

**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, 2019

OR

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

Commission File Number: 001-36577

ContraFect Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

39-2072586
(IRS Employer
Identification No.)

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

10701
(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	Trading Symbol(s)	Name of Exchange on Which Registered
Common Stock, Par Value \$0.0001 per share	CFRX	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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 28, 2019, 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 \$40.0 million, based on the closing price of the registrant's common stock on the Nasdaq Capital Market on June 28, 2019 of \$0.51 per share.

As of March 9, 2020, there were 15,332,042 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 2020 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.

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References to ContraFect

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

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

Forward Looking Information

The information in this Annual Report on Form 10-K contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the “safe harbor” created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words “anticipates,” “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 the discovery and development of direct lytic agents (“DLAs”), including lysins and amurin peptides, as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections. Antibiotic-resistant infections account for 2,000,000 illnesses in the United States and 700,000 deaths worldwide each year. We intend to address antibiotic-resistant infections using product candidates from our lysin and amurin peptide platforms. We believe DLAs are fundamentally different than antibiotics and offer a potential paradigm shift in the treatment of antibiotic-resistant infections.

Lysins are recombinantly-produced enzymes, that when applied to bacteria cleave a key component of the target bacteria’s peptidoglycan cell wall, resulting in rapid bacterial cell death. In addition to the speed of action and potent cidal activity, 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. Lysins also tend to have a “targeted spectrum,” meaning they kill only specific species of bacteria or closely related bacteria. Amurin peptides are a new class of DLAs, discovered in our laboratories, which disrupt the outer membrane of gram-negative bacteria, resulting in rapid bacterial cell death, offering a distinct mechanism of action from lysins. Amurins are further differentiated from lysins by potent “broad spectrum” *in vitro* activity against a wide range of gram-negative pathogens in, including deadly, drug-resistant *Pseudomonas aeruginosa* (“*P. aeruginosa*”), *Klebsiella pneumoniae*, *Escherichia coli*, *Acinetobacter baumannii* and *Enterobacter cloacae* bacteria species as well as difficult to treat pathogens such as *Stenotrophomonas*, *Achromobacter* and *Burkholderia* species. The highly differentiated properties of DLAs have shown these agents to be complementary to and synergistic with conventional antibiotics enabling their potential use in addition to antibiotics with the goal of improving clinical outcomes compared to antibiotics alone. The development of DLAs involves a novel clinical and regulatory strategy, using superiority design clinical trials with the goal of delivering significantly improved clinical outcomes for patients with serious, antibiotic-resistant bacterial infections, including biofilm-associated infections. We believe this approach affords potential clinical benefits to patients as well as the potential ability to mitigate against further development of antibiotic resistance.

Our most advanced clinical candidate, exebacase, is an investigational novel lysin that targets *Staphylococcus aureus* (“*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 completed a Phase 2 superiority study that evaluated its safety, tolerability, efficacy and pharmacokinetics (“PK”) when used in addition to background standard of care (“SOC”) antibiotics compared to SOC antibiotics alone for the treatment of *Staph aureus* bacteremia, including endocarditis in adult patients. In January 2019, we announced topline results from this study 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 Phase 2 study, 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 at Day 14 was 70.4% for patients treated with exebacase and 60.0% for patients dosed with SOC antibiotics alone (p=0.314). The clinical responder rate at Day 14 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 at Day 14 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). In a pre-specified analysis of MRSA-infected patients, the clinical responder rate at Day 14 in patients treated with exebacase was nearly 43-percentage points higher than 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)). In addition to the higher rate of clinical response, MRSA-infected patients treated with exebacase showed a 21-percentage point reduction in 30-day all-cause mortality (p=0.056), a four day lower mean length of hospital stay and meaningful

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reductions in hospital readmission rates. 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 have established proof of concept for exebacase and for DLAs as therapeutic agents. In particular, the data for MRSA-infected patients treated with exebacase, which, in this study, demonstrated superior outcomes in clinical response at Day 14 and in 30-day all-cause mortality as well as health economics benefits, provided the basis for our proposed Phase 3 study design and our application for Breakthrough Therapy designation to the U.S. Food and Drug Administration (“FDA”).

In September 2019, we held an End-of-Phase 2 meeting with the FDA regarding the results from the Phase 2 study and the potential for advancing exebacase into Phase 3 clinical development based on the data discussed above. Our proposed Phase 3 study design excluded patients outside the U.S. or with left-sided endocarditis due to the differences in standard-of-care for these patients. We obtained concurrence with the FDA on our proposed Phase 3 protocol, including the key design features of the study population, the endpoints and the size of the safety database that would be needed to support a Biologics License Application (“BLA”) for approval of exebacase, under the FDA’s “streamlined development” paradigm for agents to treat bacterial infections associated with high unmet medical need. Based on the outcome of the meeting, we proceeded to initiate the single Phase 3 DISRUPT (Direct Lysis of Staph aureus Resistant Pathogen Trial) study of exebacase in December 2019. The DISRUPT study is a randomized, double-blind, placebo-controlled Phase 3 clinical trial conducted in the U.S. alone to assess the efficacy and safety of exebacase in approximately 350 patients with complicated Staph aureus bacteremia, including right-sided endocarditis. Patients entering the study will be randomized 2:1 to either exebacase or placebo, with all patients receiving SOC antibiotics. The primary efficacy endpoint of the study is clinical response at Day 14 in patients with MRSA bacteremia, including right-sided endocarditis. Secondary endpoints will include clinical response at Day 14 in the All Staph aureus patient group (MRSA and methicillin-sensitive Staph aureus (“MSSA”)), 30-day all-cause mortality in MRSA patients, and clinical response at later timepoints. We will also evaluate the impact of treatment with exebacase on health resource utilization, including hospital length of stay, ICU length of stay and 30-day readmission rates. We plan to conduct an interim futility analysis following the enrollment of approximately 60% of the study population.

The FDA recently granted Breakthrough Therapy designation to exebacase for the treatment of MRSA bloodstream infections (bacteremia), including right-sided endocarditis, when used in addition to SOC anti-staphylococcal antibiotics in adult patients, based on the final data from the Phase 2 superiority trial of exebacase. Breakthrough Therapy designation is a program designed by the FDA to expedite the development and review of medicines for serious or life-threatening diseases where preliminary clinical evidence suggests that the investigational therapy may demonstrate substantial improvement on at least one clinically significant endpoint over available therapies. The Breakthrough Therapy designation provides additional benefits, such as intensified interactions with the FDA and the potential for priority review, over the Fast Track designation granted to exebacase in August 2015.

We performed a post-hoc Phase 3 simulation analysis using the Phase 2 data to evaluate the clinical outcomes for the Phase 2 patient population that would meet the Phase 3 inclusion criteria. In this simulated Phase 3 analysis population of 84 U.S. patients with documented *Staph aureus* bacteremia, including right-sided endocarditis, who received a single IV infusion of blinded study drug, the clinical responder rate at Day 14 was 83.7% for patients treated with exebacase and 54.3% for patients dosed with SOC antibiotics alone, an improvement in the responder rate of over 29-percentage points. The clinical responder rate at Day 14 in the subset of patients with MRSA bacteremia including right-sided endocarditis was 82.6% for patients treated with exebacase compared to 33.3% for patients treated with SOC antibiotics alone, an improvement in the responder rate of over 49-percentage points. In the subset of patients with MSSA bacteremia including right-sided, the clinical responder rate at Day 14 was 84.6% for patients treated with exebacase compared to 66.7% for patients treated with SOC antibiotics alone, an increase of nearly 18-percentage points.

Our Portfolio

We intend to develop and commercialize novel therapeutic agents to treat life-threatening infections, including those caused by antibiotic-resistant pathogens. The increasing prevalence of antibiotic resistance among bacterial pathogens has been widely recognized as an urgent public health threat by the U.S. Center for Disease Control (“CDC”), the World Health Organization (“WHO”) and the Infectious Disease Society of America (“IDSA”). 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. 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. As Dr. Tedros Adhanom Ghebreyesus, Director-General of WHO, has accordingly stated “never has the threat of antimicrobial resistance been more immediate and the need for solutions more urgent. Numerous initiatives are underway to reduce resistance, but we also need countries and the pharmaceutical industry to step up and contribute with sustainable funding and innovative new medicines.”

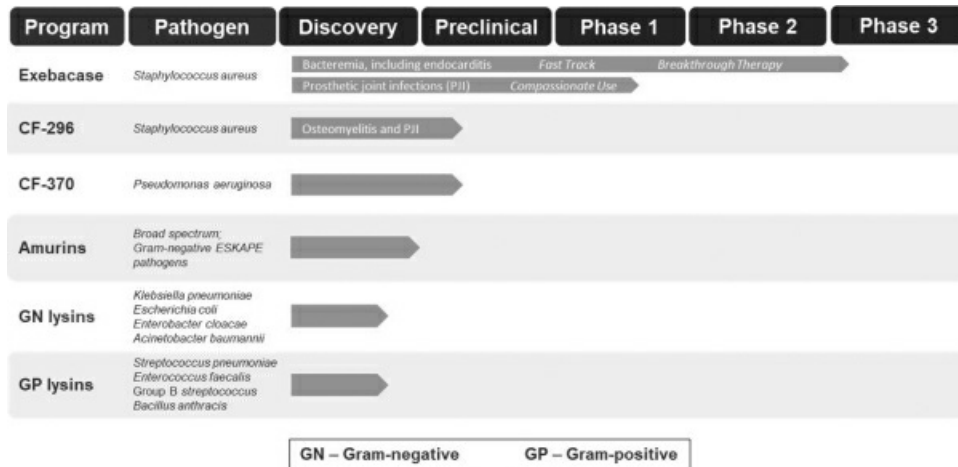
We take this mandate very seriously and have focused our research and discovery efforts on those pathogens that are considered to be urgent or serious threats to global health by the CDC or considered critical priority by the WHO. In particular, species of bacteria that are part of the ESKAPE pathogens (*Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacter species*) are urgent or serious threats, and are also the leading causes of hospital acquired infections throughout the world. We believe that DLAs will be highly complementary to conventional antibiotics in addressing these infections. We aim to improve outcomes in patient with these life-threatening bacterial infections through use of our DLA candidates developed from our novel lysin and amurin platforms.

We continue to advance novel lytic agents across our portfolio. We initiated the single Phase 3 DISRUPT study of exebacase in December 2019. We also expanded the investigator-initiated early access program for compassionate use of exebacase for individual named patients with chronic post-operative prosthetic joint infections (“PJIs”) under Temporary Authorizations for Use from the French National Agency for Medicines and Health Products Safety in collaboration with Dr. Tristan Ferry at the Hôpital de la Croix Rousse in Lyon, France. We have developed a novel, engineered variant of exebacase, known as CF-296, which we believe provides an additional opportunity to advance a potential targeted therapy for deep-seated, invasive biofilm-associated *Staph aureus* infections. We are conducting further *in vitro* and *in vivo* characterization of CF-296 to evaluate the full profile of this compound. We have been awarded up to \$7.2 million of funding from the Military Infectious Diseases Research Program, United States Army Medical Research and Development Command (“USAMRDC”) over the course of three years to advance CF-296 through Investigational New Drug application (“IND”)-enabling studies.

We have discovered and engineered a new lysin product candidate, CF-370, which in preclinical studies has demonstrated potent activity against antibiotic-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 have initiated IND-enabling activities and we expect CF-370 to be our next molecule in clinical studies. We have been awarded up to \$3.3 million in funding from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) in support of the advancement of anti-pseudomonal lysins. Beyond our lysin programs, we continue our research to advance potential product candidates from our amurin peptide platform. We will be initiating animal studies of our most promising amurins with the goal of moving this program into clinical studies as soon as possible. We have been awarded up to \$6.9 million of funding from CARB-X to support the amurin peptide program. In summary, we now have three modalities within the DLA therapeutic umbrella, including (i) native lysins for gram-positive pathogens (ii) engineered lysins for gram-negative pathogens and (iii) amurins for a wide spectrum of gram-negative pathogens.

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Our current portfolio of programs is reflected below:



Our Strategy

Our strategy is to use our novel, highly differentiated therapeutic DLAs, if approved, to achieve a leading market position in the treatment of life-threatening infectious diseases, including those caused by antibiotic-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 right-sided 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;
- Pursue additional grant opportunities from both CARB-X and the Biomedical Advanced Research and Development Authority (“BARDA”). In light of recent events with regards to the COVID-19 pandemic, we have also discussed with BARDA the potential for compassionate use of exebacase for secondary bacterial infections.
- Acquire additional 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 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

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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 right-sided endocarditis, daptomycin, was approved over 13 years ago based on non-inferiority to vancomycin (approved in 1958) with 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 both Breakthrough Therapy and Fast Track designations by the FDA for the treatment of MRSA bloodstream infections (bacteremia), including right-sided endocarditis, when used in addition to SOC anti-staphylococcal antibiotics in adult patients. 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 3 Clinical Study

We are conducting a multi-center Phase 3 clinical study of exebacase for the treatment of *Staph aureus* bacteremia, including right-sided 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 is targeting enrollment of approximately 350 patients randomized 2:1 to receive either a single dose of exebacase administered as a 2-hour IV infusion in addition to SOC antibiotics or placebo plus SOC antibiotics. The primary efficacy endpoint is clinical response at Day 14 in patients with MRSA bacteremia, including right-sided endocarditis. Secondary endpoints include clinical response at Day 14 in the All *Staph aureus* patient group (MRSA and MSSA), 30-day all-cause mortality in MRSA patients, and clinical response at Day 30 and Day 60 in both the MRSA and the All *Staph aureus* patient group. A summary of the statistical parameters of the key efficacy endpoints is shown in Table 1 below.

Table 1

	Primary Efficacy Endpoint: Clinical Response at Day 14 (MRSA Patients)	Secondary Efficacy Endpoint: Clinical Response at Day 14 (All <i>Staph aureus</i> Patients)	Secondary Efficacy Endpoint: Mortality (MRSA Patients)
Target difference	28% increase over SOC antibiotics alone	16% increase over SOC antibiotics alone	17% decrease from SOC antibiotics alone
Power	86%	83%	80%
Sample size	135 patients	339 patients	135 patients

Clinical response is defined by objective clinical response criteria including (1) resolution of signs and symptoms attributable to *Staph aureus* bacteremia/right-sided endocarditis (“SAB/RIE”) that were present at

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baseline, (2) no new signs and symptoms attributable to SAB/RIE, (3) no complications of SAB/RIE (e.g. no development of a new foci of *Staph aureus* infection after Day 7 and no septic emboli), (4) no changes in anti-staphylococcal antibiotics after treatment with study drug due to persistence, worsening or recurrence of signs or symptoms of SAB/RIE, (5) Blood culture(s) negative for *Staph aureus* by Day 14 and (6) the patient is alive. Clinical response will be determined by an independent, blinded clinical adjudication committee.

We will evaluate the impact of treatment with exebacase on health resource utilization, including length of hospital stay, length of stay in the intensive care unit and 30-day readmission rates for both all-cause and *Staph aureus* infection readmissions. We plan to conduct an interim futility analysis following the enrollment of approximately 60% of the study population.

Based on feedback from our End-of-Phase 2 meeting with the FDA, including the advancement of exebacase under the streamlined development pathway, we believe that this 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, if the results are positive, 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. If the Phase 3 study demonstrates superiority of exebacase, used in addition to SOC antibiotics as compared to antibiotics alone, we would seek inclusion of a superiority claim in the product labeling, which we believe would be highly differentiated from conventional antibiotics and would lead to rapid uptake by providers and favorable reimbursements from payors.

Phase 2 Clinical Study

We completed a 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 compared 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 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.

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 nearly 43-percentage points 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 ($p=0.010$)). In addition to the higher rate of clinical response, MRSA-infected patients treated with exebacase showed a 21-percentage point reduction in 30-day all-cause mortality ($p=0.056$), a four day lower mean length of hospital stay and meaningful reductions in hospital readmission rates.

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% ($p=0.035$).

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Based on these efficacy data, summarized in Table 2 below, treatment with exebacase in addition to SOC antibiotics resulted in clinically meaningful improvements in outcomes compared to antibiotic therapy alone.

Table 2

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
Bacteremia + right-sided endocarditis	80.0%	59.5%	0.028
Bacteremia only	81.8%	61.5%	0.035
Mortality			
30-day all-cause mortality in MRSA patients	3.7%	25.0%	0.056

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 SAEs through day 180 was also similar between the treatment groups (62.5% for the exebacase group and 59.5% for the SOC antibiotics alone group). Among all patients who received study drug, 23.6% of exebacase patients and 19.1% of placebo patients died through day 180. There were no SAEs, including deaths, that we determined to be related to exebacase. Exebacase was well-tolerated and there were no reports of hypersensitivity related to exebacase and no patients prematurely discontinued study drug in either treatment group.

Based on these safety and tolerability data, summarized in Table 3 below, we concluded that exebacase was well-tolerated in this study.

Table 3

	exebacase*	antibiotics alone
	N=72	N=47
	n (%)	n (%)
TEAE	64 (88.9)	40 (85.1)
TEAE through day 7	48 (66.7)	31 (66.0)
TEAE leading to study drug withdrawal	0	0
SAEs through day 180	45 (62.5)	28 (59.5)
SAEs determined to be related to exebacase	0	0
Total deaths through day 180	17 (23.6)	9 (19.1)

* used in addition to antibiotics

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The Phase 2 Clinical Study Report, as well as PK/PD modeling and any additional *in vitro* or *in vivo* studies were submitted and an End-of-Phase 2 Meeting with FDA was conducted prior to advancing into Phase 3.

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 adverse events (“AEs”) related to exebacase were reported, and no study stopping rules were met. A total of five non-serious AEs were reported 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 its 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 right-sided 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

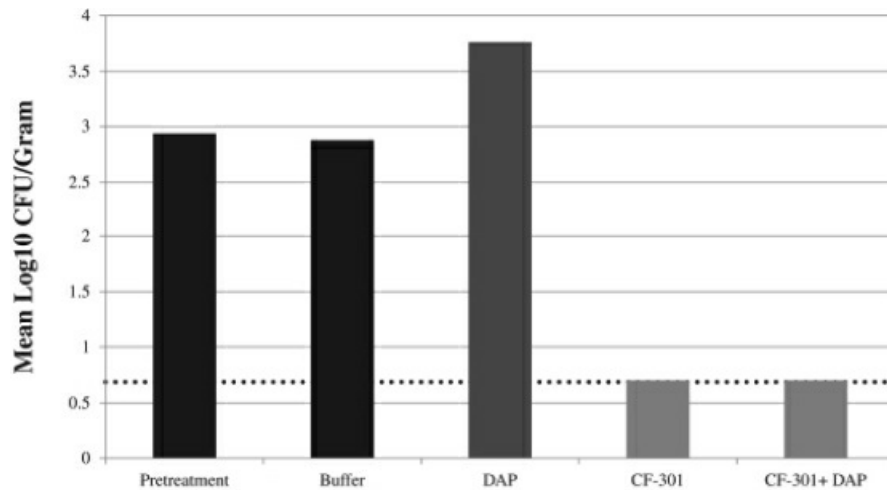
Biofilm formation is a common characteristic of certain pathogenic bacteria such as *Staph aureus* and *P. aeruginosa* and represents a major therapeutic challenge. Biofilms are characterized by densely packed bacterial cells that grow in communities and are enclosed within a complex matrix of dead bacteria 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 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

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(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 having 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 ≥ 2 .

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.

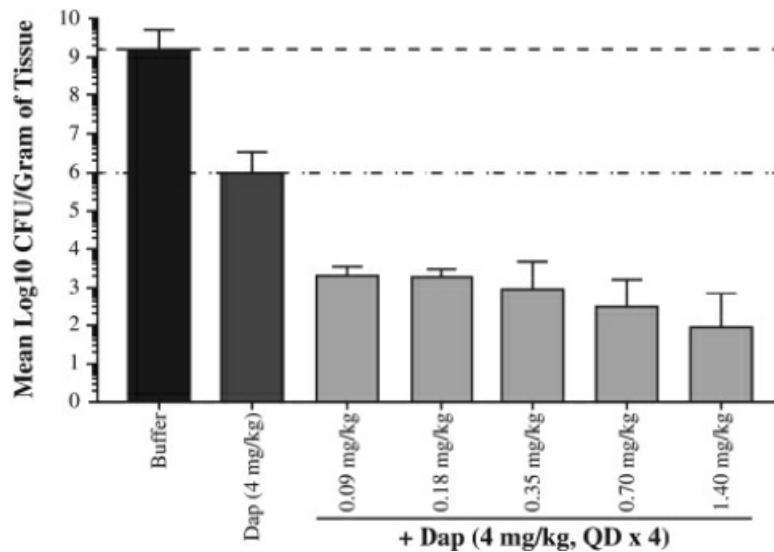
To further explore the activity of exebacase in combination with SOC antibiotics for the treatment of life-threatening, drug-resistant infections, we engaged the LA Biomed Research Institute at Harbor-UCLA Medical

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 clinical trials.

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 fermentation size 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 IND application 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 have studied 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.

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

We have engineered a lysin variant of exebacase which we believe may be 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.

CF-370: A Novel Engineered Lysin for *P. aeruginosa* Infections

Medical Opportunity

P. aeruginosa is a gram-negative pathogen that 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. More than 32,000 *P. aeruginosa* infections are multidrug-resistant, with roughly 2,700 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.

CF-370 Development

CF-370 is an investigational first-in-class anti-bacterial therapeutic candidate targeting a gram-negative pathogen. CF-370 has been engineered to bypass the outer membrane of the bacteria and to enable potent activity in human serum. We believe this is a significant milestone for direct lytic agents as native lysins are typically unable to penetrate the outer membrane of gram-negative bacteria and consequently unable to work *in vitro* in human blood or in animal models. However, based on the proprietary methods we have identified and utilize to engineer lysins, CF-370 has exhibited the hallmark *in vitro* features of the lysin class, including rapid and potent bactericidal activity, synergy with a broad range of standard of care agents and the eradication of biofilms in preclinical studies. In preclinical rabbit pneumonia models, single doses of CF-370 alone and in combination with meropenem, were tested against multi-drug resistant *P. aeruginosa* to evaluate survival and bacterial burden in lung and secondary organs. In these models, strong activity was observed for CF-370 as a monotherapy, showing that rabbits dosed with CF-370 alone had longer survival, as compared to vehicle control, and reductions in bacterial burden in the lung, kidney and spleen with single doses of CF-370. Synergy with meropenem was also noted with greater reductions in bacterial burden compared to monotherapy. In these models, CF-370 was well tolerated with no adverse clinical consequences and no deaths among animals infected with *P. aeruginosa*.

We have advanced CF-370 into IND-enabling activities and we expect it to be our next molecule in clinical studies. We have been awarded up to \$3.3 million in funding from CARB-X in support of the advancement of anti-pseudomonal lysins.

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 cidal activity, 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.

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

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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.

We have discovered and engineered a novel lysin, CF-370, an investigational first-in-class anti-bacterial therapeutic candidate targeting a gram-negative pathogen, *P. aeruginosa*. CF-370 has been engineered to bypass the outer membrane of the bacteria and to enable potent activity in human serum. We will continue to pursue new lysins that target other gram-negative pathogens, such as the *Enterobacteriaceae* family of bacteria.

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. pneumoniae* 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.

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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.

Gram-positive lysins

In addition to our proprietary lysin discovery program, we hold worldwide exclusive license rights to patents for composition of matter for nine lysins from The Rockefeller University (“Rockefeller”). The lysins each target a specific species of gram-positive bacteria, including drug-sensitive and drug-resistant forms as exemplified in Table 4 below.

Table 4: Lysins Licensed From The Rockefeller University

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

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 bacteriocidal activity, 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 *Burkholderia* 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, as shown in Table 5 below, 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.

Table 5: In Vitro Activity (minimal inhibitory concentrations) of Amurin Candidates (AM1, AM2 and AM3) Observed Against Carbapenem-Resistant Pathogens*

<u>Pathogen</u>	<u>AM1</u>	<u>AM2</u>	<u>AM3</u>	<u>Colistin</u>	<u>Meropenem</u>
<i>Escherichia coli</i>	0.5	0.25	0.625	0.5	>8
<i>Enterobacter cloacae</i>	0.25	0.125	0.0625	1	>8
<i>Klebsiella pneumoniae</i>	0.5	0.5	0.0625	>8	8
<i>Acinetobacter baumannii</i>	1	1	0.25	>8	>8

* strains listed are representative of >100 strains tested

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Similar to the pilot study performed with exebacase, we evaluated the ability of one of our lead amurins, AM2, to eradicate *Stenotrophomonas maltophilia* biofilms from the inside of hemodialysis catheters removed from infected patients. The endpoint of the model was a reduction in the amount of bacteria (measured in CFUs) in sections of the catheters treated with amurin AM2 compared to a control group (sections with no treatment) and sections treated with clinically relevant concentrations of meropenem. Treatment with amurin AM2 resulted in the reduction in the amount of bacteria below the limit of detection, $0.7 \log_{10}$ CFU/g, while both the control groups and sections treated with meropenem had CFU counts $>3.0 \log_{10}$ CFU/g. We believe these results provide important *ex vivo* translation of the *in vivo* activity to biofilms formed in the setting of human disease.

We plan to progress our amurin peptide program as rapidly as possible through preclinical profiling and into clinical studies. We are currently evaluating the *in vitro* profiles of the amurins as we continue to advance the program. We have been awarded up to \$9.6 million of funding from CARB-X 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 ESCAPE pathogens.

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 valid 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 does not always 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 certain inventions, in accordance with our business strategies, 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 twenty (20) U.S. patents, one-hundred and fourteen (114) foreign patents and two hundred and eighteen (218) U.S. and international patent applications that we have licensed from Rockefeller and/or developed in-house. Certain patents related to our lysin portfolio will expire between 2024 and 2033. Our patents and patent applications include those that are directed to compositions and methods for the treatment of infections caused by gram-positive bacteria (Group B *Streptococci*, *Staph aureus*, *Streptococcus pneumoniae*, *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 certain patent applications related to exebacase, CF-296 and the gram-negative lysins, they would expire between 2029 and 2040.

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

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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 fall within the scope of claims in the patent application or otherwise infringe a claim of the 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 have granted patents 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 or fall within the scope of 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.

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. Most of these agents are small molecules being studied in non-inferiority trials. We believe that exebacase has demonstrated synergy *in vitro* with a broad range of conventional anti-staphylococcal agents of different classes and, in the event any of these non-inferior small molecules are approved, we believe that exebacase will also be synergistic and non-competitive with them.

Based on recent data published by the WHO, there are only five biologic agents, other than ours, in clinical development for *Staph aureus* infections from iNtRon Biotechnology, Inc., (“iNtRon”), Aridis Pharmaceuticals, Inc. (“Aridis”), MedImmune (a subsidiary of AstraZeneca plc), XBiotech, Inc (“XBiotech”) and Genentech, Inc. (“Genentech”). Aridis is studying AR-301, a monoclonal antibody, in *Staph aureus* pneumonia, not bacteremia. MedImmune has been studying MEDI-4893, a monoclonal antibody, for the prevention of *Staph aureus* pneumonia in a Phase 2 study since 2014. XBiotech is planning to study 514G3, a monoclonal antibody, for the prevention of *Staph aureus* infection in hemodialysis patients. Genentech has been studying DSTA-4637S, an antibody-drug conjugate, in a Phase 1 study since 2017. Depending on the outcomes of these and future trials, exebacase may compete with these products. We believe iNtRon, a biotechnology company located in South Korea, is currently conducting a human clinical trial in South Korea alone for SAL-200, an endolysin-based drug candidate, to evaluate it as a treatment for *Staph aureus* bacteremia. Additionally, in November 2018, iNtRon 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. We are not aware of SAL-200 or any other anti-staphylococcal lysins having been applied for under an IND for clinical development in the United States.

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

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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 Diosynth Biotechnologies UK LTD (“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 vialled 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 vialled 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 “E.U.”) 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.

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

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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 PHS Act, 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 institutional review board (“IRB”) for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

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

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labeling of the product. In most cases, the FDA 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 2020, the application user fee is \$2,942,965. The manufacturer and/or sponsor under an approved NDA or BLA are also subject to annual program user fees, currently set at \$325,424 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

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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.

FDA Expedited Review Programs

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 ("QIDP"), under the Generating Antibiotic Incentives Now ("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

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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.

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. In February 2020, the FDA granted breakthrough therapy designation to exebacase for the treatment of MRSA bacteremia, including right-sided endocarditis, when used in addition to SOC anti-staphylococcal antibiotics in adult patients.

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.

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

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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.

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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 (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

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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 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 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 E.U. 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.

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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.

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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”. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court’s decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, or other efforts to challenge, repeal or replace the Affordable Care Act will impact the law, or our business or financial condition.

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 2029 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 9, 2020, we had 24 full-time employees, including 13 employees with advanced degrees. Of these full-time employees, 13 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.contrafact.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.

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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.contrafact.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 Ethics and Business Conduct, Whistleblower Policy and Procedures and the charters of the Audit & Finance Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.contrafact.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. 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 \$12.8 million, \$37.7 million and \$15.5 million for the years ended December 31, 2019, 2018 and 2017, 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

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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 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 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, 2019, we had federal and state net operating loss carryforwards of approximately \$201.3 million and \$217.8 million, respectively, and federal research and development credits of approximately \$3.1 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.

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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 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;

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- 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;

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- 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 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 and clinical 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 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

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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.

Any Breakthrough Therapy Designation that we may receive from the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We have received Breakthrough Therapy Designation for exebacase, and we may seek Breakthrough Therapy Designation for our other product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed in early clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs

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designated as Breakthrough Therapies by the FDA are also eligible for rolling review of the associated marketing application, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as priority review, where the agency aims to act on the application within eight months.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. The receipt of a Breakthrough Therapy Designation for a product candidate, including for exebacase, may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, not all products designated as Breakthrough Therapies ultimately will be shown to have the substantial improvement over available therapies suggested by the preliminary clinical evidence at the time of designation. As a result, if the Breakthrough Therapy Designation for exebacase we have received or any future designation we receive is no longer supported by subsequent data, the FDA may rescind the designation.

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 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 vialled 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 E.U. 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.

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If Fujifilm UK, or any alternate supplier of an 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.

Public health epidemics or outbreaks could adversely impact the clinical development and commercialization of our lead product candidates.

In December 2019, a novel strain of coronavirus (“COVID-19”) emerged in Wuhan, Hubei Province, China. On March 12, 2020, the WHO declared the outbreak of COVID-19 a pandemic. While initially the outbreak was largely concentrated in China and caused significant disruptions to its economy, it has now spread to several other countries and infections have been reported globally. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information which may emerge concerning the severity of COVID-19 and the actions to contain the virus or treat its impact, among others. In particular, the continued spread of the coronavirus globally could adversely impact our exebacase manufacturing and supply abilities and our ongoing clinical trial.

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;

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- 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 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,

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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”. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court’s decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, or other efforts to challenge, repeal or replace the Affordable Care Act will impact the law, or our business or financial condition.

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 2029 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.

Interim, “topline” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes

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may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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.

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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

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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, epidemics, 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.

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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;

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- 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 E.U. 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 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.

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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.

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom withdrew from the European Union ("Brexit") on January 31, 2020 and entered into a transition period during which it will continue its ongoing and complex negotiations with the European Union relating to the future trading relationship between the parties. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period. If the United Kingdom and the European Union are unable to negotiate acceptable terms or if other Member States pursue withdrawal, barrier-free access between the United Kingdom and other Member States or among the European economic area overall could be diminished or eliminated. 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. Additionally, political instability in the European Union as a result of Brexit may result in a material negative effect on credit markets and foreign direct investments in the European Union and United Kingdom.

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

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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,

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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.

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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 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 9, 2020, we have approximately 15.3 million shares of common stock outstanding, of which approximately 15.2 million shares of our outstanding common stock are freely tradable, or may become freely tradable, without restriction, in the public market unless held by our "affiliates," as defined under Rule 144 of the Securities Act of 1933, as amended (the "Securities Act"). Additionally, we have warrants to purchase approximately 3.0 million shares of our common stock outstanding as of March 9, 2020. Approximately 3.0 million shares of common stock underlying the Warrants will be freely tradable upon exercise unless held by our affiliates.

We have registered 1,305,512 shares of our common stock as of March 9, 2020 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.

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. Because we are no longer an emerging growth company, our independent registered public accounting firm will be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 if we, in the future, are an accelerated filer or a large accelerated filer, as defined in Rule 12b-2 of the Exchange Act. As such, our independent registered public accounting firm may in the future issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating.

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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 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 E.U. 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 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 E.U. 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.

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

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(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.

We are also subject to applicable U.S. state privacy and data security laws and regulations in the states in which we operate, such as the new California Consumer Privacy Act (“CCPA”) effective as of January 2020. The CCPA provides for a private right of action for unauthorized access, theft or disclosure of personal information in certain situations with possible damage awards of \$100 to \$750 per consumer per incident, or actual damages, whichever is greater, and also permits class action lawsuits. In order to comply with such laws, we may incur substantial expenses, which may divert resources from other initiatives, and a failure to comply could impact our clinical trials, financial condition and operations.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

Our corporate headquarters and laboratory is located 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 9, 2020, the last reported sale price for our common stock on the Nasdaq Capital Market was \$7.68 per share. As of March 9, 2020, there were approximately 1,600 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;

On December 9, 2019, we entered into a stock purchase agreement (the “Stock Purchase Agreement”) with Pfizer Inc. (“Pfizer”), pursuant to which we, in a private placement transaction (the “Private Placement”), agreed to issue and sell to Pfizer an aggregate of \$3.0 million of shares (the “Private Shares”) of common stock, par value \$0.0001 per share, at a purchase price equal to the price per share to be offered to the public in a concurrent public offering of common stock. On December 12, 2019, the Company announced the closing of the Private Placement concurrently with the closing of such public offering. In accordance with the Stock Purchase Agreement, at the closing, the Company issued and sold 1,111,111 shares (as adjusted to reflect our 2020 1-for-10 reverse stock split) sold pursuant to a private placement of our common stock to Pfizer Inc. at a price of \$2.70 per share generating net proceeds of \$3.0 million. The Private Placement was exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, and corresponding provisions of state securities or “blue sky” laws, as a transaction by an issuer not involving a public offering.

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, 2019.

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, 2019, 2018 and 2017 and as of December 31, 2019 and 2018 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, 2016 and 2015 and as of December 31, 2017, 2016 and 2015 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.

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Statement of Operations Data	Year Ended December 31,				
	2019	2018	2017	2016	2015
Loss from operations	\$ (27,866,448)	\$ (31,124,425)	\$ (26,563,757)	\$ (33,532,246)	\$ (25,065,336)
Net loss attributable to common stockholders	\$ (12,794,493)	\$ (37,668,424)	\$ (15,517,658)	\$ (28,538,399)	\$ (25,120,964)
Net loss per share of common stock, basic and diluted	\$ (1.54)	\$ (4.95)	\$ (2.79)	\$ (8.51)	\$ (10.77)

Balance Sheet Data	As of December 31,				
	2019	2018	2017	2016	2015
Cash, cash equivalents and marketable securities	\$ 24,184,140	\$ 30,452,253	\$ 46,853,910	\$ 35,161,154	\$ 32,921,653
Total assets	35,008,709	32,872,571	50,189,479	37,624,470	35,861,137
Long-term liabilities	9,405,853	21,533,592	14,575,366	13,693,419	1,416,443
Total stockholders' equity	15,544,906	5,541,960	31,193,445	19,512,854	30,675,510

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 the discovery and development of direct lytic agents (DLAs), including lysins and amurin peptides, as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections. Antibiotic-resistant infections account for 2,000,000 illnesses in the United States and 700,000 deaths worldwide each year. We intend to address antibiotic-resistant infections using product candidates from our lysin and amurin peptide platforms. DLAs are fundamentally different than antibiotics and offer a potential paradigm shift in the treatment of antibiotic-resistant infections.

Lysins are recombinantly-produced enzymes, that when applied to bacteria cleave a key component of the target bacteria's peptidoglycan cell wall, resulting in rapid bacterial cell death. In addition to the speed of action and potent cidal activity, 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. Lysins also tend to have a "targeted spectrum," meaning they kill only specific species of bacteria or closely related bacteria. Amurin peptides are a new class of direct lytic agents, discovered in our laboratories, which disrupt the outer membrane of gram-negative bacteria, resulting in rapid bacterial cell death, offering a distinct mechanism of action from lysins. Amurins are further differentiated from lysins by potent "broad spectrum" *in vitro* activity against a wide range of gram-negative pathogens in, including deadly, drug-resistant *Pseudomonas aeruginosa* ("*P. aeruginosa*"), *Klebsiella pneumoniae*, *Escherichia coli*, *Acinetobacter baumannii* and *Enterobacter cloacae* bacteria species as well as difficult to treat pathogens such as *Stenotrophomonas*, *Achromobacter* and *Burkholderia* species. The highly differentiated properties of DLAs have shown these agents to be complimentary to and synergistic with conventional antibiotics enabling the potential use of these agents in addition to conventional antibiotics with the goal of improving clinical outcomes compared to conventional antibiotics alone. The development of these compounds involves a novel clinical and regulatory strategy, using superiority design clinical trials with the goal of delivering significantly improved clinical

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outcomes for the treatment of serious, antibiotic-resistant bacterial infections, including biofilm-associated infections. This approach affords potential clinical benefits to patients as well as the potential ability to mitigate against further development of antibiotic resistance.

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 securities, and grant funding received. On December 18, 2019, we completed an underwritten public offering of 2,565,000 shares of our common stock at a public offering price of \$3.90 per share. On December 12, 2019, we completed an underwritten public offering of 3,715,000 shares of its common stock at a public offering price was \$2.70 per share and a concurrent private placement of 1,111,111 shares of common stock to Pfizer at a price of \$2.70 per share. The combined net proceeds of both public offerings together with the private placement was \$21.3 million after underwriting discounts and commissions and offering expenses payable by us. The preceding amounts of common stock have been adjusted to reflect the reverse stock split of our common stock at a ratio of 1-for-10 effected on February 3, 2020.

We have never been profitable and our net losses were \$12.8 million, \$37.7 million and \$15.5 million for the years ended December 31, 2019, 2018 and 2017, 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.

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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

Our most advanced clinical candidate, exebacase, is an investigational novel lysin that targets *Staphylococcus aureus* (“*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 completed a Phase 2 superiority study that evaluated its safety, tolerability, efficacy and pharmacokinetics (“PK”) when used in addition to background standard of care (“SOC”) antibiotics compared to SOC antibiotics alone for the treatment of *Staph aureus* bacteremia, including endocarditis in adult patients. In January 2019, we announced topline results from this study 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 Phase 2 study, 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 at Day 14 was 70.4% for patients treated with exebacase and 60.0% for patients dosed with SOC antibiotics alone ($p=0.314$). The clinical responder rate at Day 14 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 at Day 14 was 81.8% for patients treated with exebacase compared to 61.5% for patients treated with SOC antibiotics alone, an increase of 20.3% ($p=0.035$). In a pre-specified analysis of MRSA-infected patients, the clinical responder rate at Day 14 in patients treated with exebacase was nearly 43-percentage points higher than 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 ($p=0.010$)). In addition to the higher rate of clinical response, MRSA-infected patients treated with exebacase showed a 21-percentage point reduction in 30-day all-cause mortality ($p=0.056$), a four day lower mean length of hospital stay and meaningful reductions in hospital readmission rates. 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 have established proof of concept for exebacase and for DLAs as therapeutic agents. In particular, the data for MRSA-infected patients treated with exebacase, which, in this study, demonstrated superior outcomes in clinical response at Day 14 and in 30-day all-cause mortality as well as health economics benefits, provided the basis for our proposed Phase 3 study design and our application for Breakthrough Therapy designation to the U.S. Food and Drug Administration (“FDA”).

In September 2019, we held an End-of-Phase 2 meeting with the FDA regarding the results from the Phase 2 study and the potential for advancing exebacase into Phase 3 clinical development based on the data discussed above. We obtained concurrence with the FDA on key design features of the Phase 3 protocol, including the endpoints and the size of the safety database that would be needed to support a Biologics License Application (“BLA”) for approval of exebacase, under the FDA’s “streamlined development” paradigm for agents to treat bacterial infections associated with high unmet medical need. Based on the outcome of the meeting, we proceeded to initiate the single Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) study of exebacase in December 2019. The DISRUPT study is a randomized, double-blind, placebo-controlled Phase 3 clinical trial conducted in the U.S. alone to assess the efficacy and safety of exebacase in approximately

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350 patients with complicated *Staph aureus* bacteremia, including right-sided endocarditis. Patients entering the study will be randomized 2:1 to either exebacase or placebo, with all patients receiving SOC antibiotics. The primary efficacy endpoint of the study is clinical response at Day 14 in patients with MRSA bacteremia, including right-sided endocarditis. Secondary endpoints will include clinical response at Day 14 in the All *Staph aureus* patient group (MRSA and methicillin-sensitive *Staph aureus* (“MSSA”)), 30-day all-cause mortality in MRSA patients, and clinical response at later timepoints. We will also evaluate the impact of treatment with exebacase on health resource utilization, including hospital length of stay, ICU length of stay and 30-day readmission rates. We plan to conduct an interim futility analysis following the enrollment of approximately 60% of the study population.

The FDA recently granted Breakthrough Therapy designation to exebacase for the treatment of MRSA bloodstream infections (bacteremia), including right-sided endocarditis, when used in addition to SOC anti-staphylococcal antibiotics in adult patients, based on the final data from the Phase 2 superiority trial of exebacase. Breakthrough Therapy designation is a program designed by the FDA to expedite the development and review of medicines for serious or life-threatening diseases where preliminary clinical evidence suggests that the investigational therapy may demonstrate substantial improvement on at least one clinically significant endpoint over available therapies. The Breakthrough Therapy designation provides additional benefits, such as intensified interactions with the FDA and the potential for priority review, over the Fast Track designation granted to exebacase in August 2015.

We performed a Phase 3 simulation analysis using the actual Phase 2 data to evaluate the clinical outcomes for the Phase 2 patient population that meets the Phase 3 inclusion criteria. In this simulated Phase 3 population of 84 U.S. patients with documented *Staph aureus* bacteremia, including right-sided endocarditis, who received a single IV infusion of blinded study drug, the clinical responder rate at Day 14 was 83.7% for patients treated with exebacase and 54.3% for patients dosed with SOC antibiotics alone, an improvement in responder rate of 29.4%. The clinical responder rate at Day 14 in the subset of patients with MRSA bacteremia including right-sided endocarditis was 82.6% for patients treated with exebacase compared to 33.3% for patients treated with SOC antibiotics alone, an improvement in responder rate of 49.3%. In the subset of patients with MSSA bacteremia including right-sided, the clinical responder rate at Day 14 was 84.6% for patients treated with exebacase compared to 66.7% for patients treated with SOC antibiotics alone, an increase of 17.9%.

Other programs

We have developed a novel, engineered variant of exebacase, known as CF-296, which we believe provides an additional opportunity for a potential targeted therapy for deep-seated, invasive biofilm-associated *Staph aureus* infections. We are conducting further *in vitro* and *in vivo* characterization of CF-296 to determine the full profile of this compound. We have been awarded up to \$7.2 million of funding from the Military Infectious Diseases Research Program, United States Army Medical Research and Development Command (“USAMRDC”) over the course of three years to advance CF-296 through IND-enabling studies.

We have discovered and engineered a new lysin product candidate, CF-370, with potent activity in preclinical studies against antibiotic-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 have initiated IND-enabling activities and we expect CF-370 to be our next molecule in clinical studies. We have been awarded up to \$3.3 million in funding from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) in support of the advancement of anti-pseudomonal lysins. Beyond our lysin programs, we continue our research to advance potential product candidates from our amurin peptide platform. We plan to initiate animal studies of our most promising amurins with the goal of moving this program to the clinic as soon as possible. We have been awarded up to \$6.9 million of funding from CARB-X to support the amurin peptide program.

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To date, a large portion of our research and development work has related to the establishment of our 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. As our pipeline progresses, we are able to further leverage our employee and infrastructure resources across multiple development programs well as research projects. In the years ended December 31, 2019, 2018 and 2017, we recorded approximately \$18.1 million, \$22.4 million and \$17.3 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 to exebacase as shown below.

The following table summarizes our research and development expenses by category for the years ended December 31, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019	2018	2017
Product development	\$ 9,847,978	\$ 14,307,715	\$ 10,219,826
Professional fees	2,757,977	2,467,000	1,760,608
Personnel related	2,204,857	3,064,872	3,387,749
External research and licensing costs	1,698,063	684,281	482,803
Laboratory costs	1,078,793	1,266,780	1,011,766
Share-based compensation	469,357	626,003	451,334
Total research and development expense	<u>\$ 18,057,025</u>	<u>\$ 22,416,651</u>	<u>\$ 17,314,086</u>

The following table summarizes our research and development expenses by program for the years ended December 31, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019	2018	2017
Exebacase	\$ 11,369,534	\$ 16,218,315	\$ 10,974,804
Other research and development	4,013,277	2,507,461	2,502,199
Personnel related and share-based compensation	2,674,214	3,690,875	3,839,083
Total research and development expense	<u>\$ 18,057,025</u>	<u>\$ 22,416,651</u>	<u>\$ 17,314,086</u>

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.

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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 ("FASB") Accounting Standards Codification ("ASC") 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;

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- the expected volatility of the underlying common stock, which we estimate based on 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; 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 CMOs and CROs in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to CMOs and CROs on our estimates of the services received and efforts expended pursuant to quotes and contracts for the conduct of manufacturing or 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 FASB ASC 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. The fair value of options is calculated using the Black-Scholes option pricing model to determine the fair value of stock options on the date of grant for employee and non-employee directors and as of January 1, 2019 for the unvested non-employee stock options. The Black-Scholes option pricing model uses 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

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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

For a discussion of our results of operations for the year ended December 31, 2017, including a year-to-year comparison between 2018 and 2017, refer to Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2018.

Comparison of years ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		Dollar Change	% Change
	2019	2018		
Operating expenses:				
Research and development	\$ 18,057,025	\$ 22,416,651	\$ (4,359,626)	(19)%
General and administrative	\$ 9,809,423	\$ 8,707,774	\$ 1,101,649	13%
Other income (expense)	\$ 15,071,955	\$ (6,559,999)	\$ 21,631,954	330%

Research and Development Expenses

Research and development expense was \$18.1 million for the year ended December 31, 2019, compared with \$22.4 million for the year ended December 31, 2018, a decrease of \$4.3 million. This decrease was primarily attributable to a \$6.3 million decrease in expenditures on clinical trial costs as we completed the reporting of the Phase 2 trial of exebacase early in 2019 as compared to the active recruiting period for the trial in 2018. We also recorded an additional \$2.4 million in reimbursable grant expenses, including the new USAMRDC grant for CF-296 and the CARB-X grant for the amurin peptide program. These decreases were partially offset by an increase of \$2.2 million relating to the cGMP manufacturing of exebacase in order to supply clinical trial material for the Phase 3 DISRUPT trial, an increase of \$1.8 million on the advancement of our other product candidates, including CF-370 to nomination as our next product candidate, and an increase of \$0.4 million in licensing fees for the milestone paid to Rockefeller upon completion of the Phase 2 trial of exebacase.

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General and Administrative Expenses

General and administrative expense was \$9.8 million for the year ended December 31, 2019, compared with \$8.7 million for the year ended December 31, 2018, an increase of \$1.1 million. This increase was primarily attributable to increased legal fees as we expanded our intellectual property portfolio. Other increases included increases in compensation costs of \$0.2 million, investor relations costs of \$0.1 million and insurance costs of \$0.1 million.

Other income (expense)

Other income was \$15.1 million for the year ended December 31, 2019 compared with other expense of \$6.6 million for the year ended December 31, 2018, an increase of \$21.6 million. In 2019, we had a non-cash gain of \$14.7 million related to the change in fair value of our warrant liability and interest income of \$0.4 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 \$0.7 million of interest income.

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 \$147.8 million, \$9.6 million from the exercise of the Class B Warrants issued in our IPO, \$23.0 million from the sale of securities in private placements and the receipt of \$4.9 million of grant funding.

As of December 31, 2019, we had approximately \$24.2 million in cash and cash equivalents 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. We have also been successful obtaining grants to supplement our financings with non-dilutive funding. We continue to pursue additional grant opportunities and have proceeded to the final stage for grants from both CARB-X and BARDA. We have also discussed with BARDA the potential for compassionate use of exebacase for secondary bacterial infections. However, there can be no assurances that either BARDA or CARB-X will award funding to the Company. 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.

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Cash flows

The following table shows a summary of our cash flows for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	\$ (27,427,893)	\$ (26,258,849)
Investing activities	\$ 21,971,126	\$ 17,151,224
Financing activities	\$ 21,320,590	\$ 10,432,896

Net cash used in operating activities

Net cash used in operating activities resulted primarily from our net losses adjusted from cash charges and changes in the components of working capital. Net cash used in operating activities increased \$1.2 million in the year ended December 31, 2019 as compared to the comparable period in 2018. This increase was primarily attributable to the increased expenditure on the cGMP manufacture of exebacase and advances paid to CROs in order to initiate the Phase 3 DISRUPT trial of exebacase by the end of 2019.

Net cash provided by investing activities

Net cash provided by investing activities in the years ended December 31, 2019 and 2018 resulted from the excess of the proceeds from the maturities of marketable securities compared to the purchases of marketable securities.

Net cash provided by financing activities

Net cash provided by financing activities in the year ended December 31, 2019 resulted from the completion of offerings of our common stock in December 2019, resulting in net proceeds of \$21.3 million. 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.

Funding requirements

All of our product candidates are in 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:

- continue our ongoing clinical trials, and 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.

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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.

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Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2019 and the effect such obligations are expected to have on our liquidity and cash flows in future periods:

Contractual obligations	Payments due by period				
	Total	Less than 1 year	1 - 3 years	4 - 5 years	More than 5 years
Operating lease commitments ⁽¹⁾	\$ 5,719,613	\$ 666,391	\$ 1,373,032	\$ 1,428,502	\$ 2,251,688
License and sponsored research agreements ⁽²⁾	1,200,000	200,000	400,000	400,000	200,000
Total contractual obligations	<u>\$ 6,919,613</u>	<u>\$ 866,391</u>	<u>\$ 1,773,032</u>	<u>\$ 1,828,502</u>	<u>\$ 2,451,688</u>

(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.

(2) Represents certain amounts payable under our license agreements with The Rockefeller University.

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. 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, 2019, we had cash and cash equivalents of \$24.2 million. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have a significant impact on the fair value of our cash equivalents. If a 10% change in interest rates were to have immediately occurred on December 31, 2019, 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 and cash equivalents do not contain excessive credit or liquidity risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

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

Item 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, 2019.

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, 2019, 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 because we do not qualify as an accelerated or a large accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Changes in Internal Control Over Financial Reporting

In connection with management's evaluation of our internal control over financial reporting as of December 31, 2019, our principal executive officer and principal financial officer concluded that there were no changes to our internal control over financial reporting during the quarter ended December 31, 2019 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:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Roger J. Pomerantz, M.D., F.A.C.P.	63	President, Chief Executive Officer, Director, Chairman of the Board
Steven C. Gilman, Ph.D.	67	Director, Vice Chairman of the Board
Sol J. Barer, Ph.D.	72	Director, Lead Independent Director
David N. Low, Jr.	61	Director
Michael J. Otto, Ph.D.	71	Director
Cary W. Sucoff, J.D.	68	Director

Roger J. Pomerantz, M.D., F.A.C.P. Dr. Pomerantz has served as Chairman of our board of directors and our Chief Executive Officer since April 2019. Prior to that, he had served as Vice Chairman of our board of directors since May 2014. From November 2013 to December 2019, Dr. Pomerantz served as Chairman of the board of directors of Seres Therapeutics, Inc., a biotechnology company, and as its President and Chief Executive Officer from June 2014 to January 2019. 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 serves as Chairman of the board of directors of the public company Collplant Biotechnologies, Inc., a board member of the public company Intec Therapeutics, Inc., Chairman of the board of directors of the private company Silicon Therapeutics Inc. and a member of the board of the private company X-VAX Technology, 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 12 drugs approved world-wide in important diseases, including HIV, HCV, CMV, *Clostridium difficile* 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.

Steven C. Gilman, Ph.D. Dr. Gilman Dr. Gilman has served as Vice Chairman of our board of directors since April 2019. Prior to that, he had served as our Chairman since May 2015, Interim Chief Executive Officer from March 2016 to July 2016 and Chief Executive Officer since July 2016. 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.

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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.

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 Teva Pharmaceutical Industries, a public company, and for the private companies Centrexion and Neximmue. He is also a board member of Cerecor, Inc., a public company, and the private company 3DBio Therapeutics. He is the Founding Chair of the Hackensack Meridian Health Center for Discovery and Innovation. He is a venture advisor to the Israel Biotech Fund as well as an advisor to biopharma companies. 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.

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

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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 Roger J. Pomerantz, M.D., F.A.C.P., our Chief Executive Officer, may be found above in the section entitled "Director Biographical Information."

Natalie Bogdanos, J.D. Ms. Bogdanos, age 51, 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, at least 15 of which were serving as the chief legal officer of publicly traded biotechnology companies. 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 58, 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

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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 45, 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 54, 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 Ethics and Business Conduct applicable to all officers, directors and employees, which is available on our website at <http://ir.contrafect.com/governance-docs>. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Ethics and Business Conduct, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified above.

The remaining information required by this Item 10 will be contained under the heading "Corporate Governance" and "Executive Compensation – Compensation Committee Interlocks and Insider Participation" in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

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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 2020 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 2020 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 2020 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 2020 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 Form10-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 Form10-K.

Report of Independent Registered Public Accounting Firm	F-2
Audited Consolidated Financial Statements:	
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Comprehensive Loss	F-5
Consolidated Statements of Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Financial Statements	F-8

- (2) Financial Statement Schedules

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

- (3) Exhibits

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, Certificate of Amendment dated May 2, 2017, and Certificate of Amendment dated February 3, 2020					*
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	

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Exhibit No.	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
4.6	Form of Investor Warrant	8-K	001-36577	4.1	June 12, 2015	
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	
4.12	Description of ContraFect Corporation Securities					*
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	

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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#	Letter Agreement, dated March 13, 2017, between ContraFect Corporation and Steven C. Gilman, Ph.D.	8-K	001-36577	10.1	March 13, 2017	
10.15#	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	
10.16#	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	
10.17#	Offer Letter, dated August 24, 2015, between ContraFect Corporation and Cara Cassino, M.D.	10-K	001-36577	10.28	March 15, 2017	
10.18#	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	

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Exhibit No.	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.19#	Employment Agreement, dated as of April 2, 2019, by and between ContraFect Corporation and Roger J. Pomerantz	8-K	001-36577	10.1	April 2, 2019	
10.20#	Separation Agreement and Release, dated as of April 2, 2019, by and between ContraFect Corporation and Steven C. Gilman	8-K	001-36577	10.2	April 2, 2019	
10.21	Stock Purchase Agreement, dated December 9, 2019, by and between ContraFect Corporation and Pfizer Inc.	8-K	001-36577	10.1	December 12, 2019	
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					*

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<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>				<u>Filed/Furnished Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
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

CONTRAFECT CORPORATION

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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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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 cashflows 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 18, 2020

CONTRAFECT CORPORATION
Consolidated Balance Sheets

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,184,140	\$ 8,320,317
Marketable securities	—	22,131,936
Prepaid expenses and other current assets	6,575,375	988,799
Total current assets	30,759,515	31,441,052
Property and equipment, net	1,099,948	1,076,099
Operating lease right-of-use assets	3,043,826	—
Other assets	105,420	355,420
Total assets	<u>\$ 35,008,709</u>	<u>\$ 32,872,571</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,622,272	\$ 1,427,287
Accrued liabilities	6,803,789	4,369,732
Current portion of lease liabilities	631,889	—
Total current liabilities	10,057,950	5,797,019
Deferred rent	—	679,182
Warrant liabilities	6,068,978	20,781,663
Long-term portion of lease liabilities	3,264,128	—
Other liabilities	72,747	72,747
Total liabilities	19,463,803	27,330,611
Commitments and contingencies (Note 8)	—	—
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 25,000,000 shares authorized and none outstanding at December 31, 2019 and 2018	—	—
Common stock, \$0.0001 par value, 200,000,000 shares authorized, 15,332,042 shares issued and outstanding at December 31, 2019; 200,000,000 shares authorized, 7,940,931 shares issued and outstanding at December 31, 2018	1,533	7,941
Additional paid-in capital	227,657,758	204,884,211
Accumulated other comprehensive loss	—	(30,300)
Accumulated deficit	(212,114,385)	(199,319,892)
Total stockholders' equity	15,544,906	5,541,960
Total liabilities and stockholders' equity	<u>\$ 35,008,709</u>	<u>\$ 32,872,571</u>

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Operations

	Year Ended December 31,		
	2019	2018	2017
Operating expenses:			
Research and development, including stock-based compensation of \$469,357, \$626,002 and \$451,334, respectively	\$ 18,057,025	\$ 22,416,651	\$ 17,314,086
General and administrative, including stock-based compensation of \$977,192, \$929,521 and \$1,171,794, respectively	9,809,423	8,707,774	9,249,671
Total operating expenses	<u>27,866,448</u>	<u>31,124,425</u>	<u>26,563,757</u>
Loss from operations	(27,866,448)	(31,124,425)	(26,563,757)
Other income (expense):			
Interest income	359,270	672,227	418,135
Other expense	—	—	(905,014)
Change in fair value of warrant liabilities	14,712,685	(7,232,226)	11,532,978
Total other income (expense)	<u>15,071,955</u>	<u>(6,559,999)</u>	<u>11,046,099</u>
Net loss	<u>\$ (12,794,493)</u>	<u>\$ (37,684,424)</u>	<u>\$ (15,517,658)</u>
Per share information:			
Net loss per share of common stock, basic and diluted	<u>\$ (1.54)</u>	<u>(4.95)</u>	<u>\$ (2.79)</u>
Basic and diluted weighted average shares outstanding	<u>8,283,509</u>	<u>7,606,266</u>	<u>5,559,573</u>

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Comprehensive Loss

	Year Ended December 31,		
	2019	2018	2017
Net loss	\$ (12,794,493)	\$ (37,684,424)	\$ (15,517,658)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale securities	30,300	44,520	(23,154)
Comprehensive loss	<u>\$ (12,764,193)</u>	<u>\$ (37,639,904)</u>	<u>\$ (15,540,812)</u>

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, 2016	4,165,576	\$ 416	\$ 165,681,914	\$ (51,666)	\$ (146,117,810)	\$ 19,512,854
Issuance of securities in registered offering	3,200,000	320	27,616,245	—	—	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	7,365,576	\$ 736	\$ 192,902,997	\$ (74,820)	\$ (161,635,468)	\$ 31,193,445
Issuance of securities in registered offering	575,000	58	11,499,942	—	—	11,500,000
Financing cost of sale of securities	—	—	(1,072,607)	—	—	(1,072,607)
Issuance of common stock for exercise of warrants	355	—	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	7,940,931	\$ 794	\$ 204,891,358	\$ (30,300)	\$ (199,319,892)	\$ 5,541,960
Issuance of securities in registered offerings	6,280,000	628	20,033,372	—	—	20,034,000
Issuance of securities in private placement	1,111,111	111	2,999,889	—	—	3,000,000
Financing cost of sale of securities	—	—	(1,713,410)	—	—	(1,713,410)
Share-based compensation	—	—	1,446,549	—	—	1,446,549
Unrealized gain on marketable securities	—	—	—	30,300	—	30,300
Net loss	—	—	—	—	(12,794,493)	(12,794,493)
Balance, December 31, 2019	15,332,042	\$ 1,533	\$ 227,657,758	\$ —	\$ (212,114,385)	\$ 15,544,906

See accompanying notes.

CONTRAFECT CORPORATION
Statements of Cash Flows

	Year Ended December 31,		
	2019	2018	2017
Cash flows from operating activities			
Net loss	\$ (12,794,493)	\$ (37,684,424)	\$ (15,517,658)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	169,159	151,292	187,249
Stock-based compensation expense	1,446,549	1,555,523	1,623,128
Issuance costs allocated to warrants	—	—	905,014
Change in fair value of warrant liabilities	(14,712,685)	7,232,226	(11,532,978)
Decrease in deferred rent	—	(25,058)	(290,199)
Net amortization of premium paid on marketable securities	171,111	486,736	831,793
Changes in operating assets and liabilities:			
(Increase) decrease in prepaid expenses and other current and non-current assets	(1,262,809)	897,447	(1,059,502)
(Decrease) increase in accounts payable, accrued liabilities and other liabilities	(444,725)	1,127,409	324,160
Net cash used in operating activities	(27,427,893)	(26,258,849)	(24,528,993)
Cash flows from investing activities			
Purchases of marketable securities	—	(23,846,176)	(53,162,598)
Proceeds from maturities of marketable securities	21,991,125	41,130,888	43,802,957
Purchases of property and equipment	(19,999)	(133,488)	—
Net cash provided by (used in) investing activities	21,971,126	17,151,224	(9,359,641)
Cash flows from financing activities			
Proceeds from issuance of equity securities	23,034,000	11,500,000	40,000,000
Payment of financing costs of securities sold	(1,713,410)	(1,072,607)	(2,923,304)
Proceeds from exercise of warrants	—	5,503	—
Net cash provided by financing activities	21,320,590	10,432,896	37,076,696
Net increase in cash and cash equivalents	15,863,823	1,325,271	3,188,062
Cash and cash equivalents at beginning of period	8,320,317	6,995,046	3,806,984
Cash and cash equivalents at end of period	\$ 24,184,140	\$ 8,320,317	\$ 6,995,046
Supplemental disclosures of cash flow information			
Prepaid expenses in accrued liabilities	\$ 4,096,832	\$ —	\$ —
Right-of-use assets obtained in exchange for lease obligations	\$ 4,148,672	\$ —	\$ —
Leasehold improvement obtained in exchange for lease incentive obligations	\$ 189,227	\$ —	\$ —
Issuance of warrants to purchase common stock	\$ —	\$ —	\$ 12,383,435

See accompanying notes.

ContraFect Corporation
Notes to Financial Statements
December 31, 2019

1. Organization and Description of Business

Organization and Business

ContraFect Corporation (the “Company”) is a clinical-stage biotechnology company focused on the discovery and development of direct lytic agents (“DLAs”), including lysins and amurin peptides, as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections. The Company intends to address antibiotic-resistant infections using product candidates from our lysin and amurin peptide platforms. DLAs are fundamentally different than antibiotics and offer a potential paradigm shift in the treatment of antibiotic-resistant infections. 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 pivotal Phase 3 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 right-sided 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 \$212.1 million as of December 31, 2019. For the year ended December 31, 2019, the Company used \$27.4 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 Accounting Standard Codification (“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 December 18, 2019, the Company completed an underwritten public offering of 2,565,000 shares of its common stock at a public offering price of \$3.90 per share, resulting in gross proceeds to the Company of approximately \$10.0 million. On December 12, 2019, the Company completed an underwritten public offering of 3,715,000 shares of its common stock at a public offering price of \$2.70 per share and a concurrent private placement of 1,111,111 shares of common stock to Pfizer Inc. at a price of \$2.70 per share, resulting in gross proceeds to the Company of approximately \$13.0 million. The combined net proceeds of both public offerings together with the private placement was \$21.3 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 575,000 shares of its common stock, including shares sold pursuant to the fully exercised overallotment option granted to the

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underwriters in connection with the offering, at a public offering price of \$20.00 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 completed an underwritten public offering of 3,200,000 shares of its common stock and warrants to purchase an additional 1,600,000 shares of its common stock at an exercise price of \$15.50 per share (the “2017 Offering”). The public offering price was \$12.50 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.

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. All share and per share amounts have been adjusted to reflect a one-for-ten reverse stock split effected on February 3, 2020.

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.

The Company currently relies on a single manufacturer of exebacase drug substance and drug product, located in the United Kingdom, and there is no long-term supply agreement in place. A sustained disruption in the operations of this manufacturer or in the event the Company would need to change to a new supplier, could result into a significant delay in the ability of the Company to complete the activities needed to support a Biologics License Application for, and, if approved, commercialization of exebacase.

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Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to accruals, fair value measurements, stock-based compensation, warrant valuation and 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, 2019, 2018 or 2017. There were no marketable securities that had been in an unrealized loss position for more than 12 months as of December 31, 2018. The Company held no marketable securities as of December 31, 2019.

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

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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 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.

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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, 2019 and 2018, 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 as of December 31, 2018.

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 expenses and other current assets or accrued liabilities.

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. For non-employees, effective January 1, 2019, unvested option compensation expense is based on the adoption date fair value and is amortized over the service period 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

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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, 2019) 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, 2019.

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, 2019 and 2018, the Company recognized a reduction to its research and development expense in the amount of approximately \$3.6 million and \$1.2 million, respectively. The receivable for grants as of December 31, 2019 and 2018 was approximately \$1.1 million and \$0.5 million, respectively, and is included in prepaid expenses and other current assets. The Company has approximately \$8.3 million of approved grant award funding remaining as of December 31, 2019.

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

Leases

The Company adopted Accounting Standards Update No. 2016-02-*Leases (Topic 842)*, as of January 1, 2019, using the optional modified retrospective approach with no cumulative-effect adjustment to equity as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under previous lease guidance. The Company elected the package of practical expedients permitted under the transition guidance within Topic 842, which among other things, allowed it to carry forward the historical lease classification of those leases in place as of January 1, 2019 and to not separate lease and non-lease components when the requisite criteria is met to be treated as such. The Company determined that the only contract containing a lease was the lease of its corporate headquarters at 28 Wells Avenue in Yonkers, New York (see “Note 8—Commitments” in these consolidated financial statements for a description of the leases).

The Company recognizes right-of-use (ROU) assets at the inception of the arrangement as the present value of the lease payments plus our initial direct costs, if any, less any lease incentives. The corresponding liability is computed as the present value of the lease payments at inception. Assets are classified as either operating or

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finance ROU assets according to the classification criteria in Topic 842. The present value of the lease payments is computed using the rate implicit in the lease, if known, or the Company's incremental borrowing rate. Operating lease costs are charged to operations on a straight-line basis over the term of the lease. Under the Company's policy, it does not record an ROU asset or corresponding liability for arrangements where the initial lease term is one year or less. Those leases are expensed on a straight-line basis over the term of the lease.

Adoption of Topic 842 resulted in recording of ROU assets, net of deferred rent and a lease incentive obligation, of \$3.3 million and lease liabilities of approximately \$4.1 million as of January 1, 2019. The lease liability was classified between a current portion of \$0.6 million and a long-term portion of \$3.5 million. The new standard did not impact the Company's consolidated net loss and had no impact on cash flows.

Non-employee Stock Compensation

The Company adopted Accounting Standards Update, *Compensation-Stock Compensation (ASU 2018-07)*, as of January 1, 2019. The Company elected to utilize the contractual term for its outstanding option grants to non-employees and to recognize forfeitures of awards when incurred. The adoption of ASU 2018-07 did not have a material impact on its consolidated financial statements.

Statements of Equity

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. Additionally, the amendments expanded the disclosure requirements on the consolidated statements of equity for interim financial statements. Under the amendments, a summary of changes in each caption of stockholders' equity presented in the consolidated balance sheets must be provided in a note or separate statement. The consolidated statements of equity should present a reconciliation of a beginning balance to the ending balance of each period for which the consolidated statement of comprehensive income is required to be filed. This final rule was effective in the fourth quarter of 2018. The SEC provided relief on the effective date until the first quarter of 2019, and the Company adopted this rule in the first quarter of 2019.

Recent Accounting Pronouncements Not Yet Adopted

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, 2022. The Company is currently evaluating the impact that this new standard will have on its financial statements and related disclosures.

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.

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3. Marketable Securities

The Company held no marketable securities as of December 31, 2019. Marketable securities at December 31, 2018 consisted of the following:

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

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, the Company held 22 debt securities that individually and in total were in an immaterial unrealized loss position for less than one year. The aggregate fair value of debt securities in an unrealized loss position at December 31, 2018 was \$19,544,246. 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 was not more likely than not that the Company would have been 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.

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, 2019 and December 31, 2018:

	<u>Fair Value Measurement As of December 31, 2019</u>		
	<u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>
Cash equivalents	\$ 21,433,639	\$ —	\$ —
Warrant liabilities	—	—	6,068,978
Total	<u>\$ 21,433,639</u>	<u>\$ —</u>	<u>\$ 6,068,978</u>

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

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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, 2019	As of December 31, 2018
Expected volatility	121.4%	72.6%
Remaining contractual term (in years)	1.58	2.58
Risk-free interest rate	1.59%	2.46%
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, 2019	As of December 31, 2018
Expected volatility	104.2%	87.3%
Remaining contractual term (in years)	2.58	3.58
Risk-free interest rate	1.60%	2.49%
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, 2019, 2018 and 2017:

Warrant liabilities

	Year Ended December 31,		
	2019	2018	2017
Balance at beginning of period	\$ 20,781,663	\$ 13,549,437	\$ 12,698,980
Issuance of 2017 Warrants	—	—	12,383,435
Change in fair value	(14,712,685)	7,232,226	(11,532,978)
Balance at end of period	<u>\$ 6,068,978</u>	<u>\$ 20,781,663</u>	<u>\$ 13,549,437</u>

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,	
	2019	2018
Computer equipment	\$ 19,691	\$ 19,691
Furniture	434,697	434,697
Lab equipment	1,864,368	1,844,369
Leasehold improvements	2,028,013	1,855,004
	4,346,769	4,153,761
Less: accumulated depreciation and amortization	(3,246,821)	(3,077,662)
	<u>\$ 1,099,948</u>	<u>\$ 1,076,099</u>

Depreciation expense was \$169,159, \$151,292 and \$187,249 for the years ended December 31, 2019, 2018 and 2017, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2019	2018
Accrued research and clinical development service fees	\$ 3,865,146	\$ 2,076,764
Accrued compensation costs	1,621,008	1,585,689
Accrued professional fees	842,613	433,498
Accrued insurance costs	231,477	—
Accrued facilities operation expenses	180,158	232,673
Other accrued expenses	63,387	41,108
	<u>\$ 6,803,789</u>	<u>\$ 4,369,732</u>

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,		
	2019	2018	2017
Net loss applicable to common stockholders	\$ (12,794,493)	\$ (37,684,424)	\$ (15,517,658)
Weighted average shares of common stock outstanding	8,283,509	7,606,266	5,559,573
Net loss per share of common stock—basic and diluted	<u>\$ (1.54)</u>	<u>\$ (4.95)</u>	<u>\$ (2.79)</u>

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The following potentially dilutive securities outstanding at December 31, 2019, 2018 and 2017 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,		
	2019	2018	2017
Options to purchase common stock	1,216,338	718,788	620,015
Warrants to purchase common stock	3,033,910	3,124,303	3,627,010
	<u>4,250,248</u>	<u>3,843,091</u>	<u>4,247,025</u>

8. Commitments and Contingencies

Operating Leases

As described further in Note 2, "Summary of Significant Accounting Policies", the Company adopted Topic 842 as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company's historic accounting under Topic 840.

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 term 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.

The Company performed an evaluation of its other contracts in accordance with Topic 842 and has determined that, except for the leases described above, none of its contracts contain a lease.

The balance sheet classification of the Company's lease liabilities was as follows:

Description	December 31, 2019	December 31, 2018
Operating lease liabilities:		
Current portion of lease liabilities	\$ 631,889	\$ —
Long-term portion of lease liabilities	\$ 3,264,128	\$ —

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. The leases are renewable at the end of the lease term at the Company's option. For the purposes of determining the remaining lease term in contemplation of available extensions, the Company did not consider either renewal to be probable at this time. In determining the present value of lease payments, the Company estimated its incremental borrowing rate based on the information available at the adoption date of Topic 842. As of January 1, 2019, the remaining lease term was 9.0 years and the discount rate used to determine the operating lease liability was 9.93%.

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As of December 31, 2019, the maturities of the Company's operating lease liabilities were as follows:

	<u>Amount</u>
Year ending December 31:	
2020	\$ 666,391
2021	679,719
2022	693,313
2023	707,179
2024	721,323
Thereafter	<u>2,251,688</u>
Total lease payments	5,719,613
Less: Present value adjustment	<u>(1,823,596)</u>
Operating lease liabilities	<u>\$ 3,896,017</u>

Lease costs under the terms of the Company's leases for the year ended December 31, 2019 are as follows:

	<u>Year Ended December 31, 2019</u>
Operating lease cost (1)	\$ 616,653
Variable lease cost (2)	98,909
Total lease cost	<u>\$ 715,562</u>

- (1) Operating lease payments included in the measurement of the Company's lease liabilities are comprised of fixed payments according to the terms of the Company's leases.
- (2) Variable lease payments consist of the Company's utility costs billed by and paid to its landlord. Variable lease payments are presented as operating expenses in the Company's Consolidated Statement of Operations in the same line item as expense arising from fixed lease payments and in net cash used in operating activities in the Company's Statement of Cash Flows.

Rent expense is recognized using the straight-line method over the term of each lease. Rent expense for the years ended December 31, 2018 and 2017, was approximately \$618,000 and \$587,000, 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.

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- On September 23, 2010, the Company entered into a license agreement for the worldwide, exclusive right to develop, make, have made, use, import, lease, sell, and offer for sale products that would otherwise infringe a claim of the suite of patents and patent applications covering the composition of matter for eight individual lysin molecules for the treatment and prevention of diseases caused by gram-positive bacteria. The lysins in this suite have activity against Group B *Streptococci*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Bacillus anthracis*, *Enterococcus faecalis* and *Enterococcus faecium*.

In consideration for 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. The Company made a milestone payment under the CF-301 License of \$430,000 during the year ended December 31, 2019 for the completion of the Phase 2 trial. There were no milestone, royalty or sublicense payments made during the years ended December 31, 2018 and 2017. 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. The agreements expired on October 24, 2019. Following the expiration of the agreements, each party has 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.

Separation Agreements

On April 1, 2019, Steven C. Gilman notified the Company of his resignation as President, Chief Executive Officer and Chairman of the board of directors, effective as of April 2, 2019. In connection with his resignation, Dr. Gilman entered into a separation agreement with the Company pursuant to which Dr. Gilman will receive (i) an amount in cash equal to 25% of the annual bonus that Dr. Gilman would have earned for the 2019 calendar year had he remained continuously employed, as determined by the board based on actual performance, which amount, if any, shall be paid to Dr. Gilman in a lump sum at the same time in 2020 as annual performance bonuses for 2019 are paid to the Company's actively employed executive officers and (ii) payment of the premiums to continue coverage under the Company's group health plans, if elected, pursuant to COBRA, until December 31, 2019 or, if earlier, the date Dr. Gilman becomes no longer eligible for COBRA or becomes eligible to receive comparable coverage from a subsequent employer. Dr. Gilman will continue to serve as a director of the Company, and was appointed to serve as Vice Chairman of the Board and as Chairman of the

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Science and Technology Committee. Dr. Gilman is eligible to receive compensation for his service on the board and its committees in accordance with the Company's non-employee director compensation program. Dr. Gilman's service on the board will also constitute his continued service to the Company for purposes of the vesting and post-termination exercise period of each option to purchase shares of the Company's common stock held by Dr. Gilman as of his resignation.

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, 2019, the Company was authorized to issue 200,000,000 shares of common stock at \$0.0001 par value per share.

Follow-on Offerings

On December 18, 2019, the Company completed an underwritten public offering of 2,565,000 shares of its common stock resulting in gross proceeds to the Company of approximately \$10.0 million. On December 12, 2019, the Company completed an underwritten public offering of 3,715,000 shares of its common stock and a concurrent private placement of 1,111,111 shares of common stock to Pfizer Inc. resulting in total gross proceeds to the Company of approximately \$13.0 million. The combined net proceeds of both public offerings together with the private placement was \$21.3 million after underwriting discounts and commissions and offering expenses payable by the Company.

On August 3, 2018, the Company sold 575,000 shares of its common stock in an underwritten offering, including shares sold pursuant to the fully exercised overallotment option granted to the underwriters in connection with the offering, for gross proceeds of \$11.5 million. The Company received net proceeds of approximately \$10.4 million after underwriting discounts and commissions and offering expenses payable by the Company.

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On July 25, 2017, the Company sold 3,200,000 shares of its common stock and warrants to purchase an additional 1,600,000 shares of its common stock in an underwritten offering for gross proceeds of \$40 million (the “2017 Offering”). The Company received net proceeds of approximately \$37.1 million after underwriting discounts and commissions and offering expenses payable by the Company.

On July 27, 2016, the Company sold 1,400,000 shares of its common stock and warrants to purchase an additional 1,400,000 shares of its common stock in an underwritten 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 \$15.50 per share and expire five years from the date of issuance. The 2016 Warrants have an exercise price of \$30.00 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 \$42.30 per common share purchased. The closing of the PIPE resulted in the issuance of an aggregate of 472,812 common shares and warrants to purchase an additional 236,406 shares of common stock at an exercise price of \$80.00 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 18,903 shares of common stock underlying the Placement Agent Warrants. The Placement Warrants became exercisable upon issuance at an exercise price of \$46.50 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 20,641 shares of common stock underlying the Representative’s Warrant. The Representative’s Warrant became exercisable at an exercise price of \$75.00 per share beginning 180 days after the effective date of the Company’s registration statement (January 24, 2015) and expired on August 27, 2019. The Company classified the Representative’s Warrant as a liability since it did not

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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 510,998 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 332,142 at an exercise price of \$30.00 per share. There were 67,070 and 264,518 Note Warrants that expired during 2019 and 2018, respectively, and therefore have been terminated and are no longer exercisable. There are no Note Warrants remaining outstanding as of December 31, 2019.

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, 2019, 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, 2019 and 2018:

	December 31,	
	2019	2018
Outstanding options to purchase common stock	1,216,338	718,788
Outstanding warrants to purchase common stock	3,033,910	3,124,303
For future issuance under the 2014 Plan	101,625	282,176
	<u>4,351,873</u>	<u>4,125,267</u>

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10. Stock Warrants

As of December 31, 2019 and 2018, the Company had warrants outstanding as shown in the table below.

	December 31,	
	2019	2018
Note Warrants (1)	—	67,070
2017 Warrants	1,599,645	1,599,645
2016 Warrants	1,400,000	1,400,000
Representative's Warrant (2)	—	20,641
Placement Agent Warrants	18,915	18,915
Other warrants (3)	15,350	18,033
Warrants to purchase common stock	3,033,910	3,124,304
Weighted-average exercise price per share	\$ 22.61	\$ 23.10

- (1) During 2019 and 2018 the PIPE Warrants to purchase common stock expired in accordance with their terms. Only 553 of the PIPE Warrants were exercised prior to expiration and the remaining PIPE Warrants were terminated and are no longer exercisable.
- (2) On August 27, 2019, the Representative's Warrant to purchase common stock expired in accordance with its terms. The Representative's Warrant was not exercised prior to expiration and has been terminated and is no longer exercisable.
- (3) 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, 2019:

Exercise Prices	Shares Underlying Outstanding Warrants	Expiration Date
£ \$20.00	1,600,216	September 1, 2021 – July 25, 2022
> \$20.00	1,433,694	February 12, 2020 – January 5, 2022
	<u>3,033,910</u>	

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 157,143. 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 185,714 and 235,714, 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

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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 57,143. 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 969,685 shares of common stock have been reserved under the 2014 Plan as of December 31, 2019.

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, 2019, 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, 2018	718,796	\$31.70		
Granted	565,550	4.30		
Exercised	—	—		
Expired	(53,258)	18.19		
Forfeited	(14,750)	11.87		
Options outstanding at December 31, 2019	<u>1,216,338</u>	\$19.75	7.13	<u>\$1,098,143</u>
Vested and exercisable at December 31, 2019	<u>597,665</u>	\$33.17	5.43	<u>\$ 100,390</u>

Of the option grants outstanding to purchase 1,216,338 shares of common stock, grants to purchase 65,076 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, 2019, 2018 and 2017 was \$4.30, \$1.47 and \$1.62, respectively. Total compensation expense recognized amounted to \$1,446,549, \$1,555,523 and \$1,623,128 for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, the total remaining unrecognized compensation cost related to unvested stock options was \$2,547,923 which will be recognized over a weighted average period of approximately 2.48 years.

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

	Year Ended December 31,		
	2019	2018	2017
Risk free interest rate	2.35%	2.58%	2.07%
Expected dividend yield	—	—	—
Expected term (in years)	6.06	6.02	6.01
Expected volatility	89.7%	82.3%	79.6%

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.

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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 \$117,000, \$104,000 and \$100,000 of expense for matching contributions to the 401(k) Plan during the years ended December 31, 2019, 2018 and 2017, respectively.

13. Income Taxes

The Company has available approximately \$201,264,000 and \$217,774,000 of unused operating loss carryforwards for federal and state tax purposes, respectively, that may be applied against future taxable income. The NOL carryforwards will begin to expire in 2028 and research and development (R&D) credits will begin to expire in 2031 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 \$7,984,000 and \$9,006,000 during the years 2019 and 2018, respectively, and was approximately \$62,137,000 and \$54,153,000 at December 31, 2019 and 2018, 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, 2019, the Company had no unrecognized tax benefits or related interest and penalties accrued. The Company has not, as yet, conducted a study of 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.

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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,	
	2019	2018
Deferred tax assets:		
Net operating loss carryovers	\$ 56,646,542	\$ 49,294,211
Share-based compensation	1,770,295	1,754,362
R&D tax credits	3,149,249	2,545,920
Accrued compensation and severance	454,128	442,090
Deferred rent	—	198,278
Lease liability	1,101,248	—
Intangible assets	110,178	131,503
Total deferred tax assets	\$ 63,231,640	\$ 54,366,364
Valuation allowance	(62,136,614)	(54,152,886)
Total deferred tax assets net of valuation allowance	\$ 1,095,026	\$ 213,478
Deferred tax liabilities:		
Right-of-use asset	(909,271)	—
Depreciation	(185,755)	(213,478)
Total deferred tax liabilities	\$ (1,095,026)	\$ (213,478)
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,		
	2019	2018	2017
Federal income tax benefit at statutory rate	(21.00)%	(21.00)%	(34.00)%
State income tax, net of federal benefit	(15.09)	(5.64)	(9.95)
Permanent items including change in fair value of warrants	(21.87)	4.80	(22.03)
Change in valuation allowance	62.56	23.95	(50.33)
R&D tax credits	(4.72)	(2.11)	(3.02)
Deferred re-measurement	—	—	118.03
Other	0.12	—	(1.30)
Effective income tax (benefit) expense rate	0%	0%	0%

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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 2019 and 2018:

	2019			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Loss from operations	\$ (6,361,733)	\$ (7,407,479)	\$ (7,626,575)	\$ (6,470,661)
Net income (loss)	\$ 11,587,015	\$ (8,666,906)	\$ (5,359,118)	\$ (10,355,484)
Net income (loss) per share of common stock, basic and diluted	\$ 1.46	\$ (1.09)	\$ (0.67)	\$ (1.11)

	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	\$ (2.59)	\$ (2.73)	\$ (0.57)	\$ 0.75

15. Subsequent Event

In February 2020, the Board of Directors of the Company approved a 1-for-10 reverse stock-split of the Company's outstanding shares of common stock, warrants and options outstanding and available for future issuance. The stock split became effective on February 3, 2020. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect this reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately decreased and the respective per share value and exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the Board of Directors approved a decrease in the number of authorized shares of common stock from 200,000,000 shares to 125,000,000 shares.

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

Date: March 18, 2020

By: /s/ Roger J. Pomerantz, M.D., F.A.C.P.
Roger J. Pomerantz, M.D., F.A.C.P..
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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Roger J. Pomerantz, M.D., F.A.C.P.</u> Roger J. Pomerantz, M.D., F.A.C.P.	President and Chief Executive Officer, Chairman of the Board <i>(Principal Executive Officer)</i>	March 18, 2020
<u>/s/ Michael Messinger</u> Michael Messinger	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	March 18, 2020
<u>/s/ Sol J. Barer, Ph.D.</u> Sol J. Barer, Ph.D.	Lead Independent Director	March 18, 2020
<u>/s/ Steven C. Gilman, Ph.D.</u> Steven C. Gilman, Ph.D.	Vice Chairman of the Board	March 18, 2020
<u>/s/ David N. Low, Jr.</u> David N. Low, Jr.	Director	March 18, 2020
<u>/s/ Michael J. Otto, Ph.D.</u> Michael J. Otto, Ph.D.	Director	March 18, 2020
<u>/s/ Cary W. Sucoff</u> Cary W. Sucoff	Director	March 18, 2020

**AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
CONTRAFECT CORPORATION**

(originally incorporated on March 5, 2008)

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

A. The current name of the Corporation is ContraFect Corporation. The Corporation was originally incorporated under the name CONTRAFECT, INC. on March 5, 2008. The original Certificate of Incorporation of the Corporation was amended, supplemented and restated by (a) that certain Certificate of Amendment of Certificate of Incorporation filed on March 17, 2008, (b) that certain Certificate of Designation of Series "A" Preferred Shares filed on July 1, 2009, (c) that certain Amended and Restated Certificate of Incorporation filed on February 26, 2010, (d) that certain Second Amended and Restated Certificate of Incorporation filed on August 2, 2010, (e) that certain Certificate of Amendment of Second Amended and Restated Certificate of Incorporation filed on September 10, 2010, (f) that certain Third Amended and Restated Certificate of Incorporation filed on August 25, 2011, (g) that certain Certificate of Amendment of Third Amended and Restated Certificate of Incorporation filed on June 13, 2012, (h) that certain Fourth Amended and Restated Certificate of Incorporation filed on June 11, 2013 and (i) that certain Fifth Amended and Restated Certificate of Incorporation filed on July 25, 2014.

B. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Sections 242 and 245 of the DGCL proposing this Amended and Restated Certificate of Incorporation (this "Certificate of Incorporation") and declaring its advisability. The stockholders of the Corporation duly approved and adopted this Certificate of Incorporation by written consent in accordance with Sections 228, 242 and 245 of the DGCL.

C. This Certificate of Incorporation shall become effective upon its filing with the Secretary of State of the State of Delaware.

D. Accordingly, the Corporation's certificate of incorporation, as previously amended and restated, is hereby further amended and restated in its entirety to read as follows:

FIRST: The name of the Corporation is ContraFect Corporation.

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

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

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

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

A. COMMON STOCK.

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors of the Corporation (the "Board of Directors") upon any issuance of the Preferred Stock of any series.

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

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

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK.

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

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

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

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

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

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

EIGHTH: The Corporation shall provide indemnification as follows:

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

2. Actions or Suits by or in the Right of the Corporation The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed

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

3. Indemnification for Expenses of Successful Party. Notwithstanding any other provisions of this Article EIGHTH, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 1 and 2 of this Article EIGHTH, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified against all expenses (including attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith. Without limiting the foregoing, if any action, suit or proceeding is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to Indemnitee, (ii) an adjudication that Indemnitee was liable to the Corporation, (iii) a plea of guilty or nolo contendere by Indemnitee, (iv) an adjudication that Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Corporation, and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe his or her conduct was unlawful, Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect thereto.

4. Notification and Defense of Claim. As a condition precedent to an Indemnitee's right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (i) the employment of counsel by Indemnitee has been authorized by the Corporation, (ii) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article EIGHTH. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Corporation shall not be required to indemnify Indemnitee under this Article EIGHTH for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or

investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

5. Advance of Expenses. Subject to the provisions of Section 6 of this Article EIGHTH, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article EIGHTH, any expenses (including attorneys' fees) incurred by or on behalf of an Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter; provided, however, that the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article EIGHTH; and provided further that no such advancement of expenses shall be made under this Article EIGHTH if it is determined (in the manner described in Section 6 of this Article EIGHTH) that (i) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

6. Procedure for Indemnification and Advancement of Expenses. In order to obtain indemnification or advancement of expenses pursuant to Section 1, 2, 3 or 5 of this Article EIGHTH, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (i) the Corporation has assumed the defense pursuant to Section 4 of this Article EIGHTH (and none of the circumstances described in Section 4 of this Article EIGHTH that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (ii) the Corporation determines within such 60 day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 1, 2 or 5 of this Article EIGHTH, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 1 or 2 of this Article EIGHTH only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 1 or 2 of this Article EIGHTH, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

7. Remedies. The right to indemnification or advancement of expenses as granted by this Article EIGHTH shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 6 of this Article EIGHTH that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article EIGHTH. Indemnitee's expenses (including attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification, in whole or in part, in any such proceeding shall also be indemnified by the Corporation. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification hereunder it shall be a defense that the

Indemnitee has not met any applicable standard for indemnification set forth in the General Corporation Law of the State of Delaware.

8. Limitations. Notwithstanding anything to the contrary in this Article EIGHTH, except as set forth in Section 7 of this Article EIGHTH, the Corporation shall not indemnify an Indemnitee pursuant to this Article EIGHTH in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors of the Corporation. Notwithstanding anything to the contrary in this Article EIGHTH, the Corporation shall not indemnify an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification payments to the Corporation to the extent of such insurance reimbursement.

9. Subsequent Amendment. No amendment, termination or repeal of this Article EIGHTH or of the relevant provisions of the General Corporation Law of the State of Delaware or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

10. Other Rights. The indemnification and advancement of expenses provided by this Article EIGHTH shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article EIGHTH shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification rights and procedures different from those set forth in this Article EIGHTH. In addition, the Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article EIGHTH.

11. Partial Indemnification. If an Indemnitee is entitled under any provision of this Article EIGHTH to indemnification by the Corporation for some or a portion of the expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement to which Indemnitee is entitled.

12. Insurance. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of the State of Delaware.

13. Savings Clause. If this Article EIGHTH or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) and amounts paid in settlement in

connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article EIGHTH that shall not have been invalidated and to the fullest extent permitted by applicable law.

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

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

1. General Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

2. Number of Directors; Election of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Corporation shall be established by the Board of Directors. Election of directors need not be by written ballot, except as and to the extent provided in the By laws of the Corporation.

3. Terms of Office. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the first annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; provided that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

4. Quorum. The greater of (a) a majority of the directors at any time in office and (b) one third of the number of directors fixed pursuant to Section 2 of this Article NINTH shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

5. Action at Meeting. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors unless a greater number is required by law or by this Certificate of Incorporation.

6. Removal. Subject to the rights of holders of any series of Preferred Stock, directors of the Corporation may be removed only for cause and only by the affirmative vote of the holders of at least seventy five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors.

7. Vacancies. Subject to the rights of holders of any series of Preferred Stock, any vacancy or newly created directorship in the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor and to such director's earlier death, resignation or removal.

8. Stockholder Nominations and Introduction of Business, Etc. Advance notice of stockholder nominations for election of directors and other business to be brought by stockholders before a meeting of stockholders shall be given in the manner provided by the By laws of the Corporation.

9. Amendments to Article. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By laws of the Corporation, and notwithstanding the fact that a lesser percentage may be

specified by law, the affirmative vote of the holders of at least seventy five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article NINTH.

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

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

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

CONTRAFECT CORPORATION

By: /s/ Julia Gregory
Name: Julia Gregory
Title: Chief Executive Officer

**CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
CONTRAFECT CORPORATION**

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

FIRST: That Section 6 of Article NINTH of the Amended and Restated Certificate of Incorporation of the Corporation (the "Restated Certificate") is hereby amended and restated to read, in its entirety, as follows:

"6. Removal. Subject to the rights of holders of any series of Preferred Stock, any director of the Corporation, or the entire Board of Directors of the Corporation, may be removed, with or without cause, by the affirmative vote of the holders of at least seventy five percent (75%) in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon."

SECOND: That Section 7 of Article NINTH of the Restated Certificate is hereby amended and restated to read, in its entirety, as follows:

"7. Vacancies. Subject to the rights of holders of any series of Preferred Stock, any vacancy or newly created directorship in the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy shall hold office until the next annual meeting of stockholders and until such director's successor is elected and qualified, or until such director's earlier death, resignation or removal."

THIRD: That, at an annual meeting of stockholders of the Corporation, the aforesaid amendments were duly adopted by the stockholders of the Corporation.

FOURTH: That, the aforesaid amendments were duly adopted in accordance with the applicable provisions of Sections 228 and 242 of the General Corporation Law.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by its Interim Chief Executive Officer on this 9th day of May, 2016.

CONTRAFECT CORPORATION

By: /s/ Steven C. Gilman, Ph.D.
Steven C. Gilman, Ph.D.
Interim Chief Executive Officer

**CERTIFICATE OF AMENDMENT
TO
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
CONTRAFECT CORPORATION**

Pursuant to Section 242 of the
General Corporation Law of the State of Delaware

ContraFect Corporation (the “**Corporation**”), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware,

DOES HEREBY CERTIFY THAT:

1. The Board of Directors (the “**Board**”) of the Corporation duly adopted resolutions at a meeting of the Board in accordance with Section 242 of the General Corporation Law of the State of Delaware setting forth an amendment to the Amended and Restated Certificate of Incorporation of the Corporation, as amended (the “**Certificate of Incorporation**”), and declaring such amendment to be advisable. The resolution setting forth such amendment is as follows:

RESOLVED, that the Certificate of Incorporation be amended by amending and restating the first sentence of Article FOURTH of the Certificate of Incorporation in its entirety to read as follows:

“The total number of shares of all classes of stock which the Corporation shall have authority to issue is 225,000,000 shares, consisting of (i) 200,000,000 shares of Common Stock, \$0.0001 par value per share (“Common Stock”), and (ii) 25,000,000 shares of Preferred Stock, \$0.0001 par value per share (“Preferred Stock”).”

2. The stockholders of the Corporation duly adopted such amendment at the annual meeting of stockholders held on May 2, 2017 in accordance with Section 242 of the General Corporation Law of the State of Delaware.

3. Such amendment was duly adopted in accordance with Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Company on this 2nd day of May, 2017.

CONTRAFECT CORPORATION

By: /s/ Natalie Bogdanos
Natalie Bogdanos
General Counsel, Corporate Secretary and Member of
the Interim Office of the Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
CONTRAFECT CORPORATION

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

FIRST:

That, at a meeting of the Board of Directors of the Corporation, resolutions were duly adopted recommending and declaring advisable that the Amended and Restated Certificate of Incorporation of the Corporation be amended and that such amendments be submitted to the stockholders of the Corporation for their consideration, as follows:

RESOLVED, that the first sentence of Article FOURTH of the Amended and Restated Certificate of Incorporation of the Corporation, as amended and/or restated to date, be amended and restated in its entirety to read as follows:

"That, effective on the filing of this Certificate of Amendment of Amended and Restated Certificate of Incorporation with the Office of the Secretary of State of the State of Delaware (the "Effective Time"), a one-for-ten reverse stock split of the Corporation's Common Stock (as defined below) shall become effective, pursuant to which each ten shares of Common Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Effective Time shall be reclassified and combined into one validly issued, fully-paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Effective Time and shall represent one share of Common Stock from and after the Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). The par value of the Common Stock following the Reverse Stock Split shall remain at \$0.0001 per share. No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split. In lieu thereof, (i) with respect to holders of one or more certificates which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time, upon surrender after the Effective Time of such certificate or certificates, any holder who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive a cash payment (the "Fractional Share Payment") equal to the fraction of which such holder would otherwise be entitled multiplied by the closing price per share on the trading day immediately preceding the Effective Time as reported by The Nasdaq Capital Market (as adjusted to give effect to the Reverse Stock Split); provided that, whether or not fractional shares would be issuable as a result of the Reverse Stock Split shall be determined on the basis of (a) the total number of shares of Common Stock that were issued and outstanding immediately prior to the Effective Time formerly represented by certificates that the holder is at the time surrendering and (b) the aggregate number of shares of Common Stock after the Effective Time into which the shares of Common Stock formerly represented by such certificates shall have been reclassified; and (ii) with respect to holders of shares of Common Stock in book-entry form in the records of the Company's transfer agent that were issued and outstanding immediately prior to the Effective Time, any holder who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive the Fractional Share Payment automatically and without any action by the holder.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is 150,000,000 shares, consisting of (i) 125,000,000 shares of Common Stock, \$0.0001 par value per share ("Common Stock"), and (ii) 25,000,000 shares of Preferred Stock, \$0.0001 par value per share ("Preferred Stock")."

SECOND: That, at a special meeting of stockholders of the Corporation, the aforesaid amendments were duly adopted by the stockholders of the Corporation.

THIRD: That, the aforesaid amendments were duly adopted in accordance with the applicable provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by its President and Chief Executive Officer on this 3rd day of February, 2020.

CONTRAFECT CORPORATION

By: /s/ Roger J. Pomerantz
Roger J. Pomerantz, M.D., F.A.C.P.
President and Chief Executive Officer

DESCRIPTION OF CONTRAFECT CORPORATION SECURITIES

The following description of the capital stock of ContraFect Corporation (the “Company,” “we,” “us,” and “our”) and certain provisions of our amended and restated certificate of incorporation, as amended (our “certificate of incorporation”), and amended and restated bylaws (our “bylaws”) are summaries and are qualified in their entirety by reference to the full text of our amended and restated certificate of incorporation and amended and restated bylaws, each of which is filed as an exhibit to this Annual Report on Form 10-K, and applicable provisions of the General Corporation Law of the State of Delaware (the “DGCL”). Our authorized capital stock consists of:

- 125,000,000 shares of common stock, par value \$0.0001 per share; and
- 25,000,000 shares of preferred stock, par value \$0.0001 per share.

Common Stock

Our common stock is listed on the Nasdaq Capital Market under the symbol “CFRX.”

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Holders of our common stock are not entitled to vote on any amendment to the certificate of incorporation that relates solely to the terms of one or more series of preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to the certificate of incorporation. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the exceptions provided below, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our certificate of incorporation and amended and restated bylaws also provide that our directors may be removed, with or without cause, by the affirmative vote of the holders of at least 75% in voting power of the outstanding shares of capital stock entitled to vote thereon. Subject to the rights of holder of any series of preferred stock, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. In addition, the affirmative vote of the holders of at least 75% in voting power of the outstanding shares of capital stock entitled to vote in any annual election of directors is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our certificate of incorporation or our bylaws. See below under “—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Certificate of Incorporation and Bylaws.”

Rights Upon Liquidation. In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Other Rights. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Transfer Agent

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Dividend

Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock. We have never declared or paid any 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.

Preferred Stock

Our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

Registration Rights

The shares of common stock underlying the warrants issued in connection with our initial public offering are currently registered under a registration statement that has been declared effective by the Securities and Exchange Commission, pursuant to registration rights granted to the holders in accordance with the terms of the warrants.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our certificate of incorporation and our bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that provide for payment of a premium over the market price for our shares.

Undesignated Preferred Stock. The ability of our board of directors, without action by the stockholders, to issue up to 25,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings. Our bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, the chief executive officer, or by our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Elimination of Stockholder Action by Written Consent. Our certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Removal of Directors. Our certificate of incorporation and amended and restated bylaws provide that our directors may be removed, with or without cause, by the affirmative vote of the holders of at least 75% in voting power of the outstanding shares of capital stock entitled to vote thereon. Subject to the rights of holders of any series of preferred stock, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Stockholders Not Entitled to Cumulative Voting. Our certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute. We are subject to the provisions of Section 203 of the DGCL. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to this time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a “business combination” includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Choice of Forum. Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents; (3) any action arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim against us governed by the internal affairs doctrine. Our amended and restated bylaws also provide, to the fullest extent permitted by applicable law, that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible

that a court of law could rule that the choice of forum provision contained in our amended and restated bylaws is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of Certificate of Incorporation and Bylaws. The amendment of any of the above provisions, among others and except for the above-described provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least 75% in voting power of the outstanding shares of stock entitled to vote in an annual election of directors.

The provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

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 Statements (Form S-8 Nos. 333-217943, 333-224834 and 333-231439) pertaining to the 2014 Omnibus Incentive Plan of ContraFect Corporation, and
- (3) Registration Statements (Form S-3 Nos. 333-217989 and 333-228626) of ContraFect Corporation;

of our report dated March 18, 2020, with respect to the consolidated financial statements of ContraFect Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Hartford, Connecticut
March 18, 2020

CERTIFICATION

I, Roger J. Pomerantz, M.D., F.A.C.P., 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 18, 2020

/s/ Roger J. Pomerantz, M.D., F.A.C.P.

Roger J. Pomerantz, M.D., F.A.C.P.
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Michael Messinger, certify that:

1. I have reviewed this Annual Report on Form 10-K of ContraFect Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2020

/s/ Michael Messinger

Michael Messinger
Chief Financial Officer
(Principal Financial Officer)

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

In connection with this Annual Report on Form 10-K of ContraFect Corporation (the "Company") for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Roger J. Pomerantz, M.D., F.A.C.P., 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 18, 2020

/s/ Roger J. Pomerantz, M.D., F.A.C.P.

Roger J. Pomerantz, M.D., F.A.C.P.
President and Chief Executive Officer
(Principal Executive Officer)

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

In connection with this Annual Report on Form 10-K of ContraFect Corporation (the “Company”) for the year ended December 31, 2019, 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 18, 2020

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