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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from_____ to _____

Commission file number 001-36577

ContraFect Corporation
(Exact name of registrant as specified in its charter)

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

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

N/A
(Former name, former address, and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**CFRX**	**Nasdaq Capital Market**

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, anon-accelerated filer, a smaller reporting company, or an 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The number of shares of the registrant's Common Stock outstanding as of May 10, 2021 was 39,332,721.

CONTRAFECT CORPORATION

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FORWARD LOOKING STATEMENTS

The information in this Quarterly Report on Form 10-Q contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, the sufficiency of our cash and cash equivalents and marketable securities, 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 research and development plans and ability to bring forward additional product candidates into preclinical and clinical development;
- our expectations regarding the impact of COVID-19 on our business, operations and financial performance and position;
- our contract with the Biomedical Advanced Research and Development Authority ("BARDA") (the "BARDA Contract") and any exercise of BARDA's options to extend the BARDA Contract;
- our grant awards from the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X") and the Military Infectious Diseases Research Program, United States Army Medical Research and Development Command ("USAMRDC") and the respective options in each award for continued funding;
- 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 future marketing and sales programs;
- 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 Quarterly Report on Form 10-Q, many important factors affect our ability to achieve our stated objectives and to develop and commercialize any product candidates. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. 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 Quarterly Report on Form 10-Q 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.

RISK FACTOR SUMMARY

We are providing the following summary of the numerous risks and uncertainties that affect our business, including those fully described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. You should carefully review and consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include, but are not limited to, the following:

- 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 currently have no source of product revenue and have not yet generated any revenues from product sales.
- We have a need for substantial additional funding. If we are unable to raise capital when needed or if we are unable to receive the maximum potential funding from BARDA, CARB-X or USAMRDC, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- The timing of the milestone and royalty payments we are required to make to The Rockefeller University ("Rockefeller") under certain agreements is uncertain and could adversely affect our cash flows and results of operations.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.
- The outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials.
- We are heavily dependent on the success of our leading product candidate, exebacase. If we are ultimately unable to obtain regulatory approval for exebacase or any other product candidate our business will be substantially harmed.
- If clinical trials of exebacase or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the Food and Drug Administration ("FDA") or similar international regulatory authorities 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.
- 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.
- 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 are significantly dependent on our license agreements with Rockefeller that relate to exebacase.
- We rely on Contract Research Organizations ("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.
- Even if the FDA approves exebacase or any other product candidates, adverse effects discovered after approval could adversely affect our markets.
- 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.
- Risks associated with the manufacture of our product candidates could include cost overruns, new impurities, difficulties in process or formulation development, scaling up or reproducing manufacturing processes, equipment failures, and lack of timely availability of raw materials.
- Developments by competitors may render our products or technologies obsolete ornon-competitive.
- The level of commercial success of exebacase or any other product candidates that we develop will depend upon significant market acceptance of these products among physicians and payors.
- Coverage and reimbursement may not be available for exebacase or any other product candidates that we develop.
- 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.

- 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.
- Risks related to regulatory approval of our product candidates and other legal and compliance matters.
- Risks related to employee matters and managing growth.
- Risks related to our intellectual property.
- Risks related to our securities and organizational documents.
- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.
- 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 European Union ("EU") and European Economic Area ("E.E.A").

CONTRAFECT CORPORATION
PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CONTRAFECT CORPORATION
Consolidated Balance Sheets

(in thousands, except share and per-share data)

	March 31, 2021 (unaudited)	December 31, 2020 (audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 65,246	$ 15,485
Marketable securities	20,904	27,005
Prepaid expenses and other current assets	5,089	4,165
Total current assets	91,239	46,655
Long-term marketable securities	1,030	—
Property and equipment, net	874	910
Operating lease right-of-use assets	2,747	2,811
Other assets	740	740
Total assets	$ 96,630	$ 51,116
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,872	$ 1,806
Accrued liabilities	3,420	3,610
Current portion of lease liabilities	648	644
Total current liabilities	7,940	6,060
Warrant liabilities	23,837	29,404
Long-term portion of lease liabilities	2,875	2,959
Other liabilities	73	73
Total liabilities	34,725	38,496
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, $0.0001 par value, 25,000,000 shares authorized and none outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value, 125,000,000 shares authorized, 39,332,721 shares and 27,810,161 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	4	3
Additional paid-in capital	307,395	252,908
Accumulated other comprehensive loss	(29)	(21)
Accumulated deficit	(245,465)	(240,270)
Total stockholders' equity	61,905	12,620
Total liabilities and stockholders' equity	$ 96,630	$ 51,116

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Operations
(unaudited)

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 8,021	$ 5,104
General and administrative	2,765	2,960
Total operating expenses	10,786	8,064
Loss from operations	(10,786)	(8,064)
Other income:		
Interest income	24	70
Change in fair value of warrant liabilities	5,567	416
Total other income	5,591	486
Net loss	$ (5,195)	$ (7,578)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.18)	$ (0.49)
Basic and diluted weighted average shares outstanding	28,963,594	15,332,042

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Comprehensive Loss
(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2021	2020
Net loss	$ (5,195)	$ (7,578)
Other comprehensive (loss) income:		
Unrealized (loss) gain on available-for-sale securities	(8)	9
Comprehensive loss	$ (5,203)	$ (7,569)

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Stockholders' Equity
(unaudited)

(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2020	27,810,161	$ 3	$ 252,908	$ (21)	$ (240,270)	$ 12,620
Issuance of securities in registered offering	11,500,000	1	57,499	—	—	57,500
Financing cost of sale of securities	—	—	(3,703)	—	—	(3,703)
Issuance of common stock for exercise of warrants	22,560	—	110	—	—	110
Share-based compensation	—	—	581	—	—	581
Unrealized loss on marketable securities	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(5,195)	(5,195)
Balance, March 31, 2021	39,332,721	$ 4	$ 307,395	$ (29)	$ (245,465)	$ 61,905

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2019	15,332,042	$ 2	$ 227,658	$ —	$ (212,114)	$ 15,545
Share-based compensation	—	—	633	—	—	633
Unrealized gain on marketable securities	—	—	—	9	—	9
Net loss	—	—	—	—	(7,578)	(7,578)
Balance, March 31, 2020	15,332,042	$ 2	$ 228,291	$ 9	$ (219,692)	$ 8,609

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Cash Flows
(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (5,195)	$ (7,578)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	31	42
Share-based compensation expense	581	633
Change in fair value of warrant liabilities	(5,567)	(416)
Net amortization of premium (discount) on marketable securities	150	(7)
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other current and non-current assets	(936)	934
Increase (decrease) in accounts payable, accrued liabilities and other liabilities	1,877	(1,157)
Net cash used in operating activities	(9,059)	(7,549)
Cash flows from investing activities		
Purchases of marketable securities	—	(9,999)
Proceeds from sales of marketable securities	4,913	3,996
Net cash provided by (used in) investing activities	4,913	(6,003)
Cash flows from financing activities		
Proceeds from issuance of securities	57,500	—
Payment of financing costs of securities sold	(3,703)	—
Proceeds from the exercise of warrants	110	—
Net cash provided by financing activities	53,907	—
Net increase (decrease) in cash and cash equivalents	49,761	(13,552)
Cash and cash equivalents at beginning of period	15,485	24,184
Cash and cash equivalents at end of period	$ 65,246	$ 10,632

See accompanying notes.

CONTRAFECT CORPORATION
Notes to Unaudited Consolidated Financial Statements
March 31, 2021

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 efficacy, safety, tolerability, and pharmacokinetics when used in addition to standard of care antibiotics for the treatment of *Staph aureus* bacteremia, including right-sided endocarditis in adults and adolescents. The Phase 2 data in patients with methicillin-resistant *Staph aureus* (MRSA) bacteremia treated with exebacase, which 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 the Phase 3 study design and designation as a Breakthrough Therapy from the U.S. Food and Drug Administration.

The Company has incurred losses from operations since inception as a research and development organization and has an accumulated deficit of $245.5 million as of March 31, 2021. For the three months ended March 31, 2021, the Company used $9.1 million of cash in operations. The Company has relied on its ability to fund its operations through public and private debt and equity financings, and, to a lesser extent, grant funding. Management believes that its existing cash, cash equivalents and marketable securities, will be sufficient to fund operations for at least 12 months from the issuance date of these financial statements. The Company expects operating losses and negative cash flows to continue at significant levels in the future as it continues its clinical trials. Transition to profitability is dependent upon the successful development, approval, and commercialization of its product candidates and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through additional public or private debt and equity financings, and may seek additional capital through arrangements with strategic partners or from other sources. There can be no assurances that such financing will be available to the Company on satisfactory terms, or at all.

On August 14, 2020, the Company filed a new shelf registration statement on Form S-3 (the "Form S-3") with the SEC. The Form S-3 was declared effective by the SEC on August 31, 2020. The Form S-3 allows the Company to offer and sell from time-to-time up to $150.0 million of common stock, preferred stock, debt securities, warrants or units comprised of any combination of these securities.

On March 22, 2021, the Company completed an underwritten public offering under the Form S-3 of 11,500,000 shares of its common stock, including shares sold pursuant to the fully exercised overallotment option granted to the underwriters in connection with the offering, at a public offering price of $5.00 per share, resulting in net proceeds to the Company of approximately $53.8 million after underwriting discounts and commissions and offering expenses payable by the Company.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial information as of March 31, 2021 and for the three months ended March 31, 2021 and 2020 has been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") have been condensed or omitted pursuant to such rules and regulations. The consolidated balance sheet as of December 31, 2020 was derived from the Company's audited consolidated financial statements. The Company's audited consolidated financial statements as of and for the year ended December 31, 2020, including all related disclosures and the complete listing of significant accounting policies as described in Note 2 thereof, are included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 30, 2021.

In the opinion of management, the unaudited financial information as of March 31, 2021 and for the three months ended March 31, 2021 and 2020 reflects all adjustments, which are normal recurring adjustments, necessary to present a fair statement of financial position, results of operations and cash flows. The results of operations for the three months ended March 31, 2021 are not necessarily indicative of the operating results for the full fiscal year or any future periods.

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.

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, the Company's ability to raise capital and the effects of the novel coronavirus, or COVID-19, on the Company's business, operations and financial performance and position.

During 2020, COVID-19 was declared a pandemic and spread to multiple regions across the globe, including the United States and Europe. The pandemic has had an impact, both directly and indirectly, on the Company. The full extent of the impact on the Company's business, results of operations and financial condition, including expenses, research and development costs and clinical trial progress, will depend on future developments that remain highly uncertain.

Use of Estimates

The preparation of the consolidated 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 consolidated 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, share-based compensation, warrant valuation and income taxes. The Company's actual results may differ from these estimates under different assumptions or conditions, including the effects of significant risks and uncertainties.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of 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 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 income (loss) in stockholders' equity and a component of total comprehensive income (loss) in the consolidated statements of comprehensive income (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 three months ended March 31, 2021 or 2020. There were no marketable securities that had been in an unrealized loss position for more than 12 months as of March 31, 2021 or 2020.

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

Fair Value of Financial Instruments

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

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 820, *Fair Value Measurements and Disclosures*, 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 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 is discussed in Note 4—"Fair Value Measurements."

Share-based Compensation

The Company accounts for share-based compensation in accordance with ASC 718,*Compensation—Stock Compensation,* which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employees and non-employee directors, including employee stock options. Compensation expense based on the grant date fair value is generally amortized over the requisite service period of the award on a straight-line basis.

The fair value of options is calculated using the Black-Scholes option pricing model to determine the fair value of stock options on the date of grant based on key assumptions such as stock price, expected volatility and expected term. The Company's estimates of these assumptions are primarily based on historical data and judgment regarding future trends and factors.

Government Contracts and Grant Agreements

On March 10, 2021, the Company entered into a cost-share contract (the "BARDA Contract") with BARDA, a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. The Company evaluated the BARDA Contract under Topic 606 and determined that it does not fall within the scope of Topic 606. Accordingly, the Company considered other relevant guidance and concluded that the BARDA Contract will be accounted for consistent with its accounting practices related to its existing grant agreements.

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 applicable government contract or grant agreement and the amounts will be received. For the three months ended March 31, 2021 and 2020, the Company recognized a reduction to its research and development expense in the amount of approximately $0.9 million and $1.5 million, respectively. The receivable for government contracts and grant agreements as of March 31, 2021 and December 31, 2020 was approximately $1.4 million and $1.1 million, respectively, and is included in prepaid expenses and other current assets on the balance sheet. The Company has approximately $17.5 million of committed government contract and grant agreement funding remaining as of March 31, 2021.

Leases

The Company accounts for leases in accordance with Accounting Standards Update No.2016-02-*Leases* (Topic 842). The Company determines if an arrangement is a lease at inception and recognizes right-of-use ("ROU") assets as the present value of the lease payments plus initial direct costs, if any, less any lease incentives. Assets are classified as either operating or finance ROU assets according to the classification criteria in Topic 842. The corresponding liability is computed as the present value of the lease payments at inception. 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. The Company's leases are further discussed in Note 7—"Commitments."

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.

Net (Loss) Income Per Share

Basic net (loss) income per share is calculated by dividing net (loss) income by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net (loss) income per share 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 a dilutive net loss per share calculation, stock options and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive given the Company's net loss. Common stock equivalents may also be excluded from the calculation of diluted net income per share if the exercise prices exceed the average market price for the reporting period.

Recently Adopted Accounting Pronouncements

Fair Value Measurements

On January 1, 2020, the Company adopted Accounting Standards Update No. 2018-13-*Fair Value Measurement (Topic 820)*. Topic 820 eliminates, adds and modifies certain disclosure requirements for fair value measurements. The adoption of the new guidance did not affect the Company's consolidated financial statements.

Income Taxes

On January 1, 2021, the Company adopted Accounting Standards Update No. 2019-12-*Income Taxes (Topic 740)*, which simplifies the accounting for income taxes. The adoption of the new guidance did not affect the Company's consolidated financial statements.

Revenue Recognition

On January 1, 2021, the Company adopted Accounting Standards Update No. 2014-09-*Revenue from Contracts with Customers (Topic 606).* The standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps:

(i) identify the contract with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts determined to be within the scope of Topic 606 and when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company adopted Topic 606 using the modified retrospective approach. At the time of adoption, the Company assessed all existing contracts, which consisted only of grants from not-for-profit organizations and U.S. government agencies, and concluded that they were outside of the scope of Topic 606 as they did not meet the definition of a contract under the standard. As such, adoption of Topic 606 did not impact the Company's financial position, results of operations or cash flows.

Recently Issued 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.

3. Marketable Securities

Marketable securities at March 31, 2021 consisted of the following (in thousands):

Marketable Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Corporate Debt	$ 20,932	$ 1	$ (29)	$ 20,904
Long-term:				
Corporate Debt	1,031	—	(1)	1,030
Total	$ 21,963	$ 1	$ (30)	$ 21,934

Marketable securities at December 31, 2020 consisted of the following (in thousands):

Marketable Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Corporate debt	$ 27,026	$ 6	$ (27)	$ 27,005

Corporate debt includes obligations issued by investment-grade corporations, and may include issues that have been guaranteed by governments and government agencies. Investments classified as short-term have maturities of less than one year, and investments classified as long-term are those that have maturities of greater than one year and management does not intend to liquidate within the next twelve months. All of the Company's marketable securities have an effective maturity of less than two years.

At March 31, 2021, the Company held 16 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 March 31, 2021 was approximately $19.4 million. 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 March 31, 2021.

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 March 31, 2021 and December 31, 2020 (in thousands):

	Fair Value Measurement as of March 31, 2021		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 62,516	$ —	$ —
Current marketable securities	20,904	—	—
Long-term marketable securities	1,030	—	—
Warrant liabilities	—	—	23,837
Total	$ 84,450	$ —	$ 23,837

	Fair Value Measurement as of December 31, 2020		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 12,921	$ —	$ —
Marketable securities	27,005		
Warrant liabilities	—	—	29,404
Total	$ 39,926	$ —	$ 29,404

The Company issued warrants to the purchasers of its July 27, 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 8, "Capital Structure"). The 2016 Warrants are re-measured at each subsequent reporting period and changes in fair value are 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 March 31, 2021	As of December 31, 2020
Expected volatility	75.5%	59.7%
Remaining contractual term (in years)	0.33	0.58
Risk-free interest rate	0.03%	0.09%
Expected dividend yield	— %	— %

The Company issued warrants to the purchasers of its July 25, 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 8, "Capital Structure"). The 2017 Warrants are re-measured at each subsequent reporting period and changes in fair value are 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 March 31, 2021	As of December 31, 2020
Expected volatility	103.1%	100.1%
Remaining contractual term (in years)	1.33	1.58
Risk-free interest rate	0.12%	0.12%
Expected dividend yield	— %	— %

The Company issued warrants to the purchasers of its May 27, 2020 offering (the "2020 Warrants"). The Company determined that these warrants should be classified as a liability and considered as a Level 3 financial instrument (see also Note 8, "Capital Structure"). The 2020 Warrants are re-measured at each subsequent reporting period and changes in fair value are 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 March 31, 2021	As of December 31, 2020
Expected volatility	99.8%	111.9%
Remaining contractual term (in years)	2.17	2.42
Risk-free interest rate	0.16%	0.15%
Expected dividend yield	— %	— %

Warrant liabilities

The following tables present a reconciliation of the Company's financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Balance at beginning of period	$29,404	$6,069
Decrease in fair value (1)	(5,567)	(416)
Balance at end of period	$23,837	$5,653

(1) The change in fair values of the warrant liabilities is recorded in other income in the consolidated statement of operations.

The key inputs into the Black-Scholes option pricing model are the currentper-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 liabilities.

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Accrued research and development service fees	$ 2,278	$ 801
Accrued compensation costs	588	2,069
Accrued professional fees	373	456
Accrued facilities operation expenses	157	173
Other accrued liabilities	24	111
Total accrued liabilities	$ 3,420	$ 3,610

6. Net Loss Per Share of Common Stock

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

The following table sets forth the computation of basic and diluted net loss per share for common stockholders (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2021	2020
Net loss	$ (5,195)	$ (7,578)
Weighted average shares of common stock outstanding	28,963,594	15,332,042
Net loss per share of common stock—basic and diluted	$ (0.18)	$ (0.49)

The following potentially dilutive securities outstanding at March 31, 2021 and 2020 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	March 31,	
	2021	2020
Options to purchase common stock	1,925,197	1,818,588
Warrants to purchase common stock	12,327,590	3,033,196
Total	14,252,787	4,851,784

7. Commitments

Operating Leases

In December 2010, the Company entered into a non-cancellable operating lease for office space and laboratory facilities in Yonkers, New York expiring in December 2025. In December 2011, the Company entered into an amendment which extended the 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 (in thousands):

Description	March 31, 2021	December 31, 2020
Operating lease liabilities:		
Current portion of lease liabilities	$ 648	$ 644
Long-term portion of lease liabilities	$ 2,875	$ 2,959

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 our 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, or discount rate, based on the information available at the adoption date of Topic 842. The discount rate used to determine the operating lease liability was 9.93%.

As of March 31, 2021, the maturities of our operating lease liabilities were as follows (in thousands):

	Amount
April 1, 2021 - December 31, 2021	$ 510
Year ending December 31:	
2022	693
2023	707
2024	721
2025	736
Thereafter	1,452
Total lease payments	4,819
Less: Present value adjustment	(1,296)
Operating lease liabilities	3,523

Lease costs under the terms of the Company's leases for the three months ended March 31, 2021 and 2020 were as follows (in thousands):

	March 31, 2021	March 31, 2020
Operating lease cost (1)	$153	$153
Variable lease costs (2)	30	21
Total lease cost	$183	$174

(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.

8. Capital Structure

Common Stock

As of March 31, 2021, the Company was authorized to issue 125,000,000 shares of common stock.

Follow-on Offerings

On March 22, 2021, the Company completed an underwritten public offering of 11,500,000 shares of its common stock, including shares sold pursuant to the fully exercised overallotment option granted to the underwriters in connection with the offering, at a public offering price of $5.00 per share, resulting in net proceeds to the Company of approximately $53.8 million after underwriting discounts and commissions and offering expenses payable by the Company.

On May 27, 2020, the Company completed an underwritten public offering of 11,797,752 shares of its common stock and warrants to purchase an additional 8,848,314 shares of its common stock at an exercise price of $4.90 per share. The public offering price was $4.45 for one share of common stock and an accompanying warrant to purchase 0.75 shares of common stock, resulting in net proceeds to the Company of approximately $48.9 million after underwriting discounts and commissions and offering expenses payable by the Company. The Company completed a concurrent private placement to Pfizer Inc. ("Pfizer") of 674,156 shares of common stock and an accompanying warrant to purchase an additional 505,617 shares of its common stock at an exercise price of $4.90 per share (the "Pfizer Warrant") at a price of $4.45 for one share of common stock and an accompanying warrant to purchase 0.75 shares of common stock, resulting in net proceeds to the Company of approximately $3.0 million. Warrants to purchase 22,560 shares of common stock were exercised during the quarter ended March 31, 2021 and warrant to purchase 5,850 shares of common stock were exercised during the year ended December 31, 2020.

The Company issued warrants in its 2020, 2017 and 2016 offerings. These 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 the 2020 Warrants, 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 2020 Warrants, the 2017 Warrants and 2016 Warrants to be $31.4 million, $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 $2.2 million, $0.9 million and $1.6 million of issuance costs to the 2020 Warrants, 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.

The Pfizer Warrant does not contain the same 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. Therefore, the Company determined that the Pfizer Warrant should be classified as equity in the Company's consolidated balance sheet.

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 March 31, 2021, 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 March 31, 2021 and December 31, 2020:

	March 31, 2021	December 31, 2020
Outstanding options to purchase common stock	1,925,197	1,853,841
Outstanding warrants to purchase common stock	12,327,590	12,350,293
For future issuance under the 2014 Plan	1,052,128	41,079
	15,304,915	14,245,213

9. Stock Warrants

As of March 31, 2021 and December 31, 2020, the Company had warrants to purchase the underlying common stock outstanding as shown in the table below.

	March 31, 2021	December 31, 2020
2020 Warrants	8,819,904	8,842,464
2017 Warrants	1,599,645	1,599,645
2016 Warrants	1,400,000	1,400,000
Pfizer Warrant	505,617	505,617
Other warrants (1)	2,424	2,567
Warrants to purchase common stock	12,327,590	12,350,293
Weighted-average exercise price per share	$ 9.14	$ 9.14

(1) Other warrants are comprised of warrants issued prior to the Company's initial public offering ("IPO"), generally in exchange for services rendered to the Company.

The following table summarizes information regarding the Company's warrants outstanding at March 31, 2021:

Exercise Prices	Shares Underlying Outstanding Warrants	Expiration Date
£ $10.00	9,326,092	September 1, 2021 - May 27, 2023
> $10.00 £ $20.00	1,599,645	July 25, 2022
> $20.00	1,401,853	June 27, 2021 - January 5, 2022
	12,327,590	

10. 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 stockholders on July 3, 2014. The 2014 Plan allows for the granting of incentive and non-qualified stock options, restricted stock and stock unit awards, stock appreciation rights and other performance-based awards to the Company's employees, members of the board of directors and consultants of the Company. On July 28, 2014, the effective date of the 2014 Plan,

the number of shares of common stock reserved pursuant to the 2014 Plan was 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 ended 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 2,695,373 shares of common stock have been reserved under the 2014 Plan as of January 1, 2021.

The Company recognized compensation expense for share-based compensation based on the fair value of the underlying instrument. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. A summary of stock option activity for the three months ended March 31, 2021, 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, 2020	1,853,841	$ 14.33		
Granted	103,500	5.58		
Exercised	—	—		
Expired	(32,144)	86.61		
Forfeited	—	—		
Options outstanding at March 31, 2021	1,925,197	12.65	7.48	$315,944
Vested and exercisable at March 31, 2021	1,018,597	17.26	6.29	$146,340

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 three months ended March 31, 2021 and 2020 was $5.58 and $10.78, respectively. Total compensation expense recognized amounted to $0.6 million for each of the three months ended March 31, 2021 and 2020. As of March 31, 2021, the total remaining unrecognized compensation cost related to unvested stock options was approximately $5.1 million which will be recognized over a weighted average period of approximately 2.63 years.

The following assumptions were used to compute the fair value of stock options granted during the period:

	Three Months Ended March 31,	
	2021	2020
Risk free interest rate	0.72%	1.35%
Expected dividend yield	—	—
Expected term (in years)	6.06	6.06
Expected volatility	96.3%	94.0%

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.

Expected term—The Company based expected term on the midpoint of the vesting period and the contractual term of each respective option grant

Expected volatility—The Company estimated the expected volatility based on the Company's historical volatility data.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition in conjunction with the information set forth in our financial statements and the notes to those statements included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed by us with the Securities and Exchange Commission ("SEC") on March 30, 2021.

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 cidality, we believe lysins are differentiated by their other hallmark features, which include the demonstrated ability to eradicate biofilms and synergistically boost the efficacy of conventional antibiotics in animal models. Lysins that target *Staph aureus* and other gram-positive pathogens 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 have shown 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 some *Burkholderia* species. The highly differentiated properties of DLAs have shown these agents to be complementary to and synergistic with conventional antibiotics enabling the potential use of these agents in addition to traditional 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 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 initial public offering ("IPO"), ourfollow-on public offerings, private placements of securities, and grant funding received. On March 22, 2021, we completed an underwritten public offering of 11,500,000 shares of our common stock, including shares sold pursuant to the fully exercised overallotment option granted to the underwriters in connection with the offering, at a public offering price of $5.00 per share of common stock, resulting in net proceeds of approximately $53.8 million after underwriting discounts and commissions and offering expenses payable by us.

On March 10, 2021, we executed a cost-share contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. Under the terms of the BARDA Contract, the Company will receive $9.8 million in initial funding and up to an additional $77.0 million. The initial funding will be used to support our ongoing pivotal Phase 3 DISRUPT superiority trial of exebacase. Under the terms of the agreement, and if supported by Phase 3 DISRUPT study data, BARDA may provide the Company with additional funding upon achievement of key milestones to continue the advancement of exebacase through FDA product approval and completion of post-approval commitments. The BARDA Contract contains terms and conditions that are customary for contracts with BARDA of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience. As a government contractor, we are subject to complex and wide-ranging federal and agency-specific regulations and contractual requirements. The costs of compliance with these requirements may be significant. Failure to comply with government contracting requirements could result in termination of our contract or the imposition of penalties.

We have never been profitable and our operating loss for the three months ended March 31, 2021 was $5.2 million. Our net losses were $28.2 million and $12.8 million for the years ended December 31, 2020 and 2019, 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.

During 2020 COVID-19 was declared a pandemic and spread to multiple regions across the globe, including the United States and Europe. The pandemic has had an impact, both directly and indirectly, on the Company. We adjusted our business operations, with a majority of our employees working remotely, and as a result, incurred minor delays in internal research activities. Our Phase 3 DISRUPT clinical trial has also experienced some delays as a result of the COVID-19 pandemic, as clinical sites have experienced periodic delays to new patient enrollment due to institutional and clinical demands as dictated by local conditions. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including expenses, research and development costs, procurement of raw materials for our supply chain and clinical trial progress, will depend on future developments that are highly uncertain.

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, performance bonuses, benefits, travel andnon-cash share-based compensation expense;
- external research and development expenses incurred under arrangements with third parties such as contract research organizations, or CROs, contract manufacturers, consultants and academic institutions; and
- facilities and laboratory and other supplies.

We expense research and development costs to operations as incurred. We account fornon-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.

In December 2019, we initiated the Phase 3 DISRUPT (Direct Lysis of*Staph aureus* Resistant Pathogen Trial) study of exebacase. 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 *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 standard-of-care (“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. We obtained concurrence with the U.S. Food and Drug Administration (“FDA”) on the Phase 3 study protocol at an End-of-Phase 2 meeting with the FDA in September 2019, 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.

We completed a Phase 2 superiority study of exebacase that evaluated its safety, tolerability, efficacy and pharmacokinetics ("PK") when used in addition to background SOC antibiotics compared to SOC antibiotics alone for the treatment of *Staph aureus* bacteremia, including endocarditis in adult patients. The results from this study showed clinically meaningful improvement in clinical responder rates among patients treated with exebacase in addition to SOC antibiotics compared to SOC antibiotics alone. In the primary efficacy analysis population of 116 patients with documented *Staph aureus* bacteremia, including endocarditis, who received a single intravenous ("IV") infusion of blinded study drug, the clinical responder rate 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 also 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.

We believe these data 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 the Phase 2 superiority 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 the FDA to grant 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. 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 expedited meetings and interactions with the FDA and the potential for priority review, over the Fast Track designation granted to exebacase in August 2015.

On March 10, 2021, we entered into a cost-share contract (the "BARDA Contract") with BARDA, a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. Under the BARDA Contract, we will receive funding of up to an estimated $86.8 million to advance the development of exebacase. The base period for the BARDA Contract includes government funding of up to $9.8 million to reimburse expenses for approximately one year to support the conduct of the ongoing Phase 3 clinical trial and futility analysis. Following successful completion of the base period, the BARDA Contract provides for approximately $77.0 million of additional BARDA funding for five option stages in support of the completion of the Phase 3 clinical trial of exebacase, further clinical and non-clinical studies, manufacturing, supply chain, clinical, regulatory and administrative activities. The contract period-of-performance (base period plus option exercises) is up to approximately six years. The BARDA Contract contains terms and conditions that are customary for contracts with BARDA of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

In addition to the ongoing Phase 3 DISRUPT study of exebacase, we initiated an expanded access program to provide exebacase for the treatment of persistent bacteremia caused by methicillin-resistant Staphylococcus aureus (MRSA) in COVID-19 patients and continued 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.

Other Programs

We have made further advancements with our novel lytic agents across our portfolio. 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. In June 2019, we were 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. In July 2020, we were awarded up to $18.9 million in funding from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator), including initial funding of $4.9 million, in support of the advancement of CF-370 through IND-enabling activities toward future Phase 1 clinical trials. We expect CF-370 to be our next molecule in clinical studies. In April 2021, the United States Patent and Trademark Office issued U.S. Patent No. 10,988,520 for CF-370. This patent, which is owned solely by the Company, expires in March 2039, and is the latest U.S. patent to issue from the Company's DLA patent portfolio.

Beyond our lysin programs, we continue our research to advance potential product candidates from our amurin peptide platform. We are evaluating our most promising amurins in preclinical animal studies with the goals of determining our next product candidate and moving this program towards clinical studies as soon as possible. In March 2019, we were awarded up to $6.9 million of funding from CARB-X to support the amurin peptide program, including initial funding of $1.75 million.

In addition, we have entered into an initial funding agreement with the Cystic Fibrosis Foundation to investigate the potential utility of DLAs, including CF-370 and amurin peptides, against resistant Gram-negative pathogens which afflict Cystic Fibrosis ("CF") patients. The first stage of the agreement will profile funding for the in vitro activity of CF-370 and amurin peptides against bacterial specimens obtained from CF patients at different stages of disease. With supportive data, ContraFect plans to evaluate future clinical development of CF-370 and/or amurin peptides as therapeutic candidates for the treatment of exacerbations in CF lung disease.

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 as well as research projects. In the quarters ended March 31, 2021 and 2020, we recorded approximately $8.0 million and $5.1 million, respectively, of research and development expenses. A breakdown of our research and development expenses by category is shown below. We do not currently utilize a formal time or laboratory project expense allocation system to allocate employee-related expenses, laboratory costs or depreciation to any particular project. Accordingly, we do not allocate these expenses to individual projects or product candidates. However, we do allocate some portions of our research and development expenses in the product development, external research and licensing and professional fees categories to exebacase as shown below.

The following table summarizes our research and development expenses by category for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Product development	$5,710	$ 4,254
Personnel related	1,828	1,014
Professional fees	904	691
Laboratory costs	322	317
Share-based compensation	151	164
External research and licensing costs	31	119
Expenses reimbursed by grants	(925)	(1,455)
Total research and development expense	$8,021	$ 5,104

The following table summarizes our research and development expenses by program for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Exebacase	$5,333	$ 3,696
CF-370	546	233
Other research and development	1,088	1,452
Personnel related and share-based compensation	1,979	1,178
Expenses reimbursed by grants	(925)	(1,455)
Total research and development expense	$8,021	$ 5,104

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

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

A change in the outcome of any of these variables with respect to the development of exebacase or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of exebacase or any such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of exebacase or if we experience significant delays in enrollment in any clinical trials of exebacase, we could be required to expend significant additional financial resources and time on the completion of the clinical development of exebacase.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, includingnon-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.

Other Income

Other income consists of changes in the fair values of our warrant liabilities and interest income earned on our cash and cash equivalents and marketable securities.

Critical Accounting Policies and Use of 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.

During the three-month period ended March 31, 2021, there have been no material changes to our critical accounting policies from the information provided in the section "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K for the year ended December 31, 2020 filed by us with the SEC on March 30, 2021

Results of Operations

Comparison of Three Months Ended March 31, 2021 and 2020

The following table summarizes key components of our results of operations for the periods indicated (in thousands).

	Three Months Ended March 31,		Dollar Change
	2021	2020	
Operating expenses:			
Research and development	$ 8,021	$ 5,104	$ 2,917
General and administrative	$ 2,765	$ 2,960	$ (195)
Other income	$ 5,591	$ 486	$ 5,105

Research and Development Expenses

Research and development expenses were $8.0 million for the three months ended March 31, 2021 compared with $5.1 million for the three months ended March 31, 2020, an increase of $2.9 million. This increase was primarily attributable to a $1.3 increase in spending on clinical activities as we continued to enroll patients and expand the number of clinical sites in the Phase 3 DISRUPT study of exebacase and a $0.8 increase in spending on non-clinical studies of CF-370 and our other preclinical programs. Finally, we increased expenditures on personnel and consultants by $0.8 million as we have expanded headcount to support the continued progression of our programs across our portfolio.

General and Administrative Expenses

General and administrative expenses were $2.8 million for the three months ended March 31, 2021, compared with $3.0 million for the three months ended March 31, 2020, a decrease of $0.2 million. This was due primarily to a decrease in costs incurred for intellectual property and general corporate legal fees.

Other Income

Other income was $5.6 million for the three months ended March 31, 2021, compared with $0.5 million for the three months ended March 31, 2020, an increase of $5.1 million. The increase in other income was due primarily to the non-cash gain of $5.6 million in the current year period compared to $0.4 million in the prior year period, resulting from the change in fair value of our warrant liabilities in each reporting period.

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 $257.8 million, $9.6 million from the exercise of the Class B Warrants issued in our IPO, $26.0 million from the sale of securities in private placements and the receipt of $9.8 million of grant funding.

As of March 31, 2021, we had approximately $87.2 million in cash, cash equivalents and marketable securities.

On August 14, 2020, we filed a new shelf registration statement on FormS-3 (the "Form S-3") with the SEC. The FormS-3 was declared effective by the SEC on August 31, 2020. The Form S-3 allows us to offer and sell fromtime-to-time up to $150.0 million of common stock, preferred stock, debt securities, warrants or units comprised of any combination of these securities. On March 22, 2021, we completed an underwritten public offering under the Form S-3 of 11,500,000 shares of our common stock, including shares sold pursuant to the fully exercised overallotment option granted to the underwriters in connection with the offering, at a public offering price of $5.00 per share of common stock, resulting in net proceeds of approximately $53.8 million after underwriting discounts and commissions and offering expenses payable by us. The terms of any future offerings under the Form S-3 will be established at the time of such offering and will be described in a prospectus supplement filed with the SEC prior to the completion of any such offering. There can be no assurances that any such financing will be available to us on satisfactory terms, or at all.

We have also been successful obtaining grants to supplement our financings withnon-dilutive funding, including grants from CARB-X, USAMRDC and our cost-sharing contract with BARDA. We may continue to pursue further non-dilutive funding opportunities. In addition, there can be no assurances that either BARDA, CARB-X or USAMRDC will provide the maximum potential funding to the Company.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	$ (9,059)	$ (7,549)
Investing activities	$ 4,913	$ (6,003)
Financing activities	$ 53,907	$ —

Net cash used in operating activities

Net cash used in operating activities resulted primarily from our net losses adjusted fomon-cash charges and changes in the components of working capital. Net cash used in operating activities for the three months ended March 31, 2021 increased by $1.5 million compared to the same period in 2020, due primarily to payment of amounts owed to our contract research and manufacturing organizations in support of our Phase 3 DISRUPT trial of exebacase in the first quarter of 2021.

Net cash provided by (used in) investing activities

Net cash provided by investing activities for the three months ended March 31, 2021 were from the proceeds received from the maturities of these marketable securities. Net cash used in investing activities for the three months ended March 31, 2020 was driven by the purchases of marketable securities, less proceeds received from the maturities of marketable securities.

Net cash provided by financing activities

Net cash provided by financing activities for the three months ended March 31, 2021 resulted from the $53.8 million of net proceeds from our March 22, 2021 offering of securities and $0.1 million of proceeds from the exercise of warrants. There was no net cash provided by (used in) financing activities for the three months ended March 31, 2020.

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.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund operations for at least 12 months from the issuance date of these financial statements. 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 and grant funding but there can be no assurances that such financing or grants 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 ongoing effects of COVID-19 on, among other things, our clinical trials, manufacturing and sourcing of raw materials, financial performance, business and operations;
- the extent to which we acquire or in-license other products and technologies;
- the timing and amount of actual reimbursements under the BARDA Contract;
- 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, grants, government contracts, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or other securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We incur significant costs as a public company, including, but not limited to, increased personnel costs, increased directors fees, increased directors and officers insurance premiums, audit and legal fees, investor relations and external communications fees, expenses for compliance with the Sarbanes-Oxley Act and rules implemented by the SEC and Nasdaq and various other costs and expenses.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations- Contractual Obligations and Commitments" in our Annual Report on Form 10-K filed with the SEC on March 30, 2021.

Effects of Inflation

We do not believe that inflation or changing prices had a significant impact on our results of operations for any periods presented herein.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we are currently not party to, any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 March 31, 2021, we had cash, cash equivalents and marketable securities of $87.2 million. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the fair value of our cash equivalents or marketable securities. If a 10% change in interest rates were to have immediately occurred on March 31, 2021, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

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

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

ITEM 4. 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 Quarterly Report on Form 10-Q of the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2021.

Changes in Internal Control

As required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of our internal control over financial reporting to determine

whether any changes occurred during the quarter ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded that there were no such changes during the quarter ended March 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RISK FACTORS

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, and to a lesser extent, grant funding. 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 loss from operations for the three months ended March 31, 2021 was $5.2 million and our losses from operations were $28.2 million and $12.8 million for the years ended December 31, 2020 and 2019, 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.

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. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms.

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;
- the timing and amount of actual reimbursements under the BARDA Contract;
- the continuation of funding under our CARB-X and USAMRDC grants;

- 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;
- the effects of the COVID-19 pandemic on, among other things, our financial performance, business and operations.

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, grants, 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.

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.

If BARDA were to eliminate, reduce, or delay funding for our BARDA Contract, we would experience a negative impact on our programs associated with such funding.

On March 10, 2021, we executed a cost-share contract from BARDA, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. Under the terms of the BARDA Contract, the Company will receive $9.8 million in initial funding during the base period. Following successful completion of the base period, the BARDA Contract provides for approximately $77.0 million of additional BARDA funding for five option stages in support of the completion of the Phase 3 clinical trial of exebacase, further clinical and non-clinical studies, manufacturing, supply chain, clinical, regulatory and administrative activities. The BARDA Contract contains terms and conditions that are customary for contracts with BARDA of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience. If BARDA were to eliminate, reduce, or delay funding under the BARDA Contract or prohibit reimbursement of some of our incurred costs, we would have to seek additional funding to complete our ongoing Phase 3 DISRUPT superiority trial of exebacase or advance exebacase through FDA product approval and completion of post-approval commitments.

The BARDA Contract includes special requirements, which subject us to the risk of a reduction or loss of funding.

Our BARDA Contract subjects us to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement. In addition, if we are found to be in violation of the BARDA Contract, it could result in termination. If BARDA terminates the BARDA Contract with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, a significant negative impact on our cash flows and operations could result.

U.S. government contracts, such as our BARDA Contract, generally contain unfavorable termination provisions, which may subject us to additional risks as compared to our competitors that have not entered into such contracts. These risks include the ability of the U.S. government to unilaterally:

- terminate or reduce the scope of our contract with or without cause;
- interpret relevant regulations (federal acquisition regulation clauses);
- require performance under circumstances that may not be favorable to us;
- require an in-process review where the U.S. government will review the project and its options under the contract;
- control the timing and amount of funding, which impacts the development progress of exebacase; and
- audit and object to our contract-related costs and fees, including allocated indirect costs.

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, 2020 and 2019, we had federal and state net operating loss carryforwards of approximately $234.3 million and $201.3 million, respectively, and federal research and development credits of approximately $3.8 million and $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

The COVID-19 pandemic or other pandemics, epidemics or outbreaks of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials.

During 2020, the novel coronavirus disease, COVID-19, was declared a pandemic and spread across the globe, including the United States and Europe. The outbreak and government measures taken in response have also had a significant impact on the economy and, to a lesser extent, both directly and indirectly, on our business. We adjusted our business operations for a short period, with a majority of our employees working remotely, and as a result, incurred minor delays in internal research activities. Our Phase 3 DISRUPT clinical trial has also experienced some delays as a result of the COVID-19 pandemic, as clinical sites experience periodic delays in new patient enrollment due to institutional and clinical demands as dictated by local conditions.

As a result of the COVID-19 pandemic or other pandemic, epidemic or outbreak of an infectious disease, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contractingCOVID-19 or other health conditions or being forced to quarantine;

- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy and safety data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- interruption of, or delays in receiving, supplies of our products and product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in supply or delivery systems;
- delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays in preclinical studies due to restricted or limited operations resulting from restrictions on our or on-site activities; and
- interruption or delays of our sourced discovery and clinical activities.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic further impacts our business, preclinical studies, manufacturing, and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic and future waves of infection, the availability, adoption and effectiveness of any new vaccines, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. Additionally, concerns over the economic impact of COVID-19 pandemic have caused extreme volatility in financial and other capital markets which has and may continue to adversely impact our stock price and our ability to access capital markets.

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 may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of a BLA from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective, or in the case of biologics, safe, pure, and potent, for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program.

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. In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in obtaining regulatory review and approval. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

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 (or independent Ethics Committees ("IECs")) 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 (or IECs) 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;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs (or IECs) to suspend or terminate the trials; or
- the effects of the COVID-19 pandemic.

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

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

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

Our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. 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.

If any serious adverse events occur, clinical trials or commercial distribution of any product candidates or products we develop could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, deny approval of, or require us to cease selling any product candidates or products for any or all targeted indications. If we are required to delay, suspend or terminate any clinical trial or commercialization efforts, the

commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated. Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling in our clinical trials, our research and development efforts and business, financial condition, and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. In addition, our Phase 3 DISRUPT clinical trial has experienced some delays as a result of the COVID-19 pandemic, as some clinical sites in high impact areas have delayed new patient enrollment as dictated by local conditions. We expect that such delays could adversely affect the expected timelines for our product development and approval process and may adversely affect our business, financial condition and results of operations. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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 GCPs requirements, which are regulations and guidelines enforced by the FDA and comparable regulatory authorities 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 (or similar foreign authorities) may require us to perform additional clinical trials before approving our product candidates. We cannot assure you that, upon inspection, the FDA (or similar foreign authorities) 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 ourmon-clinical, preclinical or clinical programs. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize exebacase or any other product candidate that we seek to develop. As a result, our financial results and the commercial prospects for exebacase or any other product candidate that we seek to develop would be harmed, our costs could increase and our ability to generate revenues could be delayed or ended.

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 for the treatment of for the treatment of MRSA bacteremia, including right-sided endocarditis, when used in addition to SOC anti-staphylococcal antibiotics in adult patients, 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 or biologics 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 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, if the relevant criteria are met.

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 rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. For example, we employ the services of Fujifilm UK to supply the active pharmaceutical ingredient for exebacase. We have not yet validated the manufacturing processes or contractually secured our commercial supplies. We do not currently have long-term supply agreements. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, on January 21, 2021, the President of the United States signed an executive order entitled “Executive Order on a Sustainable Public Health Supply Chain” (the “Executive Order”) which “directs immediate actions to secure supplies necessary for responding to the COVID-19 pandemic, so that supplies are available, and remain available to the Federal Government and State, local, Tribal and territorial authorities, as well as to America’s health care workers, health systems, and patients.” The Defense Production Act (the “DPA”), which empowers the President to issue the Executive Order, allows him to direct private companies to prioritize orders from the federal government. The Executive Order directed the President’s administration to identify shortfalls in the supply of materials needed for the pandemic response, and to use the DPA to address them, if necessary. The extent to which the COVID-19 pandemic and the invocation of the DPA impacts our ability to procure sufficient supplies for the development or manufacture of our products and product candidates will depend on the severity and duration of the spread of the virus, and any actions undertaken to contain COVID-19 or treat its effects.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets andknow-how.

In the fourth quarter of 2020, we were notified by Fujifilm UK that they experienced equipment failures that would impact their manufacturing timelines. To mitigate delays, Fujifilm UK has proposed the transition of the exebacase manufacturing process to Fujifilm USA. We are currently in the transition process and expect to ultimately complete the process validation and initial commercial manufacturing of drug substance with Fujifilm USA in support of a potential BLA submission for exebacase. While steps have been and will continue to be taken to mitigate risks, we may still experience delays to the manufacturing timeline.

If Fujifilm UK, Fujifilm USA, 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 may experience delays. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers may be affected, which could disrupt their activities and, as a result, we could face difficulty sourcing key components necessary to produce supply of our product candidates. As a result, 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.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners, in particular Fujifilm UK and Fujifilm USA, for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

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

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

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

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

- the indications for which the product is approved;
- acceptance by physicians and payors of each product as a safe and effective treatment;
- the availability, efficacy and cost of competitive drugs;
- the effectiveness of our or any third-party partner’s sales force and marketing efforts;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;

- the availability of adequate reimbursement by third parties, such as insurance companies and other health care payors, and/or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA-approved labeling (or similarly approved labeling by foreign authorities); 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 (or similar foreign authorities) 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.

Since its enactment, there have been judicial, executive 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. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how or other efforts, if any, 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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.

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 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.

Even if our product candidates receive regulatory approval, they will be subject to significant post- marketing regulatory requirements and oversight.

Even if we obtain regulatory approval in (or outside) the United States, the FDA (or similar foreign authorities) 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.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For instance, the EU has adopted the Clinical Trials Regulation ("CTR") in April 2014, which is expected to come into application in 2022. The CTR will be directly applicable in all EU member states, repealing the current Clinical Trials Directive. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new CTR becomes applicable. The extent to which ongoing clinical trials will be governed by the CTR will depend on when the CTR becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the CTR becomes applicable the CTR will at that time begin to apply to the clinical trial. The CTR harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which will notably contain a centralized EU portal and database.

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. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion ofoff-label uses.

If any of our product candidates are approved and we are found to have improperly promotedoff-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging inoff-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. 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, such as the European Medicines Agency following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs and biologics or modifications to cleared or approved drugs/biologics 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.

Separately, in response to the global pandemic ofCOVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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.

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, including the COVID-19 pandemic, or natural disasters including earthquakes, typhoons, floods and fires; and
- failure to comply with the rules and regulations of the Office of Foreign Asset Control, the Foreign Corrupt Practices Act and other applicable anti-bribery rules and regulations in other jurisdictions.

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

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

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

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

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

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

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

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

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

Our product candidates may face competition sooner than anticipated.

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

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the12-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. In the EU, these exclusivity periods are even shorter. Upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic/biosimilar application. During the additional two-year period of market exclusivity, a generic/biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic/biosimilar product can be marketed until the expiration of the market exclusivity.

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;
- 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. 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;
- HIPAA, 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 (as defined by statute) and their immediate family members and payments or other transfers of value made to such physician owners. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

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.

Unfavorable consequences from the most recent and prior investigations by plaintiff attorneys could damage our reputation and disrupt our business. The adverse outcome of any litigation or arbitration proceedings commenced by or against us could have a material adverse effect on our business and impede the achievement of our development and commercialization objectives.

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

The United Kingdom's withdrawal 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. On December 24, 2020, the United Kingdom and the EU announced that they had agreed to the terms of their future trading relationship in the EU-UK Trade and Cooperation Agreement, or TCA, which became binding on both the EU and the United Kingdom on January 1, 2021. While agreement on the terms of the TCA has avoided a "no deal" Brexit scenario, and provides in principle for quota- and tariff-free trading of goods, it is nevertheless expected that the TCA will result in the creation of non-tariff barriers (such as increased shipping and regulatory costs and complexities) to the trade in goods between the United Kingdom and the EU. Further, the TCA does not provide for the continued free movement of services between the UK and the EU and imposes additional restrictions on the free movement of people between the UK and the EU. The TCA includes provisions affecting pharmaceutical businesses (including on customs and tariffs). In addition, there are some specific provisions concerning pharmaceuticals. These include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards. Significant political and economic

uncertainty remains how much the relationship between the United Kingdom and EU will differ as a result of the United Kingdom's withdrawal. 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.

Further, the United Kingdom's withdrawal from the EU has resulted in the relocation of the EMA from the United Kingdom to the Netherlands. This relocation has caused, and may continue to cause, disruption in the administrative and medical scientific links between the EMA and the UK Medicines and Healthcare products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the 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 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 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.

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, including due to the effects of the COVID-19 pandemic. 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 Quarterly 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 stockholders;
- significant lawsuits, including patent or stockholder litigation;
- general political, market and economic conditions, including as a result of health pandemics; and
- other events or factors, many of which are beyond our control.

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

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 May 10, 2021, we have approximately 39.3 million shares of common stock outstanding, of which approximately 37.4 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 12.4 million shares of our common stock outstanding as of May 10, 2021. Approximately 11.9 million shares of common stock underlying warrants will be freely tradable upon exercise unless held by our affiliates.

We have registered 1,918,794 shares of our common stock as of May 10, 2021 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.

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, no longer qualify under the SEC exemption for low-revenue "smaller reporting companies", 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.

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.

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 stockholder 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. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. 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 EU and EEA.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, the CCPA went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the CPRA recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. For example, the GDPR repealed the Data Protection Directive (95/46/EC) and is directly applicable in all E.E.A. countries (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland) since its effective date of May 25, 2018. The GDPR applies to companies established in the EEA, as well as companies that are not established in the EEA and which collect and use personal data in relation to offering goods or services to, or monitoring the behavior of, individuals located in the EEA, 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 EEA countries derogations for certain matters and, accordingly, we are also subject to national laws relating to the processing of certain data such as genetic data, biometric data and health data. It imposes a strict data protection compliance regime including: providing detailed disclosures about how personal data is collected and processed (in a concise, intelligible and easily accessible form); demonstrating that valid consent or another an appropriate legal basis is in place or otherwise exists to justify data processing activities; appointing data protection officers in certain circumstances; granting new rights for data subjects in regard to their personal data (including the right to be “forgotten” and the right to data portability), as well as enhancing current rights (e.g., data subject access requests); introducing the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches; imposing limitations on retention of personal data; maintaining a record of data processing; defining for the first time pseudonymized (i.e., key-coded) data; and complying with principal of accountability and complying with the obligation to demonstrate compliance through policies, procedures, training and audit.

We are also subject to EU rules with respect to cross-border transfers of personal data out of the E.E.A. These rules are under scrutiny from time to time. For example, the Court of Justice of the European Union (the "CJEU") ruled in July 2020 that the EU-U.S. Privacy Shield was invalid. The EU-U.S. Privacy Shield Framework was designed by the U.S. Department of Commerce and the European Commission to provide companies operate in both regions with a mechanism to comply with data protection requirements when transferring personal data from the European Union to the United States in support of numerous business activities. Following the decision of the CJEU, the EU-U.S. Privacy Shield can no longer be used as a legal basis for transferring personal data from the European Union to the United States and the CJEU made clear that reliance on standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield) may not necessarily be a sufficient alternative. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, identifying an alternative data transfer mechanism may lead to additional costs, complaints or regulatory investigations or fines. If we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we conduct our clinical trials and could adversely affect our business and financial results.

Further, following the United Kingdom's withdrawal from the EU and the EEA and the end of the transition period on December 31, 2020, we will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four to six-month grace period agreed in the EU and UK Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on 19 February 2021. If adopted, the decision will enable data transfers from EU member states to the UK for a four-year period, subject to subsequent extensions.

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 for companies: up to the greater of 4% of total annual worldwide turnover of the preceding financial year, 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 EU privacy laws on cookies, ande-marketing. The EU is in the process of replacing thee-Privacy Directive with a new set of rules taking the form of a regulation, which will be directly implemented to all EEA countries. 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 for certain breaches). 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 2021, after which a two-year transition period will follow before it is in force. We are likely to be required to expend further capital and other resources to ensure compliance with these changing laws and regulations.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

General Risk Factors

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.

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

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

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatentedknow-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 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 stockholder 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 stockholders 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.

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.

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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit No.	Description
3.1	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 (incorporated by reference to Exhibit 3.1 of the Company' Form 10-K (File No. 001-36577) filed with the SEC on March 18, 2020)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Form 10-Q (File No. 001-36577) filed with the SEC on November 13, 2020)
10.1	Cost-Sharing Agreement by and between ContraFect Corporation and the BioMedical Advanced Research and Development Authority, dated March 10, 2021 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36577) filed with the SEC on March 12, 2021).
31.1*	Certification of Principal 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 Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith
** Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ContraFect Corporation

Date: May 14, 2021

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

Date: May 14, 2021

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

Exhibit 31.1

CERTIFICATIONS

I, Roger J. Pomerantz, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ContraFect Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-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: May 14, 2021

/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)

Exhibit 31.2

CERTIFICATIONS

I, Michael Messinger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ContraFect Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-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: May 14, 2021

/s/ Michael Messinger

Michael Messinger
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS

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

I, Roger J. Pomerantz, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of ContraFect Corporation for the quarterly period ended March 31, 2021, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of ContraFect Corporation.

Date: May 14, 2021

/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)

I, Michael Messinger, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of ContraFect Corporation for the quarterly period ended March 31, 2021, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of ContraFect Corporation.

Date: May 14, 2021

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

The foregoing certification is not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act and is not to be incorporated by reference into any filing of ContraFect Corporation under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.