UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2020
OR

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

Commission File Number: 001-37798

Selecta Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-1622110**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
65 Grove Street Watertown MA	**02472**
(Address of principal executive offices)	(Zip Code)

(617) 923-1400
(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	SELB	The Nasdaq Global Market

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒
As of May 1, 2020, the registrant had 87,489,681 shares of common stock, par value $0.0001 per share, outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly Report") contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in 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"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, the plans and objectives of management for future operations and future results of anticipated products, a potential amendment to our exclusive patent license agreement with the Massachusetts Institute of Technology, and the impact of the novel coronavirus (COVID-19) pandemic on our business and operations and our future financial results, and the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential", or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the sections in this Quarterly Report titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as the following:

- our status as a development-stage company and our expectation to incur losses in the future;
- our ability to continue as a going concern, our future capital needs and our need to raise additional funds;
- our ability to build a pipeline of product candidates and develop and commercialize drugs;
- our unproven approach to therapeutic intervention;
- our ability to enroll patients in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;
- our ability to have continued access to manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- our ability to maintain our existing or future collaborations or licenses, including our ability to reach an agreement regarding an acceptable amendment of our exclusive patent license agreement with the Massachusetts Institute of Technology;
- the impact of the COVID-19 pandemic on our operations, the continuity of our business, including our preclinical studies and clinical trials, and general economic conditions;
- our ability to protect and enforce our intellectual property rights;
- federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates;
- our ability to obtain and retain key executives and attract and retain qualified personnel;
- developments relating to our competitors and our industry, including the impact of government regulation; and
- our ability to successfully manage our growth.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

(Amounts in thousands, except share data and par value)

	March 31, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 72,606	$ 89,893
Restricted cash	279	279
Accounts receivable	—	5,000
Prepaid expenses and other current assets	1,555	1,495
Total current assets	74,440	96,667
Property and equipment, net	1,134	1,222
Right-of-use asset, net	11,847	301
Long-term restricted cash	1,379	1,379
Total assets	$ 88,800	$ 99,569
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,330	$ 500
Accrued expenses	8,775	13,492
Loan payable	16,868	18,905
Lease liability	1,425	372
Deferred revenue	1,674	1,674
Total current liabilities	30,072	34,943
Non-current liabilities:		
Lease liability	10,440	—
Deferred revenue	14,656	14,680
Warrant liabilities	42,395	41,549
Total liabilities	97,563	91,172
Commitments and contingencies (Note 17)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 87,019,172 and 86,325,547 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	9	9
Additional paid-in capital	351,184	348,664
Accumulated deficit	(355,373)	(335,753)
Accumulated other comprehensive loss	(4,583)	(4,523)
Total stockholders' equity (deficit)	(8,763)	8,397
Total liabilities and stockholders' equity (deficit)	$ 88,800	$ 99,569

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

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

	Three Months Ended March 31,	
	2020	**2019**
	(Unaudited)	
Grant and collaboration revenue	$ —	$ 10
Operating expenses:		
Research and development	14,724	7,353
General and administrative	4,098	4,513
Total operating expenses	18,822	11,866
Loss from operations	(18,822)	(11,856)
Investment income	240	277
Foreign currency transaction (loss), net	82	(30)
Interest expense	(273)	(396)
Change in fair value of warrant liabilities	(846)	—
Other (expense), net	(1)	(69)
Net loss	(19,620)	(12,074)
Other comprehensive loss:		
Foreign currency translation adjustment	(60)	22
Unrealized gain on securities	—	2
Total comprehensive loss	$ (19,680)	$ (12,050)
Net loss per share:		
Basic and diluted	$ (0.21)	$ (0.31)
Weighted average common shares outstanding:		
Basic and diluted	94,723,513	38,447,319

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(Amounts in thousands, except share data)

(Unaudited)

	Common stock		Additional paid-in	Accumulated	Accumulated other comprehensive	Stockholders' Equity
	Shares	Amount	capital	deficit	loss	(Deficit)
Balance at December 31, 2019	86,325,547	$ 9	$348,664	$ (335,753)	$ (4,523)	$ 8,397
Issuance of common stock under Employee Stock Purchase Plan	78,583	—	114	—	—	114
Issuance of common stock upon exercise of options	5,128	—	3	—	—	3
Issuance of vested restricted stock units	10,937	—	—	—	—	—
Issuance of common stock through at-the-market offering, net	598,977	—	1,141	—	—	1,141
Other financing fees	—	—	(147)	—	—	(147)
Stock-based compensation expense	—	—	1,409	—	—	1,409
Currency translation adjustment	—	—	—	—	(60)	(60)
Net loss	—	—	—	(19,620)	—	(19,620)
Balance at March 31, 2020	87,019,172	$ 9	$351,184	$ (355,373)	$ (4,583)	$ (8,763)

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(Amounts in thousands, except share data)

(Unaudited)

	Common stock		Additional paid-In	Accumulated	Accumulated other comprehensive	Stockholders' Equity
	Shares	Amount	Capital	deficit	loss	(Deficit)
Balance at December 31, 2018	22,471,776	$ 3	$279,539	$ (280,403)	$ (4,557)	$ (5,418)
Issuance of common stock under Employee Stock Purchase Plan	11,943	—	20	—	—	20
Issuance of common stock upon exercise of options	115,600	—	145	—	—	145
Issuance of common stock, net of issuance costs	22,188,706	2	30,940	—	—	30,942
Stock-based compensation expense	—	—	1,180	—	—	1,180
Currency translation adjustment	—	—	—	—	22	22
Unrealized gains (losses) on securities	—	—	—	—	2	2
Net loss	—	—	—	(12,074)	—	(12,074)
Balance at March 31, 2019	44,788,025	$ 5	$311,824	$ (292,477)	$ (4,533)	$ 14,819

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(Amounts in thousands)

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Cash flows from operating activities		
Net loss	$ (19,620)	$ (12,074)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	231	181
Amortization of premiums (accretion of discounts) on investments	—	(47)
Non-cash lease expense	366	446
Loss on disposal of property and equipment	1	70
Stock-based compensation expense	1,409	1,180
Non-cash interest expense	123	189
Warrant liabilities revaluation	846	—
Changes in operating assets and liabilities:		
Accounts receivable	5,000	—
Prepaid expenses, deposits and other assets	(61)	(6,158)
Accounts payable	836	(407)
Deferred revenue	—	(2)
Accrued expenses and other liabilities	(829)	(3,618)
Net cash used in operating activities	(11,698)	(20,240)
Cash flows from investing activities		
Purchases of short-term investments	—	(18,188)
Sale of short term investments	—	1,992
Purchases of property and equipment	(135)	—
Proceeds from the sale of property and equipment	—	77
Net cash used in investing activities	(135)	(16,119)
Cash flows from financing activities		
Repayments of principal on outstanding debt	(2,100)	—
Net proceeds from issuance of common stock	—	30,942
Net proceeds from issuance of common stock- at-the-market offering	1,141	—
Issuance costs paid for December 2019 financing	(4,381)	—
Other financing fees	(147)	—
Proceeds from exercise of stock options	3	145
Proceeds from issuance of common stock under Employee Stock Purchase Plan	114	20
Net cash (used in) provided by financing activities	(5,370)	31,107
Effect of exchange rate changes on cash	(84)	22
Net change in cash, cash equivalents, and restricted cash	(17,287)	(5,230)
Cash, cash equivalents, and restricted cash at beginning of period	91,551	37,682
Cash, cash equivalents, and restricted cash at end of period	$ 74,264	$ 32,452
Supplement cash flow information		
Cash paid for interest	$ 232	$ 312
Noncash investing and financing activities		
Purchase of property and equipment not yet paid	$ 10	$ —
Equity offering costs in accrued liabilities	$ 42	$ 10
Unrealized gain on marketable securities	$ —	$ 2

The accompanying notes are an integral part of these unaudited consolidated financial statements.

1. Nature of the Business and Basis of Presentation

Selecta Biosciences, Inc. (the "Company") was incorporated in Delaware on December 10, 2007, and is based in Watertown, Massachusetts. The Company is a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance technology (ImmTOR™) platform. The Company plans to combine ImmTOR with a range of biologic therapies for rare and serious diseases that require new treatment options due to high immunogenicity of existing therapies. Since inception, the Company has devoted its efforts principally to research and development of its technology and product candidates, recruiting management and technical staff, acquiring operating assets, and raising capital.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

The Company's product candidates are in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The accompanying financial statements have been prepared on a basis that assumes the Company is a going concern, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from any uncertainty related to its ability to continue as a going concern.

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements for the three months ended March 31, 2020 and 2019 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 12, 2020 (the "Annual Report on Form 10-K"). The unaudited interim financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments that are necessary for a fair statement of the Company's financial position as of March 31, 2020 and consolidated results of operations and cash flows for the three months ended March 31, 2020. Such adjustments are of a normal and recurring nature. The results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

Liquidity and Management's Plan

The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain profitable operations. The Company is subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful development of its product candidates, raising additional capital with favorable terms, protection of proprietary technology and market acceptance of any approved future products. The successful development of product candidates requires substantial working capital which may not be available to the Company on favorable terms or at all.

To date, the Company has financed its operations primarily through the initial public offering of its common stock, a private placement of its common stock, issuances of common and preferred stock, debt, research grants and research collaborations. The Company currently has no source of product revenue, and it does not expect to generate product revenue for the foreseeable future. To date, all of the Company's revenue has been collaboration and grant revenue. The Company has devoted substantially all of its financial resources and efforts to developing its ImmTOR platform, identifying potential product candidates and conducting preclinical studies and its clinical trials. The Company is in the early stages of development of its product candidates, and it has not completed development of any ImmTOR-enabled therapies.

As of March 31, 2020, the Company's cash, cash equivalents and restricted cash were $74.3 million, of which $1.7 million was restricted cash related to lease commitments and $0.3 million was held by its Russian subsidiary designated solely for use in its operations. The Company has incurred losses and negative cash flows from operating activities since inception. As of March 31, 2020 and December 31, 2019, the Company had an accumulated deficit of $355.4 million and $335.8 million, respectively. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates, conducting preclinical studies and clinical trials, and its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy, and the Company will pursue a range of options to secure additional capital. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

Management is actively exploring licenses and other strategic collaborations that have the potential to provide non-dilutive capital and accelerate the development of new or existing product candidates incorporating the Company's ImmTOR platform. Additionally, the Company may seek to fund its operations through issuances of equity and other securities. If the Company enters into strategic collaborations and alliances, which may include existing collaboration partners, the Company may have to relinquish valuable rights to its technologies or product candidates, or grant licenses on terms that are not favorable to the Company. To the extent that the Company raises additional capital through the sale of equity, the ownership interest of its existing shareholders will be diluted and other preferences may be necessary that adversely affect the rights of existing shareholders. The Company requires additional external sources of capital to complete the planned Phase 3 clinical program for SEL-212. If the Company is unable to raise sufficient capital through strategic collaborations and the sale of equity or other securities, it intends to curtail expenses contemplated by the current operating plan, and the Company may be required to delay, limit, reduce or terminate its product development efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself. Because of the uncertainty in securing additional capital and the insufficient amount of capital resources at March 31, 2020, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q.

At this time, there is significant uncertainty relating to the trajectory of the pandemic and the impact of related responses. Any impact of COVID-19 on our business, revenues, results of operations and financial condition will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. See "Risk Factors - The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials." in Part II, Item 1A of this Quarterly Report on Form 10-Q.

All amounts due under the 2017 Term Loan (see Note 9) have been classified as a current liability as of March 31, 2020 due to the considerations discussed above and the assessment that the material adverse change clause under the 2017 Term Loan is not within the Company's control. The Company has not been notified of an event of default by the Lender as of the date of the filing of this Quarterly Report on Form 10-Q.

Guarantees and Indemnifications

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through March 31, 2020, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Selecta RUS, LLC ("Selecta (RUS)"), a Russian limited liability corporation, and Selecta Biosciences Security Corporation, a Massachusetts Security Corporation. All significant intercompany accounts and transactions have been eliminated.

Foreign Currency

The functional currency of Selecta (RUS) is the Russian ruble. Assets and liabilities of Selecta (RUS) are translated at period-end exchange rates, while revenues and expenses are translated at average exchange rates for the period. Translation gains and losses are reflected in accumulated other comprehensive loss within stockholders' equity (deficit). Foreign currency transaction gains or losses are reflected in the consolidated statements of operations and comprehensive loss.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's management considers many factors in selecting appropriate financial accounting policies and controls, and bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. In preparing these consolidated financial statements, management used significant estimates in the following areas, among others: revenue recognition, accounting for stock-based compensation, the valuation of its warrant liabilities and estimating accrued research and development expenses. The Company assesses the above estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Company's Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment, the research and development of nanoparticle immunomodulatory drugs for the treatment and prevention of human diseases.

Cash Equivalents, Short-term Investments and Restricted Cash

Cash equivalents include all highly liquid investments maturing within 90 days from the date of purchase. Investments consist of securities with remaining maturities greater than 90 days when purchased. The Company classifies these marketable securities and records them at fair value in the accompanying consolidated balance sheets. Investments with less than one year until maturity are classified as short term, while investments with maturities greater than one year are classified as long term. Unrealized gains or losses are included in accumulated other comprehensive income (loss). Premiums or discounts from par value are amortized to investment income over the life of the underlying investment.

Although available to be sold to meet operating needs or otherwise, securities are generally held through maturity. The cost of securities sold is determined based on the specific identification method for purposes of recording realized gains and losses. During the three months ended March 31, 2020, there were no realized losses on sales of investments, and no investments were adjusted for other than temporary declines in fair value.

As of March 31, 2020, the Company had restricted cash balances relating to secured letters of credit in connection with its current Headquarters Lease and New Headquarters Lease (as defined in Note 8). The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet that sum to the total of the same such amounts shown in the consolidated statement of cash flows:

	March 31,	
	2020	2019
Cash and cash equivalents	$ 72,606	$ 32,173
Restricted cash	279	279
Long-term restricted cash	1,379	—
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	$ 74,264	$ 32,452

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents, short-term deposits and investments, and accounts receivable. Cash and cash equivalents are deposited with

federally insured financial institutions in the United States and may, at times, exceed federally insured limits. Management believes that the financial institutions that hold the Company's deposits are financially creditworthy and, accordingly, minimal risk exists with respect to those balances. Generally, these deposits may be redeemed upon demand and therefore bear minimal interest rate risk. As an integral part of operating its Russian subsidiary, the Company also maintains cash in Russian bank accounts in denominations of both Russian rubles and U.S. dollars. As of March 31, 2020, the Company maintained approximately $0.3 million in Russian bank accounts, all of which was held in U.S. dollars.

The Company did not have any off-balance sheet arrangements as of March 31, 2020 and December 31, 2019.

Fair Value of Financial Instruments

The Company's financial instruments consist mainly of cash equivalents, restricted cash, accounts payable, loans payable, and common warrants. The carrying amounts of cash equivalents, restricted cash, accounts receivable, and accounts payable approximate their estimated fair value due to their short-term maturities. At March 31, 2020, the carrying amount of the Company's loan payable approximates its estimated fair value due to the short-term nature of the instrument.

Accounting standards define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. A three-level hierarchy is used to prioritize the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements), and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

> *Level 1*—Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
>
> *Level 2*—Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term of the asset or liability.
>
> *Level 3*—Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

To the extent that a 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 fair value of warrant liabilities were determined using Level 3 inputs.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, the Company's own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. The Company uses prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may change for many instruments. This condition could cause an instrument to be reclassified within levels in the fair value hierarchy. There were no transfers within the fair value hierarchy during the three months ended March 31, 2020 or the year ended December 31, 2019.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, generally seven years for furniture and fixtures, five years for laboratory equipment, software and office equipment and three years for computer equipment. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. Major additions and betterments are capitalized. Maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to operations as incurred. Costs incurred for construction in progress are recorded as assets and are not amortized until the construction is substantially complete and the assets are ready for their intended use.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In order to determine if assets have been impaired, assets are tested at the lowest level for which identifiable independent cash flows are available, which is at the entity level ("asset group"). An impairment loss is recognized when the sum of projected undiscounted cash flows is less than the carrying value of the asset group. The measurement of the impairment loss to be recognized is based on the difference between the fair value and the carrying value of the asset group. Based on management's evaluation, the fair value of the asset group, measured as the market capitalization

of the Company exceeds its carrying value, and for this reason the Company did not recognize any material impairment losses during the three months ended March 31, 2020 and 2019.

Debt Issuance Costs

Debt issuance costs and fees paid to lenders are classified as a debt discount and are recorded as a direct deduction from the face amount of the related debt. Issuance costs paid to third parties that are the direct result of the debt issuance are capitalized as a direct deduction from the face amount of the related debt. Debt issuance costs are amortized over the term of the related debt using the interest method and recorded as interest expense. Costs and fees paid to third parties are expensed as incurred.

Accumulated Other Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in the equity of a business entity during a period from transactions and other events and circumstances from non-owner sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. Comprehensive income (loss) consists of: (i) all components of net loss and (ii) all components of comprehensive loss other than net loss, referred to as other comprehensive loss. Other comprehensive loss is comprised of foreign currency translation adjustments and the unrealized gains and losses recognized through net income.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Pursuant to ASC Topic 606, *Revenue from Contracts with Customers (ASC 606)*, a customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. If a promised good or service is not distinct, it is combined with other performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For example, certain performance obligations associated with Spark and AskBio (see Note 12) will be satisfied over time, and revenue will be recognized using the output method, based on the proportion of actual deliveries to the total expected deliveries over the initial term.

Collaboration and Grant Revenue: The Company currently generates its revenue through grants, collaboration and license agreements with strategic collaborators for the development and commercialization of product candidates. Grants and license agreements with customers are accounted for in accordance with ASC 606. The Company analyzes collaboration arrangements by first assessing whether they are within the scope of ASC Topic 808, *Collaborative Arrangements (ASC 808*), and evaluates whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. Collaboration agreements with customers that are not within the scope of ASC 808 are accounted for in accordance with ASC 606. To the extent the collaboration agreement is within the scope of ASC 808, the Company also assesses whether any aspects of the agreement are within the scope of other accounting literature (specifically ASC 606). The Company early adopted ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which provides guidance on evaluating certain transactions between collaborative arrangement participants. If the Company concludes that some or all aspects of the agreement are distinct and represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC 606. The Company recognizes the shared costs incurred that are not within the scope of other accounting literature as a component of the related expense in the period incurred by analogy to ASC Topic 730, *Research and Development (ASC 730)*, and records reimbursements from counterparties as an offset to the related costs. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements in accordance with ASC 606, the Company performs the five steps above. As part of the accounting for the arrangement, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

The terms of the Company's arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed

products; (iv) reimbursements or cost-sharing of research and development (R&D) expenses; and (v) profit/loss sharing arising from co-promotion arrangements.

Licenses of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If not distinct, the license is combined with other performance obligations in the contract. For licenses that are combined with other performance obligations, the Company assesses the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Optional licenses are evaluated to determine if they are issued at a discount, and therefore, represent material rights and accounted for as separate performance obligations.

Milestone Payments: At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service. If the milestone payment is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method. The Company also evaluates the milestone to determine whether they are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated, otherwise, such amounts are constrained and excluded from the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the transaction price. Any such adjustments to the transaction price are allocated to the performance obligations on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation shall be recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are evaluated to determine if they are distinct and optional. For optional services that are distinct, the Company assesses if they are priced at a discount, and therefore, provide a material right to the licensee to be accounted for as separate performance obligations.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied) in accordance with the royalty recognition constraint.

Research and Development Costs

Costs incurred in the research and development of the Company's products are expensed as incurred. Research and development expenses include costs incurred in performing research and development activities, including salaries and benefits, facilities cost, overhead costs, contract services, supplies and other outside costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Clinical Trial Costs

Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these costs to third parties. Third party clinical trial expenses include patient costs, clinical research organization costs and costs for data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued clinical trial cost. These third party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future R&D activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. The Company also records accruals for estimated ongoing clinical research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any

reporting period. Actual results could differ from the estimates made by the Company. The historical clinical accrual estimates made by the Company have not been materially different from the actual costs.

Income Taxes

The Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more-likely-than-not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more-likely-than-not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. To date, the Company has not incurred interest and penalties related to uncertain tax positions.

Warrants

The Company determines the accounting classification of warrants that are issued, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, and then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded in the statements of operations as a gain or loss. Equity classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Stock-Based Compensation

The Company accounts for all stock-based compensation granted to employees and non-employees using a fair value method. Stock-based compensation is measured at the grant date fair value and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. The Company reduces recorded stock-based compensation for estimated forfeitures. To the extent that actual forfeitures differ from the Company's estimates, the differences are recorded as a cumulative adjustment in the period the estimates were adjusted. Stock-based compensation expense recognized in the consolidated financial statements is based on awards that are ultimately expected to vest.

Net Loss Per Share

The Company has reported losses since inception and has computed basic net loss per share by dividing net loss by the weighted average number of common shares and pre-funded warrants outstanding for the period. The Company has computed diluted net loss per common share after considering all potentially dilutive common shares, including stock options, convertible preferred stock, and warrants outstanding during the period except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential common shares have been anti-dilutive and basic and diluted loss per share have been the same.

Contingent Liabilities

The Company accounts for its contingent liabilities in accordance with ASC No. 450, *Contingencies*. A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. As of March 31, 2020 and December 31, 2019, the Company was not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

Leases

The Company accounts for its leases in accordance with ASC Topic 842, *Leases (ASC 842)*, and determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company elected not to recognize leases with a term less than one year on its balance sheet. Operating lease right-of-use (ROU) assets and their corresponding lease liabilities are recorded based on the present value of lease payments over the expected remaining lease term. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASC 842, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components. Although separation of lease and non-lease components is required, the Company elected the practical expedient to not separate lease and non-lease components. The lease component results in an operating right-of-use asset being recorded on the balance sheet and amortized on a straight-line basis as lease expense. Right-of-use assets and operating lease liabilities are remeasured upon certain modifications to leases using the present value of remaining lease payments and estimated incremental borrowing rate upon lease modification. See Note 8 for details.

Recent Accounting Pronouncements

Recently Adopted

In August 2018, 2018-13, *Fair Value Measurement (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13) which changes the fair value measurement disclosure requirements of ASC 820. Entities will no longer be required to disclose the amount of, and reasons for, transfers between Level 1 and Level 2 of the fair value hierarchy, the policy of timing of transfers between levels of the fair value hierarchy and the valuation processes for Level 3 fair value measurements. The Company adopted the new standard effective January 1, 2020, and there was no impact on its consolidated financial statements.

Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740) - Simplifying the Accounting for Income Taxes.* ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. This ASU is effective for public entities for fiscal years beginning after December 15, 2020. The Company is assessing the impact this standard will have on its consolidated financial statements and disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*. Subsequently, in November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses*. ASU 2016-13 requires entities to measure all expected credit losses for most financial assets held at the reporting date based on an expected loss model which includes historical experience, current conditions, and reasonable and supportable forecasts. ASU 2016-13 also requires enhanced disclosures to help financial statement users better understand significant estimates and judgments used in estimating credit losses. This ASU is effective for smaller reporting companies for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company is assessing the impact this standard will have on its consolidated financial statements and disclosures.

3. Marketable Securities

As of March 31, 2020, and December 31, 2019, the Company did not have marketable securities.

4. Net Loss Per Share

The Company has reported a net loss for the three months ended March 31, 2020, and 2019. For this reason basic and diluted net loss per share are the same for all periods presented. Since the shares underlying the 8,342,128 pre-funded warrants are issuable for little or no consideration, they are considered outstanding for both basic and diluted earnings per share. The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per-share

data):

	Three Months Ended March 31,	
	2020	2019
Numerator:		
Net loss attributable to common stockholders	$ (19,620)	$ (12,074)
Denominator:		
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	94,723,513	38,447,319
Net loss per share attributable to common stockholders —basic and diluted	$ (0.21)	$ (0.31)

All potential dilutive common shares have been excluded from the computation of the diluted net loss per share for all periods presented, as the effect would have been anti-dilutive. Potential dilutive common share equivalents consist of the following:

	March 31,	
	2020	2019
Stock options to purchase common stock	7,745,936	4,564,742
Unvested restricted stock units	170,313	275,000
Stock warrants to purchase common stock	23,084,120	95,619
Total	31,000,369	4,935,361

5. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The tables below present information about the Company's financial assets and liabilities that are measured and carried at fair value as of March 31, 2020 and December 31, 2019, and indicate the level within the fair value hierarchy where each measurement is classified. Below is a summary of assets and liabilities measured at fair value on a recurring basis (in thousands):

	March 31, 2020			
	Total	(Level 1)	(Level 2)	(Level 3)
Assets:				
Money market funds	$ 50,528	$ 50,528	$ —	$ —
Total	$ 50,528	$ 50,528	$ —	$ —
Liabilities:				
Warrant liabilities	$ 42,395	$ —	$ —	$ 42,395
Total	$ 42,395	$ —	$ —	$ 42,395

	December 31, 2019			
	Total	(Level 1)	(Level 2)	(Level 3)
Assets:				
Money market funds	$ 50,401	$ 50,401	$ —	$ —
Total	$ 50,401	$ 50,401	$ —	$ —
Liabilities:				
Warrant liabilities	$ 41,549	$ —	$ —	$ 41,549
Total	$ 41,549		$ —	$ 41,549

At each of March 31, 2020 and December 31, 2019, the money market funds were classified as cash and cash equivalent on the accompanying consolidated balance sheet as they mature within 90 days from the date of purchase.

Assumptions Used in Determining Fair Value of Common Warrants

In December 2019, the Company issued common warrants in connection with a private placement of common shares. Pursuant to the terms of the common warrants, the Company could be required to settle the common warrants in cash in the event of certain acquisitions of the Company and, as a result, the common warrants are required to be measured at fair value and

reported as a liability on the balance sheet. The Company recorded the fair value of the common warrants upon issuance using the Black-Scholes valuation model and are required to revalue the common warrants at each reporting date with any changes in fair value recorded in the statement of operations. The valuation of the common warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The change in the fair value of the Level 3 warrant liability is reflected in the statement of operations for the year ended March 31, 2020.

The estimated fair value of warrants is determined using Level 3 inputs inherent in the Black Scholes simulation valuation.

Estimated fair value of the underlying stock. The Company estimates the fair value of the common stock based on the closing stock price at the end of each reporting period.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury at the valuation date commensurate with the expected remaining life assumption.

Dividend rate. The dividend rate is based on the historical rate, which the Company anticipates will remain at zero.

Expected life. The expected life of the warrants is assumed to be equivalent to their remaining contractual term which expires on December 23, 2024.

Volatility. The Company estimates stock price volatility based on the Company's historical volatility and the historical volatility of peer companies for a period of time commensurate with the expected remaining life of the warrants.

A summary of the Black Scholes pricing model assumptions used to record the fair value of the warrants is as follows:

	March 31, 2020
Risk-free interest rate	0.37%
Dividend yield	—
Expected life (in years)	4.73
Expected volatility	93.43%

Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

The following table reflects the change in the Company's Level 3 warrant liabilities, (see Note 10), for the three months ended March 31, 2020 (in thousands):

	Warrant liabilities
Fair value as of December 31, 2019	$ 41,549
Change in fair value	846
Fair value as of March 31, 2020	$ 42,395

6. Property and Equipment

Property and equipment consists of the following (in thousands):

	March 31, 2020	December 31, 2019
Laboratory equipment	$ 4,374	$ 4,836
Computer equipment and software	494	515
Leasehold improvements	268	278
Furniture and fixtures	219	237
Office equipment	78	135
Construction in process	129	2
Total property and equipment	5,562	6,003
Less accumulated depreciation	(4,428)	(4,781)
Property and equipment, net	$ 1,134	$ 1,222

Depreciation expense was $0.2 million for the three months ended March 31, 2020, and 2019. The Company recorded accelerated depreciation costs of less than $0.1 million in the reported property and equipment for the three months ended March 31, 2020 relating to the new corporate headquarters move in 2020.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2020	December 31, 2019
Payroll and employee related expenses	$ 1,401	$ 2,235
Collaboration and licensing	—	1,050
Accrued patent fees	1,324	487
Accrued external research and development costs	5,414	4,379
Accrued professional and consulting services	353	446
Accrued interest	60	82
Issuance costs, December 2019 financing	—	4,381
Other	223	432
Accrued expenses	$ 8,775	$ 13,492

8. Leases

The Company accounts for its leases in accordance with ASC Topic 842, *Leases (ASC 842).*

480 Arsenal Way Lease

The Company has a non-cancellable operating lease for its laboratory and office space located at 480 Arsenal Way, Watertown, Massachusetts ("Headquarters Lease"). As part of the Headquarters Lease agreement, the landlord provided the Company a tenant improvement allowance of up to $0.7 million, which the Company fully utilized during 2012. The leasehold improvements are capitalized as a component of property and equipment. In connection with the Headquarters Lease, the Company secured a letter of credit for $0.3 million which renews automatically each year and is classified in restricted cash. In August 2016, the Company signed an amendment to the Headquarters Lease, which extended the term through March 31, 2020. In March 2020, the Company signed a new amendment to extend the lease term one additional month to April 30, 2020. The right-of-use asset and lease liability were remeasured and recorded based on the change in the lease term in which the net impact was immaterial.

75 North Beacon Street Lease

In October 2017, the Company entered into a lease for approximately 5,100 square feet of additional office space located at 75 North Beacon Street, Watertown, Massachusetts (the “75 North Beacon Lease”) for a term through March 31, 2020. On January 11, 2019, the Company vacated 75 North Beacon Street, Watertown, MA and consolidated all employees at its corporate headquarters at 480 Arsenal Way, Watertown, MA. The right-of-use asset with carrying amount of $0.2 million attributable to the 75 North Beacon Lease was written down to zero during the first quarter of 2019.

65 Grove Street Lease

In July 2019, the Company entered into a lease for 25,078 square feet of laboratory and office space located at 65 Grove Street, Watertown, Massachusetts (the “New Headquarters Lease”). The Company estimates that it will incur $0.8 million in non-reimbursable construction costs. None of these costs were incurred as of March 31, 2020. The lease began in March 2020, consistent with when the Company took control of the office space and the lease term is 8 years. The discount rate of 8.9% was determined based on the Company’s incremental borrowing rate adjusted for the lease term including any reasonably certain renewal periods. Rent payments will begin in May 2020, and the base rent for the first year is $0.2 million per month. In connection with the New Headquarters Lease, the Company secured a letter of credit from Silicon Valley Bank for $1.4 million which renews automatically each year. The Company recorded the right-of-use asset and operating lease liabilities of $11.8 million during the three months ended March 31, 2020 as control of the premises was transferred to the Company.

Moscow, Russia Lease

The Company has a month-to-month facility agreement for its Moscow, Russia office. Rent expense is recognized as incurred.

Summary of All Lease Costs Recognized Under ASC 842

Rent expense for the three months ended March 31, 2020 and 2019 was $0.6 million, $0.5 million, respectively.

For the three months ended March 31, 2020 and 2019 the components of lease costs were as follows (in thousands):

	March 31, 2020	March 31, 2019
Operating lease expense	$ 472	$ 341
Variable lease expense	199	203
Short-term lease expense	2	8
Total lease expense	$ 673	$ 552

The maturity of the Company's operating lease liabilities as of March 31, 2020 and December 31, 2019 were as follows (in thousands):

Operating leases:	March 31, 2020	December 31, 2019
2020 (remainder)	$ 1,943	$ 375
2021	1,811	—
2022	1,865	—
2023	1,921	—
2024	1,979	—
Thereafter	7,027	—
Total future minimum lease payments	$ 16,546	$ 375
Less imputed interest	4,681	3
Total operating lease liabilities	$ 11,865	$ 372
Included in the condensed consolidated balance sheet:		
Current operating lease liabilities	$ 1,425	$ 372
Non-current operating lease liabilities	10,440	—
Total operating lease liabilities	$ 11,865	$ 372

The following information represents supplemental disclosure for the statement of cash flows related to operating leases (in thousands):

Operating leases:	March 31, 2020	March 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 487	$ 363

Other than the initial recording of the right of use asset and lease liability for the New Headquarters Lease, which is non-cash, the changes in the Company’s right-of-use asset and lease liability for the three months ended March 31, 2020 and 2019 are reflected in the non-cash lease expense and accrued expenses and other liabilities, respectively, in the consolidated statements of cash flows.

The following summarizes additional information related to operating leases:

Operating leases:	March 31, 2020	December 31, 2019
Weighted-average remaining lease term	8.0 years	0.3 years
Weighted-average discount rate	8.9%	10.0%

9. Debt

2017 Term Loan

On September 12, 2017, the Company entered into a term loan facility of up to $21.0 million (the “2017 Term Loan”) with Silicon Valley Bank, a California corporation (“SVB”). The 2017 Term Loan is governed by a loan and security agreement, dated September 12, 2017, between the Company and SVB (the “Loan Agreement”). The 2017 Term Loan was funded in full on September 13, 2017 (the “Funding Date”).

On the Funding Date, the Company entered into a payoff letter with SVB, pursuant to which SVB utilized $10.0 million of the 2017 Term Loan to pay off all outstanding obligations under the 2015 Term Loan. The Company recognized a loss on extinguishment of debt in the amount of $0.7 million during the three months ended September 30, 2017.

The Company incurred less than $0.1 million in debt issuance costs in connection with the closing of the 2017 Term Loan. Debt issuance costs are presented in the consolidated balance sheet as a direct deduction from the associated liability and amortized to interest expense over the term of the related debt.

The 2017 Term Loan will mature on February 1, 2022. Each advance under the 2017 Term Loan accrues interest at a floating per annum rate equal to one-half of one percent above the prime rate (as published in the money rates section of The Wall Street Journal). The 2017 Term Loan provided for interest-only payments monthly until August 31, 2019. On September 1, 2019, the Company began making amortization payments on the Term Loan, which will continue to be payable monthly in equal installments of principal and variable interest to fully amortize the outstanding principal over the remaining term of the loan. The monthly interest is subject to recalculation upon a change in the prime rate. The Company may prepay the 2017 Term Loan in full but not in part provided that the Company (i) provides five business days’ prior written notice to SVB, (ii) pays on the date of such prepayment for all outstanding principal plus accrued and unpaid interest, 1% if prepaid after the second anniversary.

Amounts outstanding during an event of default are payable upon SVB’s demand and shall accrue interest at an additional rate of 4.0% per annum of the past due amount outstanding. The events of default under the Loan Agreement include, but are not limited to, the Company’s failure to make any payments of principal or interest under the Loan Agreement or other transaction documents, the Company’s breach or default in the performance of any covenant under the Loan Agreement or other transaction documents, the occurrence of a material adverse effect, the Company making a false or misleading representation or warranty in any material respect under the Loan Agreement, the Company’s insolvency or bankruptcy, any attachment or judgment on the Company’s assets in excess of approximately $0.3 million, or the occurrence of any default under any agreement or obligation of the Company involving indebtedness in excess of approximately $0.3 million. If an event of default occurs, SVB is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The 2017 Term Loan is secured by a lien on substantially all of the assets of the Company, other than intellectual property, provided that such lien on substantially all assets includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. The Company has also granted SVB a negative pledge with respect to its intellectual property.

The 2017 Term Loan does not include any financial covenants. The 2017 Term Loan requires a final payment fee of 5% on the aggregate principal amounts borrowed upon repayment at maturity, on a prepayment date, or upon default. The final payment fee totaling $1.1 million is recorded as a loan discount. Under the 2017 Term Loan, the Company is not required to maintain a minimum cash balance. All deposits in operating, depository and securities accounts are required to be maintained with SVB in an amount equal to the lessor of (i) 100% of the Company's cash balance or (ii) 105% of the dollar amount of the then outstanding obligations. In addition, the 2017 Term Loan contains a subjective acceleration clause whereby in an event of default, an immediate acceleration of repayment occurs if there is a material impairment of the lenders’ lien or the value of the collateral, a material adverse change in the business condition or operations, or a material uncertainty exists that any portion of the loan may not be repaid.

The Company assessed all terms and features of the 2017 Term Loan in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the 2017 Term Loan, including any put and call features. The Company determined that all features of the 2017 Term Loan were clearly and closely associated with the debt host and did not require bifurcation as a derivative liability, or the fair value of the embedded feature was immaterial to the Company's consolidated financial statements. The Company reassesses the identified features on a quarterly basis to determine if they require bifurcation.

As of March 31, 2020 and December 31, 2019, the outstanding principal balance under the 2017 Term Loan was $16.1 million and $18.2 million, respectively.

Future minimum principal and interest payments on the 2017 Term Loan as of March 31, 2020 are as follows (in thousands):

2020 (Remainder)		6,629
2021		8,626
2022		2,457
Total minimum debt payments	$	17,712
Less: Amount representing interest		(562)
Less: Debt discount and deferred charges		(282)
Less: Current portion of loan payable		(16,868)
Loan payable, net of current portion	$	—

All amounts due under the 2017 Term Loan have been classified as a current liability as of March 31, 2020 due to the considerations discussed in Note 1 and the assessment that the material adverse change clause under the 2017 Term Loan is not within the Company's control. The Company has not been notified of an event of default by SVB as of the date of the filing of this Quarterly Report on Form 10-Q.

During the three months ended March 31, 2020 and 2019, the Company recognized $0.3 million and $0.4 million, respectively, of interest expense related to the 2017 Term Loan.

10. Equity

Equity Financings

August 2017 Shelf Registration Statement

On August 11, 2017, the Company filed a universal shelf registration statement on Form S-3 (Reg. No. 333-219900) with the SEC to sell an aggregate amount of up to $200.0 million of certain of its securities. The shelf registration statement was declared effective by the SEC on August 28, 2017.

“At-the-Market” Offerings

Concurrent with the filing of the shelf registration statement, the Company entered into a sales agreement (the “Sales Agreement”) with Jefferies LLC, as sales agent, pursuant to which the Company may, from time to time, issue and sell common stock with an aggregate value of up to $50 million in an "at-the-market" offering.

Sales of common stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an “at the market offering” as defined in Rule 415(a) of the Securities Act, including sales made directly through the Nasdaq Global Market or on any other existing trading market for the Company’s common stock. The Company intends to use the proceeds from the offering for working capital and other general corporate purposes. The Company may suspend or terminate the Sales Agreement at any time.

From August 11, 2017, the date the Company entered into the Sales Agreement, to December 31, 2019, the Company sold 615,453 shares of its common stock pursuant to the Sales Agreement at an average price of approximately $1.84 per share for aggregate net proceeds of $1.0 million, after deducting commissions and other transaction costs.

During the three months ended March 31, 2020, the Company sold 598,977 shares of its common stock pursuant to the Sales Agreement at an average price of approximately $2.11 per share for aggregate net proceeds of $1.1 million, after deducting commissions and other transaction costs.

December 2019 Financing

On December 18, 2019, the Company entered into a private purchase agreement (the "2019 Purchase Agreement"), and closed the Offering on December 23, 2019. Pursuant to the 2019 Purchase Agreement, the Company sold an aggregate of 37,634,883 shares of its common stock at a purchase price of $1.46 per share, warrants to purchase an aggregate of 22,988,501 shares of common stock at a purchase price of $0.125 per share underlying each common warrant, and pre-funded warrants to purchase an aggregate of 8,342,128 shares of common stock at a purchase price of $1.46 per share, all with five year terms. The exercise price of the pre-funded warrants was $0.0001 per share and the exercise price for the common warrants is $1.46 per share. In the event of a certain sale of the Company, the terms of the common warrants require us to make a payment to such common warrant holders based on a Black-Scholes valuation (using variables as specified in the warrants). This provision does not apply to the pre-funded warrants. Therefore, the Company is required to account for the common warrants as liabilities and record them at fair value, while the pre-funded warrants met the criteria to be classified as permanent equity. The Company recorded the fair value of the common warrants of $40.7 million upon issuance using the Black-Scholes valuation model. The common warrants were revalued as of December 31, 2019 at $41.5 million; a charge in fair value of $0.8 million was recorded in the

statement of operations for the three months ended March 31, 2020. Issuance costs were allocated between the equity component with an offset to additional paid-in capital and the liability component recorded as expense on a relative fair value basis. Total net proceeds from the equity offering was $65.6 million, after deducting transaction costs and commissions of $4.4 million which was paid in the three months ended March 31, 2020.

Pursuant to the Registration Rights Agreement, the Company agreed to prepare and file a registration statement with the SEC within 45 days after the closing of the Offering for purposes of registering the resale of the Shares, shares of Common Stock issuable upon exercise of the Warrants, and any shares of Common Stock issued as a dividend or other distribution with respect to the Shares or shares of Common Stock issuable upon exercise of the Warrants. If the Company did not file such registration statement by the 45-day filing deadline, the Company would have been required to make pro-rata payments to each investor in an amount equal to 1% of the aggregate amount paid pursuant to the stock purchase agreement entered into by such investor for each 30-day period or pro-rata portion thereof following the filing deadline. The Company filed a registration statement on Form S-3 on January 29, 2020, which became effective on February 6, 2020, so no such payments were required.

The Company agreed, among other things, to indemnify the Investors, their officers, directors, members, employees and agents, successors and assigns under the registration statement from certain liabilities and to pay all fees and expenses (excluding any legal fees of the selling holder(s), and any underwriting discounts and selling commissions) incident to the Company's obligations under the Registration Rights Agreement.

June 2017 Financing

On June 26, 2017, the Company entered into a securities purchase agreement (the "Institutional Purchase Agreement") with a select group of institutional investors (the "Institutional Investors") and a securities purchase agreement with Timothy A. Springer, Ph.D., a member of the board of directors (the "Springer Purchase Agreement") for a private placement of the Company's securities (the "2017 PIPE"). The closing of the 2017 PIPE occurred on June 27, 2017.

Pursuant to the Institutional Purchase Agreement, the Company sold an aggregate of 2,750,000 shares of its common stock at a purchase price equal to $16.00 per share. Pursuant to the Springer Purchase Agreement, the Company sold to Dr. Springer an aggregate of 338,791 shares of common stock at a purchase price equal to $17.71 per share, which was equal to the most recent consolidated closing bid price on the Nasdaq Global Market on June 23, 2017, and warrants to purchase up to 79,130 shares of common stock ("Warrant Shares"), exercisable at $17.71 per Warrant Share, and with a term of five years. The purchase price for each warrant was equal to $0.125 for each Warrant Share, consistent with Nasdaq Global Market requirements for an "at the market" offering. Under the terms of the Common Stock Purchase Warrant, the warrants can be settled in unregistered shares. The Warrant Shares qualify for equity classification. The fair value of the allocated proceeds was determined on the relative fair value basis. After deducting for placement agent fees and offering expenses, the aggregate net proceeds from the 2017 PIPE were approximately $47.1 million.

On June 27, 2017, in connection with the 2017 PIPE, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the Institutional Investors and Dr. Springer. Pursuant to the Registration Rights Agreement, the Company agreed to prepare and file a registration statement with the SEC within 20 days after the closing of the 2017 PIPE for purposes of registering the resale of the shares of common stock issued and sold in the 2017 PIPE (the "Shares"), the Warrant Shares, and any shares of common stock issued as a dividend or other distribution with respect to the Shares or Warrant Shares. The 2017 PIPE registration statement was declared effective by the SEC on July 21, 2017.

The Company agreed to indemnify the Institutional Investors and Dr. Springer, their officers, directors, members, employees and agents, successors and assigns under the registration statement from certain liabilities and to pay all fees and expenses (excluding any legal fees of the selling holder(s), and any underwriting discounts and selling commissions) incident to the Company's obligations under the Registration Rights Agreement.

Warrants

During the three months ended March 31, 2020, the Company did not have any exercised or canceled warrants.

	Number of Warrants			Weighted average exercise price
	Equity classified	Liability classified	Total	
Outstanding at March 31, 2020	8,437,747	22,988,501	31,426,248	$ 1.12

Common Stock

As of March 31, 2020, the Company had 200,000,000 shares of common stock authorized for issuance, $0.0001 par value per share, with 87,019,172 shares issued and outstanding. The voting, dividend and liquidation rights of the common stockholders

are subject to and qualified by the rights, powers and preferences of the preferred stock. The common stock has the following characteristics:

Voting

The common stockholders are entitled to one vote for each share of common stock held with respect to all matters voted on by the stockholders of the Company.

Dividends

The common stockholders are entitled to receive dividends, if and when declared by the Board of Directors. Through March 31, 2020, no dividends have been declared or paid on common stock.

Liquidation

Upon liquidation of the Company, the common stockholders are entitled to receive all assets of the Company available for distribution to such stockholders.

Reserved Shares

The Company has authorized shares of common stock for future issuance as follows:

	Period ending	
	March 31, 2020	**December 31, 2019**
Exercise of common and pre-funded warrants	31,426,248	31,426,248
Shares available for future stock incentive awards	5,048,316	1,765,018
Unvested restricted stock units	170,313	181,250
Outstanding common stock options	7,745,936	6,796,669
Total	44,390,813	40,169,185

11. Stock Incentive Plans

Stock Options

The Company maintains the 2008 Stock Incentive Plan (the “2008 Plan”) for employees, consultants, advisors, and directors. The 2008 Plan provided for the granting of incentive and non-qualified stock option and restricted stock awards as determined by the Board. At inception of the 2008 Plan, a total of 2,213,412 shares of common stock were authorized for grants under the 2008 Plan. The Company ceased granting awards under the 2008 Plan upon the effectiveness of the 2016 Plan (as defined below); however, awards issued under the 2008 Plan remain subject to the terms of the 2008 Plan and the applicable 2008 Plan agreement. Shares subject to awards that were granted under the 2008 Plan and that expire, lapse or terminate following the effectiveness of the 2016 Plan become available under the 2016 Plan as shares available for future grants. All unvested stock options granted under the 2008 Plan may be exercised into restricted stock subject to forfeiture upon termination prior to vesting.

On June 7, 2016, the Company’s stockholders approved the 2016 Incentive Award Plan (the “2016 Plan”), which became effective June 21, 2016. The 2016 Plan provides for the granting of incentive and non-qualified stock option, restricted stock and other stock and cash-based awards as determined by the Board. Shares subject to awards that are granted under the 2016 Plan and that expire, lapse or terminate are available for future grants under the 2016 Plan. At inception of the 2016 Plan, a total of 1,210,256 shares of common stock were authorized for future issuance under the 2016 Plan. The number of shares of common stock that may be issued under the 2016 Plan automatically increases on the first day of each calendar year, beginning in 2017 and ending in and including 2026, by an amount equal to the lesser of: (i) 4% of the number of shares of the Company’s common stock outstanding on the last day of the applicable preceding calendar year and (ii) such smaller number of shares as is determined by the Board. During the three months ended March 31, 2020 and 2019, the number of shares of common stock that may be issued under the 2016 Plan was increased by 3,453,022 shares and 898,871 shares, respectively. As of March 31, 2020, 2,416,239 shares remain available for future issuance under the 2016 Plan.

The 2008 Plan and 2016 Plan provide that the exercise price of incentive stock options cannot be less than 100% of the fair market value of the Company's common stock on the grant date for participants who own 10% or less of the total combined voting power of the Company, and not less than 110% for participants who own more than 10% of the Company’s voting power. Options and restricted stock awards granted under the 2008 Plan and 2016 Plan vest over periods as determined by the Board, which are generally four years and, for options, with terms that generally expire ten years from the grant date.

The Company's 2018 Employment Inducement Incentive Award Plan (the "Inducement Incentive Award Plan"), which was adopted by the Board on September 25, 2018 without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules ("Rule 5635(c)(4)"), provides for the grant of equity-based awards in the form of non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock or cash based awards. In accordance with Rule 5635(c)(4), awards under the Inducement Incentive Award Plan may only be made to a newly hired employee who has not previously been a member of the Board, or an employee who is being rehired following a bona fide period of non-employment by the Company, as a material inducement to the employee's entering into employment with the Company. The Company reserved 1,175,000 shares of its common stock for issuance under the Inducement Incentive Award Plan. On March 25, 2019, the Board approved the amendment and restatement of the Inducement Incentive Award Plan to reserve an additional 2,000,000 shares of the Company's common stock for issuance thereunder. As of March 31, 2020, there are 1,100,000 shares available for future grant under the Inducement Incentive Award Plan.

The fair value of each option award was estimated on the grant date using the Black-Scholes option pricing model. Expected volatilities are based on historical volatilities from guideline companies because the Company's common stock has not traded for a period that is at least equal to the expected term of its stock option awards. The Company uses the "simplified" method to estimate the expected life of options granted and are expected to be outstanding. The risk-free interest rate used is the rate for a U.S. Treasury zero coupon issue with a remaining life consistent with the options expected life on the grant date. The Company has not paid and does not expect to pay in the foreseeable future, any cash dividends. Forfeitures are estimated at the time of grant and are adjusted, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has estimated a forfeiture rate of 10% based on historical attrition trends. The Company records stock-based compensation expense only on awards that are expected to vest.

The estimated grant date fair values of employee stock option awards granted under the 2016 Plan and the 2018 Inducement Incentive Award Plan were calculated using the Black-Scholes option pricing model, based on the following weighted-average assumptions:

	Three Months Ended March 31,	
	2020	**2019**
Risk-free interest rate	1.73%	2.45%
Dividend yield	—	—
Expected term	6.08	6.06
Expected volatility	87.96%	87.35%
Weighted-average fair value of common stock	$ 2.30	$ 2.41

The weighted average grant date fair value of stock options granted to employees during the three months ended March 31, 2020 and 2019 was $1.69, and $1.77, respectively. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2020 and 2019 was $0.1 million.

As of March 31, 2020, total unrecognized compensation expense related to unvested employee stock options was $10.2 million, which is expected to be recognized over a weighted average period of 2.5 years.

No stock option awards were granted to non-employees during the three months ended March 31, 2020 and 2019.

As of March 31, 2020, total unrecognized compensation expense related to unvested non-employee stock options was less than $0.1 million, which is expected to be recognized over a weighted average period of 0.2 years.

The following table summarizes the activity under the 2008 Plan, 2016 Plan, and 2018 Inducement Incentive Award Plan:

	Number of options	Weighted-average exercise price ($)	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Employee awards				
Outstanding at December 31, 2019	6,323,596	$ 4.91	8.71	$ 1,716
Granted	1,708,309	$ 2.30		
Exercised	(5,128)	$ 0.47		
Forfeited	(753,914)	$ 3.62		
Outstanding at March 31, 2020	7,272,863	$ 4.44	8.71	$ 1,728
Vested at March 31, 2020	1,822,514	$ 8.39	7.01	$ 115
Vested and expected to vest at March 31, 2020	6,661,467	$ 4.61	8.64	$ 1,541
Non-employee awards				
Outstanding at December 31, 2019	473,073	$ 5.89	6.23	$ 38
Granted	—	$ —		
Exercised	—	$ —		
Forfeited	—	$ —		
Outstanding at March 31, 2020	473,073	$ 5.89	5.98	$ 40
Vested at March 31, 2020	346,860	$ 5.77	4.98	$ 22
Vested and expected to vest at March 31, 2020	473,073	$ 5.89	5.98	$ 40

Restricted Stock Units

Unrecognized compensation expense for the restricted stock units was $0.7 million as of March 31, 2020, which is expected to be recognized over a weighted average period of 2.6 years.

The following table summarizes the status of the Company’s restricted stock units:

	Number of shares	Weighted average fair value ($)
Unvested at December 31, 2019	181,250	$ 5.00
Granted	—	—
Vested	10,937	6.03
Forfeited	—	—
Unvested at March 31, 2020	170,313	$ 4.93

Employee Stock Purchase Plan

On June 7, 2016, the Company’s stockholders approved the 2016 Employee Stock Purchase Plan (the “ESPP”), which became effective June 21, 2016. The ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code of 1986 with the purpose of providing employees with an opportunity to purchase the Company's common stock through accumulated payroll deductions.

Under the ESPP, the Company has set two six-month offering periods during each calendar year, one beginning March 1st and the other beginning September 1st of each calendar year, during which employees may elect to have up to 25% of their eligible compensation deducted on each payday on an after-tax basis for use in purchasing the Company's common stock on the last trading day of each offering period, subject to limits imposed by the Internal Revenue Code. The purchase price of the shares may not be less than 85% of the fair market value on the first or last trading day of the offering period, whichever is lower. The first ESPP offering period began on March 1, 2017.

At inception of the ESPP, a total of 173,076 shares of common stock were authorized and reserved for future issuance under the ESPP. The number of shares of common stock that may be issued under the ESPP will automatically increase on the first day of each calendar year, beginning in 2017 and ending in and including 2026, by an amount equal to the lesser of: (i) 1% of the

number of shares of the Company's common stock outstanding on the last day of the applicable preceding calendar year and (ii) such smaller number of shares as is determined by the Company's Board of Directors. During the three months ended March 31, 2020 and 2019, the number of shares of common stock that may be issued under the ESPP was increased by 863,254 shares and 224,717 shares, respectively. During the three months ended March 31, 2020, the Company issued 78,583 shares of common stock under the ESPP. As of March 31, 2020, 1,532,077 shares remain available for future issuance under the ESPP.

For each of the three months ended March 31, 2020 and 2019, the Company recognized less than $0.1 million of stock-based compensation expense under the ESPP.

The Company recorded stock-based compensation expense related to stock option awards, restricted stock units and the ESPP in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 623	$ 519
General and administrative	786	661
Total stock-based compensation expense	$ 1,409	$ 1,180

12. Revenue Arrangements

Asklepios Biopharmaceutical, Inc.

License Agreement for Pompe Disease

On December 17, 2019, the Company and AskBio entered into a License Agreement, referred to as the AskBio License Agreement. Pursuant to the AskBio License Agreement, AskBio has exercised its option to exclusively license the Company's intellectual property rights covering the Company's ImmTOR platform to research, develop, and commercialize certain AAV gene therapy products utilizing ImmTOR, and targeting the GAA gene, or derivatives thereof, to treat Pompe Disease.

Pursuant to the AskBio License Agreement and ancillary documents, AskBio agreed to pay to the Company upfront fees of an aggregate of $7.0 million. Assuming successful development and commercialization, the Company could receive up to an additional $237.0 million in development, regulatory, and sales milestone payments. If commercialized, the Company would be eligible to receive tiered royalties on global net sales at percentages ranging from mid-to-high single digits. Under the terms of the agreement, the Company will be eligible to receive these royalties commencing on the first commercial sale of the licensed product until the expiration of the later of (i) ten years after the first commercial sale and (ii) expiration of the last to expire valid claim on patents covering the licensed product.

Pursuant to the AskBio License Agreement, the Company will supply AskBio with its ImmTOR platform ("Supply Obligation") and AskBio will be responsible for all preclinical, clinical and commercial manufacture and supply of licensed products (other than ImmTOR) and carry out all other activities related to the research, development, and commercialization of licensed products at its sole expense, including all regulatory activities related thereto.

The Company determined that the AskBio License was not capable of being distinct from the Supply Obligation. The Company has concluded that AskBio cannot derive benefit from the license without the simultaneous transfer of the patent protected ImmTOR supply. Therefore, the License Obligation and Supply Obligation represent the only promise in the arrangement and are combined as a single performance obligation (the "AskBio License and Supply Obligation").

In determining the transaction price, the Company concluded that the future development milestones, regulatory milestones, sales milestones, and sales royalties all represent variable consideration. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company. Consideration related to sales-based milestones as well as royalties on net sales upon commercialization by AskBio, will be recognized when the related sales occur, as they were determined to relate predominantly to the intellectual property granted to AskBio and, therefore, have also been excluded from the transaction price in accordance with the royalty recognition constraint. As of March 31, 2020 and December 31, 2019, all milestones were constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

The total initial transaction price of the contract on the effective date was $7.0 million, comprised of a $2.0 million initial up-front payment upon agreement of terms, and a $5.0 million initial up-front execution fee.

As of March 31, 2020 and December 31, 2019, the Company recorded $1.7 million as a short-term contract liability and $5.3 million as a long-term contract liability representing deferred revenue associated with this agreement.

Spark Therapeutics, Inc.

Spark License Agreement

In December 2016, the Company entered into a License and Option Agreement ("Spark License Agreement") with Spark Therapeutics, Inc. ("Spark") pursuant to which the Company and Spark agreed to collaborate on the development of gene therapies for certain targets utilizing the ImmTOR platform. The Spark License Agreement provides Spark with certain exclusive, worldwide, royalty bearing licenses to the Company's intellectual property, allowing Spark to develop and commercialize gene therapies in combination with ImmTOR for an initial identified target.

In addition to an upfront cash payment of $10.0 million under the Spark License Agreement, additional payments of an aggregate of $5.0 million in two payments of $2.5 million each were paid within twelve months of December 2, 2016 ("Contract Date"). The first of the two additional payments was scheduled to be made on or before May 31, 2017 (the "May 2017 License Payment") (see "Spark Letter Agreement" below) and the second was made on October 31, 2017. Spark may also exercise options to research, develop and commercialize gene therapies utilizing the ImmTOR platform for up to four additional targets. The Company was eligible to receive a variable fee up to $2.0 million for each additional target option elected, dependent on the incidence of the applicable indication. The election period in which Spark could have exercised additional targets under the Spark License Agreement was a term of three years from the Contract Date, which expired on December 1, 2019.

Assuming successful development and commercialization, the Company could receive up to an additional $65.0 million in development and regulatory milestone payments and $365.0 million in commercialization milestone payments for each indication. If commercialized, the Company would be eligible to receive tiered royalties on global net sales at percentages ranging from mid-single to low-double digits, all of which apply on a target-by-target basis. Under the terms of the agreement, the Company will be eligible to receive these royalties commencing on the first commercial sale of the licensed product and terminating upon the later of (i) ten years after the first commercial sale, (ii) expiration of the last to expire valid claim on patents covering the jointly invented field specific improvements, or (iii) the expiration of regulatory exclusivity in the applicable country for the licensed product.

The Spark License Agreement may be terminated by Spark for convenience upon ninety days' notice. Either party may terminate the Spark License Agreement on a target-by-target basis for material breach with respect to such target.

In December 2016, the Company also entered into a Share Purchase Agreement (the "Spark Purchase Agreement") with Spark. Pursuant to the Spark Purchase Agreement, the Company sold 197,238 shares of the Company's common stock to Spark for gross proceeds of $5.0 million, or $25.35 per share of common stock, at an initial closing (the "Initial Closing"). The purchase price per share represents an amount equal to 115% of the average daily volume weighted average price ("VWAP") of the common stock during the thirty consecutive calendar days leading up to and ending on the day prior to the Contract Date.

Beyond the Initial Closing, the Spark Purchase Agreement contemplated potential future sales of shares by the Company to Spark as follows:

- First Acquisition Right. During the period beginning on May 1, 2017 and ending on June 1, 2017, Spark had the right (the "First Acquisition Right") to purchase a number of shares of common stock equal to an aggregate price of $5.0 million. See "Spark Letter Agreement" below.

- Second Acquisition Right. During the period beginning on October 1, 2017 and ending on November 1, 2017, Spark had the right (the "Second Acquisition Right") to purchase a number of shares of common stock equal to an aggregate price of $5.0 million. On October 31, 2017 Spark exercised this right and purchased 205,254 shares of common stock from the Company for $5.0 million, or $24.36 per share of common stock. The purchase price per share represents an amount equal to 115.0% of the average daily VWAP of the common stock during the thirty consecutive calendar days leading up to and ending on the day prior to the Second Acquisition Right notification date.

The First Acquisition Rights and Second Acquisition Rights are collectively referred to herein as the "Acquisition Rights".

Under the Spark Purchase Agreement, Spark agreed not to dispose of any of the shares acquired at either the Initial Closing or the from the subsequent Acquisition Rights that it may acquire until January 1, 2018 and, thereafter, transfers are contractually subject to volume limitations applicable to an "affiliate" under Rule 144 of the Securities Act.

In connection with the Spark License Agreement and Spark Purchase Agreement, the Company has made contractual payments defined in the MIT license agreement (see Note 14) totaling $2.2 million for the MIT sub-license provided to Spark, and $0.4 million relative to the calculated premium paid by Spark for the equity investments made under the Spark Purchase Agreement.

The terms of the Spark Purchase Agreement and the Spark License Agreement were negotiated at the same time between the parties and the terms of the Spark Purchase Agreement are referenced in the Spark License Agreement in multiple sections. The pricing and terms of the agreements are unique and must be considered in contemplation with each other. There are provisions within the Spark License Agreement that link to the Spark Purchase Agreement related to provisions that constitute a material breach of the license agreement. Therefore, the Company concluded that the two agreements must be combined and evaluated as a single agreement. While the Spark Purchase Agreement and the Spark License agreement are considered to be a single agreement, the Company determined that the purchase of common stock and future acquisition rights are not within the scope of ASC 606. The Company determined that the initial purchase of common stock combined with the embedded future stock Acquisition Rights had a fair value of $2.7 million and this amount was recorded in equity as of the effective date. The remaining $2.3 million of cash received in exchange for the stock and acquisition rights is included in allocable consideration, as this represents the premium paid by Spark on the purchase of common stock, and should be allocated to the remaining performance obligations.

The Company identified the following components of the agreement: (1) certain exclusive, worldwide, royalty bearing licenses to the Company's intellectual property and a license to conduct certain research activities under the collaboration, (the "Spark License"), (2) options to research, develop and commercialize gene therapies utilizing the ImmTOR platform for up to four additional target therapy options, (the "Option Obligation"), (3) manufactured supply of ImmTOR, (the "Supply Obligation") at a discount. In exchange, the Company received an upfront payment of $15.0 million and is eligible to receive additional payments of up to $35.0 million based on the achievement by Spark of future specified development milestones, up to $30.0 million based on the achievement by Spark of future specified regulatory milestones, up to $110.0 million based on the achievement by Spark of future specified commercial milestones, and up to $255.0 million based on the achievement by Spark of future specified sales milestones. The Company will also be eligible to receive tiered royalty payments that reach low double-digits based on future net sales for the duration of the royalty term.

The Company determined that the Spark License and Supply Obligation represent a single promise and performance obligation (the "Combined License and Supply Obligation"). This is because Spark cannot derive benefit from the license without the simultaneous transfer of the patent protected ImmTOR supply. The Company also determined that the Target Options, which includes the related Supply Obligation, provides the customer with a material right and is considered a performance obligation in the arrangement since it was priced at an incremental discount. Therefore, the Company determined that the Spark agreement contains five distinct performance obligations: the Combined License and Supply Obligation, and the four separate Target Options.

In determining the transaction price, the Company considered the future development milestones, regulatory milestones, commercial milestones, sales milestone, and sales royalties all represent variable consideration. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company. Separately, any consideration related to sales-based milestones as well as royalties on net sales upon commercialization by Spark, will be recognized when the related sales occur as they were determined to relate predominantly to the intellectual property granted to Spark and, therefore, have also been excluded from the transaction price in accordance with the royalty recognition constraint. As of March 31, 2020, all future milestones are constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

The Company determined that the up-front payment of $12.3 million ($15.0 million, less fair value of the equity totaling $2.7 million as discussed above) was included in the transaction price and was allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company allocated $7.1 million to the Combined License and Supply Obligation and $5.2 million to the discount on the Target Options ($1.3 million for each option) using the relative standalone selling price method to each obligation. The standalone selling price for the Combined License and Supply Obligation was determined using a discounted cash flow model. The standalone selling price for the Target Options were determined based on the fair value of the license minus the strike price of the option (the probability of exercise was included in the valuation) as well as the estimated discount of the Supply Obligation.

The estimated proceeds expected to be received from the sale of the Supply Obligation were also included in the transaction price for the Combined License and Supply Obligation. The total consideration allocated to the Combined License and Supply Obligation will be recognized using the output method, based on the proportion of actual deliveries to the total expected deliveries over the initial term which was initially estimated to be approximately four years.

On December 1, 2019, the term for Spark to exercise additional target options expired; the Company recognized $6.7 million in revenue from deferred revenue as originally allocated. In addition, during the year ended December 31, 2019, there were two deliveries resulting in less than $0.1 million of revenue recognized. No revenue related to the Spark License Agreement was recognized during the three months ended March 31, 2020.

As of March 31, 2020 and December 31, 2019, there was a contract liability of $9.2 million representing deferred revenue presented as non-current associated with this agreement.

Spark Letter Agreement

On June 6, 2017, the Company and Spark entered into a letter agreement (the “Letter Agreement”), pursuant to which the parties agreed that Spark would make the May 2017 License Payment by June 6, 2017. The May 2017 License Payment was received, and recorded as a liability as of June 30, 2017, of which some or all may potentially constitute the reimbursement described below. The parties also agreed that Spark would be deemed to have delivered notice on May 31, 2017 exercising its right to purchase the shares pursuant to the First Acquisition Right. The Letter Agreement further outlines a cost reimbursement arrangement, pursuant to which the Company agreed to reimburse Spark for all costs and expenses, including the cost of materials provided by the Company, associated with the preclinical research and toxicology studies being performed by Spark for any licensed products for a specified amount of time (the “Reimbursement Period”), in an amount not to exceed $2.5 million.

Consistent with the First Acquisition Right, Spark purchased 324,362 shares of common stock pursuant to the Spark Purchase Agreement, as amended by the Letter Agreement, for an aggregate purchase price of $5.0 million, or $15.41 per share of common stock. The purchase price per share represents an amount equal to 115.0% of the average daily VWAP of the common stock during the thirty consecutive calendar days leading up to and ending on the day prior to the First Acquisition Right notification date. At the initial contract assessment, the Company allocated $2.7 million to equity (representing the fair value of the initial purchase of common stock combined with the embedded future stock Acquisition Rights). Upon exercise of the First Acquisition Right, the Company recorded the purchase amount to stockholders’ equity (deficit).

The Company determined that the Letter Agreement resulted in a modification to the original agreement. The amount received totaling $2.5 million and the reimbursements pursuant to the Letter Agreement totaling $2.5 million were both included in the transaction price, and a liability was recorded for the amount expected to be repaid. As repayments were made, the underlying liability was reduced. To the extent that an amount was expected to be applied towards the clinical supply obligation, the analysis of variable consideration was updated accordingly.

On October 31, 2017, Spark paid the Company a $2.5 million milestone payment pursuant to the Spark License Agreement, which was included in the transaction price and allocated to the performance obligations using the relative standalone selling price. In addition, Spark exercised the Second Acquisition Right set forth in Section 2.4 of the Spark Purchase Agreement and purchased 205,254 shares of common stock from the Company for $5.0 million, or $24.36 per share of common stock. The purchase price per share represents an amount equal to 115.0% of the average daily VWAP of the common stock during the thirty consecutive calendar days leading up to and ending on the day prior to the Second Acquisition Right notification date.

On June 5, 2019, the term of the Reimbursement Period under the Letter Agreement expired. During the year ended December 31, 2019, the Company updated its estimate of variable consideration included in the transaction price to include $1.2 million of unpaid reimbursements to Spark.

Skolkovo Foundation

The Company has received grant funding from the Russia-based Development Fund of New Technologies Development and Commercialization Center ("Skolkovo"). From grant inception through March 31, 2020, the Company received $2.0 million from Skolkovo.

Based on the guidance in ASC 606, the Company concluded that the entire $2.0 million of grant funds received from Skolkovo is variable consideration. Although the Company believes it has an enforceable right to the amounts received, there is risk that an audit could result in the Company needing to refund certain amounts back to Skolkovo, resulting in variability in the transaction price. The Company utilized the “expected value” approach in determining the amount that can be recognized. The Company estimated that it will be entitled to revenue of $1.8 million from the Skolkovo grant, and recorded this amount. The remainder of $0.2 million was recorded as a contract liability.

During the year ended December 31, 2018, the Company made a decision to cease work relating to the Skolkovo grant. As a result, Skolkovo performed a formal review of project expenses incurred by the Company. Skolkovo concluded that the Company should (i) return unused grant funds to Skolkovo in the amount of less than $0.1 million and (ii) reimburse $0.1 million of costs deemed to have been overspent relative to the cost share requirement stipulated in the grant.

As of March 31, 2020, a contract liability of $0.1 million remains on the balance sheet and will not be recognized as revenue until the expiration of the three-year audit period, expected April 2021, or sooner, if resolution is reached with Skolkovo or there is a change in the estimate.

Transaction Price Allocated to Future Performance Obligations

Remaining performance obligations represent the transaction price of contracts for which work has not been performed (or has been partially performed). As of March 31, 2020, the aggregate amount of the transaction price allocated to remaining performance obligations was $16.3 million.

Contract Balances from Contracts with Customers (*AskBio, Spark and Skolkovo Foundation***)**

The following table presents changes in the Company's contract liabilities during the three months ended March 31, 2020 (in thousands):

	Balance at beginning of period	Additions	Deductions	Balance at end of period
Three Months Ended March 31, 2020				
Contract liabilities:				
Deferred revenue	$ 16,354	$ —	$ (24)	$ 16,330
Total contract liabilities	$ 16,354	$ —	$ (24)	$ 16,330

13. Related-Party Transactions

Consulting Services

The Company incurred expenses for consulting services provided by its founders totaling $0.1 million during each of the three months ended March 31, 2020 and 2019. The Company entered into consulting agreements with its founders to serve on its Scientific Advisory Board, effective January 1, 2020 to December 31, 2021, under which they will be paid quarterly for their services.

14. Collaboration Agreements

Asklepios Biopharmaceutical, Inc.

Feasibility Study and License Agreement

On August 6, 2019, the Company entered into a Feasibility Study and License Agreement with AskBio, which is referred to as the AskBio Collaboration Agreement. Pursuant to the AskBio Collaboration Agreement, the Company and AskBio agreed to license intellectual property rights to each other as part of a collaboration to research, develop, and commercialize certain adeno-associated virus ("AAV") gene therapy products utilizing the Company's ImmTOR platform to enable re-dosing of such AAV gene therapy products to treat serious rare and orphan genetic diseases for which there is a significant unmet medical need.

Pursuant to the AskBio Collaboration Agreement, the Company and AskBio agreed to conduct proof of concept studies to potentially validate the use of ImmTOR in conjunction with AAV for the treatment of methylmalonic acidemia (MMA), based on the Company's product candidate SEL-302, to mitigate the formation of neutralizing anti-AAV capsid antibodies (the POC Studies). If the POC Studies are successful, or the parties otherwise elect to do so, the parties will proceed with a collaboration to pursue the development and commercialization of AAV gene therapy product candidates utilizing ImmTOR for the treatment of certain agreed serious rare and orphan genetic diseases. If the POC Studies fail to demonstrate a proof of concept, and the parties do not mutually agree in writing to proceed with the collaboration, the AskBio Collaboration Agreement will expire.

The Company and AskBio will share responsibility for the research, development and commercialization of products developed under this collaboration. The parties will also share research, development and commercialization costs equally for all collaboration products, but with a right of either party to opt out of certain products, and thereby no longer be required to share costs for such products. Each party will receive a percentage of net profits for each product sold under the collaboration equal to the percentage of shared costs borne by such party in the development of such product. Pursuant to the AskBio Collaboration Agreement, AskBio is responsible for manufacturing the AAV capsids and AAV vectors and the Company is responsible for manufacturing ImmTOR.

The AskBio Collaboration Agreement is considered to be within the scope of ASC 808, as both parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the AskBio Collaboration Agreement and have identified the following promises in the arrangement (1) conducting research and development activities to develop and commercialize products under the collaboration, (the "R&D Services"), (2) granting a non-exclusive, non-transferable, royalty-free, fully paid up, worldwide license to certain intellectual property of the Company, (the "IP Rights") for the purpose of performing the POC Studies, (the "Research License"), (3) granting an exclusive, nontransferable, worldwide license to the IP Rights for use in certain indications (the" Collaboration License"), (4) providing manufactured supply of preclinical and clinical ImmTOR, (the "Manufactured Supply"), (5) participation on identified steering committees responsible for the oversight of the collaboration, (the "JSC Participation"), and (6) granting an exclusive option to

obtain a license under the IP Rights to research, develop and commercialize Licensed Products. The Company determined that the R&D Services, Research License, Collaboration License, Manufactured Supply, and JSC Participation were not capable of being distinct, and therefore must be combined into a single performance obligation. Therefore, promises (1) through (5) identified above were combined into a single performance obligation. Furthermore, the Company evaluated the Option Agreement and determined that it does not provide AskBio with a material right under ASC 606 as the option was not priced at a discount (see discussion of the Option exercise in Note 12). The Company noted that AskBio did not meet the definition of a customer within the scope of ASC 606 for any distinct performance obligations as the Company concluded that such items were not an output of the Company's ordinary activities. As such, the Company determined that the entire arrangement would be accounted for within the scope of ASC 808.

In accordance with ASC 808, collaboration expenses are recognized within R&D expense and selling, general and administrative expense on our condensed consolidated statements of operations. For the three months ended March 31, 2020, the Company recognized $1.2 million of collaboration expense under the AskBio Collaboration Agreement in which actual costs incurred by both parties approximate a 50% cost share.

Under certain collaborative arrangements, the Company is entitled to reimbursement of certain R&D expense. Activities under collaborative arrangements for which the Company is entitled to reimbursement are considered to be collaborative activities under the scope of ASC 808. For these units of account, the Company does not analogize to ASC 606 or recognize revenue. Rather, the Company analogizes to the guidance in ASC 730, which requires that reimbursements from counterparties be recognized as an offset to the related costs. In accordance with ASC 730, the Company records reimbursement payments received from collaboration partners as reductions to R&D expense.

Massachusetts Institute of Technology

On December 13, 2019, the Company entered into the Fourth Amendment (the MIT Amendment) to the Exclusive Patent License Agreement by and between the Company and the Massachusetts Institute of Technology (MIT) (the MIT Agreement). Pursuant to the MIT Amendment, a provision of the MIT Agreement under which the Company was obligated to initiate a Phase 3 clinical trial for a licensed product by a specified date in the fourth quarter of 2019 is tolled until the earlier of (i) a specified date in the second quarter of 2020 or (ii) the effective date of a written amendment to the MIT Agreement. Further, pursuant to the MIT Amendment, the parties agreed to negotiate in good faith to enter into a future amendment to the MIT Agreement after the Company provides MIT with an amended diligence plan. The parties have negotiated in good faith, which has included discussing an amended diligence plan, and the Company expects to enter into a new amendment to the MIT agreement.

On November 25, 2008, the Company entered into an Exclusive Patent License agreement with MIT, which is referred to as the Exclusive Patent License. The Company received an exclusive royalty-bearing license to utilize patents held by MIT in exchange for upfront consideration and annual license maintenance fees. Such fees are expensed as incurred and have not been material to any period presented.

As of March 31, 2020, and in connection with the execution of the Spark License Agreement, the Company has made contractual payments pursuant to the Exclusive Patent License totaling $2.2 million for the sublicense granted to Spark, and $0.4 million relative to the calculated premium paid by Spark for the equity investments made under the Spark Purchase Agreement. The Company made no additional payments during the three months ended March 31, 2020.

Shenyang Sunshine Pharmaceutical Co., Ltd

In May 2014, the Company entered into a license agreement with Shenyang Sunshine Pharmaceutical Co., Ltd. ("3SBio"), which is referred to as the 3SBio License. The Company has paid to 3SBio an aggregate of $3.0 million in upfront and milestone-based payments under the 3SBio License as of March 31, 2020. The Company is required to make future payments to 3SBio contingent upon the occurrence of events related to the achievement of clinical and regulatory approval milestones of up to an aggregate of $21.0 million for products containing our ImmTOR platform, and up to an aggregate of $41.5 million for products without our ImmTOR platform.

15. Income Taxes

The Company provides for income taxes under ASC 740. Under ASC 740, the Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse.

For the three months ended March 31, 2020 and 2019, the Company did not record a current or deferred income tax expense or benefit.

The Company has provided a full valuation allowance against its net deferred tax assets, as the Company believes that it is more likely than not that the deferred tax assets will not be realized.

Utilization of the net operating loss and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code due to ownership change limitations that have occurred previously, or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. As of December 31, 2019, the Company completed a Section 382 study, noting that an ownership change occurred during 2017. However, the Company has determined that all net operating losses would be available in the future. As a result, the deferred tax assets related to the federal and Massachusetts net operating losses and credit carryforwards are not currently limited.

The Company applies ASC 740 to uncertain tax positions. As of the adoption date of January 1, 2010 and through March 31, 2020, the Company had no unrecognized tax benefits or related interest and penalties accrued.

The Company has not, as of yet, conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. As a result, there would be no impact to the consolidated balance sheets, statements of operations and comprehensive loss, or cash flows if an adjustment was required.

The statute of limitations for assessment by the Internal Revenue Service and Massachusetts tax authorities is open for tax years since inception. The Company files income tax returns in the United States and Massachusetts. There are currently no federal, state or foreign audits in progress.

Upon adoption of ASC 842 and during the quarter ended March 31, 2020 for the New Headquarters lease, a deferred tax liability was recorded for the right-of-use asset. The deferred tax asset for the lease liability and the deferred tax asset for the lease incentives was reversed, with no impact to the valuation allowance or deferred tax expense.

16. Defined Contribution Plan

The Company maintains a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pretax basis. The 401(k) Plan provides for matching contributions on a portion of participant contributions pursuant to the 401(k) Plan's matching formula. All matching contributions vest ratably over 4 years and participant contributions vest immediately. Contributions by the Company totaled less than $0.1 million during each of the three months ended March 31, 2020 and 2019.

17. Commitments and Contingencies

As of March 31, 2020, the Company had operating lease agreements for offices in Watertown, MA. See Note 8 for additional information regarding the Company's leases.

Other

As permitted under Delaware law, the Company indemnifies its directors for certain events or occurrences while the director is, or was, serving at the Company's request in such capacity. The term of the indemnification is for the director's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' insurance coverage that limits its exposure and enables it to recover a portion of any future amounts paid. The Company also has indemnification arrangements under certain of its facility leases that require it to indemnify the landlord against certain costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from certain breaches, violations, or non-performance of any covenant or condition of the Company's lease. The term of the indemnification is for the term of the related lease agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. To date, the Company had not experienced any material losses related to any of its indemnification obligations, and no material claims with respect thereto were outstanding.

The Company is a party in various other contractual disputes and potential claims arising in the ordinary course of business. The Company does not believe that the resolution of these matters will have a material adverse effect the Company's business, financial position, results of operations or cash flows.

18. Subsequent Events

"At-the-Market" Offerings

Subsequent to March 31, 2020, the Company sold 470,509 shares of its common stock pursuant to the Sales Agreement at an average price of approximately $2.21 per share for net proceeds of $1.0 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Important factors that could cause or contribute to such differences include, but are not limited to, those discussed in Part II, Item 1A "Risk Factors."

OVERVIEW

We are a clinical-stage biopharmaceutical company using our ImmTOR platform with the goal to effectively and safely treat rare and serious diseases by enabling the development of novel biologic therapies that would otherwise be limited by their immunogenicity. Many such diseases are treated with biologic therapies that are foreign to the patient's immune system and therefore elicit an undesired immune response.

Our proprietary tolerogenic ImmTOR platform encapsulates an immunomodulator in biodegradable nanoparticles and is designed to mitigate the formation of anti-drug antibodies, or ADAs, by inducing antigen-specific immune tolerance to biologic drugs. We believe ImmTOR has potential to enhance the efficacy without compromising the safety of existing approved biologic drugs, improve product candidates under development and enable novel therapeutic modalities, such as re-administration of systemic gene therapy.

Our Current Programs

Chronic Refractory Gout

Our lead product candidate, SEL-212, is designed to be a monthly treatment for chronic refractory gout, a debilitating rare disease with an unmet medical need. SEL-212 consists of a combination of our ImmTOR platform co-administered with pegadricase. Pegadricase is an investigational recombinant pegylated uricase (urate oxidase), an enzyme not naturally found in humans, and is therefore highly immunogenic. This enzyme is designed to treat patients with symptomatic gout, refractory to standard uric acid lowering treatment, by breaking down the excess uric acid to the more soluble allantoin. In preclinical studies, we observed that ImmTOR, when co-administered with pegadricase, induced antigen-specific immune tolerance to pegadricase and substantially reduced the formation of associated ADAs. Based on our Phase 1/2 clinical data, we believe that SEL-212 has the potential to control serum uric acid, or SUA, levels and mitigate the formation of ADAs in response to the therapeutic enzyme.

Our Phase 1 data provided evidence that ImmTOR mitigated the formation of ADAs against pegadricase in a dose-dependent manner after a single dose of SEL-212. In our Phase 2 dose-finding study, ImmTOR inhibited the formation of ADAs in the majority of patients with up to five monthly doses, resulting in sustained reduction of SUA levels. We also observed a lower-than-expected rate of gout flares in the first months after initiation of SEL-212 treatment, with further reductions observed in months three to five. SEL-212, if successfully developed and approved, has the potential to offer a unique treatment for patients with chronic refractory gout, including reduced immunogenicity, improved efficacy, and monthly dosing compared to other U.S. Food and Drug Administration, or FDA, -approved treatments, and provide clinical evidence supporting the utility of our ImmTOR platform in providing patients with antigenic specific tolerance.

In March 2019, we initiated a Phase 2 head-to-head clinical trial of SEL-212 (COMPARE), in which SEL-212 is being compared against the current FDA-approved therapy for chronic refractory gout, KRYSTEXXA, in multiple clinical sites in the United States. We completed enrollment of the COMPARE trial in December 2019 and expect to report top-line data in the third quarter of 2020, subject to the impact of the novel coronavirus disease, COVID-19, pandemic on our business. The two-armed, open label trial has enrolled approximately 150 patients, randomized 1:1, with one arm receiving KRYSTEXXA (as set forth in the prescribing information) and the other arm receiving six monthly doses of SEL-212. The primary endpoint in the study is the percentage of patients in each arm that maintain SUA control below 6.0 mg/dL, for at least 80% of the time during months three and six. Subject to the impact of the COVID-19 pandemic on our business, we plan to commence the Phase 3 clinical program in SEL-212 in the second half of 2020, and will require additional resources to complete it.

We expect our clinical and, if approved, marketing strategy for SEL-212 to initially focus on the estimated 160,000 patients in the United States with chronic refractory gout, and to focus on those patients that are being treated by rheumatologists.

Gene Therapy

In August 2019, we entered into a feasibility study and license agreement with AskBio, or the AskBio Collaboration Agreement, pursuant to which we and AskBio will conduct proof of concept studies to potentially validate the use of our ImmTOR platform in conjunction with an AAV gene therapy to mitigate the formation of neutralizing anti-AAV capsid antibodies, which currently precludes redosing. The initial product candidate being developed under this collaboration is gene therapy for MMA which can cause severe developmental defects and premature death as a result of an accumulation of toxic metabolites. We previously conducted preclinical studies for this product candidate based on SEL-302 and will leverage that previous work within the collaboration. If the proof of concept studies are successful, we will proceed with a collaboration to pursue the development and commercialization of AAV gene therapy product candidates utilizing ImmTOR for the treatment of certain agreed serious rare and orphan genetic diseases. Subject to the impact of the COVID-19 pandemic, we plan to enter the clinic under this collaboration in the second half of 2020 and report data in 2021.

Additionally, in December 2019 we entered into the AskBio License Agreement which provides AskBio with exclusive worldwide rights to our ImmTOR platform to research, develop and commercialize certain AAV-gene therapy products targeting the GAA gene, or derivatives thereof, to treat Pompe Disease.

In September 2018, we announced a collaboration with the European consortium, CureCN, for an ImmTOR+AAV gene therapy combination product candidate in Crigler-Najjar syndrome, a rare genetic disorder characterized by an inability to properly convert and clear bilirubin from the body. We expect the CureCN consortium to obtain scientific advice from the German drug regulatory authority in the second half of 2020.

In December 2016, we entered into the Spark License Agreement which provides Spark with exclusive worldwide rights to our ImmTOR platform to research, develop and commercialize gene therapies for Factor VIII, an essential blood clotting protein relevant to the treatment of hemophilia A.

Our proprietary gene therapy product candidate, SEL-313, is being developed to treat OTC deficiency and is currently in preclinical development.

Impact of Novel Coronavirus

We are closely monitoring how the spread of the novel coronavirus is affecting our employees, business, preclinical studies and clinical trials. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. Disruptions caused by the COVID-19 pandemic may result in difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials and the incurrence of unforeseen costs as a result of preclinical study or clinical trial delays. While the COVID-19 pandemic has not had a material impact on our clinical programs as of May 5, 2020, it could have an impact on our ability to successfully complete our ongoing COMPARE trial, our ability to access capital for the planned Phase 3 clinical program of SEL-212 and other programs, and our ability to obtain supply of both active drug substances and finished drug product as well as efficient execution of the overall supply chain for SEL-212 and our other programs. We have been proactively working with our contract research organization, or CRO, clinical sites, and principal investigators to provide patients with more convenient locations to have their SUA measured for the primary endpoint of the study, such as at local laboratories or their homes, as well as alternative sites to receive infusions of study drug. We are also working with our primary and back-up suppliers for SEL-037 (pegadricase) and SEL-110 (ImmTOR) to ensure that we have adequate supply of our materials for both our clinical and preclinical programs. As of May 5, 2020, we believe we have adequate supply of all material necessary to initiate our Phase 3 clinical program of SEL-212 in chronic refractory gout and to begin our clinical trial in gene therapy under our collaboration with AskBio.

At this time, there is significant uncertainty relating to the trajectory of the pandemic and the impact of related responses. Any impact of COVID-19 on our business, revenues, results of operations and financial condition will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. See “Risk Factors - The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

FINANCIAL OPERATIONS OVERVIEW

Financial Operations

To date, we have financed our operations primarily through the public offering and private placements of our securities, funding received from research grants and collaboration arrangements and our credit facility. We do not have any products approved for sale and have not generated any product sales. All of our revenue to date has been collaboration and grant revenue.

Since inception, we have incurred significant operating losses. We incurred net losses of $19.6 million and $12.1 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had an accumulated deficit of $355.4 million. We expect to continue to incur significant expenses and operating losses for at least the next several years as we:

- conduct additional clinical trials for SEL-212;
- continue the research and development of our other product candidates as well as product candidates that we may be developing jointly with collaboration partners;
- seek to enhance our ImmTOR platform and discover and develop additional product candidates;
- seek to enter into collaboration, licensing and other agreements, including, but not limited to research and development, and/or commercialization agreements;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scales-up external manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio, including through licensing arrangements; and
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operations as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, license and collaboration agreements, and research grants. We may be unable to raise capital when needed or on reasonable terms, if at all, which would force us to delay, limit, reduce or terminate our product development or future commercialization efforts. We will need to generate significant revenues to achieve profitability, and we may never do so.

We will require additional external sources of capital to complete the planned Phase 3 clinical program for SEL-212. Under the terms of our exclusive patent license agreement with the Massachusetts Institute of Technology, or the MIT License, MIT may terminate the MIT License if we fail to meet a diligence obligation, including the initiation of a Phase 3 clinical trial by a specified date in the fourth quarter of 2019. On December 13, 2019, we entered into the Fourth Amendment, which we refer to as the MIT Amendment, to the Exclusive Patent License Agreement by and between us and the Massachusetts Institute of Technology, or the MIT Agreement. Pursuant to the MIT Amendment, a provision of the MIT Agreement under which we were obligated to initiate a Phase 3 clinical trial for a licensed product by a specified date in the fourth quarter of 2019 is tolled until the earlier of (i) a specified date in the second quarter of 2020 or (ii) the effective date of a written amendment to the MIT Agreement. Further, pursuant to the MIT Amendment, the parties agreed to negotiate in good faith to enter into a future amendment to the MIT Agreement after we provide MIT with an amended diligence plan. The parties have negotiated in good faith, which has included discussing an amended diligence plan, and we expect to enter into a new amendment to the MIT agreement. If we are unable to reach an agreement with MIT regarding an acceptable amendment of the MIT License and if we are unable to cure the breach, there could be a material adverse effect on our business.

We believe that our existing cash, cash equivalents, investments, and restricted cash as of March 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2021. Because our current operating plan does not contain sufficient resources, we will require additional external sources of capital to complete the planned Phase 3 clinical program for SEL-212. Additionally, while the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital as and when needed, including for the planned Phase 3 clinical program. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Because of the uncertainty in securing additional capital, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q. For additional information, see “Liquidity and Capital Resources.”

The consolidated financial information presented below includes the accounts of Selecta Biosciences Inc. and our wholly owned subsidiaries, Selecta (RUS) LLC, a Russian limited liability company, or Selecta RUS, and Selecta Biosciences Security Corporation, a Massachusetts securities corporation. All intercompany accounts and transactions have been eliminated.

Grant and collaboration revenue

To date, we have not generated any product sales. Our revenue consists of grant and collaboration revenue, which includes amounts recognized related to upfront and milestone payments for research and development funding under collaboration and license agreements. In addition, we earn revenue under the terms of government contracts or grants, which require the performance of certain research and development activities. We expect that any revenue we generate will fluctuate from quarter

to quarter because of the timing and amount of fees, research and development reimbursements and other payments from collaborators. We do not expect to generate revenue from product sales for at least the next several years. If we or our collaborators fail to complete the development of our product candidates in a timely manner or fail to obtain regulatory approval as needed, our ability to generate future revenue will be harmed, and will affect the results of our operations and financial position. For a further description of the agreements underlying our collaboration and grant-based revenue, see Notes 2 and 12 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Research and development

Our research and development expenses consist of external research and development costs, which we track on a program-by-program basis and primarily include CMO related costs, fees paid to CROs and internal research and development costs, which are primarily compensation expenses for our research and development employees, lab supplies, analytical testing, allocated overhead costs and other related expenses. Our internal research and development costs are often devoted to expanding our programs and are not necessarily allocable to a specific target.

We have incurred a total of $255.5 million in research and development expenses from inception through March 31, 2020, with a majority of the expenses being spent on the development of SEL-212 and a prior nicotine vaccine candidate, and the remainder being spent on our various discovery and preclinical stage product candidate programs and the general expansion of our technology.

In connection with our intention to focus on advancing our ImmTOR platform, as stated in January 2019, we have ceased ongoing work on our immune stimulation programs SELA-070 and SEL-701, and currently do not have plans to move these programs forward or to perform any additional work on either of these programs.

As we expand the clinical development of SEL-212 and our gene therapy programs, we expect our research and development expenses to increase.

We expense research and development costs as incurred. Conducting a significant amount of research and development is central to our business model. Product candidates in clinical development generally have higher development costs than those in earlier stages of development, primarily due to the size, duration and cost of clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to complete development of SEL-212, and to further advance our preclinical and earlier stage research and development projects. The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the development of SEL-212 or any of our preclinical programs or the period, if any, in which material net cash inflows from these product candidates may commence. Clinical development timelines, the probability of success and development costs can differ materially from our expectations. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently expect will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time to complete any clinical development.

The following table sets forth the components of our research and development expenses during the periods indicated (in thousands):

	Three Months Ended March 31,	
	2020	**2019**
Research and development expenses (key projects and initiatives):		
SEL-212	$ 8,648	$ 2,861
AskBio collaboration	976	—
SELA-070	—	53
Discovery and preclinical stage product candidate programs, collectively	166	289
Other internal research and development expenses	4,934	4,150
Total research and development expenses	$ 14,724	$ 7,353

General and administrative

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, business development and support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expenses, travel expenses for our general and administrative personnel and professional fees for auditing, tax and corporate legal services, including intellectual property-related legal services.

Investment income

Investment income consists primarily of interest income earned on our cash and cash equivalents and short-term investments.

Interest expense

Interest expense consists of interest expense on amounts borrowed under our credit facilities.

Other income (expense)

Other income (expense) was de minimis during the three months ended March 31, 2020, and 2019.

Change in fair value of warrant liabilities

Common warrants classified as liabilities are remeasured at fair value, utilizing a Black-Scholes valuation methodology, quarterly with the change in fair value recognized as a component of earnings.

Foreign currency transaction gain (loss)

The functional currency of our Russian subsidiary is the Russian ruble. In addition to holding cash denominated in Russian rubles, our Russian bank accounts also hold cash balances denominated in U.S. dollars to facilitate payments to be settled in U.S. dollars or other currencies. As of March 31, 2020 and December 31, 2019, we maintained cash of $0.3 million and $0.4 million, respectively, in Russian banks, all of which was denominated in U.S. dollars. The amounts denominated in U.S. dollars and used in transacting the day-to-day operations of our Russian subsidiary are subject to transaction gains and losses, which are reported as incurred.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2020 and 2019

Revenue

The following is a comparison of revenue for the three months ended March 31, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended March 31,		Increase	
	2020	2019	(decrease)	
Collaboration revenue	—	10	(10)	— %
Total revenue	$ —	$ 10	$ (10)	(100)%

During the three months ended March 31, 2020, we did not recognize revenue. During the three months ended March 31, 2019, we recognized less than $0.1 million of revenue for a shipment under our collaboration agreement with Spark.

Research and development

The following is a comparison of research and development expenses for the three months ended March 31, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended March 31,		Increase	
	2020	2019	(decrease)	
Research and development	$ 14,724	$ 7,353	$ 7,371	100%

During the three months ended March 31, 2020, our research and development expenses increased by $7.4 million, or 100%, as compared to 2019. The increase in costs was primarily the result of expenses incurred for our Phase 2 COMPARE trial for SEL-212 and for our gene therapy program in collaboration with AskBio.

General and administrative

The following is a comparison of general and administrative expenses for the three months ended March 31, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended March 31,		Increase	
	2020	2019	(decrease)	
General and administrative	$ 4,098	$ 4,513	$ (415)	(9)%

During the three months ended March 31, 2020, our general and administrative expenses decreased by $0.4 million, or 9%, as compared to 2019. The reduction in costs was the result of reduced salaries, consulting and professional fees offset by increased stock compensation expense.

Investment income

Investment income remained relatively unchanged during the three months ended March 31, 2020 as compared to 2019.

Foreign currency transaction gain (loss)

We recognized minimal foreign currency gains of less than $0.1 million and minimal losses of less than $0.1 million during each of the three months ended March 31, 2020 and 2019, respectively.

Interest expense

Interest expense was $0.3 million and $0.4 million for the three months ended March 31, 2020 and 2019, respectively, representing interest expense and amortization of the carrying costs of our credit facilities.

Change in fair value of warrant liabilities

We recognized $0.8 million charge for the increase in the fair value of warrant liabilities utilizing a Black-Scholes valuation methodology, for the three months ended March 31, 2020, primarily driven by an increase in the share price and volatility, offset by a decreased discount rate this quarter (see Note 5).

Other income (expense)

Other (expense) income was de minimis for each of the three months ended March 31, 2020 and 2019.

Net Loss

Net loss for the three months ended March 31, 2020 was $19.6 million compared to $12.1 million for the three months ended March 31, 2019.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have incurred recurring net losses. We expect that we will continue to incur losses and that such losses will increase for the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, third-party funding and other collaborations and strategic alliances.

From our inception through March 31, 2020, we have raised an aggregate of $422.1 million to fund our operations, which includes $118.5 million from the sale of preferred stock, $11.1 million in government grant funding, $25.3 million from borrowings under our credit facility, $51.3 million from our collaborations and license agreements, $64.5 million in combined net proceeds from our initial public offering, $149.3 million in combined net proceeds from private placements and follow-on offerings of our common stock, and $2.1 million in aggregate net proceeds from "at-the-market" offerings of our common stock.

Collaborations

On December 17, 2019, we entered into the AskBio License Agreement. Pursuant to the AskBio License Agreement, AskBio has exercised its option to exclusively license intellectual property rights covering ImmTOR to research, develop, and commercialize certain AAV genetherapy products utilizing ImmTOR, and targeting the GAA gene, or derivatives thereof, to treat Pompe Disease. As of March 31, 2020, we had received $7.0 million of upfront fees pursuant to the AskBio License Agreement.

Financings

In August 2017, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $50 million in an "at-the-market" offering. Sales of common stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an “at the market offering” as defined in Rule 415(a) of the Securities Act, including sales made directly through the Nasdaq Global Market or on any other existing trading market for our common stock. We intend to use the proceeds from the offering for working capital and other general corporate purposes. We may suspend or terminate the Sales Agreement at any time.

From August 11, 2017, the date we entered into the Sales Agreement, to December 31, 2019, we sold 615,453 shares of our common stock pursuant to the Sales Agreement at an average price of approximately $1.84 per share for aggregate net proceeds of $1.0 million, after deducting commissions and other transaction costs.

During the three months ended March 31, 2020, we sold 598,977 shares of our common stock pursuant to the Sales Agreement at an average price of approximately $2.11 per share for aggregate net proceeds of $1.1 million, after deducting commissions and other transaction costs.

As of March 31, 2020, our cash, cash equivalents, and restricted cash were $74.3 million, of which $1.7 million was restricted cash related to lease commitments and $0.3 million was held by our Russian subsidiary designated solely for use in its operations. Our Russian subsidiary cash is consolidated for financial reporting purposes.

In addition to our existing cash equivalents, we receive research and development funding pursuant to our collaboration agreements. Currently, funding from payments under our collaboration agreements represent our only source of committed external funds.

Indebtedness

On September 12, 2017, we entered into a term loan facility of up to $21.0 million with Silicon Valley Bank, a California corporation, or SVB, the proceeds of which were used to repay our previously existing term loan facility with Oxford Finance LLC and Pacific Western Bank, as successor in interest to Square 1 Bank, and for general corporate and working capital purposes. The term loan facility is governed by a loan and security agreement, dated September 12, 2017, between us and SVB, which was funded in full on September 13, 2017. The term loan facility with SVB is secured by a lien on substantially all assets, other than intellectual property, provided that such lien on assets includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. We also granted SVB a negative pledge with respect to our intellectual property.

The term loan facility contains customary covenants and representations, including but not limited to financial reporting obligations and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. The term loan facility also contains other customary provisions, such as expense reimbursement, non-disclosure obligations as well as indemnification rights for the benefit of SVB.

The events of default under the term loan facility include, but are not limited to, our failure to make any payments of principal or interest under the term loan facility or other transaction documents, our breach or default in the performance of any covenant under the term loan facility or other transaction documents, the occurrence of a material adverse effect, making a false or misleading representation or warranty in any material respect under the term loan facility, our insolvency or bankruptcy, any attachment or judgment on our assets in excess of approximately $0.3 million, or the occurrence of any default under any of our agreements or obligations involving indebtedness in excess of approximately $0.3 million. If an event of default occurs, SVB is entitled to take enforcement action, including acceleration of amounts due under the term loan facility. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Plan of operations and future funding requirements

As of the date of this Quarterly Report on Form 10-Q, we have not generated any product sales. We do not know when, or if, we will generate revenue from product sales. We will not generate significant revenue from product sales unless and until we obtain regulatory approval and commercialize one of our current or future product candidates. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses, and general overhead costs. We expect that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to risks in the development of our products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect that we will need substantial additional funding to support our continuing operations.

As of March 31, 2020 and December 31, 2019, we had an accumulated deficit of $355.4 million and $335.8 million, respectively. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of our product candidates, conducting preclinical studies and clinical trials, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital.

Management is exploring various sources of funding such as strategic collaborations and the issuance of equity to fund our operations. If we raise additional funds through strategic collaborations and alliances, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. To the extent that we raise additional capital through the sale of equity, the ownership interest of our existing shareholders will be diluted and other preferences may be necessary that adversely affect the rights of existing shareholders.

We will require additional external sources of capital to complete the planned Phase 3 clinical program for SEL-212. Under the terms of our exclusive patent license agreement with the Massachusetts Institute of Technology, or the MIT License, MIT may terminate the MIT License if we fail to meet a diligence obligation, including the initiation of a Phase 3 clinical trial by a specified date in the fourth quarter of 2019. On December 13, 2019, we entered into the Fourth Amendment, which we refer to as the MIT Amendment, to the Exclusive Patent License Agreement by and between us and the Massachusetts Institute of

Technology, or the MIT Agreement. Pursuant to the MIT Amendment, a provision of the MIT Agreement under which we were obligated to initiate a Phase 3 clinical trial for a licensed product by a specified date in the fourth quarter of 2019 is tolled until the earlier of (i) a specified date in the second quarter of 2020 or (ii) the effective date of a written amendment to the MIT Agreement. Further, pursuant to the MIT Amendment, the parties agreed to negotiate in good faith to enter into a future amendment to the MIT Agreement after we provide MIT with an amended diligence plan. The parties have negotiated in good faith, which has included discussing an amended diligence plan, and we expect to enter into a new amendment to the MIT agreement. If we are unable to reach an agreement with MIT regarding an acceptable amendment of the MIT License and if we are unable to cure the breach, there could be a material adverse effect on our business.

We believe that our existing cash, cash equivalents, investments, and restricted cash as of March 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2021. Subject to the impact of the COVID-19 pandemic on our business, we plan to commence our Phase 3 clinical program in SEL-212 in the second half of 2020. Because our current operating plan does not contain sufficient resources, we will require additional external sources of capital to complete the planned Phase 3 clinical program for SEL-212. Additionally, while the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital as and when needed, including for the planned Phase 3 clinical program. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Because of the uncertainty in securing additional capital, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q.

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

- the scope, progress, results and costs of our clinical trials of SEL-212;
- the number of product candidates that we pursue;
- our collaboration agreements remaining in effect, our entering into additional collaboration agreements and our ability to achieve milestones under these agreements;
- the cost of manufacturing clinical supplies of our product candidates;
- our headcount growth and associated costs;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

As noted above, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity future funding requirements is uncertain as of the filing date of this Quarterly Report on Form 10-Q as this continues to evolve globally. See “Impact of Novel Coronavirus” above and “Risk Factors - The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Summary of Cash Flows

(In thousands)	Three Months Ended March 31, 2020	2019
Cash provided by (used in):		
Operating activities	$ (11,698)	$ (20,240)
Investing activities	(135)	(16,119)
Financing activities	(5,370)	31,107
Effect of exchange rate changes on cash	(84)	22
Net change in cash, cash equivalents, and restricted cash	$ (17,287)	$ (5,230)

Operating activities

Net cash used in operating activities for the three months ended March 31, 2020 was $11.7 million compared to $20.2 million in the same period in 2019, a decrease of $8.5 million. The decrease in net cash used in operating activities was primarily due to a decrease of $6.1 million in prepaid expenses, a decrease of $5.0 million in accounts receivable, a decrease of $2.8 million in accrued expenses and other liabilities, an increase of $1.2 million in accounts payable, offset by a $6.7 million increase in recorded net loss after adjusting for non-cash charge of $0.8 million for the warrant liability.

Investing activities

Net cash used in investing activities for the three months ended March 31, 2020 was $0.1 million compared to net cash used in investing activities of $16.1 million in the same period in 2019. The net cash used in investing activities in 2020 was to purchase property and equipment. During the first quarter of 2019, the net cash used by investing was the result of purchases of short-term investments of $18.2 million to purchase short-term investments, offset by $2.0 million in sales of short-term investments.

Financing activities

Net cash used in financing activities for the three months ended March 31, 2020 was $5.4 million compared to net cash provided by financing activities of $31.1 million in the same period in 2019. The net cash used in financing activities in 2020 was the result of $4.4 million of issuance costs paid for December 2019 financing, $2.1 million principal payment on outstanding debt, offset by $1.1 million net proceeds from "at-the-market" offerings. The net cash provided by financing activities in 2019 was due to $30.9 million net proceeds from the issuance of common stock under the January 2019 Public Offering and $0.1 million from the exercise of employee stock options.

Recent Accounting Pronouncements

For a discussion of recently adopted or issued accounting pronouncements please refer to Part I, Note 2 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

As of March 31, 2020, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

Our management’s discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities in our consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

Clinical Trial Costs

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third party clinical trial expenses include patient costs, clinical research organization costs and costs for data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the

consolidated balance sheets as a prepaid asset or accrued clinical trial cost. These third party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future R&D activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. We also record accruals for estimated ongoing clinical research and development costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical clinical accrual estimates made by the Company have not been materially different from the actual costs.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Pursuant to ASC 606, *Revenue from Contracts with Customers (ASC 606)*, a customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. If a promised good or service is not distinct, it is combined with other performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For example, certain performance obligations associated with Spark (see Note 12 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q) will be satisfied over time, and revenue will be recognized using the output method, based on the proportion of actual deliveries to the total expected deliveries over the initial term.

Collaboration and Grant Revenue: We currently generate our revenue through grants, collaboration and license agreements with strategic collaborators for the development and commercialization of product candidates. Grants and license agreements with customers are accounted for in accordance with ASC 606. We analyze collaboration arrangements by first assessing whether they are within the scope of ASC Topic 808, *Collaborative Arrangements (ASC 808)*, and evaluate whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. Collaboration agreements with customers that are not within the scope of ASC 808 are accounted for in accordance with ASC 606. To the extent the collaboration agreement is within the scope of ASC 808, we also assess whether any aspects of the agreement are within the scope of other accounting literature (specifically ASC 606). We early adopted ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which provides guidance on evaluating certain transactions between collaborative arrangement participants. If we conclude that some or all aspects of the agreement are distinct and represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC 606. We recognize the shared costs incurred that are not within the scope of other accounting literature as a component of the related expense in the period incurred by analogy to ASC 730, *Research and Development (ASC 730)*, and record reimbursements from counterparties as an offset to the related costs. In determining the appropriate amount of revenue to be recognized as it fulfills our obligations under the agreements in accordance with ASC 606, we perform the five steps above. As part of the accounting for the arrangement, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

The terms of our arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost-sharing of R&D expenses; and (v) profit/loss sharing arising from co-promotion arrangements.

Licenses of intellectual property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If not distinct, the license is combined with other performance obligations in the contract. For licenses that are combined with other performance obligations, we assess the nature of the combined performance obligation to determine whether the combined

performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Optional licenses are evaluated to determine if they are issued at a discount, and therefore, represent material rights and accounted for as separate performance obligations.

Milestone Payments: At the inception of each arrangement that includes developmental and regulatory milestone payments, we evaluate whether the achievement of each milestone specifically relates to our efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of our efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service. If the milestone payment is not specifically related to our effort to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method. We also evaluate the milestones to determine whether they are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated, otherwise, such amounts are constrained and excluded from the transaction price. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts our estimate of the transaction price. Any such adjustments to the transaction price are allocated to the performance obligations on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation shall be recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are evaluated to determine if they are distinct and optional. For optional services that are distinct, we assess if they are priced at a discount, and therefore, provide a material right to the licensee to be accounted for as separate performance obligations.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied) in accordance with the royalty recognition constraint.

Warrant Liabilities

In December 2019, we issued common warrants in connection with the 2019 Purchase Agreement. Pursuant to the terms of these common warrants, we could be required to settle the common warrants in cash in the event of certain acquisitions of the Company and, as a result, the common warrants are required to be measured at fair value and reported as a liability on the balance sheet. We recorded the fair value of the common warrants of $40.7 million upon issuance using the Black-Scholes valuation model, and are required to revalue the common warrants at each reporting date with any changes in fair value recorded on our statement of operations. Inputs used to determine estimated fair value of the common warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. As of March 31, 2020, the fair value of the common warrants of $42.4 million was recorded as a long-term liability on our balance sheet, which resulted in a change in fair value of $0.8 million for the three months ended March 31, 2020.

Stock-Based Compensation

We account for all stock-based compensation granted to employees and non-employees using a fair value method. Stock-based compensation is measured at the grant date fair value using the Black-Scholes option pricing model and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. We reduce recorded stock-based compensation for estimated forfeitures. To the extent that actual forfeitures differ from management's estimates, the differences are recorded as a cumulative adjustment in the period the estimates were adjusted. Stock-based compensation expense recognized in the consolidated financial statements is based on awards that are ultimately expected to vest.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an ''emerging growth company'' such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Smaller Reporting Company

We qualify as a "smaller reporting company" under the rules of the Securities Act and the Exchange Act. As a result, in addition to the exemptions available to us as an "emerging growth company," we may choose to take advantage of certain scaled disclosure requirements available specifically to smaller reporting companies. Additionally, even if we cease to be an emerging growth company as noted above, as long as we continue to be a smaller reporting company, we may continue to rely on the reduced executive compensation disclosure obligations available to emerging growth companies. We will remain a smaller reporting company until the last day of the fiscal year in which the aggregate market value of our common stock held by non-affiliated persons and entities, or our public float, was less than $250 million as of the last business day of our most recently completed second fiscal quarter, or the last day of the fiscal year in which we have at least $100 million in revenue and at least $700 million in public float as of the last business day of our most recently completed second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of March 31, 2020 and December 31, 2019, we had cash, cash equivalents, restricted cash and investments of $74.3 million and $91.6 million, respectively, consisting of non-interest and interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term and the low risk profile of our money market accounts and investments, and our current plan to hold investments to maturity, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents or short-term investments.

In addition, we are subject to currency risk for balances held in Russian rubles in our foreign subsidiary. We hold portions of our funds in both U.S. dollars and Russian rubles. The exchange rate between the U.S. dollar and Russian ruble changes from period to period. As of March 31, 2020, we held cash and cash equivalents totaling $0.3 million in Russian banks to support our Russian subsidiary, all of which were denominated in U.S. dollars. We do not hedge against foreign currency risks. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2020.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that occurred during the three months ended March 31, 2020 that have 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 party to any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Quarterly Report on Form 10-Q. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We are a development-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses in every year. Our net loss was $19.6 million for the three months ended March 31, 2020, and $55.4 million and $65.3 million for each of the years ended December 31, 2019 and 2018, respectively. As of March 31, 2020, we had an accumulated deficit of $355.4 million. To date, we have financed our operations primarily through the public offering and private placements of our securities, funding received from research grants and collaboration arrangements and our credit facility. We currently have no source of product revenue, and we do not expect to generate product revenue for the foreseeable future. All of our revenue to date has been collaboration and grant revenue. We have devoted substantially all of our financial resources and efforts to developing our ImmTOR platform, identifying potential product candidates and conducting preclinical studies and our clinical trials. We are in the early stages of development of most of our product candidates, and we have not completed development of any ImmTOR-enabled therapies. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses will increase substantially as we:

- conduct additional clinical trials of SEL-212, our lead product candidate;
- continue the research and development of our other product candidates;
- seek to enhance our ImmTOR platform and discover and develop additional product candidates;
- seek to maintain and enter into collaboration, licensing and other agreements, including, but not limited to research and development, and/or commercialization agreements;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio, including through licensing arrangements;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operations as a public company; and
- experience any delays or encounter any issues with any of the above, including, but not limited to, failed studies, complex results, safety issues or other regulatory, manufacturing or scale-up challenges.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval and securing reimbursement for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, and establishing and managing our collaborations at various stages of a product candidate’s development. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

Even 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 depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations.

We will need substantial additional funding in order to complete development of our product candidates and commercialize our products, if approved. 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 conduct our clinical trials of SEL-212, continue to develop our gene therapy program, including our collaboration with AskBio, and continue research and development for our other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding to continue operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our clinical trials, our other research and development programs or any future commercialization efforts.

We believe that our existing cash, cash equivalents, investments, and restricted cash as of March 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2021. Subject to the impact of the COVID-19 pandemic on our business, we plan to commence our Phase 3 clinical program in SEL-212 in the second half of 2020. Because our current operating plan does not contain sufficient resources, we will require additional external sources of capital to complete the planned Phase 3 clinical program for SEL-212. Additionally, while the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital as and when needed, including for the planned Phase 3 clinical program. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Because of the uncertainty in securing additional capital, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q.

Moreover, under the terms of the MIT License, MIT may terminate the MIT License if we fail to meet a diligence obligation, including the initiation of a Phase 3 clinical trial by a specified date in the fourth quarter of 2019. If we are unable to reach an agreement with MIT regarding an acceptable amendment of the MIT License and if we are unable to cure the breach, which is currently tolled until the earlier of (i) a specified date in the second quarter of 2020 or (ii) the effective date of a written amendment to the MIT Agreement, there could be a material adverse effect on our business. See “Business - Licenses and Collaborations – Massachusetts Institute of Technology.”

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

- the scope, progress, results and costs of our clinical trials of SEL-212;
- the number of product candidates that we pursue;
- our collaboration agreements remaining in effect, our entering into additional collaboration agreements and our ability to achieve milestones under these agreements;
- the cost of manufacturing clinical supplies of our product candidates;
- our headcount growth and associated costs;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and

- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, including our clinical trial programs, or the commercialization of any product candidates, or be unable to sustain or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

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

As of March 31, 2020 and December 31, 2019, we had an accumulated deficit of $355.4 million and $335.8 million, respectively. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of our product candidates, conducting preclinical studies and clinical trials, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of filing this Quarterly Report on Form 10-Q.

We are exploring various sources of funding such as strategic collaborations and the issuance of equity to fund our operations. If we raise additional funds through strategic collaborations and alliances, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, or, grant licenses on terms that are not favorable to us. To the extent that we raise additional capital through the sale of equity, the ownership interest of our existing shareholders will be diluted and other preferences may be necessary that adversely affect the rights of existing shareholders. Because our current operating plan does not contain sufficient resources, we will require additional external sources of capital to complete the planned Phase 3 clinical program for SEL-212. Additionally, while the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital as and when needed, including for the planned Phase 3 clinical program. If we are unable to raise sufficient capital, we intend to curtail expenses contemplated by the current operating plan, and we may be required to delay, limit, reduce or terminate our product development efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If the foregoing plans are unsuccessful and we are unable to continue as a going concern, you could lose all or part of your investment in the company.

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

We commenced active operations in 2007, and our operations to date have been limited to developing and researching our ImmTOR platform and related products and programs, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. Other than SEL-212, our lead product candidate, our other product candidates are still in preclinical development. While we have completed our early development clinical trials and a Phase 2 clinical trial for SEL-212, we have not completed a clinical trial for any other product candidate, nor have we demonstrated our ability to successfully complete any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, 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. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. 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.

The terms of our credit facility place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On September 12, 2017, we entered into a term loan facility of up to $21.0 million with Silicon Valley Bank, or SVB. The term loan facility is governed by a loan and security agreement, dated September 12, 2017, between us and SVB, which was funded in full on September 13, 2017. The term loan facility with SVB is secured by a lien on substantially all of our assets, other than intellectual property, provided that such lien on substantially all assets includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. We also granted SVB a negative pledge with respect to our intellectual property.

The term loan facility contains customary covenants and representations, including but not limited to financial reporting obligations and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. The term loan facility also contains other customary provisions, such as expense reimbursement, non-disclosure obligations as well as indemnification rights for the benefit of SVB. The events of default under the term loan facility include, but are not limited to, our failure to make any payments of principal or interest under the term loan facility or other transaction documents, our breach or default in the performance of any covenant under the term loan facility or other transaction documents, the occurrence of a material adverse effect, making a false or misleading representation or warranty in any material respect under the term loan facility, our insolvency or bankruptcy, any attachment or judgment on our assets of at least approximately $0.3 million, or the occurrence of any default under any of our agreements or obligations involving indebtedness in excess of approximately $0.3 million. If an event of default occurs, SVB is entitled to take enforcement action, including acceleration of amounts due under the term loan facility. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Changes in U.S. tax law may materially adversely affect our financial condition, results of operations and cash flows.

The Tax Cuts and Jobs Act of 2017, or TCJA, has significantly changed the U.S. federal income taxation of U.S. corporations. The TCJA remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, which have lessened or increased certain adverse impacts of the TCJA and may do so in the future. We continue to work with our tax advisors and auditors to determine the full impact that the TCJA will have on us. We urge our investors to consult with their legal and tax advisors with respect to the TCJA.

Our ability to use our net operating loss and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

We have net operating loss carryforwards, or NOLs, for federal and state income tax purposes that may be available to offset our future taxable income, if any. In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs to offset future taxable income. If the U.S. Internal Revenue Service, or IRS, challenges our analysis that existing NOLs will not expire before utilization due to previous ownership changes, or if we undergo an ownership change in connection with or after a public offering, our ability to use our NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. As a result, we may not be able to use a material portion of the NOLs reflected on our balance sheet, even if we attain profitability. The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our NOLs and other deferred tax assets available to us. Under the TCJA, although the treatment of NOLs arising on or before December 31, 2017 has generally not changed, NOLs arising on or after January 1, 2018 will generally only be able to offset 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

RISKS RELATED TO THE DISCOVERY, DEVELOPMENT AND REGULATORY APPROVAL OF OUR PRODUCT CANDIDATES

Our product candidates are based on our ImmTOR platform, which is an unproven approach designed to induce antigen-specific immune tolerance to biologic drugs. We are very early in most of our clinical development efforts and may not be successful in our efforts to use our ImmTOR platform to build a pipeline of product candidates and develop marketable drugs.

All of our product candidates are derived from our ImmTOR platform, which is an unproven approach to induce antigen-specific immune tolerance and to mitigate the immunogenicity of biologic therapies currently being implemented to treat patients. We are primarily developing our ImmTOR platform to improve and enable activity in biologics that are designed to treat rare and serious diseases, with an initial focus on developing SEL-212 for the treatment of chronic refractory gout. We are also leveraging our ImmTOR platform to pursue programs in additional therapeutic areas with a focus on gene therapy.

We are developing two gene therapy product candidates for rare inborn errors of metabolism. Our lead gene therapy program, known as SEL-302, is a potential gene therapy product candidate for MMA. In August 2019, we entered into a feasibility study and license agreement with AskBio, or the AskBio Collaboration Agreement, pursuant to which we and AskBio agreed to conduct proof of concept studies to potentially validate the use of our ImmTOR platform in conjunction with an AAV gene therapy for the treatment of MMA, based on SEL-302, to mitigate the formation of neutralizing anti-AAV capsid antibodies. If the proof of concept studies are successful, we will proceed with a collaboration to pursue the development and commercialization of AAV gene therapy product candidates utilizing ImmTOR for the treatment of certain agreed serious rare and orphan genetic diseases. Our second gene therapy product candidate, known as SEL-313, is being developed to treat ornithine transcarbamylase deficiency. In September 2018, we announced a collaboration with the European consortium, CureCN, for an ImmTOR+AAV gene therapy combination product candidate in Crigler-Najjar syndrome, a rare genetic disorder characterized by an inability to properly convert and clear bilirubin from the body. We expect the CureCN consortium to obtain scientific advice from the German drug regulatory authority in the second half of 2020.

We are at an early stage of development of most of our product candidates and our technology has not yet led to, and may never lead to, approvable or marketable drugs. We may have problems identifying new product candidates and applying our technologies to these other areas. Even if we are successful in identifying new product candidates, they may not be suitable for clinical development, including as a result of harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. The success of our product candidates will depend on several factors, including the following:

- design, initiation and completion of preclinical studies and clinical trials with positive results;
- reliance on third parties (including but not limited to collaborators, licensees, clinical research organizations and contract manufacturing organizations);
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities, or establishing such capabilities ourselves;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- our existing collaboration agreements remaining in effect and our ability to enter into new collaborations throughout the development process as appropriate, from preclinical studies through to commercialization;
- acceptance of our products, if and when approved, by patients and the medical community;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved;
- protecting our rights in our intellectual property portfolio;
- operating without infringing or violating the valid and enforceable patents or other intellectual property of third parties;
- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our product candidates and technology.

If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain future revenues, which would result in significant harm to our financial position and adversely affect our stock price.

As a result, we cannot be certain that our approach, or our development of SEL-212, will lead to the development or approval of marketable products. In addition:

- due to the unproven nature of our ImmTOR therapeutics, there may be different efficacy and safety rates in various indications;
- the FDA or other regulatory agencies may lack experience in evaluating the efficacy and safety of products based on ImmTOR or a biologic sourced from China or other jurisdictions, which could result in a longer-than-expected regulatory review process, increase our expected development costs or delay or prevent commercialization of our product candidates; and

- in the event of a biologics license application, or BLA, for SEL-212 or another product and a pre-approval inspection by the FDA of the facilities of Shenyang Sunshine Pharmaceutical Co., Ltd., or 3SBio, or any other third party manufacturers we may use, the FDA may not approve the facility for production or may make observations that will take significant time for 3SBio or such other manufacturer to address.

The occurrence of any of the foregoing, would effectively prevent or delay approval of our lead and other product candidates.

We are applying our ImmTOR platform to antigen-specific immune tolerance for gene therapy involving gene augmentation, replacement or editing. Regulatory authorities in the United States and European Union have limited experience in reviewing and approving gene therapy products, which could affect the time and data required to obtain marketing authorization of any of our product candidates.

Our future success depends in part on our successful development of viable gene therapy product candidates utilizing ImmTOR platform. We may experience problems or delays in developing such product candidates and any such problems or delays (i) may result in unanticipated costs and time to develop our product candidates and/or (ii) may not be resolved in a satisfactory manner.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years. If additional clinical trials are required for certain jurisdictions, these trials can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved, and may ultimately be unsuccessful. Changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes or regulations, respectively, or changes in the regulatory review process for each submitted product application, may cause delays in the review and approval of an application.

The regulatory approval process and clinical trial requirements for novel product candidates can be more expensive and take longer than for other, better known or more extensively studied product candidates, and we cannot predict how long it will take or how much it will cost to complete clinical developments and obtain regulatory approvals for a gene therapy product candidate in either the United States or the European Union or how long it will take to commercialize a gene therapy product candidate, if and when approved. Regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions.

Additionally, under the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

A similar framework is in place in the European Union, or the EU. The European Medicines Agency, or the EMA, has a Committee for Advanced Therapies, or CAT, that is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. Advanced-therapy medical products include gene therapy medicine, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the EU, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly, complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any of our gene therapy or genome editing product candidates, but that remains uncertain at this point.

The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to evaluate the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates created with novel genome editing technology such as ours can be more lengthy, rigorous and expensive than the process for other better known or more extensively studied product candidates and technologies. Since we are developing novel treatments for diseases in which

there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or comparable regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. This may be a particularly significant risk for many of the genetically defined diseases for which we may develop product candidates alone or with collaborators due to small patient populations for those diseases, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome editing technology in a timely manner or under technically or commercially feasible conditions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Changes in applicable regulatory guidelines may lengthen the regulatory review process for our product candidates, require additional studies or trials, increase development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of such product candidates, or lead to significant post-approval limitations or restrictions. Additionally, adverse developments in clinical trials conducted by others of gene therapy products or products created using genome editing technology, or adverse public perception of the field of genome editing, may cause the FDA, the EMA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. Furthermore, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the development or commercialization of current or future product candidates.

As we advance any gene therapy product candidates, we will be required to consult with various regulatory authorities, and we must comply with applicable laws, rules, and regulations, which may change from time to time including during the course of development of our product candidates. If we fail to do so, we may be required to delay or discontinue the clinical development of certain of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Even if we comply with applicable laws, rules, and regulations, and even if we maintain close coordination with the applicable regulatory authorities with oversight over our product candidates, our development programs may fail to succeed. Regulatory authorities have substantial discretion in the approval process and may refuse to accept a marketing application as deficient or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market would materially and adversely affect our business, financial condition, results of operations and prospects.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Our lead product candidate, SEL-212, was evaluated in a Phase 2 clinical program that was initiated in October 2016 and the final patient's last visit occurred in January 2019. In March 2019, we initiated COMPARE, a Phase 2 clinical trial designed to directly compare the safety, efficacy and tolerability of SEL-212 to the currently FDA-approved uricase therapy, KRYSTEXXA, for the treatment of patients with chronic refractory gout, and completed our targeted enrollment of the COMPARE trial in December 2019. We are preparing for the start of a pivotal Phase 3 program for SEL-212.

In May 2017 we licensed LMB-100, a potent immunotoxin, from the National Cancer Institute (NCI) and a Phase 1 clinical trial of LMB-100 plus ImmTOR (SEL-403) initiated in March 2018 by NCI in patients with malignant pleural or peritoneal mesothelioma who had undergone at least one regimen of chemotherapy under a Cooperative Research and Development Agreement (CRADA) between the NCI and the Company. In October 2018, the NCI informed the Company of a Grade 5 Serious Adverse Event (patient death) in this clinical trial related to pneumonitis, which was deemed by the trial investigator to be probably related to SVP-Rapamycin and possibly related to the patient’s pleural mesothelioma condition. This patient had received previous therapies, including two courses of radiation therapy and three different immune check point inhibitors, which have been reported to be associated with pneumonitis. However, the possible relationship to SVP-Rapamycin could not be excluded. Pneumonitis has been reported in patients receiving daily oral rapamycin. In addition, a Serious Adverse Event (pericardial effusion) was seen in one of the other three patients dosed in the SEL-403 clinical trial. Pericardial effusion can also be a side effect of immunotoxin therapies targeting mesothelin. The FDA placed the IND for SEL-403 on full clinical hold in response to adverse events observed during the Phase 1 trial. Selecta has terminated the license of LMB-100 from NCI, effective April 9, 2019 and is no longer pursuing this product candidate.

Aside from these programs, our other product candidates are in preclinical development. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the

safety and efficacy of our product candidates in humans. Preclinical development is costly and inherently uncertain. For example, we have invested significant resources in our preclinical gene therapy program, which has demonstrated the potential for treatment of rare inborn errors of metabolism. Early preclinical results may not be predictive of future results, however, if our technology proves to be ineffective or unsafe as a result of, among other things, adverse side effects, pre-existing anti-drug antibodies that can neutralize the viral vector and block gene transfer, or cellular immune response to the transduced cells, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the clinical development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its outcome is inherently uncertain. A failed clinical trial can occur at any stage of testing. Moreover, 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. For example, the clinical trial results from our Phase 2 head-to-head (COMPARE) study of SEL-212, including interim results, may not be predictive of future results. Moreover, we may not be able to complete, or may be required to deviate from the current clinical trial protocol for a variety of reasons.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development or early-stage clinical trials, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including adverse events. SAEs caused by, or other unexpected properties of, any product candidates that we may choose to develop could cause us, an institutional review board or regulatory authority to interrupt, delay or halt clinical trials of one or more of such product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable non-U.S. regulatory authorities. If any product candidate that we may choose to develop is associated with SAEs or other unexpected properties, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which those undesirable characteristics would be expected to be less prevalent, less severe or more tolerable from a risk-benefit perspective. For example, in the SEL-403 Phase 1 clinical trial, a Grade 5 SAE (patient death) occurred that was deemed by the trial investigator to be probably related to SVP-Rapamycin and possibly related to the patient's pleural mesothelioma condition which led the Company to abandon development of SEL-403. In the SEL-212 Phase 1/2 clinical program, multiple SAEs have occurred, and future SAEs may occur causing the Company to incur additional costs or experience delays in completing, or causing the Company to ultimately be unable to complete, the development and commercialization of our product candidates, and delay or prevent our ability to obtain FDA approval. Moreover, preclinical and clinical data is often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory authority approval. If we fail to produce positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be negatively impacted.

In addition, we cannot be certain as to what type and how many clinical trials the FDA will require us to conduct before we may gain regulatory approval to market SEL-212 or any of our other product candidates in the United States or other countries, if any. Prior to approving a new therapeutic product, the FDA generally requires that safety and efficacy be demonstrated in two adequate and well-controlled clinical trials. We expect that we may need to conduct more than one Phase 3 trial for SEL-212 for a chronic refractory gout indication in order to gain approval from the FDA. Even if we conduct more than one Phase 3 trial for SEL-212, the FDA may not accept the data, and may delay, limit or deny approval of SEL-212. Additional clinical trials could cause us to incur significant development costs, delay or prevent the commercialization of SEL-212 or otherwise adversely affect our business.

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 for, or commercialize, our product candidates, including:

- clinical trials of our product candidates may produce unfavorable, incomplete or inconclusive results;

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with contract research organizations, or CROs, or clinical trial sites;

- we may be unable to recruit suitable patients to participate in a clinical trial, the number of patients required for clinical trials of our product candidates may be larger than we expect, enrollment in these clinical trials may be slower than we expect or participants may drop out of these clinical trials at a higher rate than we expect;

- the number of clinical trial sites required for clinical trials of our product candidates may be larger than we expect;

- 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;

- we may have to 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;

- investigators, regulators, data safety monitoring boards or institutional review boards may require that we or our investigators suspend or terminate clinical research, or we may decide to do so ourselves;

- investigators may deviate from the trial protocol, fail to conduct the trial in accordance with regulatory requirements or misreport study data;

- the cost of clinical trials of our product candidates may be greater than we expect or we may have insufficient resources to pursue or complete certain aspects of our clinical trial programs or to do so within the timeframe we planned;

- the supply or quality of raw materials or manufactured product candidates (whether provided by us or third parties) or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or in a timely manner, or we may experience interruptions in supply;

- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we expect;

- the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design or our interpretation of data from preclinical studies and clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design of our clinical trials; and

- regarding trials managed by our existing or any future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently 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, or if we are forced to delay or abandon certain clinical trials or other testing in order to conserve capital resources, we may:

- be delayed in obtaining marketing approval for our product candidates, if at all;

- lose the support of collaborators, requiring us to bear more of the burden of research and development;

- not obtain marketing approval at all;

- obtain marketing approval in some countries and not in others;

- 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;

- be subject to additional post-marketing testing requirements; or

- have a product removed from the market after obtaining marketing approval.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, from time to time our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

We are initially developing our lead product candidate, SEL-212, for the treatment of chronic refractory gout, which affects approximately 160,000 patients in the United States. Accordingly, there is a limited number of patients who could enroll in our clinical studies.

In addition to the size of the patient population, patient enrollment is also affected by other factors including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of other treatments for the disease under investigation;
- the existence of competing clinical trials;
- our efforts to facilitate timely enrollment in clinical trials;
- investigators engagement with, or enthusiasm about, the trial;
- our payments for participating in clinical trials;
- the patient referral practices of physicians;
- the design of the trial;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our common stock to decline and limit our ability to obtain additional financing.

The outbreak of the novel coronavirus disease, COVID-19, may continue to adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of coronavirus, which causes COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States, where we have planned or ongoing preclinical studies and clinical trials. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic. On March 23, 2020, the governor of Massachusetts ordered the closure of all non-essential businesses effective March 24, 2020, through May 4, 2020. Because of the nature of our operations, we are currently considered to be an essential business so, to date, our operations have only been partially affected by this order. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our principal executive office with our administrative employees continuing their work outside of our office and limited the number of staff in any given research and development laboratory. If the COVID-19 coronavirus continues to spread in the United States and

elsewhere, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, such as ImmTOR including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 coronavirus pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals and clinics serving as our clinical trial sites and hospital and clinic staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, or the closing of clinical trial sites due to the virus, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, or will withdraw from the clinical trial due to concerns over COVID-19, which could impact the results of the clinical trial, including by increasing the number of observed adverse events, or reducing the statistical power of the clinical trials;
- interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies;
- changes to the clinical endpoints, statistical analysis plan, or enrollment plans for ongoing clinical trials due to limitations in patients, resources, or sites due to COVID-19;
- interruption or delays to our sourced discovery and clinical activities; and
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We may conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or the complexity of regulatory burdens may otherwise adversely impact us.

Opening trial sites outside the United States may involve additional regulatory, administrative and financial burdens, including compliance with foreign and local requirements relating to regulatory submission and clinical trial practices. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practices, or GCPs, and the FDA must be able to validate the data from the trial through an onsite inspection, if necessary. Generally, the patient population for any clinical trials conducted outside the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. Nonetheless, there can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any trial

that we conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of any applicable product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
- increased costs and heightened supply constraints associated with the acquisition of standard of care drugs and/or combination or comparator agents for which we may bear responsibility in certain jurisdictions;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations;
- more burdensome manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- lack of consistency in standard of care from country to country;
- diminished protection of intellectual property in some countries; and
- changes in country or regional regulatory requirements.

We may not be able to obtain orphan drug designation for our product candidates, and even if we do, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. We expect to seek orphan drug designation for several of our product candidates. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA or full new drug application, or NDA, to market the same biologic or drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

The applicable exclusivity period is ten years in the European Union, but such exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

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

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

complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top-line, or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could seriously harm our business.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that SEL-212 or any other product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of a Biologics License Application, or BLA, from the FDA.

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

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our drug or device product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical studies;
- the FDA's or the applicable foreign regulatory agency may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- 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.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, including Phase 4 clinical trials, and/or the implementation of a Risk Evaluation and Mitigation Strategy, or REMS, which may be required to assure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

We may in the future seek breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. The availability of breakthrough therapy designation was established with the passage of the Food and Drug Administration Safety and Innovation Act of 2012. We cannot be sure that any evaluation we may make of our product candidates as qualifying for breakthrough therapy designation will meet the FDA's expectations. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product candidates or compromise our ability to conduct our business or obtain regulatory approvals for our product candidates.

Gene therapy remains a novel technology. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target and prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Our product candidates, including our products that utilize viral delivery systems, could produce adverse events. Adverse events in our clinical trials or following approval of any of our product candidates, even if not ultimately attributable to our product candidates, could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other

comparable foreign authorities. Further, therapies such as those we are developing involve unique side effects that could be exacerbated compared to side effects from other types of therapies with singular components. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. For example, a patient in the Phase 1 trial of SEL-403 experienced a Grade 5 SAE (patient death) related to pneumonitis, which was deemed by the trial investigator to be probably related to ImmTOR and possibly related to the patient's pleural mesothelioma condition, and in November 2018, the FDA placed the IND for SEL-403 on full clinical hold due to adverse events observed in the Phase 1 trial. Selecta has terminated the license of LMB-100 from NCI, effective April 9, 2019 and is no longer pursuing this product candidate.

Further, the SEL-212 multi-year clinical development program requiring multiple clinical trials resulted in the use of different formulations of ImmTOR. While we do not believe that differences in formulation will affect the safety or the efficacy of SEL-212, we cannot guarantee that any such formulation changes will not negatively impact the results of any clinical trials related to SEL-212, or result in a significant difference in the safety and efficacy of SEL-212.

The drug-related side effects could also affect patient enrollment in our clinical trials or the ability of any enrolled patients to complete such trials or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- regulatory authorities may impose additional restrictions on the marketing of, or the manufacturing processes for, the particular product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients, or become subject to fines, injunctions or the imposition of civil or criminal penalties;
- our reputation may suffer; and
- we could be required to develop a risk evaluation and mitigation strategy (REMS) plan to prevent, monitor and/or manage a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

In addition, if our product candidates are associated with undesirable side effects in certain patient populations, such as pediatric patients or the elderly, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would harm our business.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES AND MANUFACTURING

We rely on 3SBio in China as our primary supplier of pegadricase and on other third parties for the manufacture of our product candidates for preclinical and clinical testing, and expect to continue to do so for the foreseeable future. Our reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such quantities may not be available at an acceptable cost, or in compliance with regulatory requirements, which could delay, prevent or impair our development or commercialization efforts.

We obtain the biologic pegadricase, a component of SEL-212, primarily from 3SBio in China. Under our license agreement with 3SBio, we have limited rights to manufacture pegadricase and, while we have entered into a contract with a back-up supplier located outside of China, we expect to continue to rely on 3SBio as the primary supplier of pegadricase for the foreseeable future.

Any disruption in production or inability of 3SBio in China to produce adequate quantities of pegadricase to meet our needs, whether as a result of a natural disaster, public health emergency, such as the COVID-19 pandemic, failure to comply with regulatory requirements or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our future product candidates. Furthermore, since 3SBio is located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies, laws, rules and

regulations of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, trade tensions between the United States and China have been escalating in recent years. Most notably, several rounds of U.S. tariffs have been placed on Chinese goods being exported to the United States. Each of these U.S. tariff impositions against Chinese exports were followed by a round of retaliatory Chinese tariffs on U.S. exports to China. Pegadricase is subject to, and any other components we purchase from China may be subject to these tariffs, which could increase our manufacturing costs and could make our products, if successfully developed and approved, less competitive than those of our competitors whose inputs are not subject to these tariffs.

Moreover, as a result of the COVID-19 pandemic, certain of our suppliers and CMOs in the United States, China and other countries may be affected, which could disrupt their activities. We could face difficulty sourcing key components necessary to produce supply of SEL-212, which may negatively affect our clinical development activities. If the COVID-19 coronavirus further impacts U.S. business operations, including our CMOs and suppliers, we could face additional disruption to our supply chain that could affect the supply of drug product for both the preclinical studies and clinical trials. Additionally, as our CMOs are producers of drug substances and drug products, including vaccines and therapeutics, they could be compelled by a national government, or choose themselves, to shift their resources to the production of a COVID-19 coronavirus vaccine and/or therapeutics for COVID-19, which could disrupt any scheduled drug substance or drug product batches we may have and may prevent us from obtaining supplies for our programs in a timely manner to meet our development timelines.

Any of these matters could materially and adversely affect our business and results of operations. Any issues related to the manufacturing lots or similar action regarding pegadricase used in preclinical studies or clinical trials could delay the studies or trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply or maintain compliance with regulatory requirements by 3SBio could significantly delay our clinical development of potential products and reduce third-party or clinical researcher interest and support of our proposed trials. These interruptions or failures could also impede commercialization of our future product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

In addition to 3SBio, we rely, and expect to continue to rely, on other third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. Our reliance on such third parties increases the risk that we will not have sufficient quantities of our product candidates on a timely basis or at all, or that such quantities will be available at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. For example, we rely on third parties for the manufacture of our gene therapy preclinical materials. Gene therapy is a relatively new area for commercial biopharmaceutical development and there are a limited number of CMOs with adequate facilities and expertise in this area. As a result, we may be unable to successfully manufacture our gene therapy preclinical materials through a third party or scale up the manufacture of our gene therapy product candidates for clinical testing or commercialization, if at all.

We may be unable to establish any agreements with third-party manufacturers on acceptable terms or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including the:

- inability, failure or unwillingness of third-party manufacturers to comply with regulatory requirements, maintain quality assurance, meet our needs, specifications or schedules or continue to supply products to us;

- reduced control we have over product development, including with respect to our lead product candidate, due to our reliance on such third-party manufacturers,

- breach of manufacturing agreements by the third-party manufacturers;

- misappropriation or disclosure of our proprietary information, including our trade secrets and know-how;

- relationships that the third-party manufacturer may have with others, some of which may be our competitors, and, if it does not successfully carry out its contractual duties, does not meet expectations, experiences work stoppages, or needs to be replaced, we may need to enter into alternative arrangements, which may not be available, desirable or cost-effective; and

- termination or nonrenewal of agreements by third-party manufacturers at times that are costly or inconvenient for us.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing application to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their

manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or suppliers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, there are a limited number of manufacturers that operate under cGMP regulations that might be capable of manufacturing our products. Therefore, our product candidates and any future products that we may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the clinical development, marketing approval and commercialization of our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for required raw materials used in the manufacture of our product candidates or for the manufacture of finished product. Moreover, we often rely on one CMO to produce multiple product components. For instance, one of our CMOs produces several polymers used in our ImmTOR platform. If our current CMOs cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and expected future dependence upon others for the manufacture of our product candidates or products could delay, prevent or impair our development and commercialization efforts.

Our existing collaborations are important to our business, and future licenses may also be important to us. If we are unable to maintain any of these collaborations, or if these arrangements are not successful, or we are unable to enter into future licenses, our business could be adversely affected.

We have entered into collaborations with other parties, including pharmaceutical companies and universities, to develop products based on our ImmTOR platform, and such collaborations and licensing arrangements currently represent a significant portion of our product pipeline and are expected to represent a larger portion of our pipeline in the future. Certain of our collaborations have provided us with important funding for some of our development programs and we expect to receive additional funding under collaborations in the future although not all of our collaborations may result in funding to the Company, and certain collaborations, licenses and agreements may result in increased expenditures by the Company. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators may not perform their obligations as expected;

- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on preclinical or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- collaborations may be terminated for the convenience of the collaborator or for our failure to comply with our obligations under existing or future collaborations and, if terminated, we would potentially lose the right to pursue further development or commercialization of the applicable product candidates;

- collaborators may learn about our technology and use this knowledge to compete with us in the future;

- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others; and

- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers.

If our collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our ImmTOR platform and product candidates could be delayed and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q also apply to the activities of our therapeutic program collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business in the business and financial communities, and our stock price, could be adversely affected. In addition, we have a limited number of collaborations and if our relationship with any one or more of such collaborators were to cease, our business would be harmed as a result. For example, MIT may terminate the MIT License if we fail to meet a diligence obligation, including the initiation of a Phase 3 clinical trial by a specified date in the fourth quarter of 2019. In December 2019, we entered into the MIT Amendment. Pursuant to the MIT Amendment, the provision of the MIT License under which we were obligated to initiate a Phase 3 clinical trial for a licensed product by a specified date in the fourth quarter of 2019 is tolled until the earlier of (i) a specified date in the second quarter of 2020 or (ii) the effective date of a written amendment to the MIT Agreement. The parties agreed to negotiate in good faith to enter into a future amendment to the MIT License after we provide MIT with an amended diligence plan. However, if we are unable to reach an agreement with MIT regarding an acceptable amendment of the MIT License and if we are unable to cure the breach, there could be a material adverse effect on our business. See “Business - Licenses and Collaborations - Massachusetts Institute of Technology.”

We are actively exploring licenses and other strategic collaborations with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. However, we face significant competition in seeking appropriate collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may not be able to access specific antigens that would be suitable to development with our technology, have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely affected.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials.

We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials, including our Phase 2 and Phase 3 clinical trials of SEL-212 and for our other product candidates. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials.

Our reliance on these third parties for research and development activities will reduce our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP regulations, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or third-party contractors fail to comply with applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *ClinicalTrials.gov*, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not comply with confidentiality obligations, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated, or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates or in commercializing our product candidates.

We have no experience manufacturing our product candidates at commercial scale, and if we decide to establish our own manufacturing facility, we cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We have a pilot manufacturing facility at our Watertown, Massachusetts location where we conduct process development, scale-up activities and the manufacture of ImmTOR product candidates for preclinical use. We rely on our scaled equipment installed at our CMOs for the manufacture of the clinical supply of all of our product candidates. If our facility, or our CMOs' facilities, were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace our manufacturing capabilities. In such event, we would be forced to identify and rely entirely on alternative third-party contract manufacturers for an indefinite period of time. Any disruptions or delays at our facility or its failure to meet regulatory compliance would impair our ability to develop and commercialize our product candidates, which would adversely affect our business and results of operations.

In addition, the FDA and other comparable foreign regulatory agencies must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product candidate meet cGMP regulations. We do not currently have any of our own manufacturing facilities that meet the FDA's cGMP requirements for the production of any product candidates used in humans, and rely on our CMOs for clinical production.

We may choose to establish a manufacturing facility for our product candidates for production at a commercial scale. However, we have no experience in commercial-scale manufacturing of our product candidates and this activity will require substantial additional funds and additional qualified employees. We may not be able to develop commercial-scale manufacturing facilities that are adequate to produce materials for additional later-stage clinical trials or commercial use.

The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of such facilities, equipment, systems, processes and analytics. We may be subject to lengthy delays and expense in conducting validation studies, if we can meet the requirements at all.

RISKS RELATED TO COMMERCIALIZATION OF OUR PRODUCT CANDIDATES AND OTHER LEGAL COMPLIANCE MATTERS

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. For example, even if the statistical results from our Phase 2 head-to-head (COMPARE) trial vs. KRYSTEXXA favor SEL-212 and SEL-212 receives marketing approval, the drug may fail to gain market acceptance from physicians, patients, third-party payors

and others in the medical community who may continue to favor KRYSTEXXA. The degree of market acceptance of our product candidates, if any, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- the clinical indications for which our product candidates are approved;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates;
- the prevalence and severity of their side effects and their overall safety profiles;
- any restrictions on the use of our product candidates together with other medications;
- interactions of our product candidates with other medicines patients are taking;
- our ability to create awareness with patients and physicians about the harmful effects of uric acid deposits;
- the timing of market introduction of any approved product candidates as well as competitive products and other therapies;
- inability of certain types of patients, particularly with respect to certain rare diseases or conditions, to take our product candidates;
- their ability to remain attractive in the event of changing treatment guidelines;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

We currently have no sales organization. If we are unable to establish effective sales, marketing and distribution capabilities, or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform sales and marketing functions and we may not be successful in doing so.

In the future, we expect to build a focused sales and marketing infrastructure to market or co-promote our product candidates in the United States and potentially elsewhere, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Outside the United States, we may rely on third parties to sell, market and distribute our product candidates. We may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, including from biosimilars, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug and biologic products and technologies is highly competitive and is characterized by rapid and substantial technological development and product innovations. We are aware that pharmaceutical and biotechnology companies, including Horizon Pharma plc, offer or are pursuing the development of pharmaceutical products or technologies that may address one or more indications that our product candidates target, as well as smaller, early-stage companies, that offer or are pursuing the development of pharmaceutical products or technologies that may address one or more indications that our product candidates target. We face competition with respect to our current product candidates, and

will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement for product candidates and in marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a competing immunomodulating therapeutic that will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic or biosimilar products.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. 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 the 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 product candidate approved in the United States 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 the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the 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.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations or third-party coverage or reimbursement policies, any of which would have a material adverse effect on our business.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval, especially novel products like our gene therapy product candidates, and may be particularly difficult because of the higher prices associated with gene therapy product candidates. Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Obtaining and maintaining adequate reimbursement for our products may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our products by third-party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. Some third-party payors may require pre-approval of coverage for new and innovative therapies, such as our product candidates, before they will provide

reimbursement. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically necessary for a specific indication or cost-effective, or that coverage or an adequate level of reimbursement will be available.

Moreover, there has recently 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 bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. There can be no assurance that our product candidates, if approved for sale in the United States or in other countries, will not be subject to heightened governmental scrutiny, unfavorable regulatory inquiry or action, or congressional inquiry.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercially sell any products that we may 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:

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- loss of clinical trial participants or increased difficulty in enrolling future participants;
- significant costs to defend the related litigation or to reach a settlement;
- substantial payments to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;

We maintain general liability, product liability and umbrella liability insurance. Our existing insurance coverage may not fully cover potential liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. 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. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

Although we do not have any current plans to market and sell our products in other jurisdictions outside of the United States, we may decide to do so in the future and either we or our collaborators would need to obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product candidate be approved for reimbursement before the product candidate can be approved for sale in that country. We or our collaborators may not obtain approvals for our product candidates from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions, or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any market.

Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Arrangements with physicians, others who may be in a position to generate business for us, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, 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 a federal healthcare program such as Medicare and Medicaid. 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 False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent. Private individuals (e.g., whistleblowers) can bring these actions on behalf of the government; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, which requires applicable manufacturers of certain products for which payment is available under a federal healthcare program to report annually to the government information related to certain payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers; and requirements to comply with federal and pharmaceutical industry compliance guidelines;

- state data privacy and price transparency laws, many of which differ from each other in significant ways and often are broader than and not preempted by HIPAA or the Sunshine Act, thus complicating compliance efforts; by way of example, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context; and

- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union (including health data); in addition, the United Kingdom leaving the E.U. could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the E.U. will be regulated, especially following the United Kingdom's departure from the E.U. on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the E.U.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase and/or prescribe our product candidates, if approved, 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 laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is 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 risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Acts, or the Tax Act, was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the ACA will impact the ACA or our business. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

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

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any of our product candidates, if approved, could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unexpected problems with our products.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We and our contract manufacturers will also be subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy, or REMS, which could include requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk mitigation tools. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA closely regulates the post-approval marketing and promotion of drugs and biologics to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDA's restrictions relating to the promotion of prescription products may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, if a regulatory agency or we later discover previously unknown problems with our products, such as adverse events of unexpected severity or frequency or problems with manufacturers or manufacturing processes, the regulatory agency may impose restrictions on the products or us, including requiring withdrawal of the product from the market. Any failure to comply with applicable regulatory requirements may yield various results, including:

- litigation involving patients taking our products;

- restrictions on such products, manufacturers or manufacturing processes;

- restrictions on the labeling or marketing of a product;

- restrictions on product distribution or use;

- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of products from the market;
- suspension or termination of ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with existing and potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure or detention;
- injunctions; or
- imposition of civil or criminal penalties.

Noncompliance with other requirements in foreign jurisdictions regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with U.S. and foreign regulatory requirements regarding the development of products for pediatric populations and the protection of personal health information can also lead to significant penalties and sanctions.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues. If regulatory sanctions are applied or if regulatory approval is withheld or withdrawn, the value of our company and our operating results will be adversely affected.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also 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 administration may impact our business and industry. Namely, the Trump 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 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.

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

The ability of the FDA to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can have a material adverse effect on our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations administered by the U.S. Commerce Department's Bureau of Industry and Security, U.S. Customs regulations, various economic and trade sanctions regulations including those administered or enforced by relevant government authorities, such as by the U.S. Treasury Department's Office of Foreign Assets Control or the U.S. Department of State, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. U.S. sanctions laws and regulations may govern or restrict our business and activities in certain countries and with certain persons. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our product candidates abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Our violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, which is time-consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially adversely affected.

If we or our contract manufacturers or other third parties 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 and our contract manufacturers and other third parties with whom we do business 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. Our operations involve the use of hazardous and flammable materials, including biological materials and chemicals. Our operations also produce hazardous waste products. We generally 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 that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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. The failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we or our licensors are unable to adequately protect our proprietary technology, or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would negatively impact our business.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. 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. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. As we reach the statutory deadlines for deciding whether and where to initiate prosecution in specific foreign jurisdictions by filing national stage applications based on our Patent Cooperation Treaty, or PCT, applications, we will have to decide whether and where to pursue patent protection for the various inventions claimed in our patent portfolio, and we will only have the opportunity to obtain patents in those jurisdictions where we pursue protection. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. We also cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, we have obligations under our licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

We cannot provide any assurances that the issued patents we currently own, or any future patents, include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. Further, it is possible that a patent claim may provide coverage for some but not all parts of a product candidate or third-party product. These and other factors may provide opportunities for our competitors to design around our patents.

Moreover, other parties may have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications, and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming similar methods or by claiming subject matter that could dominate our patent position. In addition, it may be some time before we understand how the patent office reacts to our patent claims and whether they identify prior art of relevance that we have not already considered.

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 know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued 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 patents or narrow the scope of our patent protection.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings 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 product candidates 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. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering biotechnological and pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if issued, a patent's validity, inventorship, ownership or enforceability is not conclusive. Accordingly, rights under any existing patent or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors and any other third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how, and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how, and other information and technology. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business and operations.

Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be adversely affected.

If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, 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. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. 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, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, 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.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, recent patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular the first to file provisions, became effective on March 16, 2013. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to filing of a patent application. Thus, for our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre-Leahy-Smith Act law and regulations, while other patents applications in our portfolio will be subject to examination under the law and regulations, as amended by the Leahy-Smith Act. This introduces additional complexities into the prosecution and management of our portfolio.

In addition, the Leahy-Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. These provisions apply to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a federal court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims because it may be easier for them to do so relative to challenging the patent in a federal court action. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability, and any such changes could have a negative impact on our business.

Depending on these and other decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change or be interpreted in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue to us in the future. In addition, these events may adversely affect our ability to defend any patents that may issue in procedures in the USPTO or in courts.

Third parties may initiate legal proceedings alleging that we 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, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology, product candidates or use of our product candidates do not infringe third-party patents.

We are aware of numerous patents and pending applications owned by third parties, and we monitor patents and patent applications in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify

relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk we may be found, to infringe a third party's intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any such 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. 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.

Even if we are successful in such proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. 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.

Any of these risks coming to fruition could have a material adverse impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, and our issued patents covering our product candidates could be found invalid or unenforceable or could be interpreted narrowly if challenged in court.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. If we initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement, or failure to claim patent-eligible subject matter. Grounds for unenforceability assertions include allegations that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Moreover, even if not found invalid or unenforceable, the claims of our patents could be construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it

affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. 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. If we do not have sufficient patent life to protect our product candidates, proprietary technologies and their uses, our business and results of operations will be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and, in some jurisdictions, during the pendency of a patent application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are party to multiple license agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing agreements, we are obligated to pay royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreement. Our results of operations will be affected by the level of royalty payments that we are required to pay to third parties. We cannot precisely predict the amount, if any, of royalties that we will be required to pay to third parties in the future. Any disagreements with the counterparty over the amount of royalties owed could lead to litigation, which is costly. In addition, if we fail to comply with our obligations under current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of product candidates being developed using rights licensed to us under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Furthermore, our counterparties may allege that we are operating outside the scope of the licenses granted and terminate our license or otherwise require us to alter development, manufacturing or marketing activities.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties and under patents and patent applications that we own, to develop our product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We may also be unable to maintain third-party intellectual property rights. For example, MIT may terminate the MIT License if we fail to meet a diligence obligation, including the initiation of a Phase 3 clinical trial by a specified date in the fourth quarter of 2019. In December 2019, we entered into the MIT Amendment. Pursuant to the MIT Amendment, the provision of the MIT License under which we were obligated to initiate a Phase 3 clinical trial for a licensed product by a specified date in the fourth quarter of 2019 is tolled until the earlier of (i) a specified date in the second quarter of 2020 or (ii) the effective date of a written

amendment to the MIT License. The parties agreed to negotiate in good faith to enter into a future amendment to the MIT License after we provide MIT with an amended diligence plan. However, if we are unable to reach an agreement with MIT regarding an acceptable amendment of the MIT License and if we are unable to cure the breach, there could be a material adverse effect on our business. See "Business - Licenses and Collaborations - Massachusetts Institute of Technology."

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

We may be subject to claims by third parties asserting that our employees or we 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. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants 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 our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees, consultants, advisors 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. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

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.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. In this regard, in addition to the United States, we also seek to protect our intellectual property rights in other countries. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For all of the patent families in our portfolio, including the families that may provide coverage for our lead product candidate, the relevant statutory deadlines have not yet expired. Therefore, for each of the patent families that we believe provide coverage for our lead product candidate, we will need to decide whether and where to pursue additional protection outside the United States. In addition, the laws of some foreign countries, do not protect

intellectual property rights to the same extent as federal and state laws in the United States. Consequently, for our existing patent rights outside the United States and any foreign patent rights we may decide to pursue in the future, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

If we do not obtain additional protection under the Hatch-Waxman Act and similar foreign legislation extending the terms of our patents for our product candidates, our business may be harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Patent term restorations, however, are limited to a maximum of five years and cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened, our competitors may obtain earlier approval of competing products and our ability to generate revenues could be materially adversely affected.

RISKS RELATED TO OUR OPERATIONS

Our new corporate strategy may not be successful.

On January 3, 2019, following a strategic business review, we announced our new strategy to focus on the development of SEL-212 for the treatment of chronic refractory gout and advancement of our ImmTOR platform in the area of gene therapy, specifically ImmTOR in combination with AAV gene therapy for the treatment of CN and MMA, as well as the deprioritization of our oncology development program. The success of this strategic shift will depend on our ability to successfully develop our product candidates, hire and retain senior management or other highly qualified personnel, prioritize competing projects and efforts and obtain sufficient resources, including additional capital, as well as our ability to enter into collaborations with third parties. The early stage development of novel product candidates is highly unpredictable due to the lengthy and expensive process of clinical drug development, potential for safety, efficacy or tolerability problems with such product candidates, unexpected expenses or inaccurate financial assumptions or forecasts, potential delays or unfavorable decisions of regulatory agencies and competition for targeted indications or within targeted markets. Accordingly, there are no assurances our change in strategic focus will be successful, which may have an adverse effect on our results of operations or financial condition.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Carsten Brunn, Ph.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements or offer letters with Dr. Brunn and other executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, technology and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition 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 research and 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. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of lead discovery and product development, regulatory affairs, clinical affairs and manufacturing and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our expected future growth, we must continue 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 limited experience of our management team in managing a company with such expected growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel in a timely manner, if at all. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage or financially support growth could delay the execution of our business plans or disrupt our operations.

We have incurred increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we have incurred and expect to continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and made some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the SEC or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

A variety of risks associated with maintaining our subsidiary in Russia or expanding operations internationally could adversely affect our business.

In addition to our U.S. operations, we maintain a wholly owned subsidiary in Russia, Selecta RUS. We may face risks associated with maintaining our subsidiary in Russia, or with any international operations, including possible unfavorable regulatory, pricing and reimbursement, legal, political, tax and labor conditions, which could harm our business. We may also rely on collaborators to commercialize any approved product candidates outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection of and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;

- complexities associated with managing multiple-payor reimbursement regimes, government payors or patient self-pay systems;

- limits on our ability to penetrate international markets;

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations, which could result in increased operating expenses and reduced revenues;

- natural disasters, political and economic instability, including wars, events of terrorism and political unrest, outbreak of disease, including the novel COVID-19 coronavirus, boycotts, curtailment of trade and other business restrictions and economic weakness, including inflation;

- changes in diplomatic and trade relationships;

- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

- restriction on cross-border investment, including enhanced oversight by the Committee on Foreign Investment in the United States (CFIUS) and substantial restrictions on investment from China;

- certain expenses including, among others, expenses for travel, translation and insurance;

- legal risks, including use of the legal system by the government to benefit itself or affiliated entities at our expense, including expropriation of property; and

- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

Our business and operations would suffer in the event of system failures or unauthorized or inappropriate use of or access to our systems.

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, product candidates or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;

- unexpected liabilities related to acquired companies;

- difficulties integrating acquired personnel, technologies and operations into our existing business;

- diversion of management time and focus from operating our business to acquisition integration challenges;

- increases in our expenses and reductions in our cash available for operations and other uses;

- possible write-offs or impairment charges relating to acquired businesses; and

- inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the expected benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

RISKS RELATED TO OUR COMMON STOCK

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The trading price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which you purchased. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results or progress, or changes in approach or timelines, of clinical trials of our product candidates or those of our competitors;
- failure or discontinuation of any of our development programs;
- commencement of, termination of, or any development related to any collaboration or licensing arrangement;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- announcement or market expectation of additional financing efforts;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates, projections or development timelines of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- sale of common stock by us or our stockholders in the future as well as the overall trading volume of our common stock;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk factors” section.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 45% of our outstanding voting stock as of March 31, 2020. As a result, if these stockholders choose to act together, they would be able to control or significantly

influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Holders of an aggregate of approximately 1.9 million shares of our common stock as of March 31, 2020 have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the investors' rights agreement between us and such holders. We have also registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

In addition, on June 27, 2017, we issued and sold in a private placement 3,088,791 shares of our common stock (of which approximately 0.3 million shares have continuing registration rights) and a warrant to purchase 79,130 shares of our common stock, including to certain of our affiliates. Pursuant to a registration rights agreement entered into with the investors in the private placement, on July 13, 2017, we filed a Registration Statement on Form S-3 to register the shares of common stock sold in the private placement and the shares of common stock issuable upon exercise of the warrant.

Similarly, on December 23, 2019, we issued and sold in a private placement 37,634,883 shares of our common stock (of which approximately 31.6 million shares have continuing registration rights) and warrants to purchase 31,330,629 shares of our common stock, including to certain of our affiliates. Pursuant to a registration rights agreement entered into with the investors in the private placement, on January 29, 2019, we filed a Registration Statement on Form S-3 to register the shares of common stock sold in the private placement and the shares of common stock issuable upon exercise of the warrants. As a result, these shares can be freely sold in the public market.

We may not have the funds necessary to fulfill our obligation to repurchase certain warrants.

Under certain circumstances, holders of certain warrants issued in December 2019 may require us to repurchase the remaining unexercised portion of such warrants for an amount of cash equal to the value of the warrant as determined in accordance with the Black Scholes option pricing model and the terms of the warrants. Our ability to repurchase the warrants depends on our ability to generate cash flow in the future. To some extent, this is subject to general economic, financial, competitive, legislative and regulatory factors and other factors that are beyond our control. We cannot be certain that we will maintain sufficient cash reserves or that our business will generate cash flow from operations at levels sufficient to permit us to repurchase the warrants.

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 Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of the initial public offering of our common stock. 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 $1.07 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 cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. We have, historically, relied on these exemptions, and we may continue to do so until they are no longer available to us. If some investors

find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies, clinical trial programs and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Provisions in our restated certificate of incorporation and restated bylaws and under Delaware law could make an acquisition of our company, 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 restated certificate of incorporation and our restated bylaws, which became effective upon the closing of the initial public offering of our common stock may discourage, delay or prevent a merger, acquisition or other change in control of our company 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 shares of our common stock, thereby depressing the market price of our common stock. 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.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, 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.

Furthermore, our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be applicable or unenforceable in such action.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation of Selecta Biosciences, Inc.	8-K	001-37798	3.1	6/29/2016	
3.2	Amended and Restated By-laws of Selecta Biosciences, Inc.	8-K	001-37798	3.2	6/29/2016	
10.1	Non-Employee Director Compensation Program					*
31.1	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.					***
101.SCH	Inline XBRL Taxonomy Extension Schema Document					***
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					***
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					***
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					***
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					***
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					***

* Filed herewith.

** Furnished herewith.

*** Submitted electronically herewith.

† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant in the capacities and on the dates indicated.

SELECTA BIOSCIENCES, INC.

Date: May 7, 2020

By: /s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.

President and Chief Executive Officer, and Director

(Principal Executive Officer)

Date: May 7, 2020

By: /s/ Bradford D. Dahms

Bradford D. Dahms

Chief Financial Officer

(Principal Financial Officer)

Exhibit 10.1

SELECTA BIOSCIENCES, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the "***Board***") of Selecta Biosciences, Inc. (the "***Company***") shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "***Program***"), as amended by the Board effective March 25, 2020 (the "***Effective Date***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. No Non-Employee Director shall have any rights hereunder, except with respect to stock options granted pursuant to the Program. This Program shall become effective on the Effective Date.

I. CASH COMPENSATION

A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of $40,000 for service on the Board.

B. Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following annual retainers:

1. *Chairperson of the Board or Lead Independent Director*. A Non-Employee Director serving as Chairperson of the Board shall receive an additional annual retainer of $30,000 for such service, and a Non-Employee Director serving as Lead Independent Director shall receive an additional annual retainer of $20,000 for such service.

2. *Audit Committee*. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of $7,500 for such service.

3. *Compensation Committee*. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of $12,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Compensation Committee shall receive an additional annual retainer of $6,000 for such service.

4. *Nominating and Corporate Governance Committee*. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $8,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $4,000 for such service.

5. *Science Committee*. A Non-Employee Director serving as Chairperson of the Science Committee shall receive an additional annual retainer of $8,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Science Committee shall receive an additional annual retainer of $4,000 for such service.

C. Payment of Retainers. The annual retainers described in Sections I(A) and I(B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

II. EQUITY COMPENSATION

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2016 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***") and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in Sections II(A) and II(B) shall be subject to adjustment as provided in the Equity Plan, including without limitation with respect to any stock dividend, stock split, reverse stock split or other similar event affecting the Company's common stock that is effected prior to the Effective Date.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase 40,000 shares of the Company's common stock on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted an option to purchase 20,000 shares of the Company's common stock on the date of such annual meeting, provided, however that if such Non-Employee Director will serve as Chairperson of the Board as of immediately following the date of such annual meeting, such Non-Employee Director shall

receive an option to purchase 30,000 shares of the Company's common stock on the date of such annual meeting. The awards described in this Section II(B) shall be referred to as "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent that they are otherwise entitled, will receive, after termination from employment with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

E. Terms of Awards Granted to Non-Employee Directors

1. *Exercise Price*. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of common stock on the date the option is granted.

2. *Vesting*. Each Initial Award shall vest and become exercisable in thirty-six (36) substantially equal monthly installments following the date of grant, such that the Initial Award shall be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. Each Subsequent Award shall vest and become exercisable on the earlier of the first anniversary of the date of grant or the day immediately prior to the date of the next annual meeting of the Company's stockholders occurring after the date of grant, in either case subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through each such vesting date. Unless the Board otherwise determines, any portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term*. The maximum term of each stock option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

III. COMPENSATION LIMITS

Notwithstanding anything to the contrary in this Program, all compensation payable under this Program will be subject to any limits on the maximum amount of Non-Employee Director compensation set forth in the Equity Plan, as in effect from time to time.

* * * * *

Exhibit 31.1

CERTIFICATIONS

I, Carsten Brunn, Ph.D. certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Selecta Biosciences, Inc.;

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.

May 7, 2020

/s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.

President and Chief Executive Officer, and Director

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Bradford D. Dahms, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Selecta Biosciences, Inc.;

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.

May 7, 2020

/s/ Bradford D. Dahms

Bradford D. Dahms

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

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

I, Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta Biosciences, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

May 7, 2020

/s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.
President and Chief Executive Officer, and Director
(Principal Executive Officer)

Exhibit 32.2

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

I, Bradford D. Dahms, Chief Financial Officer of Selecta Biosciences, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

May 7, 2020

/s/ Bradford D. Dahms

Bradford D. Dahms
Chief Financial Officer
(Principal Financial and Accounting Officer)