

Exhibit No.	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of ContraFect Corporation, dated August 1, 2014, and Certificate of Amendment, dated May 9, 2016 and Certificate of Amendment dated May 2, 2017	8-K	001-36577	3.1	May 3, 2017	
3.2	Amended and Restated Bylaws of ContraFect Corporation	8-K	001-36577	3.2	May 10, 2016	
4.1	Form of Common Stock Certificate	S-1/A	333-195378	4.1	July 3, 2014	
4.2	Representative's Warrant, dated August 27, 2014	8-K	001-36577	4.14	October 29, 2015	
4.3	Form of Noteholder Warrant	S-1/A	333-195378	4.7	July 3, 2014	
4.4	Specimen Unit Certificate	S-1/A	333-195378	4.8	July 1, 2014	
4.5	Form of Indenture	S-3	333-206786	4.1	September 4, 2015	
4.6	Form of Investor Warrant	8-K	001-36577	4.1	June 12, 2015	

Table of Contents

Exhibit No.	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
4.7	Form of Placement Agent Warrant	8-K	001-36577	4.2	June 12, 2015	
4.8	Form of Warrant Agreement by and between ContraFect Corporation and the American Stock Transfer & Trust Company, LLC, dated July 27, 2016	8-K	001-36577	4.1	July 27, 2016	
4.9	Form of Warrant Certificate	8-K	001-36577	4.2	July 27, 2016	
4.10	Form of Warrant Agreement by and between ContraFect Corporation and the American Stock Transfer & Trust Company, LLC, dated July 25, 2017	8-K	001-36577	4.1	July 25, 2017	
4.11	Form of Warrant Certificate	8-K	001-36577	4.2	July 25, 2017	
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#	ContraFect Corporation Amended and Restated 2008 Equity Incentive Plan	S-1	333-195378	10.11	April 18, 2014	
10.6#	ContraFect Corporation Form of Stock Option Agreement	S-1	333-195378	10.12	April 18, 2014	
10.7#	ContraFect Corporation 2008 Equity Incentive Plan	S-1	333-195378	10.13	April 18, 2014	
10.8#	ContraFect Corporation 2014 Omnibus Incentive Plan	S-1/A	333-195378	10.14	July 1, 2014	
10.9	License Agreement, between Trellis Bioscience LLC and ContraFect Corporation, dated January 29, 2014	S-1/A	333-195378	10.15	July 1, 2014	
10.10	Amendment to the Trellis License Agreement, dated June 15, 2014	S-1/A	333-195378	10.16	July 1, 2014	

Table of Contents

Exhibit No.	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.11	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	
10.12	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	
10.13#	Letter Agreement, dated July 21, 2016, between ContraFect Corporation and Steven C. Gilman, Ph.D.	8-K	001-36577	10.1	July 21, 2016	
10.14#	Separation and Consulting Agreement by and between ContraFect Corporation and Michael Wittekind, Ph.D., dated October 3, 2016	10-Q	001-36577	10.1	November 9, 2016	
10.15#	Letter Agreement, dated March 13, 2017, between ContraFect Corporation and Steven C. Gilman, Ph.D.	8-K	001-36577	10.1	March 13, 2017	
10.16#	Amendment No. 1 to Offer Letter, dated May 29, 2018, between ContraFect Corporation and Steven C. Gilman, Ph.D.	8-K	001-36577	10.1	May 30, 2018	
10.17#	Offer Letter, dated June 26, 2014, between ContraFect Corporation and Natalie Bogdanos, as amended by Amendment No. 1, dated November 2, 2015	10-K	001-36577	10.27	March 15, 2017	

Table of Contents

Exhibit No.	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.18#	Offer Letter, dated August 24, 2015, between ContraFect Corporation and Cara Cassino, M.D.	10-K	001-36577	10.28	March 15, 2017	
10.19#	Amendment No. 1 to Offer Letter, dated March 15, 2017, between ContraFect Corporation and Cara Cassino, M.D.	10-K	001-36577	10.29	March 15, 2017	
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm					*
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					*
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					*

* Filed herewith.
** Furnished herewith.
# Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None

Table of Contents

CONTRAFECT CORPORATION

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of ContraFect Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ContraFect Corporation (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has an accumulated deficit, has incurred recurring losses and used significant cash flows in operations, expects continuing future losses and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

Hartford, Connecticut

March 14, 2019

CONTRAFECT CORPORATION
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 8,320,317	$ 6,995,046
Marketable securities	22,131,936	39,858,864
Prepaid expenses and other current assets	988,799	1,848,063
Total current assets	31,441,052	48,701,973
Property and equipment, net	1,076,099	1,093,903
Other assets	355,420	393,603
Total assets	$ 32,872,571	$ 50,189,479
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,427,287	$ 1,302,431
Accrued liabilities	4,369,732	3,118,237
Total current liabilities	5,797,019	4,420,668
Deferred rent	679,182	704,240
Warrant liabilities	20,781,663	13,549,437
Other liabilities	72,747	321,689
Total liabilities	27,330,611	18,996,034
Commitments and contingencies (Note 8)	—	—
Stockholders' equity:		
Preferred stock, $0.0001 par value, 25,000,000 shares authorized and none outstanding at December 31, 2018 and 2017	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized, 79,406,556 shares issued and outstanding at December 31, 2018; 200,000,000 shares authorized, 73,656,006 shares issued and outstanding at December 31, 2017	7,941	7,366
Additional paid-in capital	204,884,211	192,896,367
Accumulated other comprehensive loss	(30,300)	(74,820)
Accumulated deficit	(199,319,892)	(161,635,468)
Total stockholders' equity	5,541,960	31,193,445
Total liabilities and stockholders' equity	$ 32,872,571	$ 50,189,479

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Operations

	Year Ended December 31,		
	2018	2017	2016
Operating expenses:			
Research and development, including stock-based compensation of $626,002, $451,334 and $587,426, respectively	$ 22,416,651	$ 17,314,086	$ 22,101,720
General and administrative, including stock-based compensation of $929,521, $1,171,794 and $1,644,456, respectively	8,707,774	9,249,671	11,430,526
Total operating expenses	31,124,425	26,563,757	33,532,246
Loss from operations	(31,124,425)	(26,563,757)	(33,532,246)
Other (expense) income:			
Interest income	672,227	418,135	216,616
Other expense	—	(905,014)	(1,569,341)
Change in fair value of warrant liabilities	(7,232,226)	11,532,978	6,346,572
Total other (expense) income	(6,559,999)	11,046,099	4,993,847
Net loss	$(37,684,424)	$(15,517,658)	$(28,538,399)
Per share information:			
Net loss per share of common stock, basic and diluted	$ (0.50)	$ (0.28)	$ (0.85)
Basic and diluted weighted average shares outstanding	76,062,664	55,595,732	33,539,465

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Comprehensive Loss

	Year Ended December 31,		
	2018	2017	2016
Net loss	$(37,684,424)	$(15,517,658)	$(28,538,399)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale securities	44,520	(23,154)	(21,293)
Comprehensive loss	$(37,639,904)	$(15,540,812)	$(28,559,692)

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2015	27,482,692	$ 2,748	$148,282,546	$ (30,373)	$(117,579,411)	$ 30,675,510
Issuance of common stock for services	31,206	3	93,927	—	—	93,930
Issuance of securities in registered offering	14,000,000	1,400	16,397,372	—	—	16,398,772
Financing cost of sale of securities	—	—	(1,383,548)	—	—	(1,383,548)
Issuance of common stock for exercise of options	2,850	1	—	—	—	1
Issuance of common stock for exercise of warrants	139,258	14	55,984	—	—	55,998
Share-based compensation	—	—	2,231,883	—	—	2,231,883
Unrealized loss on marketable securities	—	—	—	(21,293)	—	(21,293)
Net loss	—	—	—	—	(28,538,399)	(28,538,399)
Balance, December 31, 2016	41,656,006	$ 4,166	$165,678,164	$ (51,666)	$(146,117,810)	$ 19,512,854
Issuance of securities in registered offering	32,000,000	3,200	27,613,365	—	—	27,616,565
Financing cost of sale of securities	—	—	(2,018,290)	—	—	(2,018,290)
Share-based compensation	—	—	1,623,128	—	—	1,623,128
Unrealized loss on marketable securities	—	—	—	(23,154)	—	(23,154)
Net loss	—	—	—	—	(15,517,658)	(15,517,658)
Balance, December 31, 2017	73,656,006	$ 7,366	$192,896,367	$ (74,820)	$(161,635,468)	$ 31,193,445
Issuance of common stock in registered offering	5,750,000	575	11,499,425	—	—	11,500,000
Financing cost of sale of securities	—	—	(1,072,607)	—	—	(1,072,607)
Issuance of common stock for exercise of warrants	3,550	—	5,503	—	—	5,503
Share-based compensation	—	—	1,555,523	—	—	1,555,523
Unrealized gain on marketable securities	—	—	—	44,520	—	44,520
Net loss	—	—	—	—	(37,684,424)	(37,684,424)
Balance, December 31, 2018	79,409,556	$ 7,941	$204,884,211	$ (30,300)	$(199,319,892)	$ 5,541,960

See accompanying notes.

CONTRAFECT CORPORATION
Statements of Cash Flows

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities			
Net loss	$(37,684,424)	$(15,517,658)	$(28,538,399)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	151,292	187,249	451,008
Stock-based compensation expense	1,555,523	1,623,128	2,231,883
Issuance of common stock in exchange for services	—	—	93,930
Issuance costs allocated to warrants	—	905,014	1,569,341
Change in fair value of warrant and embedded derivative liabilities	7,232,226	(11,532,978)	(6,346,572)
(Decrease) increase in deferred rent	(25,058)	(290,199)	22,320
Net amortization of premium paid on marketable securities	486,736	831,793	428,783
Changes in operating assets and liabilities:			
Decrease (increase) in prepaid expenses and other current and non-current assets	897,447	(1,059,502)	138,352
Increase in accounts payable and accrued liabilities	1,127,409	324,160	649,014
Net cash used in operating activities	(26,258,849)	(24,528,993)	(29,300,340)
Cash flows from investing activities			
Purchases of marketable securities	(23,846,176)	(53,162,598)	(36,459,405)
Proceeds from maturities of marketable securities	41,130,888	43,802,957	27,604,030
Purchases of property and equipment	(133,488)	—	(113,192)
Net cash provided by (used in) investing activities	17,151,224	(9,359,641)	(8,968,567)
Cash flows from financing activities			
Proceeds from issuance of equity securities	11,500,000	40,000,000	35,000,000
Payment of financing costs of securities sold	(1,072,607)	(2,923,304)	(2,952,889)
Proceeds from exercise of warrants	5,503	—	55,998
Net cash provided by financing activities	10,432,896	37,076,696	32,103,109
Net increase (decrease) in cash and cash equivalents	1,325,271	3,188,062	(6,165,798)
Cash and cash equivalents at beginning of period	6,995,046	3,806,984	9,972,781
Cash and cash equivalents at end of period	$ 8,320,317	$ 6,995,046	$ 3,806,984
Supplemental disclosures of cash flow information and non-cash investing and financing activities			
Issuance of common stock for services	$ —	$ —	$ 93,930
Issuance of warrants to purchase common stock	$ —	$ 12,383,435	$ 18,601,228

See accompanying notes.

ContraFect Corporation
Notes to Financial Statements
December 31, 2018

1. Organization and Description of Business

Organization and Business

ContraFect Corporation (the "Company") is a clinical-stage biotechnology company focused on biologic 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 platform. The Company's most advanced product candidate is exebacase, a lysin which targets *Staph aureus*, including methicillin-resistant strains, which causes serious infections such as bacteremia, pneumonia and osteomyelitis. *Staph aureus* is also a frequent source of biofilm-dependent infections of heart valves (endocarditis), prosthetic joints, indwelling devices and catheters. These infections result in significant morbidity and mortality despite current antibiotic therapy. Exebacase is being studied in a Phase 2 superiority study to evaluate its safety, tolerability, efficacy and pharmacokinetics when used in addition to background standard of care antibacterial therapy for the treatment of *Staph aureus* bacteremia, including endocarditis in adult patients.

The Company has incurred losses from operations since inception as a research and development organization and has an accumulated deficit of $199.3 million as of December 31, 2018. For the year ended December 31, 2018, the Company used $26.3 million of cash in operations. The Company expects operating losses and negative cash flows to continue at significant levels in the future as it continues its clinical trials. Without additional funding, the Company believes it will not have sufficient funds to meet its obligations within the next twelve months from the date of issuance of these consolidated financial statements. These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company plans to continue to fund its operations through public or private debt and equity financings, but there can be no assurances that such financing will continue to be available to the Company on satisfactory terms, or at all. As such, under the requirements of ASC 205-40, management may not consider the potential for future capital raises in its assessment of the Company's ability to meet its obligations for the next twelve months. If the Company is unable to obtain funding, the Company would be forced to delay, reduce or eliminate its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

On July 27, 2016, the Company completed an underwritten public offering of 14,000,000 shares of its common stock and warrants to purchase an additional 14,000,000 shares of its common stock at an exercise price of $3.00 per share (the "2016 Offering"). The public offering price was $2.50 per share of common stock and accompanying warrant, resulting in net proceeds to the Company of approximately $32.0 million after underwriting discounts and commissions and offering expenses payable by the Company.

On July 25, 2017, the Company completed an underwritten public offering of 32,000,000 shares of its common stock and warrants to purchase an additional 16,000,000 shares of its common stock at an exercise price of $1.55 per share (the "2017 Offering"). The public offering price was $1.25 per share of common stock and accompanying warrant, resulting in net proceeds to the Company of approximately $37.1 million after underwriting discounts and commissions and offering expenses payable by the Company.

On August 3, 2018, the Company completed an underwritten public offering of 5,750,000 shares of its common stock, including shares sold pursuant to the fully exercised overallotment option granted to the underwriters in connection with the offering, at a public offering price of $2.00 per share, resulting in net proceeds to the Company of approximately $10.4 million after underwriting discounts and commissions and offering expenses payable by the Company.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial information has been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

Principles of Consolidation

The Company has a wholly-owned subsidiary, ContraFect International Limited, in Scotland that establishes legal status for interactions with the European Economic Area. This subsidiary is dormant or is otherwise non-operative. Any inter-company accounts have been eliminated in consolidation.

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.

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.

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 realization of net deferred income tax assets. 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.

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.

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 consist of investments in corporate debt and U.S. Treasury 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*. The Company classifies marketable securities available to fund current operations as current assets on its consolidated balance sheets. Marketable securities are classified as long-term assets on the consolidated balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive loss in stockholders' equity and a component of total comprehensive loss in the consolidated 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 interest income in the consolidated statement of operations and comprehensive loss on a specific-identification basis. There were no realized gains or losses on marketable securities for the years ended December 31, 2018, 2017 or 2016. There were no marketable securities that had been in an unrealized loss position for more than 12 months as of December 31, 2018 or 2017.

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 consolidated 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.

Fair Value of Financial Instruments

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

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. 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 4, "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.

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. As of December 31, 2018 and 2017, no impairment of long-lived assets has occurred.

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 on the date of grant based on key assumptions such as stock price, risk free interest rates, expected volatility and expected term. The Company's estimates of these assumptions are primarily based on historical data, peer company data and judgment regarding future trends and factors.

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, 2018) 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, 2018.

Grants

The Company recognizes a receivable and the related reduction in its research and development expenses when the actual reimbursable costs have been incurred and there is reasonable assurance that the Company has complied with the conditions of the grants and the amounts will be received. For the years ended December 31, 2018 and 2017, the Company recognized a reduction to its research and development expense in the amount of approximately $1,222,000 and $1,176,000, respectively. The receivable for grants as of December 31, 2018 was approximately $202,000 and is included in prepaid expenses and other current assets. The Company has approximately $482,000 of approved grant award funding remaining as of December 31, 2018.

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. 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 Loss

Comprehensive 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.

Recently Adopted Accounting Pronouncements

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 adopted ASU 2016-01 as of January 1, 2018 and there was no impact to the Company's financial statements and related disclosures.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15*, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* (ASU 2016-15), which amended the existing accounting standards for the statement of cash flows by providing guidance on eight classification issues related to the statement of cash flows. ASU 2016-15 is effective in fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The amendments should be applied retrospectively to all periods presented. For issues that are impracticable to apply retrospectively, the amendments may be applied prospectively as of the earliest date practicable. The Company adopted ASU No. 2016-15 as of January 1, 2018 and there was no impact to the Company's financial statements and related disclosures.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18*, Statement of Cash Flows (Topic 230): Restricted Cash* (ASU 2016-18), which amended the existing accounting standards for the statement of cash flows by requiring restricted cash to be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective in fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The amendments should be applied retrospectively to all periods presented. The Company adopted ASU No. 2016-18 as of January 1, 2018 and there was no impact to the Company's financial statements and related disclosures.

In May 2017, the FASB issued Accounting Standards Update 2017-09, *Compensation – Stock Compensation* (Topic 718): Scope of Modification Accounting (ASU 2017-09). This new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU 2017-09 allows for prospective application and is effective for fiscal years beginning after December 15, 2017, and interim periods therein with early adoption permitted for interim or annual periods. The Company adopted ASU No. 2017-09 as of January 1, 2018 and there was no impact to the Company's financial statements and related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

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 sheet as an asset and a corresponding lease liability, regardless of whether they are classified as finance (previously referred to as capital leases) 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. We will adopt the new standard effective January 1, 2019.

This guidance will be effective on a modified retrospective basis and we will apply the optional transition method. The Company is currently evaluating the potential impact ASU 2016-02 may have on its financial position, results of operations, and related footnotes. The Company expects it will elect to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: i) whether existing or expired arrangements are or contain a lease, ii) the lease classification of existing or expired leases, and iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company expects it will make an accounting policy election to keep leases with an initial term of 12 months or less off of its balance sheet. The Company currently expects the lease of its corporate headquarters at 28 Wells Avenue in Yonkers, New York, as disclosed in Note 8— Commitments and Contingencies in our Annual Report on Form 10-K filed with the SEC on March 15, 2018, will be subject to the new standard and recognize as a right-of-use asset and operating lease liability upon its adoption of ASU 2016-02. The Company has begun its implementation which will increase the total assets and total liabilities that the Company reports relative to such amounts prior to adoption and continues to assess the impact that this standard has on its other contracts, if any. We expect to complete our assessment of the full financial impact of ASC 842 during the first quarter of 2019, and will include all required presentation and disclosures under ASC 842 in our Form 10-Q for the three months ending March 31, 2019.

In June 2016, the FASB issued a new Accounting Standards Update, *Financial Instruments-Credit Losses (ASU 2016-13).* ASU 2016-13 amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded through an allowance for such losses rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new standard is effective for interim and annual periods beginning after December 15, 2019. The Company is currently evaluating the impact that this new standard will have on its financial statements and related disclosures.

In June 2018, the FASB issued Accounting Standards Update, *Compensation-Stock Compensation (ASU 2018-07),* which simplifies the accounting for share-based payments granted to nonemployees by aligning the accounting with the requirements for employee share-based compensation. The new guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. The Company is assessing the impact of the adoption of this guidance on its consolidated financial statements and whether or not to adopt early.

In August 2018, the FASB issued Accounting Standards Update, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, (ASU 2018-13).* The new standard removes certain disclosures, modifies certain disclosures and adds additional disclosures related to fair value measurement. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The Company is currently evaluating the potential impact ASU 2018-13 may have on its disclosures upon adoption.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated

or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. The Company anticipates its first presentation of changes in stockholders' equity as required under the new SEC guidance will be included in its Form 10-Q for the quarter ended March 31, 2019.

3. Marketable Securities

Marketable securities at December 31, 2018 consisted of the following:

Marketable Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Corporate debt	$ 19,179,530	$ 314	$ (31,160)	$19,148,684
U.S. Treasury securities	2,982,706	546	—	2,983,252
	$ 22,162,236	$ 860	$ (31,160)	$22,131,936

Marketable securities at December 31, 2017 consisted of the following:

Marketable Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Corporate debt	$ 39,933,684	$ —	$ (74,820)	$39,858,864

U.S. Treasury securities include government debt instruments issued by the U.S. Department of the Treasury. Corporate debt includes obligations issued by investment-grade corporations, and may include issues that have been guaranteed by governments and government agencies. At December 31, 2018, the Company held only investments that have maturities of less than one year.

At December 31, 2018 and December 31, 2017, the Company held 22 and 32 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, 2018 and December 31, 2017 was $19,544,246 and $39,858,864, 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 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, 2018 and 2017.

4. Fair Value Measurements

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2018 and December 31, 2017:

	Fair Value Measurement As of December 31, 2018		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 6,850,772	$ —	$ —
Marketable securities	22,131,936	—	—
Warrant liabilities	—	—	20,781,663
Total	$ 28,982,708	$ —	$20,781,663

	Fair Value Measurement As of December 31, 2017		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 5,949,477	$ —	$ —
Marketable securities	39,858,864	—	—
Warrant liabilities	—	—	13,549,437
Total	$ 45,808,341	$ —	$13,549,437

The Company issued a warrant to the representative of the underwriter of its initial public offering (the "Representative's Warrant"). The Company determined that this warrant should be classified as a liability and considers it as a Level 3 financial instrument (see also Note 9, "Capital Structure"). The Representative's Warrant will be re-measured at each subsequent reporting period and changes in fair value will be recognized in the consolidated 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, 2018	As of December 31, 2017
Expected volatility	70.9%	88.1%
Remaining contractual term (in years)	0.67	1.67
Risk-free interest rate	2.63%	1.89%
Expected dividend yield	— %	— %

The Company issued warrants to the purchasers of its 2016 Offering (the "2016 Warrants"). The Company determined that these warrants should be classified as a liability and considered as a Level 3 financial instrument (see also Note 9, "Capital Structure"). The 2016 Warrants will be re-measured at each subsequent reporting period and changes in fair value will be recognized in the consolidated 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, 2018	As of December 31, 2017
Expected volatility	72.6%	80.3%
Remaining contractual term (in years)	2.58	3.58
Risk-free interest rate	2.46%	2.09%
Expected dividend yield	— %	— %

The Company issued warrants to the purchasers of its 2017 Offering (the "2017 Warrants"). The Company determined that these warrants should be classified as a liability and considered as a Level 3 financial instrument (see also Note 9, "Capital Structure"). The 2017 Warrants will be re-measured at each subsequent reporting period and changes in fair value will be recognized in the consolidated 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, 2018	As of December 31, 2017
Expected volatility	87.3%	81.5%
Remaining contractual term (in years)	3.58	4.58
Risk-free interest rate	2.49%	2.20%
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, 2018, 2017 and 2016:

Warrant liabilities

	Year Ended December 31,		
	2018	2017	2016
Balance at beginning of period	$13,549,437	$ 12,698,980	$ 444,324
Issuance of 2017 Warrants	—	12,383,435	—
Issuance of 2016 Warrants	—	—	18,601,228
Change in fair value	7,232,226	(11,532,978)	(6,346,572)
Balance at end of period	$20,781,663	$ 13,549,437	$12,698,980

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

5. Property, Equipment, and Leasehold Improvements

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

	December 31,	
	2018	2017
Computer equipment	$ 19,691	$ 19,691
Furniture	434,697	434,697
Lab equipment	1,844,369	1,710,881
Leasehold improvements	1,855,004	1,855,004
	4,153,761	4,020,273
Less: accumulated depreciation and amortization	(3,077,662)	(2,926,370)
	$ 1,076,099	$ 1,093,903

Depreciation expense was $151,292, $187,249 and $451,008 for the years ended December 31, 2018, 2017 and 2016, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2018	2017
Accrued research and development service fees	$2,076,764	$ 578,562
Accrued compensation costs	1,585,689	2,107,118
Accrued professional fees	433,498	168,168
Accrued facilities operation expenses	232,673	221,103
Other accrued expenses	41,108	43,286
	$4,369,732	$3,118,237

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:

	Year Ended December 31,		
	2018	2017	2016
Net loss applicable to common stockholders	$(37,684,424)	$(15,517,658)	$(28,538,399)
Weighted average shares of common stock outstanding	76,062,664	55,595,732	33,539,465
Net loss per share of common stock—basic and diluted	$ (0.50)	$ (0.28)	$ (0.85)

The following potentially dilutive securities outstanding at December 31, 2018, 2017 and 2016 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,		
	2018	2017	2016
Options to purchase common stock	7,187,885	6,200,151	4,691,746
Warrants to purchase common stock	31,243,026	36,270,103	27,214,775
	38,430,911	42,470,254	31,906,521

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 "Third Floor Lease"). 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.

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 "Fourth Floor Lease"). The Fourth Floor Lease provides for an option to renew for two additional five-year terms. Effective August 1, 2017, the Company relinquished 10,912 square feet of space under the Fourth Floor Lease and was relieved of its obligations related to such space. Monthly rental payments were adjusted and together with the Third Floor Lease, future minimum lease payments are as follows:

	Amount
Year ending December 31:	
2019	$ 653,324
2020	666,391
2021	679,719
2022	693,313
2023	707,179
Thereafter	2,973,011
	$6,372,937

Rent expense is recognized on the straight-line method over the terms of each lease. Rent expense for the years ended December 31, 2018, 2017 and 2016, was approximately $618,000, $587,000 and $880,000, respectively.

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 and subsequently, exebacase. 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 are required to pay annual maintenance fees of $200,000 in 2019 and each year thereafter until the licenses terminate, milestone payments and royalties of up to 5% on net sales from products to Rockefeller. There were no milestone, royalty or sublicense payments made during the years ended December 31, 2018 and 2017. The Company made a milestone payment under the CF-301 License of $180,000 in 2016 for the completion of the

Phase 1 trial. 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. On October 25, 2016, we entered into a third research agreement with Rockefeller, where we provide funding for the identification of novel lysin therapeutic candidates which target gram-negative pathogens. The research collaboration will focus on gram-negative pathogens such as *P. aeruginosa, E. coli,* and *K. pneumoniae*, including antibiotic-resistant strains.

Our current agreement runs through October 24, 2019. 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).

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 of up to 4%. There were no development or regulatory milestones or royalty payments made during the years ended December 31, 2018, 2017 and 2016. 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.

Separation Agreement

On December 12, 2017, the Company notified Lisa R. Ricciardi that she would no longer be needed to serve as Chief Operating Officer of the Company effective December 31, 2017. Subject to Ms. Ricciardi entering into a separation agreement, the Company accrued expense of $0.7 million for the severance payments and continued medical, dental and vision coverage under the Company's group healthcare plans, to be provided for a period of 18 months following the effective date of Ms. Ricciardi's termination, and recognized share-based compensation

expense of $0.2 million for the accelerated vesting of all unvested portions of Ms. Ricciardi's stock option grants. The total amount of these charges was recognized as part of general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2017.

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.

9. Capital Structure

Common Stock

As of December 31, 2018, the Company was authorized to issue 200,000,000 shares of common stock at $0.0001 par value per share.

Follow-on Offerings

On August 3, 2018, the Company completed an underwritten public offering of 5,750,000 shares of its common stock, including shares sold pursuant to the fully exercised overallotment option granted to the underwriters in connection with the offering, at a public offering price of $2.00 per share, resulting in net proceeds to the Company of approximately $10.4 million after underwriting discounts and commissions and offering expenses payable by the Company.

On July 25, 2017, the Company sold 32,000,000 shares of its common stock and warrants to purchase an additional 16,000,000 shares of its common stock in an underwritten follow-on offering for gross proceeds of $40.0 million (the "2017 Offering"). The Company received net proceeds of approximately $37.1 million after underwriting discounts, commissions and offering expenses payable by the Company.

On July 27, 2016, the Company sold 14,000,000 shares of its common stock and warrants to purchase an additional 14,000,000 shares of its common stock in an underwritten Follow-on Offering for gross proceeds of $35.0 million (the "2016 Offering"). The Company received net proceeds of approximately $32.0 million after underwriting discounts, commissions and offering expenses payable by the Company.

The Company issued warrants in the 2017 and 2016 Offerings. The 2017 Warrants have an exercise price of $1.55 per share and expire five years from the date of issuance. The 2016 Warrants have an exercise price of $3.00 per share and expire five years from the date of issuance. The 2017 Warrants and 2016 Warrants contain a fundamental transaction provision that obligates the Company to cash settle the warrants under a limited set of conditions not entirely within the Company's control. Due to this conditional obligation, the Company determined that both the 2017 Warrants and the 2016 Warrants should be classified as liabilities in the Company's consolidated balance sheet. At issuance, the Company determined the fair value of the 2017 Warrants and 2016 Warrants to be $12.4 million and $18.6 million, respectively, and reclassified these balances from stockholders' equity to warrant liability. The fair value of these warrants is re-measured at each reporting period and changes in fair value are recognized in the consolidated statement of operations (see Note 4, "Fair Value

Measurements"). Additionally, the Company allocated approximately $0.9 million and $1.6 million of issuance costs to the 2017 Warrants and 2016 Warrants, respectively, based on the proportion of the proceeds allocated to the fair value of the warrants. The allocated issuance costs were expensed as other expense in the Company's consolidated statement of operations.

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 (the "PIPE Warrants"). None of the PIPE Warrants were exercised prior to expiration on June 12, 2018 and therefore have been terminated and are no longer exercisable. 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 were classified to stockholders' equity in the Company's balance sheet.

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").

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. Each purchaser of the Convertible Notes also received a warrant which included an exercise price "cap" that was analogous to "down round protection" (the "Note Warrants"). 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. There were 2,645,176 Note Warrants that expired during 2018 and therefore have been terminated and are no longer exercisable. There are 670,702 shares of common stock underlying the remaining outstanding Note Warrants as of December 31, 2018. The Note Warrants expire five years from the date of issuance.

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, 2018, 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, 2018 and 2017:

	December 31,	
	2018	2017
Options to purchase common stock	7,187,885	6,200,151
Warrants to purchase common stock	31,243,026	36,270,103
	38,420,811	42,470,254

10. Stock Warrants

As of December 31, 2018 and 2017, the Company had warrants outstanding as shown in the table below.

	December 31,	
	2018	2017
Note Warrants	670,702	3,315,878
PIPE Warrants (1)	—	2,364,066
2017 Warrants	15,996,450	16,000,000
2016 Warrants	14,000,000	14,000,000
Representative's Warrant	206,410	206,410
Placement Agent Warrants	189,126	189,126
Other warrants (2)	180,338	194,623
Warrants to purchase common stock	31,243,026	36,270,103
Weighted-average exercise price per share	$ 2.31	$ 2.74

(1) On June 12, 2018, the PIPE Warrants to purchase common stock expired in accordance with their terms. None of the PIPE Warrants were exercised prior to expiration and have been terminated and are no longer exercisable.
(2) Other warrants are comprised of warrants issued prior to the Company's IPO, generally in exchange for services rendered to the Company.

The following table summarizes information regarding the Company's warrants outstanding and the corresponding exercise price at December 31, 2018:

Exercise Prices	Shares Underlying Outstanding Warrants	Expiration Date
£ $2.00	16,002,164	September 1, 2021 – July 25, 2022
$2.01 - $4.99	14,960,929	March 30, 2019 – July 27, 2021
³ $5.00	279,933	July 22, 2019 – January 5, 2022
	31,243,026	

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") under which the number of shares of common stock available for issuance was 1,571,428. For new awards, the period that vested awards would remain exercisable upon termination of service was reduced from ten years to two years. 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 were 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 ending on January 1, 2024, 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 6,520,477 shares of common stock have been reserved under the 2014 Plan as of December 31, 2018.

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. Stock option activity for the year ended December 31, 2018, is summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2017	6,200,151	$ 3.81		
Granted	2,320,000	1.47		
Exercised	—	—		
Expired	(865,606)	3.93		
Forfeited	(466,660)	1.77		
Options outstanding at December 31, 2018	7,187,885	$ 3.17	6.61	$ 290,781
Vested and exercisable at December 31, 2018	4,974,057	$ 3.78	5.73	$ 170,919

Of the option grants outstanding to purchase 7,187,885 shares of common stock, grants to purchase 657,156 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, 2018, 2017 and 2016 was $1.47, $1.62 and $3.25, respectively. Total compensation expense recognized amounted to $1,555,523, $1,623,128 and $2,231,883 for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, the total remaining unrecognized compensation cost related to unvested stock options was $2,308,848 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 Ended December 31,		
	2018	2017	2016
Risk free interest rate	2.58%	2.07%	1.22%
Expected dividend yield	—	—	—
Expected term (in years)	6.02	6.01	5.01
Expected volatility	82.3%	79.6%	79.5%

Expected volatility—The Company estimated the expected volatility based on an average of the historical volatility of a representative peer group of publicly traded biopharmaceutical companies selected based on their stage of drug development, area of therapeutic focus, number of employees and market capitalization.

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. 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. During 2015, the Company established an employer matching program for participants in the 401(k) Plan. The Company incurred approximately $104,000, $100,000 and $124,000 of expense for matching contributions to the 401(k) Plan during the years ended December 31, 2018, 2017 and 2016, respectively.

13. Income Taxes

The Company has available approximately $175,406,000 and $189,031,000 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 2038 if not utilized prior to that date. The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets. Based on the Company's history of operating losses since inception, the Company has concluded that it is

more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, 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 $9,006,000 and decreased by approximately $7,797,000 during the years 2018 and 2017, respectively, and was approximately $54,153,000 and $45,146,000 at December 31, 2018 and 2017, 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, 2018, 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.

On December 22, 2017, the Tax Cuts and Jobs Act" (the "2017 Tax Act") was enacted. The 2017 Tax Act lowered the U.S. federal corporate income tax rate from 35% to 21% effective January 1, 2018. As a result, the change in the U.S. federal tax rate required the Company to re-measure its federal deferred tax assets and liabilities. Effective for tax years beginning on January 1, 2018, the 2017 Tax Act repealed the performance exception permitting certain executive officer compensation greater than $1 million to be deducted. During the fourth quarter of 2017, the Company reduced its net deferred tax asset balance and offsetting valuation allowance by $18,284,538 for the re-measurement of its U.S. deferred tax balances. There were no changes to the interim re-measurement amount and the Company's accounting for the 2017 Tax Act is complete.

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

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryovers	$ 49,294,211	$ 40,879,826
Share-based compensation	1,754,362	1,702,036
R&D tax credits	2,545,920	1,750,785
Accrued compensation and severance	442,090	659,458
Deferred rent	198,278	200,968
Intangible assets	131,503	154,669
Total deferred tax assets	$ 54,366,364	$ 45,347,742
Valuation allowance	(54,152,886)	(45,146,454)
Total deferred tax assets net of valuation allowance	$ 213,478	$ 201,288
Deferred tax liabilities:		
Depreciation	(213,478)	(201,288)
Total deferred tax liabilities	$ (213,478)	$ (201,288)
Net deferred tax asset (liability)	$ —	$ —

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

	Year Ended December 31,		
	2018	2017	2016
Federal income tax benefit at statutory rate	(21.00)%	(34.00)%	(34.00)%
State income tax, net of federal benefit	(5.64)	(9.95)	(5.49)
Permanent items including change in fair value of warrants	4.80	(22.03)	(1.54)
Change in valuation allowance	23.95	(50.33)	42.12
R&D tax credits	(2.11)	(3.02)	(1.03)
Deferred re-measurement	—	118.03	—
Other	—	(1.30)	(0.06)
Effective income tax (benefit) expense rate	0%	0%	0%

14. Selected Quarterly Financial Data (Unaudited)

The following tables show a summary of the Company's unaudited quarterly financial data for each of the four quarters of 2018 and 2017:

	2018			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Loss from operations	$ (6,984,169)	$ (7,496,454)	$(7,799,290)	$(8,844,512)
Net (loss) income	$(19,106,481)	$(20,135,892)	$(4,377,747)	$ 5,935,696
Net (loss) income per share of common stock, basic and diluted	$ (0.26)	$ (0.27)	$ (0.06)	$ 0.07

	2017			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Loss from operations	$(6,345,013)	$(6,079,121)	$(6,735,188)	$(7,404,435)
Net loss	$(6,348,164)	$(2,836,887)	$(1,575,098)	$(4,757,509)
Net loss per share of common stock, basic and diluted	$ (0.15)	$ (0.07)	$ (0.02)	$ (0.06)

Table of Contents

SIGNATURES

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

CONTRAFECT CORPORATION

By: /s/ Steven C. Gilman, Ph.D.
Steven C. Gilman, Ph.D.
President and 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	Title	Date
/s/ Steven C. Gilman, Ph.D. Steven C. Gilman, Ph.D.	President and Chief Executive Officer, Chairman of the Board *(Principal Executive Officer)*	March 14, 2019
/s/ Michael Messinger Michael Messinger	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 14, 2019
/s/ Sol J. Barer, Ph.D. Sol J. Barer, Ph.D.	Lead Independent Director	March 14, 2019
/s/ Isaac Blech Isaac Blech	Director	March 14, 2019
/s/ David N. Low, Jr. David N. Low, Jr.	Director	March 14, 2019
/s/ Michael J. Otto, Ph.D. Michael J. Otto, Ph.D.	Director	March 14, 2019
/s/ Roger J. Pomerantz, M.D., F.A.C.P. Roger J. Pomerantz, M.D., F.A.C.P.	Vice Chairman of the Board	March 14, 2019
/s/ Cary W. Sucoff Cary W. Sucoff	Director	March 14, 2019

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8, No. 333-199046) pertaining to the Amended and Restated 2008 Equity Incentive Plan and 2014 Omnibus Incentive Plan of ContraFect Corporation,

(2) Registration Statement (Form S-8, Nos. 333-217943 and 333-224834) pertaining to the 2014 Omnibus Incentive Plan of ContraFect Corporation, and

(3) Registration Statements (Form S-3, Nos. 333-211748, 333-217989 and 333-228626) of ContraFect Corporation;

of our report dated March 14, 2019, with respect to the consolidated financial statements of ContraFect Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Hartford, Connecticut
March 14, 2019

Exhibit 31.1

CERTIFICATION

I, Steven C. Gilman, 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 14, 2019

/s/ Steven C. Gilman, Ph.D.
Steven C. Gilman, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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 14, 2019

/s/ Michael Messinger
Michael Messinger
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with this Annual Report on Form 10-K of ContraFect Corporation (the "Company") for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven C. Gilman, Ph.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge on the date hereof:

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

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

Date: March 14, 2019

/s/ Steven C. Gilman, Ph.D.
Steven C. Gilman, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with this Annual Report on Form 10-K of ContraFect Corporation (the "Company") for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Michael Messinger, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge on the date hereof:

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

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

Date: March 14, 2019

/s/ Michael Messinger
Michael Messinger
Chief Financial Officer
(Principal Financial Officer)