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 June 30, 2023

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, a non-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 August 10, 2023 was 10,704,803.

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, future revenues, our ability to continue as a going concern, 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, make regulatory filings and ultimately obtain U.S. Food and Drug Administration ("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 continued listing on the Nasdaq Capital Market;
- our expectations regarding the impact of COVID-19 on our business, operations and financial performance and position;
- our grant award from the Military Infectious Diseases Research Program, United States Army Medical Research and Development Command ("USAMRDC");
- 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;
- our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern;
- anticipated reductions in operating expenses;
- 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 and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include 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.
- Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern.
- 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, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts, and we may be forced to sell or liquidate our business. Any financial or strategic alternative we pursue may not be successful.
- 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.
- Any 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 candidates. If we are ultimately unable to obtain regulatory approval for any of our product candidates, our business will be substantially harmed.
- If clinical trials of any of our product candidates that we develop fail to demonstrate safety and efficacy, or the manufacturing for the commercial supply of drug substance or drug product fails to demonstrate robustness, stability, purity and potency to the satisfaction of the 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 our product candidates.
- We may be required to suspend or discontinue clinical trials due to adverse side effects or other safety risks that could preclude approval of any of our 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 any of our product candidates.
- We rely on contract manufacturing organizations ("CMOs") to manufacture clinical and commercial supplies of our product candidates. In addition to the 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, 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 any of our product candidates.
- Even if the FDA approves any of our 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.
- Developments by competitors may render our products or technologies obsolete or non-competitive.

•The level of commercial success of any of our 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 any of our product candidates that we develop, including as a result of healthcare reform measures.

•We may not successfully execute or achieve the expected benefits of our restructuring program and other cost saving measures we may take in the future, and our efforts may result in further actions and may adversely affect our business, financial condition and results of operations.

•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 our operations.

•Risks related to our intellectual property.

•Risks related to our securities and organizational documents.

•We do not expect that we will meet certain of Nasdaq Capital Market's continued listing requirements and other Nasdaq rules. If we are unable to increase our stockholders' equity, we will be delisted. Delisting could negatively affect the price of our common stock and could make it more difficult for us to sell securities in a future financing or for you to sell our common stock.

•Security breaches, cybersecurity attacks, failure of our data and personal information protections and those of third parties and other disruptions could compromise our information and technology systems 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 data)

	June 30, 2023 (unaudited)	December 31, 2022 (audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 14,422	$ 8,907
Marketable securities	—	4,775
Prepaid expenses	1,521	1,382
Other current assets	571	2,642
Total current assets	16,514	17,706
Property and equipment, net	556	627
Operating lease right-of-use assets	2,077	2,241
Other assets	105	105
Total assets	$ 19,252	$ 20,679
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 11,557	$ 13,671
Accrued and other current liabilities	4,239	6,498
Current portion of lease liabilities	677	671
Total current liabilities	16,473	20,840
Warrant liabilities	1,861	9,299
Long-term portion of lease liabilities	1,988	2,210
Other liabilities	38	182
Total liabilities	20,360	32,531
Commitments and contingencies	—	—
Stockholders' deficit:		
Preferred stock, $0.0001 par value, 25,000,000 shares authorized and none issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value, 125,000,000 shares authorized, 10,704,803 and 594,983 shares issued and outstanding at June 30, 2023 and December 31, 2022	1	1
Additional paid-in capital	333,535	313,884
Accumulated other comprehensive loss	—	(32)
Accumulated deficit	(334,644)	(325,705)
Total stockholders' deficit	(1,108)	(11,852)
Total liabilities and stockholders' deficit	$ 19,252	$ 20,679

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Operations
(unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 4,870	$ 16,760	$ 10,165	$ 29,485
General and administrative	3,105	3,266	6,668	6,520
Total operating expenses	7,975	20,026	16,833	36,005
Loss from operations	(7,975)	(20,026)	(16,833)	(36,005)
Other income (expense):				
Interest income, net	114	21	201	55
Other expense	(96)	—	(96)	—
Change in fair value of warrant liabilities	389	1,916	7,789	(2,296)
Total other income (expense)	407	1,937	7,894	(2,241)
Net loss	$ (7,568)	$ (18,089)	$ (8,939)	$ (38,246)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.94)	$ (36.79)	$ (3.04)	$ (77.79)
Basic and diluted weighted average shares outstanding	3,901,839	491,626	2,943,979	491,626

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Comprehensive Loss
(unaudited)

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (7,568)	$ (18,089)	$ (8,939)	$ (38,246)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	—	11	32	(129)
Comprehensive loss	$ (7,568)	$ (18,078)	$ (8,907)	$ (38,375)

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Stockholders' (Deficit) Equity
(unaudited)

(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount				
Balance, December 31, 2022	594,983	$ 1	$ 313,884	$ (32)	$ (325,705)	$ (11,852)
Issuance of securities in registered offering	128,000	—	10,000	—	—	10,000
Financing cost of sale of securities	—	—	(883)	—	—	(883)
Issuance of common stock for exercise of pre-funded warrants	842,937	—	5	—	—	5
Stock-based compensation	—	—	932	—	—	932
Unrealized gain on marketable securities	—	—	—	32	—	32
Net loss	—	—	—	—	(1,371)	(1,371)
Balance, March 31, 2023	1,565,920	$ 1	$ 323,938	$ —	$ (327,076)	$ (3,137)
Issuance of common stock for exercise of pre-funded warrants	2,104,000	—	—	—	—	—
Issuance of common stock for exercise of warrants	7,034,883	—	7,774	—	—	7,774
Financing cost of warrant inducement and exercise	—	—	(414)	—	—	(414)
Reversal of warrant liability due to exercise of warrants	—	—	1,442	—	—	1,442
Share-based compensation	—	—	795	—	—	795
Net loss	—	—	—	—	(7,568)	(7,568)
Balance, June 30, 2023	10,704,803	$ 1	$ 333,535	$ —	$ (334,644)	$ (1,108)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2021	491,626	$ 1	$ 310,011	$ (84)	$ (260,552)	$ 49,376
Stock-based compensation	—	—	919	—	—	919
Unrealized loss on marketable securities	—	—	—	(140)	—	(140)
Net loss	—	—	—	—	(20,157)	(20,157)
Balance, March 31, 2022	491,626	$ 1	$ 310,930	$ (224)	$ (280,709)	$ 29,998
Stock-based compensation	—	—	965	—	—	965
Unrealized loss on marketable securities	—	—	—	11	—	11
Net loss	—	—	—	—	(18,089)	(18,089)
Balance, June 30, 2022	491,626	$ 1	$ 311,895	$ (213)	$ (298,798)	$ 12,885

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Cash Flows
(unaudited)

(in thousands)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (8,939)	$ (38,246)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	81	76
Stock-based compensation expense	1,727	1,884
Issuance costs allocated to warrants	96	—
Change in fair value of warrant liabilities	(7,789)	2,296
Net amortization of premium on marketable securities	57	502
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other current and non-current assets	2,791	(1,283)
(Decrease) increase in accounts payable, accrued and other current liabilities	(4,973)	8,419
Net cash used in operating activities	(16,949)	(26,352)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	4,750	19,247
Purchases of property and equipment	(20)	—
Net cash provided by investing activities	4,730	19,247
Cash flows from financing activities		
Proceeds from issuance of securities	19,567	—
Payment of financing costs of securities sold	(1,393)	—
Repayments of insurance premium financing	(445)	—
Proceeds from the exercise of pre-funded warrants	5	—
Net cash provided by financing activities	17,734	—
Net increase (decrease) in cash and cash equivalents	5,515	(7,105)
Cash and cash equivalents at beginning of period	8,907	16,654
Cash and cash equivalents at end of period	$ 14,422	$ 9,549
Supplemental schedule of cash flow information		
Issuance of warrants to purchase common stock	$ 1,793	$ —
Cash paid for interest	$ 15	$ —
Supplemental schedule of non-cash financing activities		
Insurance premium financing	$ 900	$ —

See accompanying notes.

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 *S. aureus*, including methicillin-resistant strains, which causes serious infections such as bacteremia, pneumonia and osteomyelitis. *S. 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 was being studied in a pivotal Phase 3 superiority study (the "DISRUPT study") to evaluate the safety, tolerability, efficacy and pharmacokinetics of intravenous ("IV") exebacase when used in addition to background standard of care antibiotic therapy for the treatment of *S. aureus* bacteremia, including right-sided endocarditis in adolescent and adult patients. On July 7, 2022, the Data Safety Monitoring Board ("DSMB") conducted an interim futility analysis and recommended that the DISRUPT study be stopped because the conditional power of the study was below the pre-specified threshold for futility. Based on the DSMB's recommendation, patient enrollment in the Phase 3 trial was stopped ("Trial Closure"). The Company continued to monitor all already enrolled patients and all patients completed their follow-up visits. The Company expects to complete all clinical study reports as required by the U.S. Food and Drug Administration ("FDA").

On July 29, 2022, the Company initiated a restructuring plan resulting in a reduction in workforce. The restructuring plan was designed to reduce costs and align resources with the Company's anticipated product development milestones for exebacase and CF-370 and to help preserve the value of the Company's drug discovery operations. The restructuring reduced the Company's workforce from 43 full-time employees as of June 30, 2022 to 27 full-time employees as of August 15, 2022, when the reduction was completed. The Company recognized a restructuring charge of $7.7 million, including $1.6 million related to employee termination costs and other related expenses from the workforce reduction and $6.1 million from the write-off of prepaid manufacturing costs following the suspension of IV exebacase related activities.

The Company has incurred recurring losses since inception as a research and development organization and has an accumulated deficit of $334.6 million as of June 30, 2023. For the six months ended June 30, 2023, the Company used $16.9 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 and government contracts. The Company expects operating losses and negative cash flows to continue at significant levels in the future as it continues to advance its programs. As of June 30, 2023, the Company had $14.4 million in cash, cash equivalents and marketable securities, which, without additional funding, the Company believes will not be sufficient to meet its obligations within the next twelve months from the date of issuance of these consolidated financial statements. The Company plans to continue to fund its operations through public or private debt and equity financings, but there can be no assurances that such financing will continue to be available to the Company on satisfactory terms, or at all, particularly in light of the Trial Closure. As such, management has not considered the potential for future capital raises in its assessment of the Company's ability to meet its obligations for the next twelve months, and substantial doubt exists about the Company's ability to continue as a going concern for twelve months from the date the financial statements were issued. If the Company is unable to obtain funding, the Company would be forced to delay, further reduce its workforce or reduce or eliminate its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations or continue as a going concern and may be forced to sell or liquidate the business.

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

On March 22, 2021, the Company completed an underwritten public offering under the Company's registration statement on Form S-3 (Reg. No. 333-246359) (the "Form-S-3"). The Form S-3 was declared effective by the SEC on August 31, 2020 and 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. The Company issued 143,750 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 $400.00 per share, resulting in net proceeds to the Company of $53.8 million after underwriting discounts and commissions and offering expenses payable by the Company.

On December 15, 2022, the Company completed (i) a registered direct offering under the Form S-3 of 54,375 shares of its common stock and a pre-funded warrant to purchase 623,919 shares of common stock (the "2022 pre-funded warrant") and (ii) a concurrent private placement in which the Company issued a Class A warrant to purchase up to an aggregate of 1,356,589 shares of common stock (the "Class A Warrant") and a Class B warrant to purchase up to an aggregate of 678,294 shares of common stock (the "Class B Warrant") (collectively, the "2022 Offering"). All shares of common stock, the 2022 pre-funded warrant, the Class A Warrant and the Class B Warrant were issued together to a single accredited investor purchaser for consideration equating to $10.32 per share of common stock (or 2022 pre-funded warrant to purchase one share of common stock, less a nominal exercise price), together with a Class A Warrant to purchase two shares of common stock and a Class B warrant to purchase one share of common stock, in the case of each of the Class A Warrant and Class B Warrant, for no additional consideration but each with an exercise price per share of $10.32, for aggregate net proceeds to the Company of $6.1 million after placement agent fees and offering expenses payable by the Company.

On March 2, 2023, the Company completed (i) a registered direct offering under the Form S-3 of 128,000 shares of its common stock and a pre-funded warrant to purchase 2,372,000 shares of common stock (the "2023 pre-funded warrant") and (ii) a concurrent private placement in which the Company issued a warrant to purchase up to an aggregate of 5,000,000 shares of common stock (the "2023 Warrant") (collectively, the "2023 Offering"). All securities in the 2023 Offering were issued to the same single accredited investor purchaser as in the 2022 Offering for consideration equating to $4.00 per share of common stock (or 2023 pre-funded warrant to purchase one share of common stock, less a nominal exercise price), together with a 2023 Warrant to purchase two shares of common stock for no additional consideration but with an exercise price per share of $4.00, for aggregate net proceeds to the Company of $9.1 million after placement agent fees and offering expenses payable by the Company.

On June 26, 2023, the Company entered into an inducement offer to exercise common stock purchase warrants (the "Inducement Agreement") with an institutional investor (the "Holder") to purchase up to an aggregate of 7,034,883 shares of the Company's common stock. The Inducement Agreement provided the Holder with the opportunity to exercise all of (i) the Class A Warrant, (ii) Class B Warrant and (iii) the 2023 Warrant (collectively, the "Existing Warrants") held by the Holder, each at a reduced exercise price from $4.00 to $1.36 per underlying share, which was equal to the most recent closing price of the Company's common stock on The Nasdaq Capital Market prior to the execution of the Inducement Agreement. In consideration for exercising the Existing Warrants (the "Warrant Exercise"), at an exercise price equal to $1.36 per underlying share, the Company issued to the Holder or (i) a new unregistered Class C Common Stock Purchase Warrant (the "Class C Warrant") to purchase up to 1,406,977 shares of common stock, at an exercise price equal to $1.36 per underlying share and (ii) a new unregistered Class D Common Stock Purchase Warrant (the "Class D Warrant" and together with the Class C Warrant, the "New Warrants") to purchase up to 5,627,906 shares of common stock, at an exercise price equal to $1.36 per underlying share (such shares of common stock issuable upon exercise of the New Warrants, the "New Warrant Shares"). The proceeds to the Company from the Warrant Exercise were $9.6 million, prior to deducting fees to the financial advisor and estimated expenses.

The significant changes in common stock outstanding have impacted and are expected to continue to impact the year-over-year comparability of the Company's net loss per share calculations. All share and per share amounts have been adjusted for all periods presented to reflect a one-for-eighty reverse stock split effected on February 14, 2023.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial information as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022 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, 2022 was derived from the Company's audited consolidated financial statements, including all related disclosures, included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 31, 2023. There have been no material changes to the complete listing of significant accounting policies as described in Note 2 thereof.

In the opinion of management, the unaudited financial information as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022 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 and six months ended June 30, 2023 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 COVID-19 and the recent failure of certain financial institutions, on the Company's business, operations and financial performance and position.

The Company currently relies on a single manufacturer of drug substance for each of its product candidates and two manufacturers of drug product, one located in the United States and one in Western Europe, and there are no long-term supply agreements in place. A sustained disruption in the operations of any of these manufacturers, or in the event the Company would need to change to a new supplier, could result in a significant delay in the ability of the Company to complete any associated activities.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to stock-based compensation, warrant valuation, research and development accruals and prepaid expenses and realization of net deferred income tax assets. The Company's actual results may differ from these estimates under different assumptions or conditions.

Concentrations of Credit Risk

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

Cash and Cash Equivalents

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

Marketable Securities

Marketable securities consist of investments in corporate debt 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, together with accrued interest receivable, net of any allowance for credit losses, are recorded at fair value on the consolidated balance sheet, with unrealized gains and losses included as a component of accumulated other comprehensive loss in stockholders' deficit and a component of total comprehensive loss in the consolidated statements of comprehensive loss, until realized. The fair value of these securities is based on quoted prices for identical or similar assets. Realized gains and losses are

included in interest income in the consolidated statement of operations on a specific-identification basis. There were no realized gains or losses on sales of marketable securities for the six months ended June 30, 2023 or 2022. There were no marketable securities that had been in an unrealized loss position for more than 12 months as of June 30, 2023 or December 31, 2022.

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 judgment and therefore cannot be determined with precision. The fair value of the Company's warrant liabilities is based upon unobservable inputs, as described further below.

The Company discloses information on all assets and liabilities reported at fair value using a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company had no liabilities classified as Level 1 or Level 2. The carrying amounts reported in the accompanying financial statements for accounts payable and accrued expenses approximate their respective fair values due to their short-term maturities. The fair value of the warrant liabilities is discussed in Note 4, "Fair Value Measurements."

Stock-based Compensation

Stock-based compensation is measured and recognized as compensation expense for all stock-based payment awards made to employees, directors, and non-employees, including employee stock options. Compensation expense based on the grant date fair value is generally amortized over the requisite service period of the award on a straight-line basis.

The fair value of options is calculated using the Black-Scholes option pricing model on the date of grant based on key assumptions such as stock price, risk free interest rates, expected volatility, expected term, and expected dividend yield. The Company's estimates of these assumptions are 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 base period for the BARDA Contract included government funding of up to $9.8 million to reimburse expenses to support the conduct of the Phase 3 DISRUPT study and futility analysis. In connection with the Trial Closure, the BARDA Contract was modified to provide for up to $6.6 million in funding to support a futility outcome root-cause analysis and the close-out of the Phase 3 DISRUPT study of exebacase. The BARDA Contract ended on July 31, 2023.

The Company recognizes a receivable in other current assets with a related reduction in its research and development expenses when the actual reimbursable costs have been incurred and the Company has complied with the conditions of the applicable government contract or grant agreement and the amounts will be received. The Company recognized a reduction to its research and development expense in the amount of $0.6 million and $2.2 million for the three months ended June 30, 2023 and 2022, and $3.2 million and $4.3 million for the six months ended June 30, 2023 and 2022, respectively. The receivable for government contracts and grant agreements as of June 30, 2023 and December 31, 2022 was $0.6 million and $2.6 million, respectively. The Company has $2.0 million of committed government contract and grant agreement funding remaining as of June 30, 2023.

Restructuring

The Company has made estimates and judgments regarding the amount and timing of its restructuring expense and liability, including current and future period termination benefits and other costs to be incurred when related actions take place. Actual results may differ from these estimates. Restructuring charges are reflected in the Company's consolidated statements of operations.

Net Loss Per Share

Basic net loss per share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share applicable to common stockholders is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the dilutive net loss per share applicable to common stockholders' calculation, stock options and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share applicable to common stockholders, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

Recently Adopted Accounting Pronouncements

Credit Losses

On January 1, 2023, the Company adopted Accounting Standards Update No. 2016-13, *Financial Instruments-Credit Losses (ASU 2016-13).* ASU 2016-13 amended 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 adoption of the new guidance did not affect the Company's consolidated financial statements.

3. Marketable Securities

The Company held no marketable securities as of June 30, 2023.

Marketable securities at December 31, 2022 consisted of the following (in thousands):

Marketable Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Corporate debt	$ 4,807	$ —	$ (32)	$ 4,775

Corporate debt includes obligations issued by investment-grade corporations. At December 31, 2022, the Company held only investments that have maturities of less than one year.

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 June 30, 2023 and December 31, 2022 (in thousands):

	Fair Value Measurement as of June 30, 2023		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 13,496	$ —	$ —
Marketable securities	—	—	—
Warrant liabilities	—	—	1,861
Total	$ 13,496	$ —	$ 1,861

	Fair Value Measurement as of December 31, 2022		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 7,596	$ —	$ —
Marketable securities	4,775	—	—
Warrant liabilities	—	—	9,299
Total	$ 12,371	$ —	$ 9,299

The Company issued warrants to the purchasers of its 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 9, "Capital Structure"). The 2020 Warrants were re-measured at each subsequent reporting period and changes in fair value have been recognized in the consolidated statement of operations. The following assumptions were used in a Black-Scholes option-pricing model to determine the fair value of the warrant liability as of December 31, 2022. On May 27, 2023, the 2020 Warrants expired in accordance with their terms and are no longer exercisable.

	As of December 31, 2022
Expected volatility	80.2 %
Remaining contractual term (in years)	0.42
Risk-free interest rate	4.76 %
Expected dividend yield	— %

The Company issued the Class A Warrant and Class B Warrant to the purchaser of its 2022 Offering (together, the "2022 Warrants"). The Company determined that these warrants should be classified as a liability and considered as a Level 3 financial instrument (see also Note 9, "Capital Structure"). On June 26, 2023, the Class A Warrant and Class B Warrant, together with the 2023 Warrant, were exercised in full pursuant to the Inducement Agreement. The 2022 Warrants were re-measured at each subsequent reporting period and on June 26, 2023 and the changes in fair value have been 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:

	Class A Warrants		Class B Warrants	
	As of June 26, 2023	As of December 31, 2022	As of June 26, 2023	As of December 31, 2022
Expected volatility	135.5 %	99.8 %	129.5 %	140.3 %
Remaining contractual term (in years)	4.63	5.08	0.13	0.58
Risk-free interest rate	4.13 %	3.99 %	5.32 %	4.76 %
Expected dividend yield	— %	— %	—%	—%

The Company issued the Class C Warrant pursuant to the Inducement Agreement and determined that this warrant should be classified as a liability and considered as a Level 3 financial instrument (see also Note 9, "Capital Structure"). The Class C Warrant was re-measured at each subsequent reporting period and the changes in fair value have been 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 June 30, 2023	At Issuance
Expected volatility	129.1 %	129.1 %
Remaining contractual term (in years)	5.25	5.25
Risk-free interest rate	4.13 %	4.02 %
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 and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Balance at beginning of period	$ 1,899	$ 6,742	$ 9,299	$ 2,530
Issuance of Class C Warrant	1,793	—	1,793	—
(Decrease) increase in fair value (1)	(389)	(1,916)	(7,789)	2,296
Exercise of underlying warrants (2)	(1,442)	—	(1,442)	—
Balance at end of period	$ 1,861	$ 4,826	$ 1,861	$ 4,826

(1)The change in fair values of the warrant liabilities is recorded in other income in the consolidated statement of operations.
(2)The remaining fair value of the warrant liabilities at the time of exercise was transferred into additional paid-in capital in the consolidated balance sheet.

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

5. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following as of June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023	December 31, 2022
Accrued compensation costs	$ 1,756	$ 1,676
Accrued professional fees	1,268	970
Accrued research and development service fees	701	3,443
Accrued insurance and facilities operation expenses	484	252
Other accrued expenses	30	157
Total accrued and other current liabilities	$ 4,239	$ 6,498

In February 2023, the Company entered into a financing agreement for $0.9 million for a portion of the Company's annual directors and officers insurance premiums. The balance is due in monthly installments over eight months with an annual interest rate of 6.25%. The remaining balance was $0.5 million as of June 30, 2023 and was included in accounts payable and accrued and other current liabilities on the consolidated balance sheet.

6. Net Loss Per Share of Common Stock

Diluted loss per share is the same as basic loss per share for all periods presented because the effects of potentially dilutive items were anti-dilutive given the Company's net loss. Basic loss per share is computed by dividing net loss available to common stockholders by the weighted-average number of common shares outstanding, including the weighted average effect of the pre-funded warrants the Company issued in connection with the 2022 and 2023 Offerings, the exercise of which requires nominal consideration for the delivery of shares of common stock. As such, the Company has considered the 574,937 common shares underlying the pre-funded warrants that were unexercised as of December 31, 2022 to be outstanding beginning on January 1, 2023 for the purposes of calculating basic EPS. There were no pre-funded warrants outstanding as of June 30, 2023.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (7,568)	$ (18,089)	$ (8,939)	$ (38,246)
Weighted average shares of common stock outstanding	3,901,839	491,626	2,943,979	491,626
Net loss per share of common stock—basic and diluted	$ (1.94)	$ (36.79)	$ (3.04)	$ (77.79)

The following potentially dilutive securities outstanding at June 30, 2023 and 2022 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	June 30,	
	2023	2022
Options to purchase common stock	79,519	55,612
Warrants to purchase common stock	7,034,883	136,563
Total	7,114,402	192,175

7. Commitments and Contingencies

Operating Leases

In December 2010, the Company entered into a non-cancellable operating lease for office space and laboratory facilities in Yonkers, New York expiring in December 2025. In December 2011, the Company entered into an amendment which extended the 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 balance sheet classification of the Company's lease liabilities was as follows (in thousands):

Description	June 30, 2023	December 31, 2022
Operating lease liabilities:		
Current portion of lease liabilities	$ 677	$ 671
Long-term portion of lease liabilities	$ 1,988	$ 2,210

The Company adopted Topic 842 in accounting for its lease liabilities as of January 1, 2019. Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used a discount rate of 9.93%, which was an estimate of its incremental borrowing rate based on the information available at the adoption date. The leases are renewable at the end of the lease term at the Company's option. For the purposes of determining the remaining lease term in contemplation of available extensions, the Company did not consider either

renewal to be probable and therefore the remaining lease term used to determine the operating lease liability was 9.0 years at the adoption date.

As of June 30, 2023, the maturities of our operating lease liabilities were as follows (in thousands):

	Amount
July 1, 2023—December 31, 2023	$ 354
Year ending December 31:	
2024	721
2025	736
2026	750
2027	702
Total lease payments	3,263
Less: Present value adjustment	(598)
Operating lease liabilities	$ 2,665

Lease costs under the terms of the Company's leases for the three and six months ended June 30, 2023 and 2022 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating lease cost (1)	$ 150	$ 154	$ 301	$ 307
Variable lease costs (2)	22	42	51	81
Total lease cost	$ 172	$ 196	$ 352	$ 388

(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.

Rockefeller University

License Agreements

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

- On July 12, 2011, the Company entered into a license agreement for the worldwide, exclusive right to a patent covering the composition of matter for the lysin PlySS2 for the treatment and prevention of diseases caused by gram-positive bacteria (the "CF-301 License"). The Company rebranded PlySS2 as CF-301 and subsequently, exebacase. The license gives the Company the right to exclusively develop, make, have made, use, import, lease, sell and offer for sale products that would otherwise infringe a claim of this patent application or patent.

- On June 1, 2011, the Company entered into a license agreement for the exclusive rights to The Rockefeller University's interest in a joint patent application covering the method of delivering antibodies through the cell wall of gram-positive bacteria to the periplasmic space. This intellectual property was developed as a result of the sponsored research agreement between the Company and The Rockefeller University and was jointly discovered and filed by the two parties.

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

In consideration for the licenses, the Company paid Rockefeller license initiation fees in cash and stock. The Company is currently required to pay $0.2 million each year until the licenses terminate. Depending on the success of its programs, the Company may also incur regulatory milestone payments up to a total of $5.0 million and royalties of up to 5% on net sales from products to Rockefeller. The Company is allowed to grant sublicenses to third parties without prior approval, subject to certain conditions and the

payment of a certain percentage of all payments we receive from sublicensees. There were no milestone, royalty or sublicense payments made during the three or six months ended June 30, 2023 or 2022. The Company has made total milestone payments under the CF-301 License of $0.8 million as of June 30, 2023.

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

Legal Contingencies

From time to time, the Company may be involved in disputes and legal proceedings in the ordinary course of its business. These proceedings may include allegations of infringement of intellectual property, employment or other matters. The Company records a liability in its financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in a liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss to the extent necessary to make the financial statements not misleading. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in the Company's financial statements. The Company currently has no legal proceedings ongoing that management estimates could have a material effect on the Company's financial statements.

8. Restructuring

On July 29, 2022, the Company initiated a restructuring plan resulting in a reduction in workforce. The restructuring plan was designed to reduce costs and align resources with the Company's anticipated product development milestones for exebacase and CF-370 and to help preserve the value of the Company's drug discovery operations. The restructuring reduced the Company's workforce from 43 full-time employees as of June 30, 2022 to 27 full-time employees as of August 15, 2022, when the reduction was completed. The Company recognized a restructuring charge of $7.7 million, including $1.6 million related to employee termination costs, including severance, health benefits and other related expenses from the workforce reduction, and $6.1 million from the write-off of prepaid manufacturing costs following the suspension of IV exebacase manufacturing activities.

The restructuring costs were included in accounts payable and accrued and other current liabilities. Activity for the three and six months ended June 30, 2023 is summarized as follows (in thousands):

	Three Months Ended June 30, 2023	Six Months Ended June 30, 2023
Balance at beginning of period	$ 6,927	$ 7,143
Payments made	(3,315)	(3,531)
Balance at end of period	$ 3,612	$ 3,612

As of June 30, 2023, the Company had $3.6 million remaining in accounts payable and accrued and other current liabilities, which the Company expects to be paid by the end of the first quarter of 2024.

9. Capital Structure

On February 10, 2023, the stockholders of the Company approved a reverse stock-split of the Company's outstanding shares of common stock at a ratio ranging from any whole number between 1-for-10 and 1-for-80, as determined by the Board of Directors in its discretion. The Board subsequently determined to implement a reverse stock split at a ratio of 1-for-80. The stock split became effective on February 14, 2023. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect this reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately decreased and the respective per share value and exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

Common Stock

As of June 30, 2023, the Company was authorized to issue 125,000,000 shares of common stock.

Follow-on Offerings

On May 27, 2020, the Company completed an underwritten public offering of 147,471 shares of its common stock and warrants to purchase an additional 110,603 shares of its common stock at an exercise price of $392.00 per share. The public offering price was $356.00 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 $48.9 million after underwriting discounts and commissions and offering expenses payable by the Company. The Company completed a concurrent private placement to Pfizer of 8,427 shares of common stock and an accompanying warrant to purchase an additional 6,320 shares of its common stock at an exercise price of $392.00 per share of common stock (the "Pfizer Warrant"), resulting in net proceeds to the Company of $3.0 million.

On March 22, 2021, the Company completed an underwritten public offering of 143,750 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 $400.00 per share, resulting in net proceeds to the Company of $53.8 million after underwriting discounts and commissions and offering expenses payable by the Company.

On December 15, 2022, the Company completed the 2022 Offering. All shares of common stock, the 2022 pre-funded warrant, the Class A Warrant and the Class B Warrant were issued together to a single accredited investor purchaser for consideration equating to $10.32 share of common stock (or 2022 pre-funded warrant to purchase one share of common stock, less a nominal exercise price), together with a Class A Warrant to purchase two shares of common stock and a Class B warrant to purchase one share of common stock, in the case of each of the Class A Warrant and Class B Warrant, for no additional consideration but each with an exercise price per share of $10.32, for aggregate net proceeds to the Company of $6.1 million after placement agent fees and offering expenses payable by the Company. As of January 20, 2023, the 2022 pre-funded warrant had been fully exercised.

At issuance, the 2022 Warrants were not exercisable and only became exercisable following (i) stockholder approval of (and the effectiveness of) an amendment to the Company's certificate of incorporation that either combines outstanding shares of common stock with such combination ratio as determined by the Company's board of directors and/or authorizes additional shares of common stock to such number as determined by the Company's board of directors, in each case, so as to enable the issuance of the number of shares of common stock underlying the 2022 Warrants (disregarding any limitations on the exercise thereof), and (ii) the issuance of all shares of common stock issued in, or issuable pursuant to the exercise of the 2022 pre-funded warrant or 2022 Warrants issued in, the 2022 Offering as may have been required by the applicable rules and regulations of the Nasdaq Stock Market.

On February 10, 2023, the stockholders of the Company approved the issuance of all shares of common stock issued in, or issuable pursuant to the exercise of the 2022 pre-funded warrant or 2022 Warrants issued in the 2022 Offering as may have been required by the applicable rules and regulations of the Nasdaq Stock Market, the approval of which, together with the approval and effectiveness of the 1-for-80 reverse stock-split effected on February 14, 2023, commenced the exercisability of the 2022 Warrants as of February 14, 2023. The resulting expiration dates of the 2022 Warrants have been reflected, where applicable, in the accompanying financial statements and notes thereto. On March 2, 2023, the exercise price of the 2022 Warrants, which are subject to an anti-dilution adjustment, were adjusted to $4.00 per share as a result of the 2023 Offering.

On March 2, 2023, the Company completed the 2023 Offering. All securities in the 2023 Offering were issued to the same single accredited investor purchaser from the 2022 Offering for consideration equating to $4.00 per share of common stock (or 2023 pre-funded warrant to purchase one share of common stock, less a nominal exercise price), together with a warrant to purchase two shares of common stock for no additional consideration but with an exercise price per share of $4.00, for aggregate net proceeds to the Company of $9.1 million after placement agent fees and offering expenses payable by the Company. As of April 17, 2023, the 2023 pre-funded warrant had been fully exercised.

On June 26, 2023, the Company entered into the Inducement Agreement with the Holder to exercise common stock purchase warrants and purchase up to an aggregate of 7,034,883 shares of the Company's common stock. The Inducement Agreement provided the Holder with the opportunity to exercise all of the Existing Warrants held by the Holder, each at a reduced exercise price from $4.00 to $1.36 per underlying share, which was equal to the most recent closing price of the Company's common stock on The Nasdaq Capital Market prior to the execution of the Inducement Agreement. In consideration for exercising the Existing Warrants at an exercise price equal to $1.36 per underlying share, the Company issued to the Holder the Class C Warrant to purchase up to 1,406,977 shares of common stock, at an exercise price equal to $1.36 per underlying share and the Class D Warrant to purchase up to 5,627,906 shares of common stock, at an exercise price equal to $1.36 per underlying share. The proceeds to the Company from the Warrant Exercise were $9.6 million, prior to deducting fees to the financial advisor and estimated expenses.

At issuance, the New Warrants were not exercisable and only become exercisable following stockholder approval of the issuance of all shares of common stock issued in, or issuable pursuant to the exercise of the New Warrants issued pursuant to the Inducement Agreement as may have been required by the applicable rules and regulations of the Nasdaq Stock Market.

The Class C Warrant and the warrants issued by the Company in its 2022 and 2020 offerings of securities contained certain terms that the Company determined required classification as liabilities in accordance with ASC 815. At issuance, the Company determined the fair value of the Class C Warrant, the 2022 Warrants and the 2020 Warrants to be $1.8 million, $11.0 million and $31.4 million, respectively, and recorded these balances as warrant liabilities, and reducing the amount of net proceeds recorded as additional paid-in-capital. The fair value of the 2022 Warrants exceeded the proceeds received in the 2022 Offering and the excess of $4.0 million was expensed as other expense. The Company consummated the 2022 Offering on market terms available at the time of the transaction to provide additional funding to advance its product candidates. 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 $0.1 million, $0.9 million and $2.2 million of issuance costs to the Class C Warrant, the 2022 Warrants and the 2020 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. The Class D Warrant, the 2023 Warrant and the Pfizer Warrant do not contain the same provisions and therefore the Company determined that the Class D Warrant, the 2023 Warrant and 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 June 30, 2023, 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 June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Outstanding pre-funded warrants to purchase common stock	—	574,937
Outstanding options to purchase common stock	79,519	55,565
Outstanding warrants to purchase common stock	7,034,883	2,151,451
For future issuance under the 2014 Omnibus Incentive Plan	1,162	1,317
For future issuance under the 2021 Employment Inducement Plan	12,375	12,375
	7,127,939	2,795,645

10. Stock Warrants

As of June 30, 2023 and December 31, 2022, the Company had warrants to purchase the underlying common stock outstanding as shown in the table below.

	June 30, 2023	December 31, 2022
Class C Warrants	1,406,977	—
Class D Warrants	5,627,906	—
2022 Warrants	—	2,034,883
2020 Warrants	—	110,248
Pfizer Warrant	—	6,320
Warrants to purchase common stock	7,034,883	2,151,451
Weighted-average exercise price per share	$ 1.36	$ 31.00

11. Stock Option and Incentive Plans

Amended and Restated 2008 Equity Incentive Plan

In July 2008, the Company adopted the 2008 Equity Incentive Plan (the "Plan"). On February 26, 2013, the board of directors approved an amended and restated plan (the "Amended Plan") under which the number of shares of common stock available for

issuance was 1,964. 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 2,321 and 2,946, respectively. As of the closing of the Company's IPO, there were no further grants made under the Amended Plan.

2014 Omnibus Incentive Plan

In April 2014, the Company's board of directors adopted the 2014 Omnibus Incentive Plan (the "2014 Plan"). The 2014 Plan was approved by the Company's shareholders on July 3, 2014. The 2014 Plan allows for the granting of incentive and non-qualified stock options, restricted stock and stock unit awards, stock appreciation rights and other performance-based awards to the Company's employees, members of the board of directors and consultants of the Company. On July 28, 2014, the effective date of the 2014 Plan, the number of shares of common stock reserved pursuant to the 2014 Plan was 715. 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 77,157 shares of common stock have been reserved under the 2014 Plan as of January 1, 2023.

2021 Employment Inducement Omnibus Incentive Plan

In September 2021, the Company's board of directors adopted the 2021 Employment Inducement Omnibus Incentive Plan (the "2021 Plan"), under which the number of shares of common stock reserved for issuance was 12,500. The 2021 Plan allows for the granting of non-qualified stock options, restricted stock and stock unit awards, stock appreciation rights and other performance-based awards only to newly hired employees of the Company who have not previously been an employee or member of the board, or an employee who is being rehired following a bona fide period of non-employment by the Company.

2022 Employee Stock Purchase Plan

In March 2022, the Company's board of directors adopted the 2022 Employee Stock Purchase Plan (the "2022 ESPP"). The 2022 ESPP was approved by the Company's shareholders on May 17, 2022. The 2022 ESPP allows employees to buy Company stock through after-tax payroll deductions at a discount from market value. One component of the 2022 ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code, whereas the other component authorizes the grant of rights which need not qualify as rights granted pursuant to an "employee stock purchase plan" under Section 423. The number of shares of common stock initially available for issuance under the 2022 ESPP was 10,000 shares of common stock. As of June 30, 2023, no purchase rights were outstanding under the 2022 ESPP.

Under the 2022 ESPP, employees may purchase common stock through after-tax payroll deductions. In the absence of a contrary designation, the purchase price will be 85% of the lower of the fair market value of our common stock on the first trading day of an offering period or the last trading day of an offering period.

The Company recognized compensation expense for stock-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 six months ended June, 2023, 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, 2022	55,565	$ 548.79		
Granted	25,125	5.03		
Exercised	—	—		
Expired	(1,046)	1,763.01		
Forfeited	(125)	19.20		
Options outstanding at June 30, 2023	79,519	359.96	8.07	$ —
Vested and exercisable at June 30, 2023	40,549	$ 572.07	7.11	$ —

The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. There were no options granted during the three months ended June 30, 2023. The weighted average grant date fair value of options granted

during the three months ended June 30, 2022 was $3.32, and during the six months ended June 30, 2023 and 2022 was $5.03 and $3.33, respectively. Total compensation expense recognized amounted to $0.8 million and $1.0 million for the three months ended June 30, 2023 and 2022, respectively, and $1.7 million and $1.9 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, the total remaining unrecognized compensation cost related to unvested stock options was approximately $2.9 million which will be recognized over a weighted average period of approximately 1.8 years.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Risk free interest rate	—	2.94 %	4.00 %	2.15 %
Expected dividend yield	—	—	—	—
Expected term (in years)	—	5.52	6.06	5.95
Expected volatility	—	91.0 %	102.1 %	91.2 %

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.

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, 2022 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 31, 2023.

All share and per share amounts have been adjusted to reflect a one-for-eighty reverse stock split effected on February 14, 2023.

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. We believe DLAs are fundamentally different than antibiotics and offer a potential paradigm shift in the treatment of antibiotic-resistant infections. According to one of the most recent and comprehensive reports on the global burden of bacterial antimicrobial resistance ("AMR"), there were an estimated 4.95 million deaths associated with bacterial AMR in 2019, including 1.27 million deaths directly attributable to bacterial AMR. The six leading pathogens for deaths associated with resistance (*Escherichia coli ("E. coli")*, *Staphylococcus aureus ("S. aureus")*, *Klebsiella pneumoniae ("K. pneumoniae")*, *Streptococcus pneumoniae*, *Acinetobacter baumannii ("A. baumannii")*, and *Pseudomonas aeruginosa* ("*P. aeruginosa*")) were responsible for 929,000 deaths. Only one pathogen–drug combination, methicillin-resistant *S. aureus* ("MRSA"), caused more than 100,000 deaths in 2019.

Lysins are recombinantly-produced enzymes; when applied to bacteria, they 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. Amurin peptides are a new class of DLAs, discovered in our laboratories, which disrupt the outer membrane of gram-negative bacteria, resulting in rapid bacterial cell death, offering a distinct mechanism of action from lysins. Amurins have a potent, broad spectrum of *in vitro* activity against a wide range of gram-negative pathogens, including deadly, drug-resistant *P. aeruginosa*, *K. pneumoniae, E. coli, A. 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 underscore their potential use in addition to antibiotics with the goal of improving clinical outcomes compared to antibiotics alone. The development of DLAs involves a novel clinical and regulatory strategy, using superiority design clinical trials with the goal of delivering significantly improved clinical outcomes for patients with serious and/or antibiotic-resistant bacterial infections, including biofilm-associated infections. We believe this approach affords potential clinical benefits to patients as well as the potential ability to mitigate against further development of antibiotic resistance.

We have not generated any revenues and, to date, have funded our operations primarily through our initial public offering ("IPO"), our follow-on public offerings, private placements of securities, and funding received from government contracts and various grants.

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 base period for the BARDA Contract included government funding of up to $9.8 million to reimburse expenses to support the conduct of the Phase 3 DISRUPT study and futility analysis. In connection with the Trial Closure, the BARDA Contract was modified to provide for up to $6.6 million in funding to support a futility outcome root-cause analysis and the close-out of the Phase 3 DISRUPT study of exebacase. The BARDA Contract ended on July 31, 2023.

On March 22, 2021, the Company completed an underwritten public offering under the Company's registration statement on Form S-3 (Reg. No. 333-246359) (the "Form-S-3"). The Form S-3 was declared effective by the SEC on August 31, 2020 and 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. The Company issued 143,750 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 $400.00 per share, resulting in net proceeds to the Company of $53.8 million after underwriting discounts and commissions and offering expenses payable by the Company.

On December 15, 2022, the Company completed (i) a registered direct offering under the Form S-3 of 54,375 shares of its common stock and a pre-funded warrant to purchase 623,919 shares of common stock (the "2022 pre-funded warrant") and (ii) a

concurrent private placement in which the Company issued a Class A warrant to purchase up to an aggregate of 1,356,589 shares of common stock (the "Class A Warrant") and a Class B warrant to purchase up to an aggregate of 678,294 shares of common stock (the "Class B Warrant" and together with the Class A Warrant, the "2022 Warrants") (collectively, the "2022 Offering"). All shares of common stock, the 2022 pre-funded warrant, the Class A Warrant and the Class B Warrant were issued together to a single accredited investor purchaser for consideration equating to $10.32 share of common stock (or 2022 pre-funded warrant to purchase one share of common stock, less a nominal exercise price), together with a Class A Warrant to purchase two shares of common stock and a Class B warrant to purchase one share of common stock, in the case of each of the Class A Warrant and Class B Warrant, for no additional consideration but each with an exercise price per share of $10.32, for aggregate net proceeds to the Company of $6.1 million after placement agent fees and offering expenses payable by the Company.

On January 31, 2023, the stockholders of the Company approved the issuance of all shares of common stock issued in, or issuable pursuant to the exercise of the 2022 pre-funded warrant or 2022 Warrants issued in, the 2022 Offering as was required by the applicable rules and regulations of the Nasdaq Stock Market LLC ("Nasdaq"), the approval of which, together with the approval and effectiveness of the 1-for-80 reverse stock-split effected on February 14, 2023, commenced the exercisability of the 2022 Warrants as of February 14, 2023.

On March 2, 2023, the Company completed (i) a registered direct offering under the Form S-3 of 128,000 shares of its common stock and a pre-funded warrant to purchase 2,372,000 shares of common stock (the "2023 pre-funded warrant") and (ii) a concurrent private placement in which the Company issued a warrant to purchase up to an aggregate of 5,000,000 shares of common stock (collectively, the "2023 Offering). All securities in the 2023 Offering were issued to the same single accredited investor purchaser as in the 2022 Offering for consideration equating to $4.00 per share of common stock (or 2023 pre-funded warrant to purchase one share of common stock, less a nominal exercise price), together with a warrant to purchase two shares of common stock for no additional consideration but with an exercise price per share of $4.00, for aggregate net proceeds to the Company of $9.1 million after placement agent fees and offering expenses payable by the Company.

On June 26, 2023, the Company entered into an inducement offer to exercise common stock purchase warrants (the "Inducement Agreement") with an institutional investor (the "Holder") to purchase up to an aggregate of 7,034,883 shares of the Company's common stock. The Inducement Agreement provided the Holder with the opportunity to exercise all of (i) the Class A Warrant, (ii) Class B Warrant and (iii) the 2023 Warrant (collectively, the "Existing Warrants") held by the Holder, each at a reduced exercise price from $4.00 to $1.36 per underlying share, which was equal to the most recent closing price of the Company's common stock on Nasdaq prior to the execution of the Inducement Agreement. In consideration for exercising the Existing Warrants (the "Warrant Exercise"), at an exercise price equal to $1.36 per underlying share, the Company issued to the Holder (i) a new unregistered Class C Common Stock Purchase Warrant (the "Class C Warrant") to purchase up to 1,406,977 shares of common stock, at an exercise price equal to $1.36 per underlying share and (ii) a new unregistered Class D Common Stock Purchase Warrant (the "Class D Warrant" and together with the Class C Warrant, the "New Warrants") to purchase up to 5,627,906 shares of common stock, at an exercise price equal to $1.36 per underlying share (such shares of common stock issuable upon exercise of the New Warrants, the "New Warrant Shares"). The proceeds to the Company from the Warrant Exercise were $9.6 million, prior to deducting fees to the financial advisor and estimated expenses.

We have never been profitable and our losses from operations were $8.9 million, $64.6 million and $47.3 million for the six months ended June 30, 2023 and the years ended December 31, 2022 and 2021, respectively. As of June 30, 2023, we had an accumulated deficit of $334.6 million. For the six months ended June 30, 2023, the Company used $16.9 million of cash in operations. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect the expenses for each program to increase as candidates advance through preclinical activities and clinical trials to seek regulatory approval and, if approved, commercialization. Accordingly, we will need additional financing to support our continuing operations and to continue as a going concern. We expect to seek to fund our operations through public or private equity, debt financings, equity-linked financings, collaborations, strategic alliances or transactions, licensing arrangements, research grants or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all, particularly in light of the Trial Closure (as defined below) and the substantial decline in the price of our common stock. 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. Without additional funding, the Company believes it will not have sufficient funds to meet its obligations within the next twelve months from the date of issuance of the consolidated financial statements included in this Quarterly Report on Form 10-Q. These factors raise substantial doubt about the Company's ability to continue as a going concern. The recent substantial decline in the price per share of our common stock will likely make it more difficult for us to obtain financing.

On April 12, 2023, we received formal notice from the Nasdaq indicating that the Nasdaq Hearings Panel (the "Panel") had granted the Company's request for continued listing on The Nasdaq Capital Market, subject to the Company evidencing compliance with all applicable criteria for continued listing, including the $2.5 million minimum stockholders' equity requirement set forth in Nasdaq Listing Rule 5550(b)(1) (the "Rule"), by no later than June 30, 2023. On July 21, 2023, we received notice from Nasdaq that

we had regained compliance with the Rule (the "Compliance Notice"). However, the Company expects that it may not comply with the Rule upon filing of this Quarterly Report on Form 10-Q. In the Compliance Notice, Nasdaq indicated that if the Company fails to comply with the Rule within one year of the Compliance Notice, the Company would receive a Delist Determination Letter. The Company expects to have the ability to appeal any Delist Determination Letter. If we are delisted from the Nasdaq, it may become more difficult for us to obtain equity financing. For additional information regarding risks associated with potential delisting, see Part II, Item 1A, "We are required to meet the Nasdaq Capital Market's continued listing requirements and other Nasdaq rules, or we may risk delisting. Delisting could negatively affect the price of our common stock and could make it more difficult for us to sell securities in a future financing or for you to sell our common stock".

If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. We will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

We have not generated any revenues to date. In the future, we may generate revenues from product sales. In addition, to the extent we enter into licensing or collaboration arrangements, we may have additional sources of revenue. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of payments that we may recognize upon the sale of our products, to the extent that any products are successfully commercialized, and the amount and timing of fees, reimbursements, milestone and other payments received under any future licensing or collaboration arrangements. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and development expenses

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

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

We expense research and development costs to operations as incurred. We account for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made.

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

Exebacase

Our first DLA product candidate, exebacase, is currently being studied in an ongoing Phase 1b/2 study in patients with chronic prosthetic joint infections ("PJIs") of the knee due to *S. aureus* or coagulase-negative Staphylococci. In addition to PJIs, Staphylococci, and *S. aureus* in particular, is also a common cause of bacteremia, pneumonia and osteomyelitis as well as biofilm-associated infections of heart valves (endocarditis), indwelling devices and catheters. These infections result in significant morbidity and mortality despite currently available antibiotic therapies.

Exebacase is the first lysin to enter U.S. clinical trials and represents a first-in-class anti-bacterial therapeutic candidate. Exebacase was granted Breakthrough Therapy designation for development as a treatment for MRSA bloodstream infections (bacteremia), including right-sided endocarditis, when used in addition to standard-of-care anti-staphylococcal antibiotics ("SOCA") in adult patients, by the U.S. Food and Drug Administration ("FDA") in February 2020. The Phase 2 data for MRSA-infected patients 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 FDA to grant Breakthrough Therapy designation.

In December 2019, we initiated the Phase 3 DISRUPT (Direct Lysis of *S. aureus* Resistant Pathogen Trial) superiority design study of exebacase. The DISRUPT study was 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 adult and adolescent patients with complicated *S. aureus* bacteremia, including right-sided endocarditis. Patients entering the study were randomized 2:1 to either exebacase or placebo, with all patients receiving SOC antistaphylococcal 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 included clinical response at Day 14 in the All *S. aureus* patient group (MRSA and methicillin-sensitive *S. aureus* ("MSSA")), 30-day all-cause mortality in MRSA patients, and clinical response at later timepoints.

In July 2022, the Data Safety Monitoring Board ("DSMB") of the Company's Phase 3 DISRUPT study completed a pre-specified, interim futility analysis and recommended that the DISRUPT study be stopped because the conditional power of the study was below the pre-specified threshold for futility in the DSMB charter. The recommendation was based on an analysis of the clinical response rate at day 14 (the primary efficacy endpoint of the study) in 84 patients, or approximately 60% of the total planned MRSA population with bacteremia, including right-sided endocarditis. Based on the DSMB's recommendation, patient enrollment in the Phase 3 trial was stopped and the trial was closed ("Trial Closure"). We continued to monitor all already enrolled patients and all patients completed their follow-up visits. We also expect to complete all clinical study reports as required by the FDA.

Analysis of the complete dataset including all patient follow-up has been completed. The 259 enrolled patients were randomly assigned in a 2:1 ratio to receive either exebacase or placebo in addition to SOCA. Randomization was stratified by MRSA or MSSA and by the presence or absence of poorly controlled diabetes. Clinical responder rates at Day 14 in the MRSA population were 50.0% in the exebacase-treated group compared to 60.6% in the SOCA alone group (p=0.392). The result was unexpected based on the prior Phase 2 study of exebacase that established proof-of concept in patients with MRSA bacteremia, including right-sided endocarditis. In the SOCA alone group, the clinical responder rate was unexpectedly high and the mortality rate was unexpectedly low based on the prior Phase 2 study and previously published clinical trials. Significant heterogeneity among the patient population, a small sample size at the time of the futility analysis, and imbalances in prognostic factors (including severity of illness at baseline as measured by APACHE II score, which favored the SOCA alone arm) contributed to the results. Overall rates of adverse events were similar in both groups and there were no adverse events of hypersensitivity related to exebacase.

On September 30, 2022, we submitted a Clinical Trial Authorization ("CTA") with the French National Agency for the Safety of Medicines and Health Products ("ANSM") for the study of intra-articular exebacase in patients with chronic prosthetic joint infections of the knee due to *S. aureus* or coagulase-negative Staphylococci ("CoNS"). The CTA was approved by ANSM in November 2022 and, following IRB/EC approval of the study protocol, we initiated dosing of patients. We expect to report interim clinical data from the first cohort of patients in the second half of 2023.

The approved trial is a Phase 1b/2 study of exebacase in the setting of an arthroscopic debridement with joint retention and systemic antibiotics ("DAIR") procedure in patients with chronic PJI of the knee due to *S. aureus* and/or CoNS. The study is a randomized, double-blind, placebo-controlled two-part clinical study to be conducted at a single center in France to assess the efficacy and safety of exebacase. Part 1 will evaluate the safety, PK, early clinical outcomes, and microbiologic response in patients through Day 42. Up to 2 dose levels of intra-articularly administered exebacase in addition to systemic antibiotics will be studied in up to 2 patient cohorts. Part 2 will consist of a long-term follow-up study of safety and efficacy parameters in patients who complete Part 1 of the study. Follow-up assessments will be performed on Days 90, 180, 360 and 720, including health resource utilization and QoL measures. Patients entering the study will be randomized 3:1 to either exebacase or placebo, with all patients receiving study drug in the setting of a DAIR Procedure.

CF-370

Our next product candidate, CF-370, is designed to target a range of gram-negative bacteria, including *P. aeruginosa*, *K. pneumoniae* and *A. baumannii,* and has demonstrated potent *in vivo* activity against these pathogens, even against multidrug-resistant ("MDR") and extensively drug-resistant ("XDR") strains. Gram-negative pathogens are a major cause of morbidity and mortality in patients with hospital-acquired or ventilator-associated pneumonia and *P. aeruginosa* remains a major medical challenge for cystic fibrosis patients with chronic lung infections.

We believe agents which target *P. aeruginosa, K. pneumoniae*, *Enterobacteriaceae* and *E. coli* will be important therapeutic options for the treatment of serious, potentially life-threatening invasive infections caused by MDR and XDR pathogens. Because of the novel mechanism by which direct lytic agents kill bacteria and the lack of observable cross resistance to conventional antibiotics, the ß-lactam enzymes that degrade many antibiotics are not expected to have any effect on the activity of our investigational agents. We believe that direct lytic agents will help to improve clinical outcomes and decrease mortality of infections caused by these pathogens.

We have studied CF-370 in multiple animal models with external organizations with both sensitive and resistant strains and using CF-370 in addition to either amikacin ("AMK") or meropenem, demonstrating the superiority of the combination of CF-370

with SOC antibiotics. We believe the results from these studies provide *in vivo* proof-of-concept for CF-370 as a potential treatment for pulmonary infections caused by gram-negative pathogens and for direct lytic agents as a potential new modality to combat the threat of multidrug-resistant gram-negative pathogens. We continue to progress CF-370 through Investigational New Drug Application ("IND") enabling activities and we expect it to be our next molecule in clinical studies. We plan to submit an IND to the FDA in the third quarter of 2023 and, if allowed to proceed, to initiate phase 1 clinical studies of CF-370 in healthy volunteers shortly thereafter.

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 and CF-370 programs. As our pipeline progresses, we are able to leverage our employee and infrastructure resources across multiple development and research programs. We recorded approximately $4.9 million and $16.8 million of research and development expenses for the three months ended June 30, 2023 and 2022 and $10.2 million and $29.5 million, respectively, for the six months ended June 30, 2023 and 2022, respectively. 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 and CF-370 as shown below.

The following table summarizes our research and development expenses by category for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Product development	$ 2,927	$ 14,458	$ 8,624	$ 25,017
Personnel related	1,358	2,418	2,583	4,809
Professional fees	492	1,110	961	2,135
Laboratory costs	380	530	716	1,089
Stock-based compensation	233	267	463	530
External research and licensing costs	30	205	51	247
Expenses reimbursed by grants	(550)	(2,228)	(3,233)	(4,342)
Total research and development expense	$ 4,870	$ 16,760	$ 10,165	$ 29,485

The following table summarizes our research and development expenses by program for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Exebacase	$ 2,100	$ 12,096	$ 7,070	$ 22,484
CF-370	1,214	3,314	2,272	4,265
Other research and development	515	892	1,011	1,738
Personnel related and stock-based compensation	1,591	2,686	3,045	5,340
Expenses reimbursed by grants	(550)	(2,228)	(3,233)	(4,342)
Total research and development expense	$ 4,870	$ 16,760	$ 10,165	$ 29,485

Our research and development expenses have decreased substantially beginning in the fourth quarter of 2022, after the workforce reduction and suspension of IV exebacase manufacturing activities in the third quarter of 2022, and also after the final patients in the DISRUPT study completed their follow-up visits and all study sites were closed. Research and development expenses could increase in the future in connection with the commencement of any new clinical trials for our product candidates. However, the successful development of our 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;

- third-party manufacturing of our product candidates and the active pharmaceutical ingredients for our product candidates;
- 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 our product candidates could mean a significant change in the costs and timing associated with the development of such product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including non-cash stock-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 decrease modestly in future periods as a result of decreased headcount, however, legal, accounting, compliance, investor and public relations, and other expenses associated with being a public company continue to increase, particularly insurance premiums.

Restructuring

On July 29, 2022, we implemented a restructuring plan to reduce costs and align resources with the Company's anticipated product development milestones for exebacase and CF-370 and to help preserve the value of the Company's drug discovery operations, resulting in a reduction to our workforce of 16 employees, or approximately 37% of our headcount prior to the reduction and the suspension of IV exebacase manufacturing activities. Pursuant to our restructuring plan, we expect that our future operating expenses, both research and development and general and administrative expenses, will be substantially reduced as compared to the year ended December 31, 2022. In connection with our restructuring, we recognized $7.7 million of charges, including $1.6 million related to employee termination costs, including severance, health benefits and other related expenses from the workforce reduction, and $6.1 million from the write-off of prepaid manufacturing costs following the suspension of IV exebacase activities.

Other Income and Expenses

Other income and expenses consist primarily of interest income, changes in the fair value measurement of our warrant liabilities, the excess of the fair value of warrants issued, if any, over the related proceeds received and offering expenses, if any, allocated to the issuance of warrants. Interest income includes interest earned on our cash and cash equivalents and available-for-sale securities. The changes in the fair value of our warrant liabilities are derived using the Black-Scholes option pricing model. The key inputs into the model are the current per-share value and the expected volatility of the Company's common stock. Significant changes in these inputs will directly increase or decrease the estimated fair value of the Company's warrant liabilities, resulting in a non-cash gain or charge in each reporting period.

Critical Accounting 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 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 six-month period ended June 30, 2023, there have been no material changes to our critical accounting estimates 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, 2022 filed by us with the SEC on March 31, 2023.

Results of Operations

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2023	2022	Dollar Change	2023	2022	Dollar Change
Operating expenses:						
Research and development	$ 4,870	$ 16,760	$ (11,890)	$ 10,165	$ 29,485	$ (19,320)
General and administrative	$ 3,105	$ 3,266	$ (161)	$ 6,668	$ 6,520	$ 148
Other income (expense), net	$ 407	$ 1,937	$ (1,530)	$ 7,894	$ (2,241)	$ 10,135

Comparison of Three Months Ended June 30, 2023 and 2022

Research and Development Expenses

Research and development expenses were $4.9 million for the three months ended June 30, 2023 compared with $16.8 million for the three months ended June 30, 2022, a decrease of $11.9 million. This decrease was primarily attributable to significant reductions in expenditures, including a decrease of $7.1 million on chemistry, manufacturing and controls ("CMC") activities for exebacase, a decrease of $2.8 million on preclinical studies of exebacase and CF-370, a decrease of $1.6 million on contract research organizations ("CROs") to support the completion of the clinical study report for the Phase 3 DISRUPT study of exebacase and a decrease of $1.3 million on headcount and related operating costs as a result of the reduction of the Company's workforce in the third quarter of 2022. Additionally, there was a $0.6 million reduction in the cost of external consultants who were no longer needed to support late-stage development activities for exebacase. Finally, there was a $1.7 million decrease in the reimbursable expenditures under our BARDA contract, partially offsetting the overall decrease.

General and Administrative Expenses

General and administrative expenses were $3.1 million for the three months ended June 30, 2023, compared with $3.3 million for the three months ended June 30, 2022, a decrease of $0.2 million. This was due primarily to a decrease in personnel costs and related expenses.

Other Income, net

Other income was $0.4 million for the three months ended June 30, 2023 compared with $1.9 million for the three months ended June 30, 2022, a decrease of $1.5 million. The decrease in other income was due primarily to the non-cash gain of $0.4 million in the current year period compared to $1.9 million in the prior year period, resulting from the change in fair value of our warrant liabilities in each reporting period.

Comparison of Six Months Ended June 30, 2023 and 2022

Research and Development Expenses

Research and development expenses were $10.2 million for the six months ended June 30, 2023 compared with $29.5 million for the six months ended June 30, 2022, a decrease of $19.3 million. This decrease was primarily attributable to significant reductions in expenditures, including a decrease of $8.9 million on the CMC activities for exebacase, a decrease of $4.9 million on CROs to support the continued closure of the study and completion of the clinical study report for the Phase 3 DISRUPT study of exebacase, a decrease of $2.5 million on preclinical studies of exebacase and CF-370 and a decrease of $2.5 million on headcount and related operating costs as a result of the reduction of the Company's workforce in the third quarter of 2022. Additionally, there was a $1.2 million reduction in the cost of external consultants who were no longer needed to support late-stage development activities for exebacase. Finally, there was an $1.1 million decrease in the reimbursable expenditures under our BARDA contract, partially offsetting the overall decrease.

General and Administrative Expenses

General and administrative expenses were $6.7 million for the six months ended June 30, 2023, compared with $6.5 million for the six months ended June 30, 2022, an increase of $0.2 million. This was due primarily to an increase in costs for expenses incurred to maintain the listing of our common stock on Nasdaq.

Other Income (Expense), net

Other income was $7.9 million for the six months ended June 30, 2023 compared with other expense of $2.2 million for the six months ended June 30, 2022, an increase in income of $10.1 million. The increase in other income was due primarily to the non-cash gain of $7.8 million in the current year period compared to a non-cash charge of $2.3 million in the prior year period, both 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, funding received from government contracts and granting organizations. 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 IPO, we have funded our operations through the sale of registered securities for gross proceeds of $274.8 million, $19.2 million from the exercise of warrants, $26.0 million from the sale of securities in private placements and the receipt of $32.0 million of funding from grant agreements and government contracts. See a summary of our recent equity offerings described above under “Overview”.

As of June 30, 2023, we had $14.4 million in cash, cash equivalents and marketable securities which we do not believe will be sufficient to meet our obligations within the next twelve months from the date of issuance of our consolidated financial statements that are included elsewhere in this Quarterly Report on Form 10-Q. Combined with our accumulated deficit and our forecasted cash expenditures, these factors raise substantial doubt about our ability to continue as a going concern.

As such, under the requirements of Accounting Standard Codification (“ASC”) 205-40, we may not consider the potential for future capital raises in our assessment of our ability to meet our obligations for the next twelve months. We plan to continue to fund our operations through public or private debt and equity financings, but there can be no assurances that such financing will continue to be available to us on acceptable terms, or at all, particularly in light of the Trial Closure and the recent substantial decline in the price of our common stock, and the terms of any public or private offerings of stock could be significantly dilutive to existing stockholders. In 2022, we implemented a restructuring plan, as described above to reduce costs and align resources with our anticipated product development milestones for exebacase and CF-370 and to help preserve the value of our drug discovery operations. If we are unable to obtain funding, we would be forced to further reduce our workforce, or delay, reduce or eliminate our research and development programs, which could adversely affect our business prospects, or we may be unable to continue operations or continue as a going concern and may be forced to sell or liquidate our business.

In the past, we have obtained grants to supplement our financings with non-dilutive funding, including grants from CARB-X, USAMRDC and our former cost-sharing contract with BARDA. Our grant programs under CARB-X have ended. Our contract with BARDA ended on July 31, 2023. We may continue to pursue further non-dilutive funding opportunities and have initiated proposal processes with government agencies for potential non-dilutive funding for the advancement of lysins as biodefense agents. However, there can be no assurances that we will be successful in obtaining new non-dilutive funding or receive the maximum potential funding to the Company under any of our ongoing agreements.

In addition, we are actively seeking a strategic partnership or collaboration with one or more parties, which may include the licensing, sale or divestiture of some of our proprietary technologies. We also actively consider other financial and strategic alternatives, which may include raising additional capital or potential fundamental transactions. Pending a decision to undertake any financial or strategic alternatives, we are continuing research and development activities in accordance with our current innovative therapeutics strategy while managing our cash position. There is no finite timetable for completion of any of these strategic alternatives and we can provide no assurance that any alternative we pursue will have a positive impact on our results of operations or financial condition.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,	
	2023	**2022**
Net cash (used in) provided by:		
Operating activities	$ (16,949)	$ (26,352)
Investing activities	$ 4,730	$ 19,247
Financing activities	$ 17,734	$ —

Net cash used in operating activities

Net cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. Net cash used in operating activities for the six months ended June 30, 2023 decreased by $9.4 million compared to the same period in 2022, due primarily to decreased payments to our contract research and manufacturing organizations as we no longer incur expenditures on late-stage activities related to the clinical study and manufacturing of exebacase.

Net cash provided by investing activities

Net cash provided by investing activities for both the six months ended June 30, 2023 and 2022 were primarily from the proceeds received from the maturities of marketable securities.

Net cash provided by financing activities

Net cash provided by financing activities for the six months ended June 30, 2023 resulted primarily from the $18.2 million of net proceeds from the exercise of warrants pursuant to the June 26, 2023 Inducement Agreement and our March 2, 2023 offering of securities. This was partially offset by $0.4 million of payments on the financing agreement for the Company's annual directors and officers insurance premiums. There was no net cash provided by or used in financing activities for the six months ended June 30, 2022.

Funding Requirements

All of our product candidates are in clinical or preclinical development. We expect to continue to incur significant expenses 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;
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts;
- 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;
- seek to identify additional product candidates;
- acquire or in-license other products and technologies; and
- maintain, leverage and expand our intellectual property portfolio.

For a description of our contractual obligations, see Note 7, “Commitments and Contingencies” to the notes to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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

- the 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 product candidates;
- the extent to which we acquire or in-license other products and technologies;
- costs associated with manufacturing of our product candidates and the active pharmaceutical ingredients for our product candidates;
- 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, or we may be unable to continue operations or continue as a going concern and may be forced to sell or liquidate our business.

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.

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. We continue to monitor the impact of inflationary pressures on purchases and new contractual commitments.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This item is not required for smaller reporting companies.

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 June 30, 2023.

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 June 30, 2023 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 June 30, 2023 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 losses from operations for the six months ended June 30, 2023 and the years ended December 31, 2022 and 2021 were $8.9 million, $64.6 million and $47.3 million, 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 any future commercialization efforts.

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

We currently operate with limited resources. We have incurred significant losses since our inception and have never generated revenue or profit, and it is possible we will never generate revenue or profit. Based on our current operating plans, and without additional funding, we believe we will not have sufficient funds to meet our obligations within the next twelve months from the

issuance of our consolidated financial statements that are included elsewhere in this Quarterly Report on Form 10-Q. These factors raise substantial doubt about our ability to continue as a going concern. We have relied on our ability to fund our operations primarily through public and private debt and equity financings, and, to a lesser extent, funding received from government contracts and granting organizations, but there can be no assurances that such financing or funding will continue to be available to us on satisfactory terms, or at all.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop any of our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, particularly in light of our stopping patient enrollment in our Phase 3 trial of exebacase. If we are unable to obtain funding, we would be forced to further reduce our workforce or delay, reduce or eliminate our research and development programs, which could adversely affect our business prospects, or we may be unable to continue operations or continue as a going concern and may be forced to sell or liquidate our business.

The recent substantial decline in the price per share of our common stock will likely make it more difficult for us to obtain financing. Substantial doubt about our ability to continue as a going concern may further adversely affect the price per share of our common stock. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our consolidated financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments to reflect the possible inability of the Company to continue as a going concern within one year after the issuance of such financial statements. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company.

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

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

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

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

Even if we are able to generate revenues from the sale of our products, we may not become profitable. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital to expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

We will need to obtain substantial additional funding in connection with our continuing operations, particularly if we continue the clinical development of exebacase or CF-370 or develop new product candidates or acquire new product candidates or technologies. In 2022, we implemented a restructuring plan resulting in a reduction to our workforce of 16 employees, or approximately 37% of the Company's headcount prior to the reduction. If we are unable to raise capital when needed or on attractive terms, we could be forced to further reduce our workforce or delay, reduce or eliminate our research and development programs or any future commercialization efforts, or sell or liquidate the Company. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the recent failure of certain financial institutions, COVID-19, the current conflict between Russia and Ukraine and interest rate increases. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms.

The Company maintains a significant portion of its cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at these institutions can exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

In addition, we are actively seeking a strategic partnership or collaboration with one or more parties, which may include the licensing, sale or divestiture of some of our proprietary technologies. We also actively consider other financial and strategic alternatives, which may include raising additional capital or potential fundamental transactions. Pending a decision to undertake any financial or strategic alternatives, we are continuing development and collaboration activities in accordance with our current innovative medicines strategy while managing our cash position. There is no finite timetable for completion of any of these strategic alternatives and we can provide no assurance that any alternative we pursue will have a positive impact on our results of operations or financial condition.

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

- the complexity, timing and results of our clinical trials of our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of developing our product candidates for additional indications;
- our ability to establish scientific or business collaborations on favorable terms, if at all;
- the costs of preparing, filing and prosecuting patent or other intellectual property applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the extent to which we in-license or acquire other product candidates or technologies;
- the scope, progress, results and costs of product development for our product candidates; and
- the effects of COVID-19 and future outbreaks of infection, global supply chain disruptions, international political instability, and rising inflation and interest rates 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. For example, in 2022, we stopped patient enrollment in our Phase 3 trial of exebacase based on the recommendation of the DSMB.

In addition, if approved, any product candidates that we develop may not achieve commercial success. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives and to continue as a going concern. 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.

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, 2022, we had federal and state net operating loss carryforwards of $283.7 million and $302.0 million, respectively, and federal research and development credits of $8.2 million, the use of which could be limited or eliminated by virtue of one or more "ownership changes."

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

Any future pandemics, epidemics or outbreaks of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials.

The measures taken in response to COVID-19 have had a significant impact on the economy and, to a lesser extent, both directly and indirectly, on our business. We adjusted our business operations, with a majority of our employees working remotely. Our Phase 3 DISRUPT clinical trial was also affected, as clinical sites experienced periodic delays in new patient enrollment.

As a result of COVID-19 and variants of the virus or another 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 contracting COVID-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 COVID-19 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 on-site activities;

•interruption or delays of our sourced discovery and clinical activities; and

•the ability of our contract research organizations ("CROs"), contract manufacturing organizations and suppliers to meet their contractual obligations in connection with the conduct of our clinical trial for our current product candidate and for any future product candidate.

The extent to which COVID-19 further impacts 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, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic and future waves of infection, including the spread of variants of the virus, the availability, adoption and effectiveness of vaccines and treatments, 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 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 candidates. 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 any of our product candidates, our business will be substantially harmed.

Our near-term business prospects are substantially dependent on our ability to develop our product candidates. In 2022, we stopped patient enrollment in our Phase 3 trial of exebacase based on the recommendation of the DSMB. We expect that conclusions drawn from the ongoing data review will inform next steps for any potential further development of exebacase for the treatment of Staph bacteremia. We cannot market or sell any of our product candidates in the United States without FDA approval. To commercialize any product candidate outside of the United States, we will need applicable foreign regulatory approvals. The clinical development of any 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 or outside the United States, until we receive similar approval from foreign regulatory authorities.

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 or other regulatory authorities 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 any 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 any of our product candidates 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 any of our 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 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 any of our product candidates, which would significantly harm our business. In addition, disruptions caused by COVID-19 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 any of our product candidates that we develop fail to demonstrate safety and efficacy, or the manufacturing for the commercial supply of drug substance or drug product fails to demonstrate robustness, stability, purity and potency 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 or any of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidate, we must complete preclinical development, perform extensive process validation and complete the manufacturing of our initial commercial supply of product to demonstrate robustness, stability, purity and potency of our drug product, 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. For example, on July 7, 2022, the DSMB for the Phase 3 DISRUPT study recommended that the trial be stopped because the conditional power of the study was below the pre-specified threshold for futility and we subsequently terminated patient enrollment in the Phase 3 DISRUPT study.

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 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 COVID-19.

If we are required to conduct additional clinical trials or other testing of any of our product candidates 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.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to

all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the (EU) CTR or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted.

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 or similar risk management system, 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 consent;

•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. For example, our Phase 3 DISRUPT clinical trial experienced some delays in patient enrollment as a result of the COVID-19 pandemic, as some clinical sites in high impact areas delayed new patient enrollment as dictated by local conditions. Such delays impacted and could further 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 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 any of our 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 our product candidates. 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 and similar foreign 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 and comparable regulatory authorities enforce their 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 any of our product candidates to a statistically significant degree, our clinical trials will require an adequately large number of test subjects. Any clinical trial that a CRO conducts abroad on our behalf is subject to similar regulation. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, we may have to repeat clinical trials, which would delay the regulatory approval process.

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

If any of our relationships with these CROs change or terminate, we may not be able to enter into arrangements with alternative CROs or clinical study management organizations, or be able to do so on commercially reasonable terms. Switching or adding additional CROs or other clinical study management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO or clinical study management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

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 or biologics 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.

We rely on contract manufacturing organizations ("CMOs") to manufacture clinical and commercial supplies of our product candidates. In addition to the 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, 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 any of our product candidates.

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture any of our 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.

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 successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA (or similar regulatory authorities);
- 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;
- 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 or if the third-party otherwise does not satisfactorily perform according to the terms of the agreements between us and 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 and know-how.

In the fourth quarter of 2020, we were notified by Fujifilm UK that they experienced equipment failures that would impact their manufacturing timelines. As a result, we transferred manufacturing to Fujifilm USA and, at this time, expect to complete the process validation and initial commercial manufacturing of drug substance with Fujifilm USA, if required. 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 COVID-19, 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 or commercialization and prevent or delay its successful development or commercialization.

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 or similar 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 or foreign regulatory authorities, 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 our product candidates.

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

Even if any of our 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 any of our product candidates 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 any of our product candidates that we develop, including as a result of healthcare reform measures, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of any of our product candidates 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 any of our product candidates 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 any of our product candidates 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 ACA became law in the United States. The ACA substantially changed the way health care is financed by both governmental and private insurers. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to drugs dispensed 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. 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 ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA is expected to remain in effect in its current form.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, resulted in aggregate reductions of Medicare payments to providers, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, 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. More recently, on March 11, 2021, President Biden signed into law the American Rescue Plan Act of 2021, which eliminates the statutory cap on the Medicaid drug rebate, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

More recently, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. 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 any future products.

In addition to actions at the federal level, individual states in the United States have also proposed and enacted legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

We expect to experience pricing pressures in connection with the sale of any of our product candidates 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 any of our product candidates in the United States or elsewhere. However, we may not be able to enter into arrangements with third parties to sell any of our product candidates 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 any of our product candidates 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 are seeking to form strategic alliances and we may not realize the benefits of such alliances.

We are actively seeking to form 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 any 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 any 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 any 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 any 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, any product candidates, and our ability to generate revenue will be materially impaired.

Any of our product candidates 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. Any 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. Similar risks exist in foreign jurisdictions.

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, or similar requirements outside the United States, 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 or similar requirements outside the United States 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, or similar applications in foreign jurisdictions, 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.

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. 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 of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-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 in off-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 potential future Biologics License Applications, or BLAs, for substantive review or may

conclude after review of our data that our application is insufficient to obtain regulatory approval of any of our product candidates. If the FDA does not accept or approve any or all of our potential future 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 any of our product candidates, 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 and foreign regulatory authorities 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 or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities 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 EMA 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, 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 COVID-19 pandemic, in March 2020, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 environment, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the spread of COVID-19. 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.

If foreign approval for any of our product candidates 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 our product candidates whenever it may be approved and wherever we have the right to market it. Consequently, we expect that we will be subject to additional risks related to entering into international business relationships, including:

- potentially reduced protection for intellectual property rights;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with laws for employees working and traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting active pharmaceutical ingredient and/or finished drug product supply or manufacturing capabilities abroad;

•business interruptions resulting from geo-political actions, including war and terrorism, epidemics or natural disasters including earthquakes, typhoons, floods and fires; and

•failure to comply with the rules and regulations of the Office of Foreign Asset Control, the Foreign Corrupt Practices Act and other applicable anti-bribery rules and regulations in other jurisdictions.

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 our product candidates 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 ACA 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.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. In the EU, these exclusivity periods are even shorter. Upon receiving marketing authorization, new chemical or biological 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 foreign, 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;

- 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 ACA 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and their immediate family members and payments or other transfers of value made to such physician owners;

•analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information; and

•similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

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.

The UK left the EU on January 31, 2020. It is currently unclear to what extent the UK Government will seek to align its regulations with the EU. The EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and "assimilated" into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the (EU) CTR is not applicable in Great Britain. While the EU-UK Trade and Cooperation Agreement ("TCA"), includes the mutual recognition of Good Manufacturing Practice ("GMP") inspections of manufacturing facilities for medicinal products and GMP documents issued, it does not contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards. There may be divergent local requirements in Great Britain from the EU in the future, which may impact clinical and development activities that occur in the UK in the future. Similarly, clinical trial submissions in the UK will not be able to be bundled with those of EU member states within the EMA Clinical Trial Information System, adding further complexity, cost and potential risk to future clinical and development activity in the UK. Significant political and economic uncertainty remains about how much the relationship between the UK and EU will differ as a result of the UK's withdrawal.

These developments, or the perception that any related developments could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our common stock.

The uncertainty regarding new or modified arrangements between the UK and other countries following the withdrawal may have a material adverse effect on the movement of personnel, goods, information or data between the UK and members of the EU and the United States, including the interruption of or delays in imports into the UK of goods originating within the EU and exports from

the UK of goods originating there. For example, shipments into the UK of medicinal product substance manufactured for us in the EU may be interrupted or delayed and thereby prevent or delay the manufacture in the UK of medicinal product. Similarly, shipments out of the UK of medicinal product to the United States or the EU 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.

Increased scrutiny of and evolving expectations for environmental, social and governance ("ESG") initiatives may impose additional costs or otherwise adversely impact our business.

There has been an increased focus from investors, capital providers, shareholder advocacy groups, other market participants, customers, and other stakeholder groups regarding companies' ESG initiatives. While we may at times engage in voluntary initiatives (such as voluntary disclosures, certifications, or goals, among others) or commitments to improve the ESG profile of our Company, such initiatives or achievements of such commitments may be costly and may not have the desired effect. Additionally, some investors may use third-party or proprietary ESG ratings to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our ESG practices are inadequate. The criteria by which companies' ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy new criteria or do not meet the criteria, some investors may conclude that our policies with respect to ESG are inadequate and choose not to invest in us.

If our ESG practices do not meet evolving investor or other stakeholder expectations and our standards, reputation, ability to attract or retain employees and desirability as an investment or business partner could be negatively impacted. Similarly, our failure or perceived failure to adequately pursue or fulfill any ESG goals and objectives or to satisfy various reporting standards, if any, could expose us to additional regulatory, social or other scrutiny, the imposition of unexpected costs, or damage to our reputation, which in turn could have a material adverse effect on our business and could cause the market value of our common stock to decline.

Risks Related to Employee Matters and Our Operations

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.

Furthermore, in light of our 2022 reduction in headcount as part of our restructuring program as described below, we may find it difficult to maintain valuable aspects of our culture, to prevent a negative effect on employee morale or attrition beyond our planned reduction in headcount, and to attract competent personnel who are willing to embrace our culture in the future. Our executive officers and other employees are at-will employees, which means they may terminate their employment relationship with us at any time, and their knowledge of our business and industry would be extremely difficult to replace. We may not be able to retain the services of any members of our senior management or other key employees. If we do not succeed in retaining and motivating existing employees or attracting well-qualified employees in the future, our business, financial condition and results of operations could be materially and adversely affected.

We may not successfully execute or achieve the expected benefits of our 2022 restructuring program and other cost saving measures we may take in the future, and our efforts may result in further actions and may adversely affect our business, financial condition and results of operations.

On July 29, 2022, we implemented a restructuring plan to reduce costs and align resources with the Company's anticipated product development milestones for exebacase and CF-370 and to help preserve the value of the Company's drug discovery operations, resulting in a reduction to our workforce of 16 employees, or 37% of our headcount prior to the reduction and the suspension of IV exebacase manufacturing activities. The reduction included the resignation of Cara Cassino, M.D. as Chief Medical Officer and Executive Vice President of Research and Development of the Company. We recognized a restructuring charge in the third quarter of 2022 of $7.7 million, including $1.6 million related to employee termination costs, including severance, health benefits and other related expenses from the workforce reduction, and $6.1 million from the write-off of prepaid manufacturing costs, which will result in future cash expenditures of up to $3.4 million as of June 30, 2023.

The restructuring program is based on our current estimates, assumptions and forecasts, which are subject to known and unknown risks and uncertainties, including assumptions regarding cost savings, cash burn rate, and effectiveness of our reduced spend. Accordingly, we may not be able to fully realize the cost savings, enhanced liquidity and other benefits anticipated from the restructuring program. Additionally, implementation of the restructuring program and any other cost-saving initiatives may be costly and disruptive to our business, the expected costs and charges may be greater than we have forecasted, and the estimated cost savings may be lower than we have forecasted. In addition, our initiatives could result in personnel attrition beyond our planned reduction in headcount or reduce employee morale, which could in turn adversely impact productivity, including through a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods, or our ability to attract highly skilled employees. Unfavorable publicity about us or our restructuring program could result in reputational harm and could diminish confidence in our brand and business model. The restructuring program has required, and may continue to require, a significant amount of management's and other employees' time and focus, which may divert attention from effectively operating our business.

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 has been 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 COVID-19 and the recent failure of certain financial institutions. 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.

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 on Form 10-Q, 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.

We may not meet certain of Nasdaq Capital Market's continued listing requirements and other Nasdaq rules upon the filing of this Quarterly Report on Form 10-Q. If we are unable to comply with the continued listing requirement for listing on Nasdaq, we are likely to be delisted. Delisting could negatively affect the price of our common stock, which could make it more difficult for us to sell securities in a future financing or for you to sell our common stock.

We are required to meet the continued listing requirements of the Nasdaq Capital Market and other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. For example, we are required to maintain a minimum bid price for our listed common stock of $1.00 per share and maintain stockholders' equity of at least $2.5 million. If we do not meet these continued listing requirements, our common stock could be delisted.

On November 22, 2022, we received an expected letter from The Nasdaq Stock Market LLC ("Nasdaq"), referred to herein as the Nasdaq Staff Deficiency Letter, indicating that our stockholders' deficit as reported in our Quarterly Report on Form 10-Q for the period ended September 30, 2022, did not satisfy the continued listing requirement under Nasdaq Listing Rule 5550(b)(1) (the "Rule") for the Nasdaq Capital Market, which requires that a listed company's stockholders' equity be at least $2.5 million. On July 21, 2023, we received notice from Nasdaq that we had regained compliance with the Rule (the "Compliance Notice"). However, the Company expects that it may not comply with the Rule upon filing of this Quarterly Report on Form 10-Q. In the Compliance Notice, Nasdaq indicated that if the Company fails to comply with the Rule within one year of the Compliance Notice, the Company would receive a Delist Determination Letter. The Company expects to have the ability to appeal any Delist Determination Letter.

We continue to evaluate various alternative courses of action to be compliant with the continued listing requirement under the Rule for the Nasdaq Capital Market. However, there can be no assurance that we will be able to satisfy the Nasdaq Capital Market's continued listing requirements in the future.

Delisting from the Nasdaq Capital Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, or on the "pink sheets." In such case, our stockholders' ability to trade, or obtain quotations of the market value of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our securities, if delisted from the Nasdaq Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the over-the-counter markets or the pink sheets. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

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 August 10, 2023, we have approximately 10.7 million shares of common stock outstanding, of which substantially all 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 7.0 million shares of our common stock outstanding as of August 10, 2023.

We have registered 80,056 shares of our common stock as of May 10, 2023 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. Our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error (e.g., social engineering, phishing), fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. 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 COVID-19 and the current conflict between Russia and Ukraine, 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. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, 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. Similar laws have passed in Virginia and Colorado and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. 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, in July 2020, the Court of Justice of the European Union (the "CJEU") limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the EU-U.S. Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses ("SCCs"). 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 (SCCs) may not necessarily be a sufficient alternative. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements were required to be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021 and laid its proposal before Parliament, with the UK SCCs expected to come into force in March 2022, with a two-year grace period. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. 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, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or 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 provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. 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, we have had 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 European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision and remains under review by the Commission during this period. The relationship between the UK 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 may lead to additional costs and increase our overall risk exposure.

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

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

We 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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, the failure of multiple financial institutions, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. If any of our financial institutions fail, the funds in operating accounts at our financial institutions could exceed FDIC insurance limits and our cash balances could be negatively impacted. In addition, there is a risk that one or more of our CROs, suppliers or other third-party providers may be impacted by financial institution failure or not survive an economic downturn or recession. As a result, our business, results of operations and price of our common shares may be adversely affected.

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, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Other than sales previously reported in the Company's Current Report on Form 8-K filed with the SEC on June 27, 2023, the Company did not sell any unregistered securities during the period covered by this report.

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, Certificate of Amendment dated February 3, 2020, and Certificate of Amendment dated February 24, 2022 (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	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ContraFect Corporation, dated February 14, 2023 (incorporated by reference to Exhibit 3.1 of the Company' Form 8-K (File No. 001-36577) filed with the SEC on February 14, 2023)
3.3	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)
4.1	Form of Class C Common Stock Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K (File No. 001-3657) filed with the SEC on June 27, 2023)
4.2	Form of Class D Common Stock Warrant (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K (File No. 001-3657) filed with the SEC on June 27, 2023)
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*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* 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: August 14, 2023

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: August 14, 2023

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 Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2023

/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 Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2023

/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 June 30, 2023, 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: August 14, 2023

/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 June 30, 2023, 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: August 14, 2023

/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.