

**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 September 30, 2019

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
(State or other jurisdiction of
incorporation or organization)

39-2072586
(I.R.S. Employer
Identification No.)

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

10701
(Zip Code)

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

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

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

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

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

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

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

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

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

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

The number of shares of the registrant's Common Stock outstanding as of November 7, 2019 was 79,409,556.

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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 (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (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, our beliefs regarding lysins, future operations, future financial position, the sufficiency of our cash and cash equivalents and marketable securities, future revenues, projected costs, prospects and plans and objectives of management, and our ability to meet Nasdaq Capital Market’s continued listing requirements. 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:

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

As more fully described under the heading “Risk Factors” contained elsewhere in this Quarterly Report on Form 10-Q, many important factors affect our ability to achieve our stated objectives and to develop and commercialize any product candidates. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks and uncertainties set forth in our filings with the SEC. You should read this Quarterly Report on Form 10-Q with the understanding that our actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

CONTRAFECT CORPORATION
PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CONTRAFECT CORPORATION
Consolidated Balance Sheets

	September 30, 2019	December 31, 2018
	(unaudited)	(audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,501,589	\$ 8,320,317
Marketable securities	—	22,131,936
Prepaid expenses and other current assets	2,340,520	988,799
Total current assets	12,842,109	31,441,052
Property and equipment, net	1,147,727	1,076,099
Operating lease right-of-use assets	3,098,179	—
Other assets	355,420	355,420
Total assets	<u>\$ 17,443,435</u>	<u>\$ 32,872,571</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,373,643	\$ 1,427,287
Accrued liabilities	2,657,354	4,369,732
Current portion of lease liabilities	628,676	—
Total current liabilities	7,659,673	5,797,019
Deferred rent	—	679,182
Warrant liabilities	2,159,192	20,781,663
Long-term portion of lease liabilities	3,332,866	—
Other liabilities	72,747	72,747
Total liabilities	13,224,478	27,330,611
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 25,000,000 shares authorized and none outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.0001 par value, 200,000,000 shares authorized; 79,409,556 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	7,941	7,941
Additional paid-in capital	205,969,917	204,884,211
Accumulated other comprehensive loss	—	(30,300)
Accumulated deficit	(201,758,901)	(199,319,892)
Total stockholders' equity	4,218,957	5,541,960
Total liabilities and stockholders' equity	<u>\$ 17,443,435</u>	<u>\$ 32,872,571</u>

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Operations
(unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Operating expenses				
Research and development	\$ 5,250,327	\$ 5,710,455	\$ 14,161,543	\$ 15,698,129
General and administrative	2,376,248	2,088,835	7,234,244	6,581,784
Total operating expenses	<u>7,626,575</u>	<u>7,799,290</u>	<u>21,395,787</u>	<u>22,279,913</u>
Loss from operations	(7,626,575)	(7,799,290)	(21,395,787)	(22,279,913)
Other income (expense):				
Interest income, net	80,747	174,778	334,307	490,170
Change in fair value of warrant liabilities	2,186,710	3,246,765	18,622,471	(21,830,377)
Total other income (expense)	<u>2,267,457</u>	<u>3,421,543</u>	<u>18,956,778</u>	<u>(21,340,207)</u>
Net loss	<u>\$ (5,359,118)</u>	<u>\$ (4,377,747)</u>	<u>\$ (2,439,009)</u>	<u>\$ (43,620,120)</u>
Basic and diluted net loss per share	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>	<u>\$ (0.03)</u>	<u>\$ (0.58)</u>
Shares used in computing basic and diluted net loss per share	<u>79,409,556</u>	<u>77,447,599</u>	<u>79,409,556</u>	<u>74,934,774</u>

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Comprehensive Loss
(unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Net loss	\$ (5,359,118)	\$ (4,377,747)	\$ (2,439,009)	\$ (43,620,120)
Other comprehensive gain:				
Unrealized gain on available-for-sale securities	—	24,677	30,300	55,445
Comprehensive loss	<u>\$ (5,359,118)</u>	<u>\$ (4,353,070)</u>	<u>\$ (2,408,709)</u>	<u>\$ (43,564,675)</u>

See accompanying notes.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2018	79,409,556	\$ 7,941	\$ 204,884,211	\$ (30,300)	\$ (199,319,892)	\$ 5,541,960
Share-based compensation	—	—	323,774	—	—	323,774
Unrealized gain on marketable securities	—	—	—	31,336	—	31,336
Net income	—	—	—	—	11,587,015	11,587,015
Balance, March 31, 2019	79,409,556	\$ 7,941	\$ 205,207,985	\$ 1,036	\$ (187,732,877)	\$ 17,484,085
Share-based compensation	—	—	369,927	—	—	369,927
Unrealized gain on marketable securities	—	—	—	960	—	960
Net loss	—	—	—	—	(8,666,906)	(8,666,906)
Balance, June 30, 2019	79,409,556	\$ 7,941	\$ 205,577,912	\$ 1,996	\$ (196,399,783)	\$ 9,188,066
Share-based compensation	—	—	392,005	—	—	392,005
Unrealized loss on marketable securities	—	—	—	(1,996)	—	(1,996)
Net loss	—	—	—	—	(5,359,118)	(5,359,118)
Balance, September 30, 2019	79,409,556	\$ 7,941	\$ 205,969,917	\$ —	\$ (201,758,901)	\$ 4,218,957

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2017	73,656,006	\$ 7,366	\$ 192,896,367	\$ (74,820)	\$ (161,635,468)	\$ 31,193,445
Share-based compensation	—	—	437,681	—	—	437,681
Unrealized loss on marketable securities	—	—	—	(16,800)	—	(16,800)
Issuance of common stock for exercise of warrants	2,500	—	3,875	—	—	3,875
Net loss	—	—	—	—	(19,106,481)	(19,106,481)
Balance, March 31, 2018	73,658,506	\$ 7,366	\$ 193,337,923	\$ (91,620)	\$ (180,741,949)	\$ 12,511,720
Share-based compensation	—	—	416,133	—	—	416,133
Unrealized gain on marketable securities	—	—	—	47,568	—	47,568
Issuance of common stock for exercise of warrants	1,050	—	1,628	—	—	1,628
Net loss	—	—	—	—	(20,135,892)	(20,135,892)
Balance, June 30, 2018	73,659,556	\$ 7,366	\$ 193,755,684	\$ (44,052)	\$ (200,877,841)	\$ (7,158,843)
Share-based compensation	—	—	383,158	—	—	383,158
Unrealized gain on marketable securities	—	—	—	24,677	—	24,677
Issuance of common stock in registered offering	5,750,000	575	11,499,425	—	—	11,500,000
Financing cost of sale of securities	—	—	(1,072,607)	—	—	(1,072,607)
Net loss	—	—	—	—	(4,377,747)	(4,377,747)
Balance, September 30, 2018	79,409,556	\$ 7,941	\$ 204,565,660	\$ (19,375)	\$ (205,255,588)	\$ (701,362)

See accompanying notes.

CONTRAFECT CORPORATION
Consolidated Statements of Cash Flows
(unaudited)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (2,439,009)	\$ (43,620,120)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	126,786	110,263
Stock-based compensation expense	1,085,706	1,236,972
Change in fair value of warrant liabilities	(18,622,471)	21,830,377
Decrease in deferred rent	—	(19,292)
Net amortization of premium on marketable securities	171,111	406,211
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other current and non-current assets	(1,369,019)	82,865
Increase in accounts payable, accrued liabilities and other liabilities	1,257,043	770,661
Net cash used in operating activities	<u>(19,789,854)</u>	<u>(19,202,063)</u>
Cash flows from investing activities		
Purchases of marketable securities	—	(20,267,927)
Proceeds from sales of marketable securities	21,991,125	33,130,888
Purchases of property and equipment	<u>(19,999)</u>	<u>(133,488)</u>
Net cash provided by investing activities	21,971,126	12,729,473
Cash flows from financing activities		
Proceeds from issuance of securities	—	11,500,000
Payment of financing cost of securities sold	—	(1,072,607)
Proceeds from exercise of warrants	<u>—</u>	<u>5,503</u>
Net cash provided by financing activities	<u>—</u>	<u>10,432,896</u>
Net increase in cash and cash equivalents	2,181,272	3,960,306
Cash and cash equivalents at beginning of period	8,320,317	6,995,046
Cash and cash equivalents at end of period	<u>\$ 10,501,589</u>	<u>\$ 10,955,352</u>
Supplemental disclosures of cash flow information:		
Right-of-use assets obtained in exchange for lease obligations	\$ 4,148,672	\$ —
Leasehold improvement obtained in exchange for lease incentive obligations	\$ 189,227	\$ —

See accompanying notes.

CONTRAFECT CORPORATION
Notes to Unaudited Consolidated Financial Statements
September 30, 2019

1. Organization and Description of Business

Organization and Business

ContraFect Corporation (the “Company”) is a clinical-stage biotechnology company focused on biologic therapeutic products for life-threatening infectious diseases, particularly those treated in hospital-based settings. The Company intends to address multi-drug resistant infections using its therapeutic product candidates from its portfolio of direct lytic agents (DLAs), including lysins and amurin peptides. The Company’s most advanced product candidate is exebacase, a lysin which targets *Staphylococcus aureus* (*Staph aureus*) including methicillin-resistant *Staph aureus* (MRSA), which causes serious infections such as bacteremia, pneumonia and osteomyelitis. *Staph aureus* is also a frequent cause of biofilm-associated infections of heart valves (endocarditis), prosthetic joints, indwelling devices and catheters. These infections result in significant morbidity and mortality despite current antibiotic therapy. The Company has completed a Phase 2 superiority design study of exebacase as a treatment for *Staph aureus* bacteremia, including endocarditis. The study evaluated and compared the safety, tolerability, efficacy and pharmacokinetics of exebacase when used in addition to standard-of-care (SOC) antibiotics to SOC antibiotics alone. The Company intends to initiate a Phase 3 trial of exebacase based on the positive data generated from the Phase 2 study.

The Company has incurred losses from operations since inception as a research and development organization and has an accumulated deficit of \$201.8 million as of September 30, 2019. For the nine months ended September 30, 2019, the Company used \$19.8 million of cash in operations. The Company expects operating losses and negative cash flows to continue at significant levels in the future as it continues its clinical trials. Without additional funding, the Company believes it will not have sufficient funds to meet its obligations within the next twelve months from the date of issuance of these consolidated financial statements. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The Company plans to continue to fund its operations through public or private debt and equity financings, but there can be no assurances that such financing will continue to be available to the Company on satisfactory terms, or at all. As such, under the requirements of ASC 205-40, management may not consider the potential for future capital raises in its assessment of the Company’s ability to meet its obligations for the next twelve months. If the Company is unable to obtain funding, the Company would be forced to delay, reduce or eliminate its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial information as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 has been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (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, 2018 was derived from the Company’s audited consolidated financial statements. The Company’s audited consolidated financial statements as of and for the year ended December 31, 2018, including all related disclosures and the complete listing of significant accounting policies as described in Note 2 thereof, are included in the Company’s Annual Report on Form 10-K that was filed with the SEC on March 14, 2019.

In the opinion of management, the unaudited financial information as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 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 nine months ended September 30, 2019 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 and the Company's ability to raise capital.

Use of Estimates

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

Concentrations of Credit Risk

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

Cash and Cash Equivalents

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

Marketable Securities

Marketable securities consist of investments in corporate debt and U.S. Treasury securities. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, *Investments – Debt and Equity Securities*. The Company classifies marketable securities available to fund current operations as current assets on its consolidated balance sheets. Marketable securities are classified as long-term assets on the consolidated balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity and a component of total comprehensive income (loss) in the consolidated statements of comprehensive income (loss), until realized. The fair value of these securities is based on quoted prices for identical or similar assets. Realized gains and losses are included in interest income in the consolidated statement of operations and comprehensive loss on a specific-identification basis. There were no realized gains or losses on marketable securities for the three and nine months ended September 30, 2019 or 2018. There were no marketable securities that had been in an unrealized loss position for more than 12 months as of December 31, 2018.

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

Fair Value of Financial Instruments

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

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 820, *Fair Value Measurements and Disclosures*, establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality.

The three levels of the fair value hierarchy are described below:

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

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

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

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

The carrying amounts reported in the accompanying financial statements for accounts payable and accrued expenses approximate their respective fair values due to their short-term maturities. The fair value of the warrant liabilities is discussed in Note 4, "Fair Value Measurements."

Share-based Compensation

The Company accounts for share-based compensation in accordance with ASC 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employees and non-employee directors, including employee stock options. For employee and non-employee directors, compensation expense based on the grant date fair value is generally amortized over the requisite service period of the award on a straight-line basis. For non-employees, effective January 1, 2019, unvested option compensation expense is based on the adoption date fair value and is amortized over the service period on a straight line basis.

The fair value of options is calculated using the Black-Scholes option pricing model to determine the fair value of stock options on the date of grant for employee and non-employee directors and as of January 1, 2019 for the unvested non-employee stock options based on key assumptions such as stock price, expected volatility and expected term. The Company's estimates of these assumptions are primarily based on historical data, peer company data and judgment regarding future trends and factors.

Grants

The Company recognizes a receivable and the related reduction in its research and development expenses when the actual reimbursable costs have been incurred and there is reasonable assurance that the Company has complied with the conditions of the grants and the amounts will be received. The Company recognized a reduction to its research and development expense in the amount of approximately \$1.3 million and \$0.3 million for the three months ended September 30, 2019 and 2018 respectively, and \$2.4 million and \$1.1 million for the nine months ended September 30, 2019 and 2018, respectively. The receivable for grants as of September 30, 2019 and December 31, 2018 was approximately \$1.2 million and \$0.2 million respectively, and is included in prepaid expenses and other current assets on the balance sheet. The Company has approximately \$9.4 million of approved grant award funding remaining as of September 30, 2019.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of a dilutive net loss per share calculation, stock options and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive given the Company's net loss.

Recently Adopted Accounting Pronouncements

Leases

The Company adopted Accounting Standards Update No. 2016-02-*Leases (Topic 842)*, as of January 1, 2019, using the optional modified retrospective approach with no cumulative-effect adjustment to equity as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under previous lease guidance. The Company elected the package of practical expedients permitted under the transition guidance within Topic 842, which among other things, allowed it to carry forward the historical lease classification of those leases in place as of January 1, 2019 and to not separate lease and non-lease components when the requisite criteria is met to be treated as such. The Company determined that the only contract containing a lease was the lease of its corporate headquarters at 28 Wells Avenue in Yonkers, New York (see "Note 7—Commitments" in these consolidated financial statements for a description of the leases).

The Company recognizes right-of-use (ROU) assets at the inception of the arrangement as the present value of the lease payments plus our initial direct costs, if any, less any lease incentives. The corresponding liability is computed as the present value of the lease payments at inception. Assets are classified as either operating or finance ROU assets according to the classification criteria in Topic 842. The present value of the lease payments is computed using the rate implicit in the lease, if known, or the Company's incremental borrowing rate. Operating lease costs are charged to operations on a straight line basis over the term of the lease. Under the Company's policy, it does not record an ROU asset or corresponding liability for arrangements where the initial lease term is one year or less. Those leases are expensed on a straight line basis over the term of the lease.

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

Non-employee Stock Compensation

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

Statements of Equity

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. Additionally, the amendments expanded the disclosure requirements on the consolidated statements of equity for interim financial statements. Under the amendments, a summary of changes in each caption of stockholders' equity presented in the consolidated balance sheets must be provided in a note or separate statement. The consolidated statements of equity should present a reconciliation of a beginning balance to the ending balance of each period for which the consolidated statement of comprehensive income is required to be filed. This final rule was effective in the fourth quarter of 2018. The SEC provided relief on the effective date until the first quarter of 2019, and the Company adopted this rule in the first quarter of 2019.

Recent Accounting Pronouncements Not Yet Adopted

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

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

3. Marketable Securities

The Company held no marketable securities at September 30, 2019. Marketable securities at December 31, 2018 consisted of the following:

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

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

At December 31, 2018, the Company held 21 debt securities that individually and in total were in an immaterial unrealized loss position for less than one year. The aggregate fair value of debt securities in an unrealized loss position at December 31, 2018 was \$18,551,296. The Company evaluated its securities for other-than-temporary impairment and considered the decline in market value for the securities to be primarily attributable to current economic and market conditions. It is not more likely than not that the Company will be required to sell the securities prior to the recovery of the amortized cost basis. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of December 31, 2018.

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 September 30, 2019 and December 31, 2018:

	Fair Value Measurement as of September 30, 2019		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 8,688,134	\$ —	\$ —
Warrant liabilities	—	—	2,159,192
Total	<u>\$ 8,688,134</u>	<u>\$ —</u>	<u>\$ 2,159,192</u>

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

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The Company issued a warrant to the representative of the underwriter of its initial public offering (the “Representative’s Warrant”). The Company determined that this warrant should be classified as a liability and considered it as a Level 3 financial instrument (see also Note 8, “Capital Structure”). The Representative’s Warrant was re-measured at each subsequent reporting period and changes in fair value were recognized in the consolidated statement of operations. The Representative’s Warrant expired in accordance with its terms on July 28, 2019. The following assumptions were used in a Black-Scholes option-pricing model to determine the fair value of the warrant liability:

	As of December 31, 2018
Expected volatility	70.9%
Remaining contractual term (in years)	0.67
Risk-free interest rate	2.63%
Expected dividend yield	— %

The Company issued warrants to the purchasers of its 2016 Offering (the “2016 Warrants”). The Company determined that these warrants should be classified as a liability and considered as a Level 3 financial instrument (see also Note 8, “Capital Structure”). The 2016 Warrants are re-measured at each subsequent reporting period and changes in fair value are recognized in the consolidated statement of operations. The following assumptions were used in a Black-Scholes option-pricing model to determine the fair value of the warrant liability:

	As of September 30, 2019	As of December 31, 2018
Expected volatility	102.8%	72.6%
Remaining contractual term (in years)	1.83	2.58
Risk-free interest rate	1.63%	2.46%
Expected dividend yield	— %	— %

The Company issued warrants to the purchasers of its 2017 Offering (the “2017 Warrants”). The Company determined that these warrants should be classified as a liability and considered as a Level 3 financial instrument (see also Note 8, “Capital Structure”). The 2017 Warrants are re-measured at each subsequent reporting period and changes in fair value are recognized in the consolidated statement of operations. The following assumptions were used in a Black-Scholes option-pricing model to determine the fair value of the warrant liability:

	As of September 30, 2019	As of December 31, 2018
Expected volatility	97.6%	87.3%
Remaining contractual term (in years)	2.83	3.58
Risk-free interest rate	1.56%	2.49%
Expected dividend yield	— %	— %

The following tables present a reconciliation of the Company’s financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three and nine months ended September 30, 2019 and 2018:

Warrant liabilities

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Balance at beginning of period	\$ 4,345,902	\$38,626,579	\$ 20,781,663	\$13,549,437
(Decrease) increase in fair value (1)	(2,186,710)	(3,246,765)	(18,622,471)	21,830,377
Balance at end of period	<u>\$ 2,159,192</u>	<u>\$35,379,814</u>	<u>\$ 2,159,192</u>	<u>\$35,379,814</u>

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

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The key inputs into the Black-Scholes option pricing 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.

5. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2019	December 31, 2018
Accrued compensation costs	\$ 968,169	\$ 1,585,689
Accrued research and development service fees	583,176	2,076,764
Accrued insurance costs	459,381	—
Accrued professional fees	416,229	433,498
Accrued facilities operation expenses	193,391	232,673
Other accrued liabilities	37,008	41,108
Total accrued liabilities	<u>\$ 2,657,354</u>	<u>\$ 4,369,732</u>

6. Net Loss Per Share of Common Stock

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (5,359,118)	\$ (4,377,747)	\$ (2,439,009)	\$ (43,620,120)
Weighted average shares of common stock outstanding	<u>79,409,556</u>	<u>77,447,599</u>	<u>79,409,556</u>	<u>74,934,774</u>
Net loss per share of common stock - basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>	<u>\$ (0.03)</u>	<u>\$ (0.58)</u>

The following table sets forth the potentially dilutive securities outstanding at September 30, 2019 and 2018 that were excluded from the computation of diluted weighted average shares outstanding:

	September 30,	
	2019	2018
Options to purchase common stock	12,465,806	7,248,198
Warrants to purchase common stock	<u>30,339,059</u>	<u>31,265,182</u>
Total	<u>42,804,865</u>	<u>38,513,380</u>

7. Commitments

Leases

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

In December 2010, the Company entered into a non-cancellable operating lease for office space and laboratory facilities in Yonkers, New York expiring in December 2025. In December 2011, the Company entered into an amendment which extended the term of the lease through December 2027 (the "Third Floor Lease"). The lease provides for the option to renew for two additional five-year terms. The premises were occupied in June 2011. Monthly rent payments began the date the office and laboratory facilities were ready for occupancy.

In January 2012, the Company entered into a non-cancellable operating lease for additional office space and laboratory facilities in the same building in Yonkers, New York expiring in December 2027 (the "Fourth Floor Lease"). The Fourth Floor Lease provides for an option to renew for two additional five-year terms. Effective August 1, 2017, the Company relinquished 10,912 square feet of space under the Fourth Floor Lease and was relieved of its obligations related to such space.

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

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

<u>Description</u>	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Operating lease liabilities:		
Current portion of lease liabilities	\$ 628,676	\$ —
Long-term portion of lease liabilities	\$ 3,332,866	\$ —

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

As of September 30, 2019, the maturities of the Company's operating lease liabilities were as follows:

	<u>Amount</u>
October 1, 2019-December 31, 2019	\$ 163,331
Year ending December 31:	
2020	666,391
2021	679,719
2022	693,313
2023	707,179
Thereafter	2,973,011
Total lease payments	5,882,944
Less: Present value adjustment	(1,921,402)
Operating lease liabilities	<u>\$ 3,961,542</u>

Cash paid for amounts included in the measurement of lease liabilities for the three and nine months ended September 30, 2019 was \$159,576 and \$478,287, respectively, and was included in net cash used in operating activities in the Consolidated Statements of Cash Flows.

Rent expense is recognized using the straight-line method over the term of each lease. Rent expense for each of the three months ended September 30, 2019 and 2018, was approximately \$154,000, and for each of the nine months ended September 30, 2019 and 2018 was \$461,000 and \$462,000, respectively.

8. Capital Structure

Common Stock

As of September 30, 2019, the Company was authorized to issue 200,000,000 shares of common stock at \$0.0001 par value per share.

Follow-on Offerings

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

On July 25, 2017, the Company sold 32,000,000 shares of its common stock and warrants to purchase an additional 16,000,000 shares of its common stock in an underwritten follow-on offering for gross proceeds of \$40.0 million (the "2017 Offering"). The Company received net proceeds of approximately \$37.1 million after underwriting discounts, commissions and offering expenses payable by the Company. The warrants issued in the 2017 Offering have an exercise price of \$1.55 per share and expire five years from the date of issuance (the "2017 Warrants"). No 2017 Warrants were exercised in the three months ended September 30, 2019 or 2018 or in the nine months ended September 30, 2019. 2017 Warrants to purchase 3,550 shares of common stock were exercised in the nine months ended September 30, 2018.

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On July 27, 2016, the Company sold 14,000,000 shares of its common stock and warrants to purchase an additional 14,000,000 shares of its common stock in an underwritten follow-on offering for gross proceeds of \$35.0 million (the “2016 Offering”). The Company received net proceeds of approximately \$32.0 million after underwriting discounts, commissions and offering expenses payable by the Company. The warrants issued in the 2016 Offering have an exercise price of \$3.00 per share and expire five years from the date of issuance (the “2016 Warrants”). No 2016 Warrants were exercised in the three and nine months ended September 30, 2019 or 2018.

The 2017 Warrants and 2016 Warrants contain a fundamental transaction provision that obligates the Company to cash settle the warrants under a limited set of conditions not entirely within the Company’s control. Due to this conditional obligation, the Company determined that both the 2017 Warrants and the 2016 Warrants should be classified as liabilities in the Company’s consolidated balance sheet. At issuance, the Company determined the fair value of the 2017 Warrants and 2016 Warrants to be \$12.4 million and \$18.6 million, respectively, and reclassified these balances from stockholders’ equity to warrant liability. The fair value of these warrants is re-measured at each reporting period and changes in fair value are recognized in the consolidated statement of operations (see Note 4, “Fair Value Measurements”). Additionally, the Company allocated approximately \$0.9 million and \$1.6 million of issuance costs to the 2017 Warrants and 2016 Warrants, respectively, based on the proportion of the proceeds allocated to the fair value of the warrants. The allocated issuance costs were expensed as other expense in the Company’s consolidated statement of operations.

Private Placement

On June 12, 2015, the Company closed a private placement of its securities with a group of institutional investors (the “PIPE”). Each investor received one share of common stock and a warrant to purchase one-half share of common stock at a price of \$4.23 per common share purchased. The closing of the PIPE resulted in the issuance of an aggregate of 4,728,128 common shares and warrants to purchase an additional 2,364,066 shares of common stock at an exercise price of \$8.00 per full share (the “PIPE Warrants”). None of the PIPE Warrants were exercised prior to expiration on June 12, 2018 and therefore have been terminated and are no longer exercisable. The Company received net proceeds from the PIPE of \$18.3 million, after deducting expenses payable by the Company.

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

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

Representative’s Warrant

The Maxim Group, LLC, the representative of the underwriter in the Company’s initial public offering (IPO), received the Representative’s Warrant to purchase 3% of the total number of shares of common stock sold in the IPO, including those shares sold upon the exercise of the over-allotment option, for a total of 206,410 shares of common stock underlying the Representative’s Warrant. The Representative’s Warrant expired on July 28, 2019 in accordance with its terms and is no longer exercisable. The Company classified the Representative’s Warrant as a liability since it did not meet the requirements to be included in equity. The fair value of the Representative’s warrant was re-measured at each reporting period and changes in fair value were recognized in the consolidated statement of operations (see Note 4, “Fair Value Measurements”).

Convertible Notes

The Company issued approximately \$15.0 million aggregate principal amount of its 8.00% Convertible Notes due May 31, 2015 (the “Convertible Notes”) from June 2013 through June 2014. On August 1, 2014, in conjunction with the closing of the Company’s IPO, the principal amount of the Convertible Notes, and all accrued and unpaid interest thereon, automatically converted into 5,109,988 shares of common stock. Each purchaser of the Convertible Notes also received a warrant which included an exercise price “cap” that was analogous to “down round protection” (the “Note Warrants”). Upon the closing of the IPO and based on the terms of the Note Warrants, the Company determined the total number of shares of the Company’s common stock underlying the Note Warrants to be 3,321,416 at an exercise price of \$3.00 per share. There were 2,645,176 Note Warrants that expired during 2018 and 670,702 Note Warrants expired during the nine months ended September 30, 2019, and therefore have been terminated and are no longer exercisable. There are no Note Warrants outstanding as of September 30, 2019.

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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 September 30, 2019, no dividends have been declared or paid on the Company's common stock since inception.

Reserved for Future Issuance

The Company has reserved for future issuance the following number of shares of common stock as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Options to purchase common stock	12,465,806	7,187,885
Warrants to purchase common stock	30,339,059	31,243,026
	<u>42,804,865</u>	<u>38,430,911</u>

9. Stock Warrants

As of September 30, 2019 and December 31, 2018, the Company had warrants outstanding as shown in the table below.

	September 30, 2019	December 31, 2018
Note Warrants	—	670,702
2017 Warrants	15,996,450	15,996,450
2016 Warrants	14,000,000	14,000,000
Representative's Warrant	—	206,410
Placement Agent Warrants	189,126	189,126
Other warrants (1)	153,482	180,338
Warrants to purchase common stock	<u>30,339,059</u>	<u>31,243,026</u>
Weighted-average exercise price per share	<u>\$ 2.26</u>	<u>\$ 2.31</u>

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

The following table summarizes information regarding the Company's warrants outstanding at September 30, 2019:

Exercise Prices	Shares Underlying Outstanding Warrants	Expiration Date
£ \$2.00	16,002,164	September 1, 2021 – July 25, 2022
\$2.01 - \$4.99	14,274,086	February 12, 2020 – July 27, 2021
³ \$5.00	62,809	October 26, 2020 – January 5, 2022
	<u>30,339,059</u>	

10. Stock Option and Incentive Plans

Amended and Restated 2008 Equity Incentive Plan

In July 2008, the Company adopted the 2008 Equity Incentive Plan (the "Plan"). On February 26, 2013, the board of directors approved an amended and restated plan (the "Amended Plan") under which the number of shares of common stock available for issuance was 1,571,428. For new awards, the period that vested awards would remain exercisable upon termination of service was reduced from ten years to two years. The board of directors also increased the number of shares of common stock available under the Company's Amended Plan on February 24, 2014 and April 29, 2014 to 1,857,142 and 2,357,142, respectively. As of the closing of the Company's IPO, there were no further grants made under the Amended Plan.

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2014 Omnibus Incentive Plan

In April 2014, the Company's board of directors adopted the 2014 Omnibus Incentive Plan (the "2014 Plan"). The 2014 Plan was approved by the Company's stockholders on July 3, 2014. The 2014 Plan allows for the granting of incentive and non-qualified stock options, restricted stock and stock unit awards, stock appreciation rights and other performance-based awards to the Company's employees, members of the board of directors and consultants of the Company. On July 28, 2014, the effective date of the 2014 Plan, the number of shares of common stock reserved pursuant to the 2014 Plan was 571,429. The 2014 Plan provides for an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year 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) an amount determined by the Company's board of directors. Consistent with the provision for annual increases, an additional 9,696,859 shares of common stock have been made available for issuance under the 2014 Plan.

The Company recognized compensation expense for share-based compensation based on the fair value of the underlying instrument. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. A summary of stock option activity for the nine months ended September 30, 2019, is summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2018	7,187,885	\$ 3.17		
Granted	5,655,500	0.43		
Exercised	—	—		
Expired	(230,079)	2.72		
Forfeited	(147,500)	1.19		
Options outstanding at September 30, 2019	<u>12,465,806</u>	1.95	7.27	\$ —
Vested and exercisable at September 30, 2019	<u>5,901,063</u>	3.35	5.27	\$ —

The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of options granted during the nine months ended September 30, 2019 and 2018 was \$0.43 and \$1.45, respectively. Total compensation expense recognized amounted to \$392,005 and \$383,158 for the three months ended September 30, 2019 and 2018, respectively, and \$1,805,706 and \$1,236,972 for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, 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 2.65 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Risk free interest rate	1.58%	—	2.35%	2.57%
Expected dividend yield	—	—	—	—
Expected term (in years)	5.58	—	6.06	6.02
Expected volatility	90.6%	—	89.7%	82.3%

Expected volatility—The Company based the expected volatility on the historical volatility of its own common shares.

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

Risk-free interest rate—The Company estimated the risk-free interest rate in reference to yield on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award.

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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.

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, 2018 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 14, 2019.

Overview

We are a clinical-stage biotechnology company focused on discovering and developing direct lytic agents (DLAs) for the treatment of life-threatening infectious diseases, including those caused by drug-resistant pathogens. Drug-resistant infections account for 2,000,000 illnesses in the United States and 700,000 deaths worldwide each year. We intend to address drug-resistant infections using product candidates from our lysin and amurin peptide platforms. In nature, lysins are produced by bacteriophage, which are viruses that infect bacteria. When recombinantly produced as purified proteins and applied to bacteria, lysins cleave a key component of the target bacteria's peptidoglycan cell wall, resulting in rapid bacterial cell death. Conventional antibiotics require bacterial cell division and metabolism to occur in order to exert their intended effect (i.e., cell death or cessation of growth). Based on *in vitro* tests, lysins, however, are fundamentally different in that they kill bacteria rapidly by enzymatic cleavage of the bacterial cell wall without need for bacterial growth and cell division. In addition to the speed of action and potent cidal activity, we believe lysins are differentiated by their other hallmark features, which include the demonstrated ability to eradicate biofilms and synergistically boost the efficacy of conventional antibiotics in animal models. Importantly, lysins also have a "narrow spectrum," meaning they kill only specific species of bacteria or closely related bacteria. As such, we believe that lysins targeting gram-positive pathogens will not have negative effects on the beneficial, normal human GI microbiome, in contrast to conventional "broad spectrum" antibiotics which can kill the body's normal, beneficial bacteria. We believe that the therapeutic profile of lysins is complimentary to that of conventional antibiotics. As such, our initial approach includes the use of lysins in addition to conventional antibiotics for the treatment of serious, drug-resistant bacterial infections, including biofilm-associated infections, to achieve greater efficacy and improve clinical outcomes, as well as potentially protecting against antibiotic resistance.

We recently completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding the advancement of our lead lysin candidate, exebacase. We obtained concurrence with the FDA on key design features of the Phase 3 protocol, including the Day 14 primary efficacy endpoint for methicillin-resistant *Staph aureus* (MRSA) bacteremia, including right-sided endocarditis, and that positive results from this single Phase 3 study could support a Biologics License Application (BLA) for approval of exebacase under the FDA paradigm for streamlined development of antibacterial agents for patients with unmet needs. We plan to initiate a single Phase 3 superiority design clinical trial (the "DISRUPT" study – Direct Lysis of *Staph aureus* Resistant Pathogen Trial) designed to determine whether exebacase used in addition to standard-of-care (SOC) antibiotics provides superior clinical responder rates compared to SOC antibiotics alone among adult patients with *Staph aureus* bacteremia, including right-sided endocarditis.

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

We have not generated any revenues and, to date, have funded our operations primarily through our IPO, our follow-on public offerings, private placements of convertible preferred stock and convertible debt to our investors, and grant funding received.

We have a history of losses and our net losses were \$37.7 million, \$15.5 million and \$28.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. Our operating losses for the three and nine months ended September 30, 2019 were \$7.6 million and \$21.4 million, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through preclinical activities and clinical trials to seek regulatory approval and, if approved, commercialize such product candidates. Accordingly, we will need additional financing to support our continuing operations. We expect to seek to fund our operations through public or private equity, debt financings, equity-linked financings, collaborations, strategic alliances, licensing arrangements, research grants or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

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

Research and Development Expenses

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

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

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

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

Exebacase

Exebacase is a novel lysin that targets *Staph aureus*, including MRSA strains, which causes serious infections such as bacteremia, pneumonia and osteomyelitis. *Staph aureus* is also a frequent cause of biofilm-associated infections of heart valves (endocarditis), prosthetic joints, indwelling devices and catheters. These infections result in significant morbidity and mortality despite currently available antibiotic therapies. We have completed a Phase 2 superiority design clinical study with exebacase which evaluated its safety, tolerability, efficacy and PK when used in addition to SOC antibiotics for the treatment of *Staph aureus* bacteremia, including endocarditis in adult patients.

We have announced positive topline results from this first-in-patient Phase 2 superiority study of exebacase which showed clinically meaningful improvement in clinical responder rates among patients treated with exebacase in addition to SOC antibiotics compared to SOC antibiotics alone. In the primary efficacy analysis population of 116 patients with documented *Staph aureus* bloodstream infection, who received a single intravenous (IV) infusion of blinded study drug, the clinical responder rate was 70.4% for patients treated with exebacase and 60.0% for patients dosed with SOC antibiotics alone. In a pre-specified analysis of MRSA-infected patients, the clinical responder rate in patients treated with exebacase was 42.8% higher than the clinical responder rate in patients treated with SOC antibiotics alone (74.1% for patients treated with exebacase compared to 31.3% for patients treated with SOC antibiotics alone (p=0.010)). The clinical responder rate of patients with bacteremia including right-sided endocarditis was 80.0% for patients treated with exebacase compared to 59.5% for patients treated with SOC antibiotics alone, an increase of 20.5% (p=0.028). In the subgroup of patients with a final diagnosis of bacteremia, the clinical responder rate was 81.8% for patients treated with exebacase compared to 61.5% for patients treated with SOC antibiotics alone, an increase of 20.3% (p=0.035). Exebacase was well-tolerated and treatment emergent adverse events, including treatment-emergent SAEs were balanced between the treatment groups. There were no SAEs that we determined to be related to exebacase, there were no reports of hypersensitivity related to exebacase and no patients discontinued treatment with study drug in either treatment group. The study also generated positive health economic data whereby exebacase reduced length of stay and 30-day readmission rates for US patients with MRSA bacteremia including endocarditis compared to patients treated with SOC antibiotics alone. Among US MRSA patients discharged alive from the hospital, the median length of stay was reduced by 4 days. The 30-day all cause readmission rate was reduced to 16.0% from 30.8%. We believe these data establish proof of concept for exebacase, and for direct lytic agents as potential therapeutics.

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We recently completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding the advancement of our lead lysin candidate, exebacase. At this meeting we obtained concurrence with the FDA on key design features of the Phase 3 protocol and that positive results from this single Phase 3 study could support a Biologics License Application (BLA) for approval of exebacase. Based on this feedback, we plan to initiate a single Phase 3 clinical trial of exebacase for the treatment of patients with *Staph aureus* bacteremia, including right-sided endocarditis. The Phase 3 DISRUPT trial will be a randomized, double-blind, placebo-controlled clinical study conducted in the U.S. to assess the efficacy and safety of exebacase in approximately 350 patients with *Staph aureus* bacteremia, including right-sided endocarditis. Patients entering the Phase 3 study will be randomized 2:1 to either exebacase or placebo, with all patients receiving standard-of-care antibiotics. The primary efficacy endpoint will be clinical responder rates at Day 14 in patients with MRSA bacteremia, including right-sided endocarditis. Key secondary endpoints will include clinical responder rates at Day 14 in the All *Staph aureus* bacteremia patient group (MRSA and methicillin-sensitive *Staph aureus* (MSSA)), 30-day all-cause mortality in MRSA patients, and clinical responder rates at Day 60. We anticipate initiating the Phase 3 study by the end of 2019, and plan to conduct an interim futility analysis following the enrollment of approximately 60% of the study population.

Other Programs

We continue to explore variants of exebacase to expand our portfolio of lysins targeting biofilm-associated *Staph aureus* infections. We have engineered a novel mutant variant, CF-296, which we believe has properties which may make it particularly useful for the treatment of prosthetic joint infections. We are evaluating CF-296 in animal models to further characterize this compound. In June 2019, we were awarded up to \$7.2 million of funding from Military Infectious Diseases Research Program (MIDRP), United States Army Medical Research and Development Command (USAMRDC) over the course of three years to support the CF-296 program.

Our lysin research efforts are focused on a broad-based gram-negative discovery program which aims to identify, optimize and develop lysins that target deadly gram-negative pathogens. We have discovered and engineered lysins with potent activity against drug-resistant *P. aeruginosa* bacteria in *in vitro* studies, a major cause of morbidity and mortality, often related to hospital acquired pneumonia and a major medical challenge, particularly for patients with cystic fibrosis. We are initiating animal studies of our most promising anti-pseudomonal lysins with the goal of moving this program to the clinic as soon as possible. We were awarded \$1.0 million in funding from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) in 2017 to support this program and in January 2019 we were awarded an additional \$2.3 million in the amount of funding to be received through the first quarter of 2020.

Beyond our lysin programs, we continue our proprietary research to expand our pipeline of direct lytic agents to address unmet medical needs with novel antimicrobial agents. We have discovered a new class of direct lytic agents, known as amurin peptides, which display potent bactericidal activity against a wide range of gram-negative pathogens in preclinical studies, including deadly, multi-drug resistant and extensively drug resistant *P. aeruginosa*, *Klebsiella pneumoniae*, *Escherichia coli*, *Acinetobacter baumannii* and *Enterobacter cloacae* bacteria species. We are currently evaluating the *in vitro* and *in vivo* profiles of these amurin peptides. In March 2019, we were awarded up to \$6.9 million of funding over a four-year period from CARB-X to support the amurin peptide program.

In May 2019, we entered into an option agreement with Trellis Bioscience LLC (Trellis), pursuant to which we have granted Trellis an option for a period of 18 months to re-acquire, and/or as the case may be, license all rights to the CF-404 program, contingent on Trellis receiving adequate financing or commitments to adequately finance the CF-404 program to IND status. During the option period, we will continue to pay for storage costs of the related product candidates and we will also be responsible for all costs of maintaining and protecting the patent portfolio as per the existing license agreement between Trellis and the Company. Trellis may request reasonable support from our employees during the option period with respect to the preparation of IND reports, preparation of grant applications and consultation advice regarding the IND planning process, in each case at a rate of \$400 per hour. If the financing event is not achieved during the option period, then the option terminates and the option agreement will have no further force or effect. If the financing event is achieved during the option period, then the option agreement provides that we and Trellis may enter into a definitive license agreement. In consideration for the option, Trellis will receive a license from us to all CF-404 related intellectual property owned by the Company. In connection with the option agreement, we will no longer be pursuing an IND submission for CF-404.

To date, a large portion of our research and development work has related to the establishment of our lysin platform technologies, the advancement of our research projects to discovery of clinical candidates, manufacturing and preclinical testing of our clinical candidates and clinical testing of exebacase. We currently expect to focus the majority of our resources on the exebacase program. In the future, we intend to further leverage our employee and infrastructure resources across multiple development programs. For the three months ended September 30, 2019 and 2018, we recorded approximately \$5.3 million and \$5.7 million, respectively, of research and development expenses and for the nine months ended September 30, 2019 and 2018, we recorded approximately \$14.2 million and \$15.7 million, respectively, of research and development expenses. A breakdown of our research and development expenses by category is shown below. We do not currently utilize a formal time or laboratory project expense allocation system to allocate employee-related expenses, laboratory costs or depreciation to any particular project. Accordingly, we do not allocate these expenses to individual projects or product candidates. However, we do allocate some portions of our research and development expenses in the product development, external research and licensing and professional fees categories, to exebacase, as shown below.

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The following table summarizes our research and development expenses by category for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Product development	\$ 3,177,431	\$ 3,469,488	\$ 8,045,758	\$ 10,079,952
External research and licensing costs	628,989	417,185	1,441,025	461,215
Professional fees	542,902	618,743	1,933,059	2,108,188
Personnel related	511,803	681,677	1,562,631	1,615,128
Laboratory costs	264,424	349,786	818,584	926,132
Share-based compensation	124,778	173,576	360,486	507,514
Total research and development expense	<u>\$ 5,250,327</u>	<u>\$ 5,710,455</u>	<u>\$ 14,161,543</u>	<u>\$ 15,698,129</u>

The following table summarizes our research and development expenses by program for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Exebacase	\$ 3,465,484	\$ 3,944,405	\$ 9,120,241	\$ 11,391,364
Other research and development	1,143,462	910,797	3,118,185	1,691,063
Personnel related and share-based compensation	636,581	855,253	1,923,117	2,615,702
Total research and development expense	<u>\$ 5,250,327</u>	<u>\$ 5,710,455</u>	<u>\$ 14,161,543</u>	<u>\$ 15,698,129</u>

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

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

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including non-cash share-based compensation expense, in our executive, finance, legal, human resource and business development functions. Other general and administrative expenses include facility costs, insurance expenses and professional fees for legal, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as a result of increased headcount, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and increased insurance premiums, among other factors.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents and available-for-sale securities.

Critical Accounting Policies and Use of Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

During the three and nine-month periods ended September 30, 2019, there have been no material changes to our critical accounting policies from the information provided in the section “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report on Form 10-K for the year ended December 31, 2018 filed by us with the SEC on March 14, 2019, other than the adoption of Topic 842 as discussed below.

Leases

We determine if an arrangement includes a lease at inception. Operating leases were included in operating lease right-of-use assets, current portion of lease liabilities, and long-term lease liabilities in our Consolidated Balance Sheet as of January 1, 2019. Right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date. Our leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that we will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term. We have elected not to apply the recognition requirements of Topic 842 for short-term leases.

Results of Operations

The following table summarizes key components of our results of operations for the periods indicated.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Dollar Change	2019	2018	Dollar Change
Operating expenses:						
Research and development	\$ 5,250,327	\$ 5,710,455	\$ (460,128)	\$ 14,161,543	\$ 15,698,129	\$ (1,536,586)
General and administrative	\$ 2,376,248	\$ 2,088,835	\$ 287,413	\$ 7,234,244	\$ 6,581,784	\$ 652,460
Other (income) expense, net.	\$(2,267,457)	\$(3,421,543)	\$ (1,155,344)	\$(18,956,778)	\$21,340,207	\$(40,295,727)

Comparison of Three Months Ended September 30, 2019 and 2018

Research and Development Expenses

Research and development expense was \$5.2 million for the three months ended September 30, 2019 compared with \$5.7 million for the three months ended September 30, 2018, a decrease of \$0.5 million. This decrease was primarily attributable to a \$1.7 million decrease in spending related to our Phase 2 clinical study of exebacase, as all related contract research services were completed in the current year period compared to the higher cost of active patient enrollment in the prior year period. This decrease was partially offset by a \$1.3 million increase in manufacturing costs to support the advancement of exebacase into Phase 3 clinical development compared to the prior year period.

General and Administrative Expenses

General and administrative expense was \$2.4 million for the three months ended September 30, 2019, compared with \$2.1 million for the three months ended September 30, 2018, an increase of \$0.3 million. This increase was due primarily to an increase of \$0.2 million in costs incurred for legal and professional fees and an increase of \$0.1 million in share-based compensation expense.

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Other income (expense), net

Other income was \$2.3 million for the three months ended September 30, 2019, compared with \$3.4 million for the three months ended September 30, 2018, a decrease of \$1.1 million. The decrease in other income relates primarily to the non-cash gain of \$2.2 million in the current year period compared to \$3.2 million in the prior year period, resulting from the change in fair value of our warrant liabilities at each reporting period.

Comparison of Nine Months Ended September 30, 2019 and 2018

Research and Development Expenses

Research and development expense was \$14.2 million for the nine months ended September 30, 2019 compared with \$15.7 million for the nine months ended September 30, 2018, a decrease of \$1.5 million. This decrease was primarily attributable to a \$3.8 million decrease in clinical spending driven by the completion of our Phase 2 clinical study of exebacase in the current year period compared to the higher cost of active patient enrollment in the prior year period. This decrease was partially offset by a \$1.8 million increase in manufacturing costs to support the advancement of exebacase into Phase 3 clinical development compared to the prior year period and a \$0.5 million increase in licensing costs as we recognized the milestone payment to Rockefeller for completion of the Phase 2 study. The increase in expenditures on our other programs compared to the prior year period were offset by the amounts funded by the grants awarded to us by CARB-X and USAMRDC in 2019.

General and Administrative Expenses

General and administrative expense was \$7.2 million for the nine months ended September 30, 2019, compared with \$6.6 million for the nine months ended September 30, 2018, an increase of \$0.6 million. This increase was due primarily to an increase of \$0.6 million in costs incurred for intellectual property and general corporate legal fees.

Other income (expense), net

Other income was \$19.0 million for the nine months ended September 30, 2019, compared with other expense of \$21.3 million for the nine months ended September 30, 2018, an increase in other income of \$40.3 million. The increase in other income relates primarily to the non-cash gain of \$18.6 million in the current year period compared to a non-cash expense of \$21.8 in the prior year period, resulting from the change in fair value of our warrant liabilities at 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 grant funding. To date, we have not generated any revenue from the sale of products. We have incurred operating losses and generated negative cash flows from operations since inception.

Since the date of our initial public offering, we have funded our operations primarily through the sale of registered securities for gross proceeds of \$127.8 million, \$9.6 million from the exercise of the Class B Warrants issued in our IPO and \$20.0 million from the sale of securities in a private placement.

As of September 30, 2019, we had approximately \$10.5 million in cash and cash equivalents which will not be sufficient to meet our obligations within the next twelve months from the date of issuance of our unaudited 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. We have relied on our ability to fund our operations primarily through public and private debt and equity financings, but there can be no assurances that such financing will continue to be available to us on satisfactory terms, or at all. As such, under the requirements of ASC 205-40, we may not consider the potential for future capital raises in our assessment of our ability to meet our obligations for the next twelve months. If we are unable to obtain funding, we would be forced to delay, reduce or eliminate our research and development programs, which could adversely affect our business prospects, or we may be unable to continue operations. In accordance with the requirements of ASC 205-40, we have concluded that substantial doubt exists about our ability to continue as a going concern for twelve months from the date of issuance of our unaudited consolidated financial statements that are included elsewhere in this Quarterly Report on Form 10-Q.

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Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
Net cash provided by (used in):		
Operating activities	\$ (19,789,854)	\$ (19,202,063)
Investing activities	\$ 21,971,126	\$ 12,729,473
Financing activities	\$ —	\$ 10,432,896

Net Cash Used in Operating Activities

Net cash used in operating activities resulted primarily from our net losses adjusted from cash charges and changes in the components of working capital. Net cash used in operating activities for the nine months ended September 30, 2019 increased by \$0.6 million compared to the same period in 2018, due to payment of amounts owed to our contract research organizations in the first nine months of 2019 in completing the Phase 2 clinical study of exebacase.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2019 and 2018 was used to fund our operations and resulted from the proceeds received from the maturities of marketable securities less the funds used for capital expenditures.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2018 resulted from \$11.5 million of proceeds from a registered offering of our common stock, less the \$1.1 million of offering costs.

Funding Requirements

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

- initiate our planned phase 3 clinical trial and any additional clinical trials of our product candidates;
- continue our ongoing preclinical studies, and initiate additional preclinical studies, of our product candidates;
- continue the research and development of our other product candidates and our platform technology;
- seek to identify additional product candidates;
- acquire or in-license other products and technologies;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish, either on our own or with strategic partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

Without additional funding, we believe we will not have sufficient funds to meet our obligations within the next twelve months from the date of issuance of our unaudited consolidated financial statements that are included elsewhere in this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we may enter into collaborations with third parties for development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. We plan to continue to fund our operations through public or private debt and equity financings, but there can be no assurances that such financing will be available to us on satisfactory terms, or at all. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our lead product candidates;

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- the scope, progress, results and costs of compound discovery, preclinical development, laboratory testing and clinical trials for our other product candidates;
- the extent to which we acquire or in-license other products and technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish any future collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt offerings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or other securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations- Contractual Obligations and Commitments” in our Annual Report on Form 10-K filed with the SEC on March 14, 2019.

Effects of Inflation

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

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. As of September 30, 2019, we had cash and cash equivalents of \$10.5 million. Because of the short-term nature of cash equivalents, we do not believe that an increase in market rates would have any significant impact on the fair value of our cash equivalents. If a 10% change in interest rates were to have immediately occurred on September 30, 2019, this change would not have had a material effect on the fair value of our cash and cash equivalents balances as of that date.

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

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

ITEM 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 September 30, 2019.

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 September 30, 2019 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 September 30, 2019 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

The following description of risk factors includes any material changes to, and supersedes the description of, risk factors associated with the Company's business previously disclosed in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K, filed with the SEC on March 14, 2019. 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.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this Form 10-Q or elsewhere. The following information should be read in conjunction with our financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Quarterly Report on Form 10-Q.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and do not expect to generate revenue for at least the next several years. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with no approved products, and we have not generated any revenue from product sales to date. To date, we have focused exclusively on developing our product candidates and have funded our operations primarily through the sale of common stock and warrants, convertible preferred stock and issuances of convertible debt to our investors. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the pharmaceutical industry, and you should analyze our company in light of such risks and uncertainties.

Since inception, we have incurred significant operating losses. Our loss from operations was \$21.4 million for the nine months ended September 30, 2019 and we had an accumulated deficit of \$201.8 million as of September 30, 2019. Our net losses were \$37.7 million, \$15.5 million and \$28.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. We have devoted substantially all of our efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

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

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

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

We currently operate with limited resources. We have incurred significant losses since our inception and have never generated revenue or profit, and it is possible we will never generate revenue or profit. Based on our current operating plans, and without additional funding, we believe we will not have sufficient funds to meet our obligations within the next twelve months from the issuance of our unaudited 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, but there can be no assurances that such financing will continue to be available to us on satisfactory terms, or at all.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

We were incorporated in 2008 and commenced active research operations in 2010. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital and acquiring and developing exebacase and other potential product candidates. While we have completed a Phase 2 trial, we have not yet demonstrated our ability to successfully complete a Phase 3 clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

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

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

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

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

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

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

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

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

- we may not be able to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that exebacase or any other product candidate is safe and effective for any indication;
- the results of clinical trials may not meet the level of clinical or statistical significance required for approval by the FDA or comparable foreign regulatory authorities;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may not be able to demonstrate that exebacase or any other product candidate’s clinical and other benefits outweigh its safety risks;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

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- the FDA or comparable foreign regulatory authorities may identify deficiencies in data generated at our clinical trial sites;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the clinical practices of the third-party contract research organizations (CROs) we use for clinical trials; and
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators enter into agreements for clinical and commercial supplies.

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

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

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

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

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

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

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

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

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

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

Our clinical trials may be suspended at any time for a number of reasons. For example, although not observed in the exebacase Phase 1 and Phase 2 studies, it is possible that exposure to exebacase could result in adverse clinical events such as localized inflammation in the region surrounding blood vessels, or having a hypersensitivity reaction, such as serum sickness or anaphylaxis. A clinical trial may be prevented from commencing or may be suspended or terminated by us, our collaborators, IRBs, the FDA or other regulatory authorities due to the risks of or occurrence of such adverse events, an unacceptable safety risk to participants, a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of the data safety monitoring board or IRBs for a clinical trial. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues, if at all, from any of these product candidates will be delayed or eliminated. Any of these occurrences may significantly harm our business.

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

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

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

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

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

Under our various license agreements with Rockefeller, we are obligated to use our diligent efforts to develop and commercialize licensed products, including exebacase. Rockefeller may terminate the agreement in the event of our breach of the terms of the license agreements. In the event of such termination, Rockefeller has the right to retain its license and other rights under the agreement, subject to continuing royalties and other obligations. Our breach of the agreement, including non-payment of any milestone payment, and Rockefeller's subsequent termination of the agreement, could result in the loss of our rights to develop and commercialize exebacase, which would seriously harm our ability to generate revenues or achieve profitability.

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

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

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

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

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

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

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

- regulatory authorities may withdraw their approval of the product;

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

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

There are underlying risks associated with the manufacture of our product candidates, which could include cost overruns, new impurities, difficulties in process or formulation development, scaling up or reproducing manufacturing processes and lack of timely availability of raw materials.

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

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

We employ the services of other vendors to produce exebacase in its final vialled drug product form. We do not have contracts for the commercial supply of exebacase drug product.

We intend to pursue agreements with third-party manufacturers regarding commercial supply at an appropriate future time. We intend to locate second fill finish third-party manufacturers to supply other world regions such as the EU or Asia.

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

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

If Fujifilm UK, or any alternate supplier of active pharmaceutical ingredient, or any supplier of finished drug product for our product candidates, experiences any significant difficulties in its respective manufacturing processes, does not comply with the terms of its agreement with us or does not devote sufficient time, energy and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our product candidates, which could impair our ability to supply our product candidates at the levels required for our clinical trials and commercialization and prevent or delay its successful development and commercialization. For example, a lot of the exebacase investigational drug product did not meet manufacturing release specifications, resulting in the delay of our Phase 2 study.

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

The pharmaceutical and biotechnology industries are intensely competitive. We compete directly and indirectly with other pharmaceutical companies, biotechnology companies and academic and research organizations in developing therapies to treat diseases. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Many of our competitors have substantially greater financial, technical and other

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

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

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

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

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

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

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

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

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

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

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

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

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

In order to market exebacase or any other products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in the United States or any foreign country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in the United States or any foreign country and we do not have experience as a company in obtaining regulatory approval in international markets.

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

We do not have the capabilities to market, sell and distribute any of our drug products. In order to commercialize any products, we must develop these capabilities on our own or make arrangements with third parties for the marketing, sales and distribution of our products. The establishment and development of our own sales force would be expensive and time consuming and could delay any

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

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

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

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

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

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

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

We face extensive regulatory requirements and our products may face future development and regulatory difficulties.

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

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

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

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

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

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

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

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

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

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

If foreign approval for exebacase or any other product candidate is obtained, there are inherent risks in conducting business in international markets.

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

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

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

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

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

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

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

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

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

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

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

Our product candidates may face competition sooner than anticipated.

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

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

We may be subject, directly or indirectly, to federal and state healthcare laws, including applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

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

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

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- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal transparency requirements under the Affordable Care Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report to the Department of Health and Human Services information related to physician payments and other transfers of value and ownership and investment interests held by physicians and their immediate family members and payments or other transfers of value made to such physician owners;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain personal data, including the General Data Protection Regulation (GDPR), which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the E.U. and E.E.A. (including with regard to health data).

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, imprisonment and the curtailment or restructuring of our operations. Further, defending against any such actions, even if successful, can be costly, time-consuming and may require significant personnel resources. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The unfavorable consequences of any plaintiff attorney investigation or the adverse outcome of litigation or arbitration proceedings commenced by or against us could materially harm our business.

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

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

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

Following a national referendum in which a majority of voters in the United Kingdom elected to withdraw from the European Union, the government of the United Kingdom formally initiated the process for withdrawal in March 2017 (Brexit). The terms of any withdrawal are subject to a complex and ongoing negotiation between the United Kingdom and the European Union whose result and timing remain unclear and which has created significant political and economic uncertainty about the future trading relationship between the United Kingdom and the European Union in the event of a withdrawal, particularly in light of the possibility that an immediate, so-called “no deal” withdrawal could occur without a negotiated agreement

These developments, or the perception that any of them 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, restrict the ability of key market participants to operate in certain financial markets or restrict our access to capital. Moreover, depending on the terms of Brexit, the United Kingdom could lose its present rights or terms of access to the single EU market and EU customs areas and to the global trade deals negotiated by the European Union on behalf of its members. The uncertainty regarding new or modified arrangements, or initially the absence of such arrangements, between the United Kingdom and other countries following Brexit may have a material adverse effect on the movement of goods between the United Kingdom and members of the European Union and the United States, including the interruption of or delays in imports into the United Kingdom of goods originating within the European Union and exports from the United Kingdom of goods originating there. For example, shipments into the United Kingdom of drug substance manufactured for the Company in the European Union may be interrupted or delayed and thereby prevent or delay the manufacture in the United Kingdom of drug product. Similarly, shipments out of the United Kingdom of drug product to the United States or the European Union may be interrupted or delayed and thereby prevent or delay the delivery of drug product to clinical sites. Such a situation could hinder our ability to conduct current and planned clinical trials and have an adverse effect on our business.

Risks Related to Employee Matters and Managing Growth

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

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

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

For our Company to successfully develop and commercialize our product candidates, we may need to expand our development, regulatory and sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

In order to successfully develop and commercialize our product candidate, we may need to increase the number of our employees and expand the scope of our operations, particularly in the areas of drug discovery, drug development, regulatory affairs and commercialization. To manage our anticipated future growth, we would need to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the various levels of experience of our management team in managing a company with significant growth, we may not be able to effectively manage a significant expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Securities

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

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

Prior to our initial public offering, there was no public market for our common stock. The trading price of our securities has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report, these factors include:

- our ability to implement our preclinical, clinical and other development or operational plans;
- adverse regulatory decisions;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- new laws or regulations, or new interpretations of existing laws or regulations, applicable to our business;
- actual or anticipated fluctuations in our financial condition or annual or quarterly results of operations;

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

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

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

We are required to meet the continued listing requirements of the Nasdaq Capital Market and other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of \$1.00 per share. If we do not meet these continued listing requirements, our common stock could be delisted. On February 20, 2019, we received a letter from The Nasdaq Stock Market LLC (Nasdaq) indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until August 19, 2019, to regain compliance. The letter stated that the Nasdaq staff would provide written notification that we have achieved compliance with the Bid Price Rule if at any time before August 19, 2019, the bid price of our common stock closed at \$1.00 per share or more for a minimum of ten consecutive business days. The letter had no immediate effect on the listing or trading of our common stock. We were unable to gain compliance with the Bid Price Rule by August 19, 2019 and requested an additional 180 calendar day period to do so. On August 20, 2019, Nasdaq notified us that we were eligible for such an additional 180 day grace period, or until February 17, 2020, to regain compliance. Nasdaq's determination was based on our having met the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market, with the exception of the Bid Price Rule, and on our having provided written notice to Nasdaq of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not regain compliance with the Bid Price Rule by February 17, 2020, Nasdaq will provide written notification that our securities will be delisted. At that time, we may appeal Nasdaq's determination to a Hearings Panel ("Panel"). If we appeal, the Panel will request a plan to regain compliance. Panels have generally viewed a reverse stock split as the only definitive plan to resolve a bid price deficiency. There can be no assurance that such an appeal would be successful.

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

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

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

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

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

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

Sales of substantial amounts of shares of our common stock or warrants in the public market, or the perception that these sales may occur, could adversely affect the price of our securities and impair our ability to raise capital through the sale of additional equity securities. As of November 7, 2019, we have approximately 79.4 million shares of common stock outstanding, of which approximately 77.1 million shares of our outstanding common stock are freely tradable, or may become freely tradable, without restriction, in the public market unless held by our “affiliates,” as defined under Rule 144 of the Securities Act of 1933, as amended (the “Securities Act”). Additionally, we have warrants to purchase approximately 30.3 million shares of our common stock outstanding as of November 7, 2019. Approximately 30.0 million shares of common stock underlying the Warrants will be freely tradable upon exercise unless held by our affiliates.

We have registered 13,055,129 shares of our common stock as of November 7, 2019 that we may issue under our employee benefit plans. These shares can be freely sold in the public market upon issuance, unless pursuant to their terms these stock awards have transfer restrictions attached to them. Additionally, pursuant to the 2014 Omnibus Incentive Plan (the “2014 Plan”), our management is authorized to grant stock options and other equity linked award to our employees, directors and consultants. The 2014 Plan provides that the number of shares available for future grant under our 2014 Plan will automatically increase on January 1st each year, from January 1, 2015 through January 1, 2024, by an amount equal to four percent of all shares of our capital stock outstanding as of December 31st of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. Unless our board of directors elects not to increase the number of shares underlying our 2014 Plan each year, our stockholders may experience additional dilution, which could cause our stock price to decline.

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

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

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

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

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

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

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

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

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

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

Reports published by analysts, including projections in those reports that exceed our actual results, could adversely affect the price and trading volume of our common stock.

The projections of securities research analysts may vary widely and may not accurately predict the results we actually achieve. The price of our common stock may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, the price of our common stock could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, the price or trading volume of our common stock could decline.

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

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

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

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

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

We are an “emerging growth company,” as defined in the JOBS Act, and will remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

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

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

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for our securities, thereby depressing the market prices of our securities. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a shareholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Risks Related to Cybersecurity, Data Protection and Privacy

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

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

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

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

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

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

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

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
3.1	<u>Amended and Restated Certificate of Incorporation dated August 1, 2014, Certificate of Amendment, dated May 9, 2016 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36577) filed with the SEC on May 10, 2016), and Certificate of Amendment dated May 2, 2017 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36577) filed with the SEC on May 3, 2017)</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36577) filed with the SEC on May 10, 2016)</u>
31.1*	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1**	<u>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</u>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith

** Furnished herewith

SIGNATURES

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

ContraFect Corporation

Date: November 12, 2019

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: November 12, 2019

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

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: November 12, 2019

/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)

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: November 12, 2019

/s/ Michael Messinger

Michael Messinger
Chief Financial Officer
(Principal Financial Officer)

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 September 30, 2019, 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: November 12, 2019

/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 September 30, 2019, 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: November 12, 2019

/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.