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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, 2017

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.)
480 Arsenal Way **Watertown, MA**	**02472**
(Address Of Principal Executive Offices)	(Zip Code)

617-923-1400

(Registrant's Telephone Number, Including Area Code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 5, 2017 the registrant had 18,581,202 shares of common stock, par value $0.0001 per share, outstanding.

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Part I. FINANCIAL INFORMATION

Part II. OTHER INFORMATION

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 and Section 21E of the Securities Exchange Act of 1934. 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, and the plans and objectives of management for future operations and future results of anticipated products 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 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 establish our own manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- our ability to maintain our existing or future collaborations or licenses;
- 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; 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, 2017	December 31, 2016
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 26,637	$ 58,656
Short-term deposits and investments	41,885	25,485
Restricted cash	81	78
Accounts receivable	63	215
Prepaid expenses and other current assets	2,820	2,382
Total current assets	71,486	86,816
Property and equipment, net	2,054	2,047
Restricted cash and other deposits	316	316
Other assets	—	122
Total assets	$ 73,856	$ 89,301
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,317	$ 3,882
Accrued expenses	5,521	3,921
Loans payable, current portion	4,519	4,067
Deferred revenue, current portion	1,947	1,836
Total current liabilities	13,304	13,706
Non-current liabilities:		
Deferred rent and lease incentive	210	222
Loans payable, net of current portion	6,867	7,977
Deferred revenue, net of current portion	12,385	12,439
Total liabilities	32,766	34,344
Commitments and contingencies (Notes 8 and 13)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively.	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 18,552,385 and 18,438,742 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively.	1	1
Additional paid-in capital	212,249	211,125
Receivable from stock option exercises	(70)	(75)
Accumulated deficit	(166,710)	(151,576)
Accumulated other comprehensive loss	(4,380)	(4,518)
Total stockholders' equity	41,090	54,957
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 73,856	$ 89,301

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,	
	2017	2016
	(Unaudited)	
Grant and collaboration revenue	$ 137	$ 2,088
Operating expenses:		
Research and development	11,044	6,648
General and administrative	3,875	2,381
Total operating expenses	14,919	9,029
Loss from operations	(14,782)	(6,941)
Investment income	113	13
Foreign currency transaction gain (loss), net	(165)	(220)
Interest expense	(300)	(310)
Other expense, net	—	(18)
Net loss	(15,134)	(7,476)
Other comprehensive loss:		
Foreign currency translation adjustment	123	231
Unrealized gain (loss) on securities	15	—
Comprehensive loss	$ (14,996)	$ (7,245)
Net loss	(15,134)	(7,476)
Accretion of redeemable convertible preferred stock	—	(2,356)
Net loss attributable to common stockholders	$ (15,134)	$ (9,832)
Net loss per share attributable to common stockholders		
Basic and diluted	$ (0.82)	$ (4.52)
Weighted average common shares outstanding		
Basic and diluted	18,474,227	2,175,037

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

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Stockholders' Equity

(Amounts in thousands, except share data)

(Unaudited)

	Common stock		Additional paid-In	Stock option		Accumulated other comprehensive	Stockholders'
	Shares	Amount	Capital	receivable	Accumulated deficit	loss	Equity
Balance at December 31, 2016	18,438,742	$ 1	$ 211,125	$ (75)	$ (151,576)	$ (4,518)	$ 54,957
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	—	—	—
Issuance of common stock upon exercise of options	113,643	—	431	5	—	—	436
Stock-based compensation expense	—	—	693	—	—	—	693
Currency translation adjustment	—	—	—	—	—	123	123
Unrealized gains (losses) on securities	—	—	—	—	—	15	15
Net loss	—	—	—	—	(15,134)	—	(15,134)
Balance at March 31, 2017	18,552,385	$ 1	$ 212,249	$ (70)	$ (166,710)	$ (4,380)	$ 41,090

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,	
	2017	2016
	(Unaudited)	
Operating activities		
Net loss	$ (15,134)	$ (7,476)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	175	178
Amortization of premiums and accretion of discounts on investments	89	—
Stock-based compensation expense	693	282
Non-cash interest expense	144	41
Change in fair value of redeemable convertible preferred stock warrant	—	20
Changes in operating assets and liabilities:		
Accounts receivable	152	(805)
Prepaid expenses and other assets	(316)	(35)
Restricted cash and other deposits	(3)	(1,752)
Accounts payable	(2,589)	(424)
Deferred revenue	57	386
Accrued expenses and other liabilities	1,413	(581)
Net cash used in operating activities	(15,319)	(10,166)
Investing activities		
Purchase of short term investments	(16,474)	(3,412)
Purchases of property and equipment	(58)	(143)
Net cash used in investing activities	(16,532)	(3,555)
Financing activities		
Principle payments on loan payable	(728)	—
Deferred IPO costs paid	—	(1,684)
Exercise of stock options	436	7
Net cash provided by financing activities	(292)	(1,677)
Effect of exchange rate changes on cash	124	112
Net decrease in cash and cash equivalents	(32,019)	(15,286)
Cash and cash equivalents at beginning of period	58,656	32,337
Cash and cash equivalents at end of period	$ 26,637	$ 17,051
Cash paid during the year for:		
Interest	241	243
Supplemental noncash investing and financing activities:		
Purchase of property and equipment not yet paid	$ 125	$ —
Accrued dividends and accretion of preferred stock to redemption value	—	2,356
Unrealized gain on marketable securities	$ 15	$ —

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

Selecta Biosciences, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

(Year Ended December 31, 2016 and Unaudited Three Months Ended March 31, 2017 and 2016)

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 biopharmaceutical company dedicated to developing the first generation of nanoparticle immunomodulatory drugs for the treatment and prevention of human diseases. 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 pre-clinical 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, 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.

On June 21, 2016 the Company completed an initial public offering (the "IPO") of its common stock and issued and sold 5,000,000 shares of common stock at a price to the public of $14.00 per share for net proceeds of $60.8 million after deducting underwriting discounts and commissions and offering expenses. On July 25, 2016, 289,633 additional shares of the Company's common stock were sold to the underwriters pursuant to the exercise of their option to purchase additional shares of common stock at a price to the public of $14.00 per share resulting in additional net proceeds of approximately $3.7 million after deducting underwriting discounts, commissions and offering expenses, bringing the total IPO net proceeds to $64.5 million. Upon the closing of the IPO on June 27, 2016, all outstanding shares of the Company's convertible preferred stock automatically converted into 10,126,118 shares of the Company's common stock. In addition, at this time, the warrants to purchase shares of the Company's Series D and Series E convertible preferred stock were converted into warrants to purchase shares of the Company's common stock.

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements for the three months ended March 31, 2017 and 2016 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, 2016 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 28, 2017, which we refer to as the 2016 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 which are necessary for a fair statement of the Company's financial position as of March 31, 2017 and consolidated results of operations and cash flows for the three months ended March 31, 2017. Such adjustments are of a normal and recurring nature. The results of operations for the three months ended March 31, 2017 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2017.

Liquidity

The Company has incurred losses since inception and negative cash flows from operating activities. As of March 31, 2017 and December 31, 2016, the Company had an accumulated deficit of $166.7 million and $151.6 million, respectively. The Company's cash and cash equivalents as of March 31, 2017 and December 31, 2016, includes $2.2 million and $2.4 million of unrestricted cash held by its Russian subsidiary. The future success of the Company is dependent upon its ability to obtain additional capital through issuances of equity and debt securities and from collaboration and grant agreements in order to further the development of its technology and product candidates, and ultimately upon its ability to attain profitable operations. There can be no assurance that the Company will be able to obtain the necessary financing to successfully develop and market its product candidates or attain profitability.

Based on the current operating plan, we expect that our cash, cash equivalents, short-term investments and restricted cash as of March 31, 2017, will fund our operating expenses and capital expenditure requirements into mid-year 2018. 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. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress in these trials is uncertain. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

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, 2017, 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' 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, the fair value of common stock and other equity instruments, accounting for stock-based compensation, income taxes, collectability of accounts receivable, useful lives of long-lived assets, accrued expenses, and accounting for project development. The Company assesses the above estimates on an ongoing basis; however, actual results could materially differ from those estimates.

The Company's management made significant estimates and assumptions in determining the fair value of its common stock for those periods reported prior to the completion of the IPO. The Company utilized various valuation methodologies in accordance with the framework of the 2004 American Institute of Certified Public Accountants' Technical Practice Aid, Valuation of Privately-

Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. Each valuation methodology included estimates and assumptions that require the Company's judgment. These estimates and assumptions included a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

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.

Reverse stock split

In connection with the initial public offering, the Company's Board of Directors and stockholders approved a one-for-3.9 reverse stock split of the Company's common stock. The reverse stock split became effective June 7, 2016. All share and per share amounts presented have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

Cash Equivalents and Short Term Investments

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 investments as available-for-sale and records them at fair value in the accompanying consolidated balance sheets. 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.

The Company, as part of its cash management strategy, may invest in reverse repurchase agreements. All reverse repurchase agreements are tri-party and have maturities of three months or less at the time of investment. These agreements are collateralized by U.S. treasury securities for an amount no less than 102% of their value.

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 reporting periods, there were no realized gains or losses on sales of investments, and no investments were adjusted for other than temporary declines in fair value.

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, 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 credit worthy 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, 2017, the Company maintained approximately $2.3 million in Russian bank accounts, of which $2.2 million was held in U.S. dollars.

The Company has minimal credit risk as the majority of accounts receivable relates to amounts due under a government sponsored grant, collaboration with large pharmaceutical companies or grants from well-known and supported non-profit organizations. The Company did not have any off balance sheet arrangements as of March 31, 2017 and December 31, 2016.

Fair Value of Financial Instruments

The Company's financial instruments consist mainly of cash equivalents, short-term investments, restricted cash, accounts receivable, accounts payable, loans payable, common stock warrants, and redeemable convertible preferred stock warrants. The

carrying amounts of cash equivalents, short term investments, restricted cash, accounts receivable, and accounts payable approximate their estimated fair value due to their short term maturities. The carrying amount of loans payable approximates their estimated fair value due to the consistency between the prevailing market rates in effect and the effective interest rate of 11.6% for the debt arrangement.

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 the Company's loan payable was 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, 2017 or the year ended December 31, 2016.

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, five years for equipment and three years for computer and office 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 periodically evaluates its long-lived assets for potential impairment. Impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends, and product development cycles. Impairment in the carrying value of each asset is assessed when the undiscounted expected future cash flows derived from the asset are less than their carrying value. The Company did not recognize any impairment charges during the three months ended March 31, 2017 and March 31, 2016.

Debt Issuance Costs

Debt issuance costs and fees paid to lenders are recorded as a direct deduction from the face amount of the related debt. Debt issuance costs are accounted for as additional debt discount and 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)

The components of accumulated other comprehensive income (loss), net of tax, were as follows (in thousands):

	Foreign exchange translation adjustment	Unrealized gains (losses) on available-for-sale securities	Accumulated other comprehensive income (loss)
Balance at December 31, 2016	$ (4,482)	$ (36)	$ (4,518)
Other comprehensive gain (loss) during the period	123	15	138
Balance at March 31, 2017	$ (4,359)	$ (21)	$ (4,380)

Comprehensive income (loss) is the total net earnings and all other non-owner changes in equity. Except for net income and unrealized gains and losses on available-for-sale securities and foreign exchange translation adjustments, the Company does not have any transactions or other economic events that qualify as comprehensive income (loss). There were no reclassifications out of accumulated other comprehensive income or loss as well as no tax effect for the period presented.

Revenue Recognition

The Company's revenue is primarily generated from research grants in both the United States and Russia, and, prior to its termination, a license and research collaboration agreement with Sanofi. The Company recognizes revenue in accordance with ASC Topic 605, *Revenue Recognition*. Accordingly, revenue is recognized when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;

- Delivery has occurred or services have been rendered;

- The seller's price to the buyer is fixed or determinable; and

- Collectability is reasonably assured.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, current portion. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Collaboration Revenue

The Company enters into collaborative arrangements for the development and commercialization of product candidates utilizing Company's Synthetic Vaccine Particles (SVP™) technology. The terms of these agreements contain multiple deliverables which may include (i) licenses, or options to obtain licenses, to our technology platforms, (ii) rights to future technological improvements, (iii) research and development activities to be performed on behalf of the collaborative partner or as part of the collaboration, (iv) the manufacture of pre-clinical or clinical materials for the collaborative partner, and (v) options to acquire licenses for additional therapeutic areas. Payments to the Company under these agreements may include nonrefundable license fees, option fees, exercise fees, payments for research and development activities, payments for the manufacture of preclinical or clinical materials, payments based upon the achievement of certain milestones and royalties on product sales.

When evaluating multiple element arrangements such as the agreements discussed in Note 13, the Company considers whether the deliverables under the arrangement represent separate units of accounting. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units.

The Company determines the estimated selling price for deliverables within each agreement using vendor-specific objective evidence ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE is not available, or best estimate of selling price if neither VSOE nor TPE is available. Determining the best estimate of selling price for a deliverable requires significant judgment. Since the Company is a clinical stage company without a marketable product, and currently there

is no technologically comparative product on the market, to determine either VSOE or TPE, the Company has used its best estimate of selling price to estimate the selling price for licenses and deliverables related to the Company's proprietary technology. Under the circumstances, the Company considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating the Company's best estimate of selling price, the Company evaluates whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration between multiple deliverables.

Options for future deliverables are considered substantive if, at the inception of the arrangement, the Company is at risk as to whether the collaboration partner will choose to exercise the option. Factors that the Company considers in evaluating whether an option is substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the arrangement without exercising the option, the cost to exercise the option and the likelihood that the option will be exercised. When an option is considered substantive and there is no significant incremental discount, the option is not considered a deliverable in the arrangement and no consideration is allocated to it. Conversely, when an option is not considered substantive or it is considered substantive but is priced at an incremental discount, it would be considered a deliverable at the inception of the arrangement and a corresponding amount would be included in the initial consideration.

The Company may receive upfront payments when licensing its intellectual property in conjunction with a manufacturing or a research and development agreement. When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, the Company generally recognizes revenue attributed to the license over the Company's contractual or estimated performance period. When management believes the license to its intellectual property has stand-alone value, the Company generally recognizes revenue attributed to the license upon delivery. The periods over which revenue should be recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods. Payments or reimbursements resulting from the Company's deliveries of manufactured products and research and development efforts are recognized as the services are performed.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone, whether the milestone consideration is reasonable relative to all deliverables and payment terms, as well as the level of effort and investment required. Revenues from milestones, if they are nonrefundable and deemed substantive, are recognized upon successful accomplishment of the milestones. Milestones that are not considered substantive are accounted for as license payments and recognized over the remaining period of performance.

Grant Agreements

Grant revenue is generally recognized as the related research and development work is performed. Grant arrangements frequently include payment milestones which the Company has judged to be non-substantive milestones as they are typically entitled to receive payment regardless of the outcome of the research work. Revenue under such arrangements is recognized using a proportional performance method, but not in excess of cash actually received.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets.

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 costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activation, and other information provided to the Company by its vendors.

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 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. 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. Should such costs be incurred, they would be classified as a component of income tax expense.

Preferred stock

Prior to the completion of the IPO, the Company classified Preferred Stock as temporary equity and initially records it at the original issuance price, net of issuance costs and discounts. The carrying value is accreted up to the redemption value over the earliest redemption period. The carrying value is also adjusted for dividends expected to be paid upon redemption or liquidation according to the preferred stock terms on each balance sheet date.

Warrants

The Company has issued common stock warrants and redeemable convertible preferred stock warrants to investors and lenders. Common stock warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from other debt and equity instruments, are contingently exercisable, do not embody an obligation for the Company to repurchase its own shares, and permit the holders to receive a fixed number of common shares upon exercise. In addition, such warrants require physical settlement and do not provide any guarantee of value or return. Common stock warrants are initially recorded at their issuance date fair value and are not subsequently re-measured. These warrants are valued using the Black-Scholes option pricing model ("Black-Scholes").

Redeemable convertible preferred stock warrants are classified as a liability and are initially recorded at their fair value and re-measured on each subsequent balance sheet date while the warrants are outstanding. Changes in fair value are recorded in interest expense, net in the accompanying consolidated statements of operations and comprehensive loss. The redeemable convertible warrants are valued using Black-Scholes.

In connection with the automatic conversion of the Company's convertible preferred stock, which occurred upon the closing of the IPO on June 27, 2016, the preferred stock warrants became warrants to purchase common stock. The Company performed the final mark to market adjustment on the preferred stock warrant using the fair value of the underlying common shares of $14.00 per share on June 27, 2016 and recorded the change in fair value in other income (expense), net in the consolidated statement of operations and comprehensive loss. The preferred stock warrant liability was then reclassified to additional paid-in-capital as the preferred stock warrants became warrants to purchase common stock.

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 awarded to employees 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. Stock-based compensation awarded to non-employees are subject to revaluation over their vesting terms. 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 financial statements is based on awards that are ultimately expected to vest.

Comprehensive Loss

Comprehensive 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 loss consists of both: (i) all components of net loss and

(ii) all components of comprehensive loss other than net loss, referred to as other comprehensive loss. For all periods presented, other comprehensive loss is comprised of foreign currency translation adjustments and the unrealized gains and losses on investments.

Net Loss Per Share

The Company has reported losses since inception and has computed basic net loss per share attributable to common stockholders by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. The Company has computed diluted net loss per common share after giving consideration to 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.

Deferred Rent

Rent expense and lease incentives from operating leases are recognized on a straight-line basis over the lease term. The difference between rent expense recognized and rental payments is recorded as deferred rent in the accompanying consolidated balance sheets.

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, 2017 and December 31, 2016, 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.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the impact of recently issued standards that are not yet effective will have a material impact on the Company's financial position or results of operations upon adoption.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (“ASU 2014-09”), which amends the guidance for revenue recognition to replace numerous industry- specific requirements. ASU 2014-09 implements a five-step process for customer contract revenue recognition that focuses on transfer of control, as opposed to transfer of risk and rewards. ASU 2014-09 also requires enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenues and cash flows from contracts with customers. Other major provisions include ensuring the time value of money is considered in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (modified retrospective method). The amendments in ASU 2014-09 are effective for reporting periods beginning after December 15, 2017. Early adoption is permitted, but not before December 15, 2016. The new standard will be effective for us beginning December 31, 2018, and adoption as of the original effective date of January 1, 2018.

The Company initiated an assessment of the potential changes from adopting ASU 2014-09 and is in the process of evaluating whether the expected effect of these changes is material to its financial statements. The assessment includes identifying and analyzing the impact of the standard by reviewing the Company's current accounting policies and practices to identify potential differences that would result from applying the requirements of the new standard to each revenue contract associated with all of the Company's revenue streams. As of March 31, 2017, the Company had one revenue contract that would require assessment under ASU 2014-09. The Company plans to adopt the new standard effective January 1, 2018 using the modified retrospective method. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact the Company’s current conclusions.

In February 2016, FASB issued ASU No. 2016-02, *Leases* (“ASU 2016-02”). ASU 2016-02 requires a lessee to separate the lease components from the non-lease components in a contract and recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease

term. It also aligns lease accounting for lessors with the revenue recognition guidance in ASU 2014-09. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the effect of the adoption of this guidance on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-9, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-9"), which simplifies several aspects of accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, the estimation of forfeitures, shares withheld for taxes and classification on the statement of cash flows. This guidance is effective for the Company on January 1, 2017 and early adoption was permitted. The Company adopted ASU 2016-09 during the first fiscal quarter ended on March 31, 2017. As part of the adoption of this guidance the Company will continue to use estimated forfeitures in its calculation of stock-based compensation expense.

The excess tax benefits and tax deficiencies from stock-based compensation awards accounted for under ASC 718 are recognized as income tax benefit or expense, respectively, in the statements of operations. The income tax related items had no effect on the current period presentation as the Company maintains a full valuation allowance against its deferred tax assets. In addition, excess tax benefits for share-based payments are presented as an operating activity in the statements of cash flows rather than financing activity. The changes have been applied prospectively in accordance with the ASU and prior periods have not been adjusted. As a result of the adoption, the net operating losses deferred tax assets will increase by $0.3 million and will be offset by a corresponding increase in the valuation allowance.

In August 2016, the FASB issued ASU No. 2016-15, *Statements of Cash Flows - Classifications of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to clarify how companies present and classify certain cash receipts and cash payments in the statement of cash flows. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the effect of the adoption of this guidance on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, S*tatement of Cash Flows, Restricted Cash* ("ASU 2016-18"). This guidance requires that a statement of cash flows explain the total change during the period of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning of period and end of period to total amounts shown on the statement of cash flows. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. Upon implementation of ASU 2016-18 the Company will present $0.4 million in the Consolidated Statements of Cash Flows in the "Cash and cash equivalents at beginning of period". The Company is currently evaluating the effect of the adoption of this guidance on its consolidated financial statements.

3. Available-for-Sale Marketable Securities

As of March 31, 2017 and December 31, 2016, the Company's available-for-sale marketable securities consisted of debt securities issued by the U.S. government and corporate debt securities.

The following tables summarize the Company's available-for-sale marketable securities by major type of security as of March 31, 2017 and December 31, 2016 (in thousands):

	March 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ —	$ —	$ —	$ —
Corporate bonds	41,206	32	(53)	41,185
Total available-for-sale marketable securities	$ 41,206	$ 32	$ (53)	$ 41,185

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ —	$ —	$ —	$ —
Corporate bonds	24,821	17	(53)	24,785
Total available-for-sale marketable securities	$ 24,821	$ 17	$ (53)	$ 24,785

All available-for-sale marketable securities are classified in the Company's Condensed Balance Sheets as Short term deposits and investments.

The Company classifies its marketable debt securities based on their contractual maturity dates. As of March 31, 2017, the Company's marketable debt securities mature at various dates through September 2017. The fair values and amortized cost of marketable debt securities by contractual maturity were as follows (in thousands):

	March 31, 2017		December 31, 2016	
	Fair Value	Amortized Cost	Fair Value	Amortized Cost
Less than one year	$ 41,185	$ 41,206	$ 24,785	$ 24,821

As of March 31, 2017 the Company held a total of 12 out of 30 positions that were in an unrealized loss position, none of which had been in an unrealized loss position for 12 months or greater. Based on the Company's review of these securities, the Company believes that the cost basis of its available-for-sale marketable securities is recoverable and that, therefore, it had no other-than-temporary impairments on these securities as of March 31, 2017. The Company does not intend to sell these debt securities and the Company believes it is not more likely than not that it will be required to sell these securities before the recovery of their amortized cost basis, which may be maturity.

4. Net Loss Per Share

Because the Company has reported a net loss attributable to common stockholders for all periods presented, basic and diluted net loss per share attributable to common stockholders are the same for those periods. 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,	
	2017	2016
	(unaudited)	
Numerator:		
Net (loss)	$ (15,134)	$ (7,476)
Less: accretion on preferred stock	—	(2,356)
Net loss attributable to common stockholders	$ (15,134)	$ (9,832)
Denominator:		
Weighted-average common shares outstanding—basic and diluted	18,474,227	2,175,037
Net loss per share attributable to common stockholders—basic and diluted	$ (0.82)	$ (4.52)

Potential common shares issuable upon conversion of warrants to purchase common stock and stock options that are excluded from the computation of diluted weighted average shares outstanding are as follows:

	March 31,	
	2017	2016
	(unaudited)	
Redeemable convertible preferred stock	—	9,890,580
Stock options to purchase common stock	2,025,664	1,736,682
Stock warrants to purchase common stock	97,302	650,618
Redeemable convertible preferred stock warrants	—	26,832
Total	2,122,966	12,304,712

5. Fair Value Measurements

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, 2017 and December 31, 2016, and indicate the level within the fair value hierarchy where each measurement is classified. Below is a summary of assets measured at fair value on a recurring basis (in thousands):

	March 31, 2017			
	(level 1)	(level 2)	(level 3)	Total
Money market funds, included in cash equivalents	$ 818	$ —	$ —	$ 818
Tri-party repurchase agreements, included in cash equivalents	$ —	$ —	$ —	$ —
Corporate bonds, included in investments	$ 41,185	$ —	$ —	$ 41,185

	December 31, 2016			
	(level 1)	(level 2)	(level 3)	Total
Money market funds, included in cash equivalents	$ 183	$ —	$ —	$ 183
Tri-party repurchase agreements, included in cash equivalents	$ —	$ 27,000	$ —	$ 27,000
Corporate bonds, included in investments	$ 24,785	$ —	$ —	$ 24,785

At March 31, 2017, all cash and cash equivalent investments where held in money market funds. At December 31, 2016, all cash and cash equivalent investments where held in money market funds and tri-party repurchase agreements. The tri-party repurchase agreements are collateralized by government securities for an amount not less than 102% of their value. All tri-party repurchase agreements have maturities of three months or less at the time of investment.

The average maturity date for Corporate Bonds, included in investments at March 31, 2017 and December 31, 2016 was 246 days and 297 days, respectively. Fair value of Corporate Bonds approximates amortized value.

6. Property and Equipment

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

	March 31, 2017	December 31, 2016
	(unaudited)	
Laboratory equipment	$ 4,940	$ 4,713
Computer equipment and software	578	562
Leasehold improvements	222	222
Furniture and fixtures	239	226
Office equipment	64	64
Total property and equipment	6,043	5,787
Less accumulated depreciation	(3,989)	(3,740)
Property and equipment, net	$ 2,054	$ 2,047

Depreciation expense was $0.2 million for the three months ended March 31, 2017 and 2016, respectively.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2017	December 31, 2016
	(unaudited)	
Payroll and employee related expenses	$ 912	$ 1,551
Legal	88	196
Current portion of deferred rent and lease incentive	48	29
Accrued patent fees	432	415
Accrued external research and development costs	3,124	794
Accrued audit fees	195	224
Accrued grant refund	152	152
Accrued interest	76	81
Other	494	479
Accrued expenses	$ 5,521	$ 3,921

8. Commitments and Contingencies

Operating Leases

The Company has a non-cancellable operating lease for its laboratory and office space located in Watertown, Massachusetts. As part of the 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 tenant improvement allowance is accounted for as a lease incentive obligation and is being amortized as a reduction to rent expense over the lease term. The leasehold improvements are capitalized as a component of property and equipment.

In connection with the lease, the Company secured a letter of credit for $0.3 million which renews automatically each year and is classified in restricted cash and other deposits in the accompanying consolidated balance sheets.

In April 2015, the Company amended the lease agreement to exchange 13,711 square feet of space for another 15,174 square feet of space within the same building. Rental payments on the prior space ceased as of March 31, 2015 and rental payments on the new space began on October 1, 2015.

In August 2016, the Company signed an amendment to the operating lease, which extends the lease term of the Company's laboratory and office space through March 31, 2020. The lease agreement includes a rent escalation clause, and accordingly, rent expense is being recognized on a straight-line basis over the lease term.

Deferred rent and lease incentive liability totaled $0.3 million and $0.3 million as of March 31, 2017 and December 31, 2016, respectively. Included in that amount, the current portion of deferred rent and lease incentive liability is classified as accrued expenses and was less than $0.1 million at March 31, 2017 and December 31, 2016, respectively.

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

Rent expense, net of sublease payments, for the three months ended March 31, 2017 and 2016 was $0.5 million and $0.4 million, respectively.

As of December 31, 2016, the future minimum lease payments under the lease agreement, as amended by the lease amendments are as follows (in thousands):

Year ended December 31,		
2017	$	1,244
2018		1,291
2019		1,330
2020		335
Total minimum lease payments	$	4,200

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 does not expect significant claims related to these indemnification obligations and, accordingly, has concluded that the fair value of these obligations is negligible, and no related reserves have been established.

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.

9. Debt

Term Loans

On August 9, 2013, the Company entered into a loan and security agreement with two lenders to borrow up to $7.5 million. The Company initially borrowed $3.0 million in August 2013 and subsequently borrowed an additional $4.5 million in July 2014. The amounts borrowed are collectively referred to as "Term Loans." In December 2015, the Company refinanced its existing debt facility that was originally entered into on August 9, 2013, as amended with Oxford Finance LLC ("Oxford") and Square 1 Bank ("Square 1"), to increase the amount of the borrowing to $12.0 million and to extend the repayment term. The lenders for the refinanced debt facility are Oxford and Pacific Western Bank ("Pacific Western"). Pacific Western had acquired Square 1 since the time of the original loan. Such a change in lender does not constitute third party financing on its own, and does not require extinguishment accounting. As a result of the refinancing, the stated interest rate was also adjusted to reflect the current market borrowing rate. As of March 31, 2017 and December 31, 2016, the outstanding principal balance under the Term Loans was $11.3 million and $12.0 million, respectively.

According to ASC 470-50-40, the refinancing and modification of the prior debt in a non-troubled debt situation must be treated as either an extinguishment or a modification based on whether the present value of the cash flows under the terms of the new debt instrument is different by greater than, or less than, 10% from the present value of the remaining cash flows under the terms of the original instrument. For cash flow changes greater than 10%, the debt modification is accounted for as a debt extinguishment, whereby the original debt is derecognized and the new debt is initially recorded at fair value, with the difference recognized as an extinguishment gain or loss. For cash flow changes of less than 10%, the new loan is considered a modification and no gain or loss is recognized. In considering all cash flow changes, the Company concluded that the refinancing of the debt as of December 31, 2015 is a modification of the debt and not a debt extinguishment, and as a result the debt is initially recorded at its amortizable value net of discounts and deferred costs.

The Term Loans are collateralized by the assets of the Company and bear interest at 8.1% per annum. The monthly payments for the Term Loans are initially interest only through January 2017. Principal repayments for the Term Loans are due over 30 monthly installments beginning on February 1, 2017. The Term Loans may be prepaid at the Company's option at any time prior to maturity subject to a prepayment fee of 3% if prepaid prior to the first anniversary of the borrowing date, 2% if prepaid after the first anniversary but before the second anniversaries, and 1% if prepaid after the second anniversary.

The Term Loans do not include any financial covenants. The Term Loans require a final payment fee of 6.0% on the aggregate principal amounts borrowed upon repayment at maturity, on a prepayment date, or upon default. The final payment fee totaling $0.7 million is recorded as a loan discount. In addition, the Term Loans contain 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. To date, there have been no such events and the lender has not exercised its right under this clause. As a result, the Company concluded that a material adverse change has not occurred and is unlikely to occur, therefore, no liability has been recorded in connection with the clause. Under the Term Loans, the Company is not required to maintain a minimum cash balance.

In connection with the Term Loans, the Company granted the lenders warrants in August 2013 to purchase up to 26,668 shares of the Company's Series D Preferred and additional warrants in July 2014 to purchase up to 40,000 shares of the Company's Series D Preferred. As of the IPO, the warrants to purchase up to 66,668 shares of the Company's Series D Preferred were converted to warrants to purchase 17,888 shares of the Company's common stock at an exercise price of $16.77 per share. These warrants are classified as permanent equity in the accompanying consolidated balance sheets and will expire ten years from the date of issuance.

Additionally, with the refinancing of the Term Loans at December 31, 2015, the Company granted the lenders 37,978 shares of the Company's Series E Preferred which also was converted at the IPO to warrants to purchase 15,094 shares of Company's common stock at an exercise price of $11.32 per share. These warrants are classified as permanent equity in the accompanying consolidated balance sheets and will expire ten years from the date of issuance.

The initial grant date fair value of the warrants of $0.1 million and $0.1 million for each issuance respectively, was recorded as a loan discount.

Term Loan discounts are amortized as additional interest expense over the term of the loans. During the three months ended March 31, 2017 and 2016, the Company recognized $0.3 million and $0.3 million, respectively, of interest expense related to the Term Loan.

In December 2016, a total of 16,493 warrants to purchase common stock were exercised under a cashless exercise, resulting in a net issuance of 4,697 shares of common stock. The warrant exercise prices had been established at the time that the warrants were converted.

Future minimum payments on the Term Loans as of March 31, 2017 are as follows (in thousands):

Year ended December 31,		
Remaining for 2017	$	4,432
2018		5,319
2019		3,379
Total minimum debt payments		13,130
Less: Amount representing interest		(1,136)
Less: Debt discount and deferred charges		(608)
Less: Current portion of loans payable		(4,519)
Loans payable, net of current portion	$	6,867

Convertible Notes

In April 2015, the Company issued convertible notes as a bridge loan to be automatically converted into the Company's capital stock upon the consummation of a private placement of the Company's Preferred Stock. The convertible notes bore interest at 8% per annum, compounding monthly. In the event the Company was unable to consummate the private placement by July 15, 2015, the Company would be required to issue warrants to purchase shares of the Company's common stock equal to 20% of the convertible note principal divided by $17.55. On July 24, 2015, the Company issued warrants to the convertible note holders to purchase up to 80,813 shares of the Company's common stock at an exercise price of $17.55 per share for a term of three years. The carrying value and accrued interest of the outstanding convertible notes were automatically converted into 1,619,550 shares of Series E Preferred. As part of the Series E Preferred issuance, the convertible note holders also received warrants to purchase up to 103,817 shares of the Company's common stock (Note 10). The difference between the carrying value and accrued interest of the convertible notes that were converted and the combined fair value of the Series E Preferred

shares and common stock warrants issued were negligible. There was no interest expense related to the convertible notes for the three months ended March 31, 2017 and 2016.

10. Preferred Stock

Prior to the completion of its IPO, the Company had 37,835,623 and 28,804,969 authorized shares of Preferred Stock as of December 31, 2015 and 2014, respectively. The Company issued Preferred Stock with a $0.0001 par value to investors for cash or as settlement for outstanding debt under convertible notes (Note 9).

The Company had issued Preferred Stock of (i) 2,589,868 shares of Series A redeemable convertible preferred stock ("Series A Preferred"), (ii) 7,437,325 shares of Series B redeemable convertible preferred stock ("Series B Preferred"), (iii) 5,000,002 shares of Series C redeemable convertible preferred stock ("Series C Preferred"), (iv) 8,099,994 shares of Series D Preferred, (v) 2,111,109 shares of Series SRN Redeemable Convertible Preferred Stock ("Series SRN Preferred") and (vi) 8,888,888 shares of Series E Preferred.

In April 2014 and August 2014, the Company issued an additional 3,211,105 shares of Series D Preferred at $4.50 per share for total net proceeds of $14,349,239. In July 2014, the Company issued an additional 1,333,332 shares of Series SRN Preferred at $4.50 per share for total net proceeds of $5.8 million. In connection with the issuance of the additional shares of Series SRN Preferred, the Series SRN Preferred terms were amended. Significant terms that were amended included a change of the Series SRN Preferred optional and mandatory conversion price (other than a special conversion event, as defined in the certificate of incorporation) to $16.77 per share, the elimination of a time-based tranche investment requirement, and the removal of a call option for the Company to repurchase the Series SRN Preferred shares. Based upon the qualitative characteristics of the amendments, the Company determined that the changes significantly modified the terms of Series SRN Preferred resulting in an extinguishment of the then outstanding SRN Preferred shares. As a result, the carrying value of Series SRN Preferred of $5.0 million at the date of the amendment was derecognized, and the amended Series SRN Preferred shares were recorded at their fair value of $4.50 per share. The difference of $1.5 million was recorded as additional paid in capital.

In August 2015 and September 2015, the Company issued an aggregate of 7,269,338 shares of Series E Preferred at $4.50 per share for total gross proceeds of $32.7 million with issuance costs totaling $0.2 million. In addition, the Company issued 1,619,550 shares of Series E Preferred in connection with the conversion of convertible notes (Note 9). In connection with the Series E Preferred issuances, each Series E Preferred stockholder also received warrants to purchase a number of shares of the Company's common stock that equal to 25% of the number of Series E Preferred shares issued. The fair value of the issued common stock warrants is accounted for as an issuance discount on the Series E Preferred. The common stock warrants are classified as permanent equity and were recorded as additional paid-in capital.

All outstanding shares of the Company's convertible preferred stock automatically converted into 10,126,118 shares of the Company's common stock upon the closing of the IPO on June 27, 2016.

11. Common Stock

As of March 31, 2017, the Company has 200,000,000 shares of Common Stock authorized for issuance, $0.0001 par value per share, with 18,552,385 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. Common stock voting rights on certain matters are subject to the powers, preferences, and rights of the Senior Preferred.

Dividends

The common stockholders are entitled to receive dividends, if and when declared by the Board of Directors. The Company may not declare or pay any cash dividends to the common stockholders unless dividends are first declared and paid to the holders of Preferred Stock in accordance with their respective terms. Through March 31, 2017, no dividends have been declared or paid on common stock.

Liquidation

After holders of Preferred Stock are satisfied of their liquidation preferences upon any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company, the common stockholders are then entitled to receive that portion of the remaining funds to be distributed to all holders of the Company's stock on an as-converted basis.

Reserved Shares

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

	Periods ending	
	March 31, 2017	December 31, 2016
	(unaudited)	
Exercise of common warrants	97,302	97,302
Shares available for future stock incentive awards	1,858,944	939,317
Exercise of outstanding common stock options	2,025,664	2,128,346
Total	3,981,910	3,164,965

12. Stock Incentive Plans

Stock Options

The Company maintained 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. As of March 31, 2017, a total of 2,213,412 shares of common stock were authorized for grants under the 2008 Plan with 18,947 shares available for future grants. All unvested stock options granted under the 2008 Plan may be exercised into restricted stock subject to forfeiture provisions upon termination.

The 2008 Plan provided that the exercise price of incentive stock options cannot be less than 100% of the fair market value of the 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 granted under the 2008 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 fair value of each option award was estimated on the grant date using Black-Scholes. Expected volatilities were based on historical volatilities from guideline companies, since there was no active market for the Company's common stock. The Company used 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, any cash dividends in the foreseeable future. Forfeitures were estimated at the time of grant and were adjusted, if necessary, in subsequent periods if actual forfeitures differed from those estimates. The Company had estimated a forfeitures rate of 10% based on historical attrition trends. The Company records stock-based compensation expense only on the awards that are expected to vest.

As of the effective date of our Registration Statement on Form S-1 relating to the initial public offering of our common stock on June 21, 2016, the Company ceased granting awards under the 2008 Plan; however, awards issued under the 2008 Plan remain subject to the terms of the 2008 Plan and the applicable 2008 Plan agreement.

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. As of March 31, 2017, a total of 1,947,779 shares of common stock are authorized for grants under the 2016 Plan with 1,482,541 shares available for future grant.

The 2016 Plan provides that the exercise price of incentive stock options cannot be less than 100% of the fair market value of the 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 granted under the 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 weighted average assumptions used for employee stock option grants issued for the three month period ended March 31, 2017 and 2016 are as follows:

	Three Months Ended March 31,	
	2017	2016
Risk-free interest rate	2.07%	1.54%
Expected dividend yield	—	—
Expected life	5.92	6.03
Expected volatility	84.41%	75.26%
Weighted-average fair value of common stock	$ 10.89	$ 7.02

The resulting weighted average grant date fair value of stock options granted to employees during the three months ended March 31, 2017 and 2016 was $7.77 and $4.64, respectively. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2017 and 2016 was $0.6 million and less than $0.1 million, respectively.

As of March 31, 2017 and 2016, total unrecognized compensation expense related to unvested employee stock options was $5.2 million and $2.4 million, respectively, which is expected to be recognized over a weighted average period of 2.8 years and 3 years, respectively.

During the three months ended March 31, 2017, there were no options granted to non-employees. The weighted average assumptions used for unvested non-employee stock options that were granted during the three months ended March 31, 2016 are as follows:

	Three Months Ended March 31,
	2016
Risk-free interest rate	1.89%
Expected dividend yield	—
Expected life (in years)	9.94
Expected volatility	82.48%

The unvested options held by non-employees are revalued using the Company's estimate of fair value on each vesting and reporting date through the remaining vesting period. Non-employee stock-based compensation expense of $0.1 million and less than $0.1 million was recorded during the three months ended March 31, 2017 and 2016, respectively.

As of March 31, 2017 and 2016, total unrecognized compensation expense related to unvested non-employee stock options was $0.9 million and $0.5 million, respectively.

The following table summarizes the activity under the 2008 Plan and the 2016 Plan during the three months ended March 31, 2017:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Employee				
Outstanding at December 31, 2016	1,720,741	$ 7.73	7.43	$ 16,425
Granted	16,125	$ 10.89		
Exercised	(53,664)	$ 3.65		
Forfeited	(5,143)	$ 6.77		
Outstanding at March 31, 2017	1,678,059	$ 7.89	7.28	$ 6,693
Vested at March 31, 2017	843,379	$ 4.35	5.68	$ 5,512
Vested and expected to vest at March 31, 2017	1,576,207	$ 7.65	7.17	$ 6,553
Non-Employee				
Outstanding at December 31, 2016	407,605	$ 4.42	5.79	$ 5,224
Granted	—	$ —		
Exercised	(60,000)	$ 4.20		
Forfeited	—	$ —		
Outstanding at March 31, 2017	347,605	$ 4.46	5.54	$ 2,286
Vested at March 31, 2017	275,074	$ 3.50	4.69	$ 2,072
Vested and expected to vest at March 31, 2017	343,951	$ 4.44	5.53	$ 2,286

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. A total of 357,456 shares of common stock are 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.

The fair value of the purchase rights granted under the ESPP for the offering period beginning March 1, 2017 was estimated by applying Black-Scholes using the following assumptions:

	Three Months Ended March 31, 2017
Risk-free interest rate	0.91%
Expected dividend yield	—
Expected life	0.5
Expected volatility	68.9%

For the three months ended March 31, 2017, the Company recorded less than $0.1 million of stock-based compensation expense and issued no shares of common stock to employees under the ESPP. There was no stock-based compensation expense related to the ESPP recorded for the three months ended March 31, 2016.

Restricted Stock

During the year ended December 31, 2013, the Company issued 30,317 shares of restricted common stock to employees upon the early exercise of stock options. During the year ended December 31, 2014, the Company issued 2,564 shares of restricted common stock to employees. Under the terms of each agreement, the Company has the right to repurchase any unvested shares when/if the shareholders terminate their employment relationship with the Company, at a price equal to the original exercise price. Accordingly, the Company recorded the cumulative payments received of $0.1 million for the purchase of the restricted shares as a liability. The Company records payment received from the granting of restricted stock as a liability which is amortized over the vesting period. The liability became fully amortized as of December 31, 2016.

As of March 31, 2017, there was no unrecognized compensation cost related to unvested restricted stock.

The Company recorded stock-based compensation expense related to stock options and restricted common stock in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2017	2016
Research and development	$ 335	$ 167
General and administrative	358	115
Total	$ 693	$ 282

13. Revenue Arrangements

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 SVP™ technology. 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 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 will be due within twelve months of the contract dated December 2, 2016 ("Contract Date"). Spark may also exercise options to research, develop and commercialize gene therapies utilizing the SVP technology for up to four additional targets. The Company is 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. As per the agreement, the election period in which Spark can exercise additional targets is a term of three years from the Contract Date, or 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 License Agreement may be terminated by Spark for convenience upon ninety days' notice. Either party may terminate the 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 "Purchase Agreement") with Spark. Pursuant to the 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. Under the Stock Purchase Agreement, Spark has agreed not to dispose of any of the Initial Closing Shares or any Acquisition Right Shares that it may acquire until January 1, 2018 and, thereafter, transfers will be contractually subject to volume limitations applicable

to an "affiliate" under Rule 144 of the Securities Act. Closings under the Stock Purchase Agreement are subject to customary conditions. Beyond the Initial Closing, the Purchase Agreement provides for 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 will have the right (the "First Acquisition Right") to purchase a number of shares of Common Stock equal to an aggregate price of $5.0 million.

- Second Acquisition Right. During the period beginning on October 1, 2017 and ending on November 1, 2017, Spark will have the right (the "Second Acquisition Right") to purchase a number of shares of Common Stock equal to an aggregate price of $5.0 million.

The First Acquisition Rights and Second Acquisition Rights are collectively referred to herein as the "Acquisition Rights". The number of shares issued under the Acquisition Rights will be determined based on the calculated purchase price on the date of notification, which is defined as 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 Acquisition Right notification date. The aggregate number of shares that the Company may issue pursuant to the Stock Purchase Agreement may not exceed the lesser of (i) 2,758,112 shares and (ii) such number of shares that would require the Company to obtain prior shareholder approval under the Nasdaq Marketplace Rules.

In connection with the execution of the Spark License Agreement and Purchase Agreement, the Company made contractual payments defined in the MIT license agreement (Note 15) totaling $1.5 million for the MIT sub-license provided to Spark, and $0.2 million relative to the calculated premium paid by Spark for the initial equity investment made under the Purchase Agreement. No additional payments were required to be made during the three months ended March 31, 2017.

Accounting Analysis

The Spark License Agreement contains the following deliverables: (1) certain exclusive, worldwide, royalty bearing licenses to the Company's intellectual property and a license to conduct certain research activities under the collaboration, or the License Deliverable, (2) options to research, develop and commercialize gene therapies utilizing the SVP technology for up to four additional target therapy options, or the Option Deliverable, and (3) manufactured supply of pre-clinical and clinical SVP, or the Supply Deliverable. The Company considered the provisions of the multiple-element arrangement guidance in determining how to recognize the revenue associated with the identified deliverables. The Company has accounted for access to certain of the Company's technology through the various licenses and rights to use under the license deliverables listed above and the delivery of the manufactured supply as a single unit of accounting. The deliverables are not considered to have standalone value from one another and amounts allocated to these obligations will be recognized throughout the estimated period of delivery of the supply.

The Option Deliverable is determined to be substantive at the outset of the agreement, and therefore will not be considered an element of the arrangement when allocating the consideration as there is considerable uncertainty that the options would be exercised. Although the options are not considered a deliverable at inception, it was determined that there is a significant and incremental discount that requires inclusion as an element of the initial allocation of contract consideration.

In addition, the Company evaluated the stock purchase agreement and the collaboration and license agreement as one arrangement and 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.

The Company evaluated and determined that the Acquisition Rights under the stock purchase agreement are not freestanding instruments as these rights are not legally detachable from the Company's common stock. In addition, the Company has further assessed that the Acquisition Rights were clearly and closely related to the economic characteristic and risk of the Common Stock. The Company determined that the Acquisition Rights are embedded and inseparable from the initial stock purchase and no subsequent remeasurement is necessary.

Allocable arrangement consideration at inception consisted of the total non-contingent payments aggregating to $15 million. 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), $7.1 million to the License and Supply Deliverable combined unit of accounting and $5.2 million to the discount on the Option Deliverable. The total arrangement consideration for the License and Supply deliverable and the Option deliverable was allocated using the relative best estimate of selling price method to each deliverable. The best estimate of selling price for the License and Supply deliverable was determined using a discounted cash

flow model that includes Level 3 fair value measurements. The best estimate of selling price for the Option Deliverable was determined based on the fair value of the license minus the strike price of the option. The consideration allocated to the combined unit of accounting for the License and Supply Deliverable, totaling $7.1 million, will be recognized based on the expected deliveries over an initial term which is estimated to be approximately four years. The discount associated with the Option Deliverable, totaling $5.2 million, will be recognized, if the options are exercised, over the related expected deliveries of supply. If the options expire without exercise, the related deferred revenue will be recognized upon expiration (December 1, 2019).

Revenues totaling less than $0.1 million were recognized related to the Spark License Agreement during the three months ended March 31, 2017. There were no revenues recognized for the three months ended March 31, 2016.

The Company determined that each potential future clinical and regulatory milestone was non-substantive, therefore, any consideration received will be allocated to the License and Supply Deliverable and Option Deliverable using the relative selling price.

Sales-based milestones and royalty payments are expected to be recognized when earned.

As of March 31, 2017, there was $12.2 million of deferred revenue related to this agreement. A total of $1.9 million was recorded as a current liability and $10.3 million was classified as a long term liability in the accompanying consolidated balance sheet.

Sanofi Collaboration Agreement

On November 27, 2012, the Company and Sanofi entered into a license and research collaboration agreement focused on the identification and development of vaccines against food allergies (the “Sanofi Agreement”). Under the arrangement, the Company agreed to perform research to identify an initial vaccine candidate for development and commercialization by Sanofi under an exclusive license.

Pursuant to the Sanofi Agreement, the Company received an upfront payment of $2.0 million for the initial indication in November 2012 and an additional payment of $3.0 million in August 2013. In November 2014, Sanofi exercised the option to include celiac disease as an additional indication, and in May 2015, the Sanofi Agreement was amended to add terms specific to the celiac disease indication and to terminate Sanofi's right to exercise its option for any additional indications. Sanofi paid the Company an additional $2.0 million upon the exercise of the option in May 2015 and an additional $1.0 million in July 2016 upon attaining the first milestone for the celiac disease indication. To date, Sanofi has paid the Company $8.0 million in the aggregate under the Sanofi Agreement.

Except as authorized by Sanofi or permitted under the Sanofi Agreement, during the term of the Sanofi Agreement, exclusivity obligations prevent the Company from researching, developing, or commercializing products in these indications or granting third party licenses under the intellectual property rights and technologies licensed to Sanofi for use in these indications.

As per the agreement, the research term expired for the first indication on the third anniversary (November 27, 2015) of the agreement. The Company completed its research obligations within the initial three year period and is not obligated to perform any further research on the specific indication under the agreement. A vaccine candidate for development and commercialization was not selected by Sanofi by the end of the research plan, and therefore no further milestone payments have been received.

The Company identified the deliverables under the arrangement as the license, the research necessary to identify the development candidate, and participation of the Joint Research Committee ("JRC"). The Company determined that the exclusive license granted to Sanofi did not have standalone value from the research to be performed to identify the vaccine development candidate. As a result, each upfront and milestone consideration was allocated to the combined unit of account comprising the license and research services, and is being recognized over the estimated development period using a proportional performance method. The consideration allocated to participation on the JRC was not material. The Company recognized no revenue and $0.1 million for the three months ended March 31, 2017 and 2016, respectively.

Termination of the Sanofi Collaboration Agreement

On November 9, 2016, the Company received written notice from Sanofi that Sanofi had elected to terminate in its entirety the Sanofi Agreement. The termination of the Sanofi Agreement was effective on May 8, 2017, or the Termination Date, which was six months from the date of the notice.

As discussed above, Sanofi has paid the Company $8.0 million in the aggregate under the Sanofi Agreement to date. The Company would have been eligible to receive additional development-based, regulatory-based and sales-based milestone payments and tiered royalties on net sales of any approved product generated by the collaboration had the Sanofi Agreement not been terminated. As of December 31, 2016, the Company has recognized the remaining $2.2 million in revenue associated with the Sanofi Agreement, as the Company has no more performance obligation under the contact.

All rights granted to Sanofi terminated and reverted to the Company effective on the Termination Date, and Sanofi is required to grant to the Company a royalty bearing, exclusive license, with the right to grant sublicenses, under certain Sanofi intellectual property solely to the extent necessary to research, develop, make, have made, use, offer for sale, import, export and otherwise commercialize the vaccine candidates developed under the Sanofi Agreement. The exclusivity obligations discussed above also expired on the Termination Date.

The Company has exercised its right to acquire the development programs under the Sanofi Agreement. The Company is solely responsible for performing and funding any development and clinical trial activities relating to further development of vaccine candidates that it chooses to undertake after the Termination Date.

Other Research and Collaboration Agreements

The Company has entered into other research and collaboration agreements in 2017 and 2016 for which the Company recognized no revenue and less than $0.1 million for the three months ended March 31, 2017 and 2016, respectively.

Grant Agreements

The Company receives funding in the form of grants from the National Institutes of Health (“NIH”), the Juvenile Diabetes Research Foundation (“JDRF”), the Bill and Melinda Gates Foundation, the Russian Ministry of Industry and Trade (“Minpromtorg”), and the Russia based Development Fund of New Technologies Development and Commercialization Center (“Skolkovo”).

NIH

The Company has two grants through the NIH. The first grant, for an aggregate amount of $8.1 million, was awarded in May 2014 to support research in the development of a next generation vaccine for smoking cessation and relapse prevention. The Company recognized no revenue for the three months ended March 31, 2017 and $1.8 million for the three months ended March 31, 2016.

The second grant is for an aggregate amount of $0.2 million, which was awarded in September 2015 for the development of nanoparticles for immune tolerance to factor VIII. The Company recognized revenue of less than $0.1 million for the three months ended March 31, 2017 and 2016, related to this grant.

JDRF

The Company had two contracts in effect with JDRF during 2014 and only one of those contracts was in effect during 2015 and 2016. The first contract was a continuation and completion of the 2011 grant for $0.8 million. The Company recognized the remaining $0.2 million of revenue during the year ended December 31, 2014 under this contract.

The second JDRF grant is a joint grant with Sanofi entered into in September 2014 for $0.4 million to conduct Type 1 Diabetes research. The Company recognized revenue of less than $0.1 million for the three months ended March 31, 2017 and 2016, respectively, related to this grant.

Bill and Melinda Gates Foundation

The Company received a grant in 2013 from the Bill and Melinda Gates Foundation for $1.2 million to fund the Company’s immunology research on malaria antigens. During 2014, the grant amount was increased to a total of $1.6 million and the term was extended to a three-year research term. Revenue is recognized on a proportional performance basis as it relates to employee time expended on the research, along with reimbursement for external costs directly related to, and approved, by the grant terms. For the three months ended March 31, 2017 and 2016, the Company recognized revenue of less than $0.1 million and $0.1 million, respectively.

Minpromtorg

The Company had a contract awarded from Minpromtorg for approximately $4.6 million to fund the Company's nicotine cessation vaccine clinical trial to be conducted in Russia. The grant covered a term from July 9, 2013 through December 31, 2015, and provided for reimbursement of expenses incurred by the Company from the clinical trial. Under the agreement term, the Company was subject to a penalty in the event that the clinical trial was delayed or terminated prior to completion. As a result of the penalty provision, the Company concluded the amounts received under the agreement were not fixed or determinable. In 2014, the Company terminated its plan to conduct the clinical trial in Russia subjecting the Company to the penalty obligation.

In February 2015, the Company received an executed final settlement agreement from Minpromtorg that included the repayment of funds previously received by the Company totaling $0.2 million, and a penalty fee that equaled to 10% of the contract value, or $0.2 million. The Company paid the settlement payment in March 2015 and all mutual claims under the contract were terminated. According to the terms of the agreement, Minpromtorg has the right to audit the expenditure incurred under the agreement for a period up to three years from each research milestone date. All grant funding received in excess of the penalty settlement will remain as a liability on the balance sheet until such time the audit period has expired and at which time, the amount will be recognized as revenue. Through March 31, 2017, the Company received payments totaling approximately $1.4 million.

The first audit period expired on December 31, 2015, and as a result $0.4 million of revenue was recognized for the year ended December 31, 2015. The second and third audit periods expired during the twelve months ended December 31, 2016, and as a result $0.5 million of revenue was recognized for the year ended December 31, 2016. As of December 31, 2016, the deferred revenue associated with Minpromtorg contract has been fully recognized. There was no revenue recognized during the three months ended March 31, 2017 and 2016.

Skolkovo

On November 28, 2014, the Company executed a grant awarded by Skolkovo for the development of a therapeutic vaccine using nanoparticles to treat chronic infection caused by HPV and diseases associated with this infection. The grant covers a period from August 1, 2014 through July 21, 2017. The grant provides for up to $2.7 million that covers 48.5% of the estimated total cost of the research plan with the remaining 51.5% of estimated costs to be contributed by the Company. The Company has received from Skolkovo $1.8 million through the three months ended March 31, 2017.

At any time during the term of the grant agreement, but not more than once per quarter, Skolkovo has the right to request information related to the project and to conduct an audit of the expenses incurred by the Company. In the event the project or the expenses do not meet predefined requirements, the Company may be required to reimburse the funds received up to three years after the completion of the project. As a result, the Company has determined that the grant funding is not fixed or determinable and all amounts received to date are recorded as deferred revenue in the consolidated balance sheet until the completion of the Skolkovo audit or the expiration of the audit term.

14. Related-Party Transactions

As part of the Series B Preferred and Series D Preferred financings (as described in Note 10), the Company's landlord (the "Landlord") purchased 49,254 shares of Series B Preferred at $2.03 per share for total proceeds of $0.1 million and 488,888 shares of Series D Preferred at $4.50 per share for total proceeds of $2.2 million. Additionally, in April 2015, the Landlord participated in the Company's bridge loan in the amount of $0.2 million, which converted into Series E Preferred (see Note 10). The Landlord paid the same price as the price paid by other investors in each of these Preferred Stock purchases. At the IPO, all preferred stock was converted to common stock.

The Company incurred expenses for consulting services provided by its founders totaling less than $0.1 million and $0.1 million during the three months ended March 31, 2017 and 2016, respectively.

15. Technology License Agreements

MIT

On November 25, 2008, the Company entered into an Exclusive Patent License agreement with the Massachusetts Institute of Technology ("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. In the event the Company sublicenses the MIT patents to a third party, it will be required to remit to MIT a percentage (ranging from 10% to 30%) of sublicense income. In addition, the Company is obligated to pay MIT a certain amount upon the achievement of defined clinical milestones, up to a total of $1.5 million. On December 18, 2008, the Company entered into a patent-cross-license agreement with BIND Therapeutics, Inc. whereby each party receives a license for the use of the other patents in their respective fields of use. In exchange for this license, the Company paid a one-time expense in 2008.

As of March 31, 2017, and in connection with the execution of the Spark License Agreement, the Company has made contractual payments pursuant to the Exclusive Patent License totaling $1.5 million for the sublicense granted to Spark, and $0.2 million relative to the calculated premium paid by Spark for the initial equity investment made under the Purchase Agreement.

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. Pursuant to the 3SBio License, the Company was granted an exclusive license to certain pegsiticase-related patents and related "know-how" owned or in-licensed by 3SBio for the worldwide (except for Greater China and Japan) development and commercialization of products based thereupon for human therapeutic, diagnostic and prophylactic use. The Company was also granted a worldwide (except for Greater China) exclusive license to develop, commercialize and manufacture or have manufactured products combining the Company's proprietary SVP technology with pegsiticase or related compounds supplied by 3SBio (or otherwise supplied if the Company's rights to manufacture are in effect) for human therapeutic, diagnostic and prophylactic use. The Company was also granted a co-exclusive license to manufacture and have manufactured pegsiticase and related compounds for preclinical and clinical use or, if the 3SBio License is terminated for 3SBio's material breach, for any use under the 3SBio License. Otherwise, the Company is obligated to obtain all of its supply of such compounds for Phase 3 clinical trials and commercial use from 3SBio under the terms of supply agreements to be negotiated.

Pursuant to the 3SBio License, the Company is required to use commercially reasonable efforts to develop and commercialize a product containing pegsiticase or a related compound. If the Company does not commercialize any such product in a particular country in Asia, Africa or South America within 48 months after approval of any such product in the United States or a major European country, then 3SBio will have the right to do so, but only until the Company commercializes a product combining the Company's SVP technology with any such compound in such country. The Company has paid to 3SBio an aggregate of $1.0 million in upfront and milestone-based payments under the 3SBio License. An additional liability totaling $2.0 million for milestone payments has been expensed in 2016, and is included with Accounts Payable on the balance sheet as of December 31, 2016. 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 the Company's SVP technology, and up to an aggregate of $41.5 million for products without the Company's SVP technology. The Company is also required to pay 3SBio tiered royalties on annual worldwide net sales (on a country-by-country and product-by-product basis) related to the pegsiticase component of products at percentages ranging from the low-to-mid single digits for products containing the Company's SVP technology, and a range of no more than ten percent points from the mid-single digits to low double-digits for products without the Company's SVP technology. The Company will pay these royalties to 3SBio, subject to specified reductions, on a country-by-country and product-by-product basis until the later of (i) the date that all of the patent rights for that product have expired in that country, or (ii) a specified number of years from the first commercial sale of such product in such country.

The 3SBio License expires on the date of expiration of all of the Company's royalty payment obligations unless earlier terminated by either party for an uncured material default or for the other party's bankruptcy. Any such termination by 3SBio for material default may be on a country-by-country or product-by-product basis in certain circumstances. The Company may also terminate the 3SBio License on a country-by-country or product-by-product basis for any reason effective upon 60 days' prior written notice to 3SBio or, with respect to a given product, immediately upon written notice to 3SBio if the Company identifies a safety or efficacy concern related to such product.

Massachusetts Eye and Ear Infirmary and The Schepens Eye Research Institute, Inc.

In May 2016, the Company entered into a license agreement with the Massachusetts Eye and Ear Infirmary and The Schepens Eye Research Institute, Inc. (collectively, "MEE"), which is referred to as the MEE License. Under the MEE License, the Company was granted an exclusive commercial worldwide license, with the right to grant sublicenses through multiple tiers, to make, have made, use, offer to sell, sell and import certain products and to practice certain processes, the sale, use or practice of

which are covered by patents and proprietary know-how owned or controlled by MEE, for use of Anc80 gene therapy vectors for gene augmentation therapies expressing certain target sequences.

MEE also granted the Company exclusive options to exclusively license certain of their intellectual property rights relating to several additional target sequences and variations thereof each linked to a specified disease. During a defined option period, the Company may exercise this right for up to a designated number of target sequences. If the Company exercises its options, under certain circumstances, the Company may substitute alternative target sequences for previously selected target sequences.

The Company agreed to use commercially reasonable efforts to develop and commercialize licensed products pursuant to a development plan, and to market and sell at least one product for each target sequence for which the Company exercised its option as soon as reasonably practicable. Subject to certain exceptions, following commercial launch, the Company must use commercially reasonable efforts to market, sell, and maintain public availability of licensed products in a certain number of specified major markets.

Pursuant to the MEE Agreement, the Company agreed to pay MEE a license fee in the low six figures, annual license maintenance fees ranging from the mid-twenty thousands to mid-seventy thousands and an option maintenance fee in the low five figures for each exercisable option. The Company also agreed to reimburse MEE for a specified percentage of the past patent expenses for the patents licensed to the Company. The Company also agreed to pay development milestones on a licensed product-by-licensed product basis, totaling up to an aggregate of between $4.2 million to $37.0 million and sales milestones on a licensed product-by-licensed product basis, totaling up to an aggregate of between $50.0 million to $70.0 million; tiered royalties on a licensed product-by-licensed product and country-by-country basis equal to a percentage of net sales ranging from mid-single digits to mid-teens, subject to the prevalence of the targeted disease and certain reductions; and a percentage, in a range expected to be in the mid-teens depending on timing, of any sublicense income the Company receives from sublicensing its rights granted thereunder, subject to certain reductions and exclusions. Upon exercise of each option, the Company agreed to pay MEE an option exercise fee ranging from low-six figures to mid-six figures, depending on the prevalence of the targeted disease.

The MEE License will continue until the expiration of the last to expire of the patent rights licensed thereunder. The Company may terminate the MEE License in whole or in part upon prior written notice. MEE may terminate the MEE License on a target sequence-by-target sequence basis if the Company fails to make any scheduled payments in respect of such target sequence or if the Company materially breaches a diligence obligation in respect of such target sequence, in each case if the Company fails to cure within a specified time period. MEE may terminate the MEE License in its entirety if the Company materially breaches certain of its obligations related to diligence, representations and warranties, and maintenance of insurance; if the Company challenges the validity or enforceability of any patents licensed thereunder; if any of the Company's executive officers are convicted of a felony relating to manufacture, use, sale or importation of licensed products; or upon the Company's insolvency or bankruptcy.

As of March 31, 2017, the Company has paid a total of $0.1 million in license fees due under the agreement.

16. Income Taxes

The Company did not provide for any income taxes in any of the three months ended March 31, 2017 or 2016.

In 2014, the Company's Russian subsidiary was granted a 10 year tax holiday in Russia. The Company's foreign operations continue to benefit from the tax holiday, which is set to expire December 31, 2023.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its U.S. net deferred tax assets. As required by the provisions of ASC 740, Income Taxes, management has determined that it is more-likely-than-not that the Company will not utilize the benefits of federal and state U.S. net deferred tax assets for financial reporting purposes. Accordingly, the net deferred tax assets are subject to a valuation allowance at March 31, 2017 and December 31, 2016.

17. 401(k) Savings Plan

The Company maintains a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a 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 totaling $0.1 million and $0.1 million for the years ended March 31, 2017 and 2016, respectively, have been recorded in the consolidated statements of operations and comprehensive loss.

18. Subsequent Events

On April 27, 2017, the Company entered into a Patent License Agreement (the "License Agreement") with the U.S. Department of Health and Human Services, as represented by the National Cancer Institute, an Institute or Center of the National Institutes of Health. Under the terms of the License Agreement, the NIH granted to the Company an exclusive worldwide license under specified patent rights and a non-exclusive worldwide license under specified other patent rights in the field of use of anti-mesothelin targeted immunotoxins for the treatment of mesothelin-expressing cancers. The Company has the right to grant sublicenses under the licenses granted by the NIH with NIH's prior consent, not to be unreasonably withheld. The license grant is subject to typical statutory requirements and reserved rights as required under federal law and NIH requirements. In addition, if the NIH determines that the public health and safety so require, the NIH may require the Company to grant sublicenses to responsible applicants, on reasonable terms, in any licensed field under the licensed patent rights, unless the Company can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the licensed patent rights.

In consideration for the rights granted under the License Agreement, the Company agreed to pay an upfront payment of $50,000, earned royalties equal to a percentage, in the low single digits, of net sales (subject to certain annual minimum royalty payments), payments of up to an aggregate of $9.3 million upon achievement of specified benchmarks, and a percentage, ranging from the mid single digits to mid teens, of revenues from sublicensing arrangements. The Company is obligated to use commercially reasonable efforts to exploit, and make publicly available, the inventions described in the licensed patent rights. The Company may not transfer or assign the License Agreement to a third party without the NIH's consent, and if the NIH consents to any assignment, the Company is obligated to pay the NIH a percentage in the low single digits of the consideration received by the Company for such assignment.

The term of the License Agreement will extend to the date of expiry of the last-to-expire patent in the licensed patent rights, unless either party terminates the License Agreement earlier. The NIH may terminate the License Agreement if the Company is in default of the performance of any material obligations under the License Agreement, including certain specified benchmark and other obligations, if the default has not been remedied within ninety days after the date of notice in writing of the default. In addition, the NIH may terminate the License Agreement or modify, at its option, the License Agreement, if the NIH determines that such termination or modification is necessary to meet the requirements for public use specified by federal regulations issued after the date of the License Agreement and these requirements are not reasonably satisfied by the Company. The Company may terminate the License Agreement or any licenses in any country or territory by giving the NIH sixty days written notice.

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 financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied, by these forward-looking statements.

OVERVIEW

We are a clinical-stage biopharmaceutical company using our proprietary synthetic vaccine particle, or SVP, technology to discover and develop targeted therapies that are designed to modulate the immune system to effectively and safely treat rare and serious diseases. 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 SVP technology encapsulates an immunomodulator in biodegradable nanoparticles to induce antigen-specific immune tolerance to mitigate the formation of anti-drug antibodies, or ADAs, in response to life-sustaining biologic drugs. We believe our SVP technology has the potential for broad applications to both enhance existing biologic drugs and enable novel therapies. Our lead product candidate, SEL-212, is a combination of a therapeutic enzyme and our SVP technology designed to be the first biologic treatment for gout that durably controls uric acid in refractory gout and dissolves and removes harmful deposits of uric acid crystals in chronic tophaceous gout, each a painful and debilitating disease with unmet medical need. SEL-212 is currently in a comprehensive Phase 1/2 clinical program. The Phase 1/2 clinical program is comprised of two Phase 1 clinical trials and a Phase 2 clinical trial, which commenced in October 2016, and is designed to evaluate the ability of SEL-212 to control uric acid levels and mitigate the formation of ADAs. The Phase 1 clinical trials have been completed and we initiated the Phase 2 clinical trial in the fourth quarter of 2016.

We were incorporated in 2007 under the laws of the State of Delaware and our corporate headquarters is in Watertown, Massachusetts. Our operations to date have been limited to organizing and staffing our company, business planning, acquiring operating assets, raising capital, developing our technology, identifying potential nanoparticle immunomodulatory product candidates, research and development, undertaking preclinical studies and conducting clinical trials. To date, we have financed our operations primarily through our initial public offering, or IPO, of common stock in June 2016, private placements of our preferred stock, common stock and debt 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 generated from research grants and contracts.

Since inception, we have incurred significant operating losses. We incurred net losses of $15.1 million and $7.5 million for the three months ended March 31, 2017 and 2016, respectively. As of March 31, 2017, we had an accumulated deficit of $166.7 million. We expect to continue incurring significant expenses and operating losses for at least the next several years as we:

- conduct and expand clinical trials for SEL-212, our lead product candidate;
- continue the research and development of our other product candidates;
- seek regulatory approval 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;
- hire additional staff, including clinical, scientific, operational and financial personnel, to execute our business plan; and
- add personnel and clinical, scientific, operational, financial and management information systems to support our product development and potential future commercialization efforts, and to enable us to operate 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 with partners, 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.

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.

We expect that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into the middle of 2018. For additional information, see "-Liquidity and Capital Resources."

FINANCIAL OPERATIONS OVERVIEW

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 as a result 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. As a result of the termination of the license and research collaboration agreement that we entered into with Sanofi in November 2012, or the Sanofi Agreement, which termination was effective on May 8, 2017, we will not receive any further collaboration payments related to the Sanofi Agreement. For a further description of the agreements underlying our collaboration and grant-based revenue, see Notes 2 and 13 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Research and development

Research and development expenses consist of costs incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, including stock-based compensation, an allocation of facilities expenses, overhead expenses, manufacturing process-development and scale-up activities, clinical trial and related clinical manufacturing expenses, fees paid to contract research organizations, or CROs, and investigative sites, payments to partners under our license agreements and other outside expenses. Our research and development costs are often devoted to expanding our programs and are not necessarily allocable to a specific target.

Our research and development expenses consist of external research and development costs, which we track on a program-by-program basis and primarily include contract manufacturing organization, or CMO, and contract research organization, or CRO, related costs, 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. As we expand the clinical development of SEL-212, we expect our research and development expenses to increase. In addition, as a result of the termination of the Sanofi Agreement, which was effective on May 8, 2017, we exercised our right to acquire the development programs under the Sanofi Agreement. The exercise itself did not require the payment of any consideration to Sanofi. We are solely responsible for performing and funding any development and clinical trial activities relating to further development of vaccine candidates that we choose to undertake after the termination date of the Sanofi Agreement. We have incurred a total of $116.2 million in research and development expenses from inception through March 31, 2017, with a majority of the expenses being spent on the development of SEL-212 and a prior nicotine vaccine, and the remainder being spent on our various discovery and preclinical stage product candidate programs and the general expansion of our technology.

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 and duration 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, except percentages):

	Three Months Ended March 31,	
	2017	2016
External research and development expenses:		
SEL-212	$ 4,988	$ 2,182
Discovery and preclinical stage product programs, collectively	817	1,081
Internal research and development expenses	5,239	3,385
Total research and development expenses	$ 11,044	$ 6,648

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. We expect that our general and administrative expenses will increase in future periods, reflecting an expanding infrastructure and increased professional fees associated with being a public reporting company and maintaining and expanding our 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 facility.

Other expense

Other expense for the three months ended March 31, 2017 and 2016 was de minimis.

Foreign currency

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. At March 31, 2017 and December 31, 2016, we maintained cash of $2.3 million and $2.5 million, respectively, in Russian banks, of which $2.2 million and $1.6 million was denominated in U.S. dollars for the periods ended March 31, 2017 and December 31, 2016, respectively. The amounts denominated in U.S. dollars and used in transacting the day to day operations are subject to transaction gains and losses, which are reported as incurred.

Income taxes

As of December 31, 2016, we had net operating loss carryforwards, or NOLs, for federal and state income tax purposes of $102.1 million and $95.6 million, respectively, which expire at various times through 2036. In 2014, our wholly owned subsidiary, Selecta RUS, was granted a “Skolkovo designated” resident status in Russia. As a result, the subsidiary operates as a corporate tax exempt entity, with lower employee and employment taxes. All foreign net operating loss carryforwards have been eliminated. The state NOLs began expiring in 2015 and will continue to expire through 2036. At December 31, 2016, we had available federal and state research and development income tax credits of approximately $2.1 million and $1.5 million respectively, which may be available to reduce future income taxes, if any, at various times through 2036.

Utilization of the NOLs and credits may be subject to a substantial annual limitation due to ownership change limitations provided by Section 382 of the Code. Specifically, this limitation may arise in the event of a cumulative change in our ownership of more than 50% within any three-year period. The amount of the annual limitation is determined based on our value immediately before the ownership change. Subsequent ownership changes may further affect the limitation in future years. The annual limitation may result in the expiration of our net operating losses and credits before we can use them. We have recorded a valuation allowance on all of our deferred tax assets, including our deferred tax assets related to our NOLs and research and development tax credit carryforwards. We plan to undertake a study to analyze and determine if any historical ownership changes have occurred to determine if there are any permanent limitations on our ability to utilize NOLs and other tax attributes in the future. In addition, we may experience ownership changes after this offering as a result of subsequent shifts in our stock ownership. As a result, we are unable to estimate the effect of these limitations, if any, on our ability to utilize NOLs and other tax attributes in the future.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2017 and 2016

Revenue

The following is a comparison of revenue for the three months ended March 31, 2017 and 2016 (in thousands, except percentages):

	Three Months Ended March 31,		Increase (decrease)	
	2017	2016		
	(unaudited)			
Grant revenue	$ 122	$ 1,926	$ (1,804)	(94)%
Collaboration revenue	15	162	(147)	(91)%
Total revenue	$ 137	$ 2,088	$ (1,951)	(93)%

During the three months ended March 31, 2017, total revenue decreased by $2.0 million, or 93%, as compared to the three months ended March 31, 2016. The decrease was primarily the result of reduced revenue from the company's NIDA grant, resulting in a $1.8 million reduction year over year. A decrease in collaboration revenues was the result of the termination of the Sanofi collaboration in November 2016 resulting in a decrease of $0.1 million, as well as a decrease of less than $0.1 million in reduced revenues resulting from the wind down of other collaborations.

Research and development

The following is a comparison of research and development expenses for the three months ended March 31, 2017 and 2016 (in thousands, except percentages):

	Three Months Ended March 31,		Increase (decrease)	
	2017	2016		
	(unaudited)			
Research and development	$ 11,044	$ 6,648	$ 4,396	66%

During the three months ended March 31, 2017, our research and development expenses increased by $4.4 million, or 66%, as compared to the comparable period in 2016, reflecting (i) $2.8 million of external costs as the Company transitioned further into Phase 2 trials for SEL-212, (ii) $0.6 million for lab supplies and external costs associated with the manufacture of SEL-110 and other pipeline projects, (iii) $0.5 million of compensation costs related to headcount growth to support the clinical trial programs and pipeline advancements, (iv) $0.3 million for additional research and development allocations related to facilities and office costs and (v) $0.2 million of stock compensation expense.

General and administrative

The following is a comparison of general and administrative expenses for the three months ended March 31, 2017 and 2016 (in thousands, except percentages):

	Three Months Ended March 31,		Increase	
	2017	2016	(decrease)	
	(unaudited)			
General and administrative	$ 3,875	$ 2,381	$ 1,494	63%

For the three months ended March 31, 2017, our general and administrative expenses increased $1.5 million, or 63%, as compared to the 2016 period, primarily due to (i) $0.6 million related to growth in headcount to support public company filings and control processes, (ii) $0.2 million increase in consulting fees for market research and investor relations, (iii) $0.2 million increase in accounting fees associated with implementing quarterly reviews and filings of our financial statements, (iv) $0.2 million of stock compensation costs, (v) $0.2 million in patent costs driven by the continued increase in the Company's patent inventory and (vii) $0.1 million of other expenses.

Investment income

Investment income increased by $0.1 million during the three months ended March 31, 2017 as compared to the comparable period in 2016. This increase was due to an increase of $34.3 million of investments held by the Company as of March 31, 2017 compared to the holdings as of March 31, 2016.

Foreign currency gain (loss)

We recognized a foreign currency gain of $0.2 million and $0.2 million during the three months ended March 31, 2017 and 2016 respectively, reflecting the fluctuation of the U.S. dollar to the Russian ruble from the beginning to the end of each period.

Interest expense

Interest expense was $0.3 million for each of the three months ended March 31, 2017 and 2016, respectively, representing interest expense and amortization of the carrying costs of our credit facility.

Other income (expense)

Other income (expense) was de minimis for the three months ended March 31, 2017 and 2016.

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, 2017, we had raised an aggregate of $236.5 million to fund our operations, of which $118.5 million was from the sale of preferred stock, $9.9 million was from government grants and $14.3 million was from borrowings under our credit facility, $29.3 million was through our collaborations and license agreements, and $64.5 million in combined net proceeds from our initial public offering in June 2016, and the underwriters' exercise in part of their option to purchase additional shares of our common stock in July 2016.

As of March 31, 2017, our cash equivalents and short term investments were $68.5 million, of which $2.3 million was held by our Russian subsidiary designated solely for use in its operations including $0.1 million of restricted cash. Our Russian subsidiary cash is consolidated for financial reporting purposes.

In addition to our existing cash equivalents and short term investments, we receive research and development funding pursuant to our research grants and collaboration agreements. In November 2016, we received written notice from Sanofi that Sanofi

had elected to terminate in its entirety the Sanofi Agreement. The termination of the Sanofi Agreement was effective on May 8, 2017. Currently, funding from research grants and payments under our remaining collaboration agreements represent our only source of committed external funds.

Indebtedness

In August 2013, we entered into a credit facility with Oxford Finance, LLC, or Oxford, and Pacific Western Bank, as successor in interest to Square 1 Bank, as co-lenders. The credit facility initially provided funding for an aggregate principal amount of up to $7.5 million. The term loan A portion of the facility was funded on the facility's closing date in the aggregate principal amount of $3.0 million. In July 2014, we borrowed the remaining $4.5 million of the available capacity under a term loan B portion of the facility. On December 31, 2015, we expanded the credit facility to a total of $12.0 million, and drew down all available funding at the closing, with the full amount borrowed referred to as the term loan.

The credit facility is secured by substantially all of our personal property other than our intellectual property. The term loan under the credit facility bears interest at an annual rate equal to the greater of (i) 8.0% and (ii) the sum of (a) the 30-day U.S. LIBOR rate five business days prior to the applicable funding date plus (b) 7.68%. We are required to make interest payments through January 1, 2017, or the interest only period. Following the interest only period, all outstanding borrowings under the credit facility will begin amortizing with monthly payments of principal and interest being made over 30 consecutive monthly installments. All loans under the facility mature on July 1, 2019, and include a final payment fee equal to 6.0% of the total amount borrowed under the credit facility. This final payment has been recorded as a discount to the loan balance and is being amortized into interest expense over the life of the loan.

The term loan is prepayable at our option in whole, but not in part, subject to a prepayment fee of 3.0% if the term loan is prepaid prior to the first anniversary of the December 31, 2015 borrowing date, the borrowing date, 2.0% if the terms loans are prepaid between the first and second anniversary of the borrowing date and 1.0% if the term loan is prepaid after the second anniversary of the borrowing date. We are also required to prepay the term loan upon the occurrence of customary events of default set forth in the credit agreement. In addition, the term loan contains a subjective acceleration clause whereby an event of default and immediate acceleration of the borrowings under credit agreement occurs in the event of a material impairment of the perfection or priority of the lenders' lien in the collateral or the value of such collateral, a material adverse change in our business operations or condition (financial or otherwise) or a material impairment of the prospect of repayment of any portion of the obligations.

The credit facility includes affirmative and negative covenants applicable to us and our subsidiaries. The affirmative covenants include, among others, covenants requiring us to (and to cause our subsidiaries to) maintain our legal existence and governmental approvals, deliver certain financial reports, maintain inventory and insurance coverage, maintain unrestricted cash in a control account equal to or greater than the lesser of 105% of all outstanding amounts under the credit facility and 100% of the cash and cash equivalents of our company and our wholly owned subsidiary, Selecta Biosciences Security Corporation, and protect material intellectual property. The negative covenants include, among others, restrictions on us and our subsidiaries transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and allowing a change in control, in each case subject to certain exceptions. Additionally, the credit facility restricts us from making certain payments or transfers to our Russian subsidiary, Selecta RUS, subject to certain exceptions. The credit facility does not include any other financial covenants.

The credit facility also includes events of default, the occurrence and continuation of which provide the co-lenders with the right to exercise remedies against us and the collateral securing the loans under the credit facility, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency and the insolvency of our subsidiaries, the occurrence of a material adverse event, the occurrence of any default under certain other indebtedness, and a final judgment against us in an amount greater than $100,000.

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. Moreover, as a result of the termination of the Sanofi Agreement, which was effective on May 8, 2017, we exercised our right to acquire the

development programs under the Sanofi Agreement. This exercise itself did not require the payment of any consideration to Sanofi. We are solely responsible for performing and funding any development and clinical trial activities relating to further development of vaccine candidates that we choose to undertake after the termination date of the agreement. 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 in connection with our continuing operations.

Based on the current operating plan, we expect that our cash, cash equivalents, short-term investments and restricted cash as of March 31, 2017, will fund our operating expenses and capital expenditure requirements into the middle of 2018. 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. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress in these trials is uncertain. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Our future capital requirements will depend on many factors, including:

- the progress and results of our clinical trials of SEL-212;
- our collaboration agreements remaining in effect, our ability to enter into additional collaboration agreements and our ability to achieve milestones under these agreements;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the number and development requirements of other product candidates that we pursue;
- 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; and
- the extent to which we acquire or in-license other products and technologies.

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 and revenue from license and collaboration arrangements. Except for any obligations of our collaborators to reimburse us for research and development expenses or to make milestone payments under our agreements with them, we do not have any committed external source of liquidity. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

Comparison of the Three Months Ended March 31, 2017 and 2016

The following is a summary of cash flows for the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31,	
	2017	2016
Beginning of the period	$ 58,656	$ 32,337
Net cash used in operating activities	(15,319)	(10,166)
Net cash used in investing activities	(16,532)	(3,555)
Net cash used in financing activities	(292)	(1,677)
Effect of exchange rate changes on cash	124	112
End of the period	$ 26,637	$ 17,051

Net cash used in operating activities

Net cash used in operating activities was $15.3 million for the three months ended March 31, 2017 as compared to $10.2 million for the three months ended March 31, 2016. The increase in net cash used in operating activities of $5.1 million reflects a $7.7 million increase in recorded net loss associated with the increased research and development expenses as we advanced from Phase 1 to Phase 2 trials coupled with (i) $0.3 million in recorded deferred revenues and (ii) a decrease in recorded accounts payable and other liabilities of $0.2 million offset by (i) $1.7 million of restricted cash and other deposits (ii) additional (non-cash) stock-based compensation expense of $0.4 million and (iii) $1.0 million in reduced accounts receivable.

Net cash used in investing activities

Net cash used in investing activities was $16.5 million for the three months ended March 31, 2017, as compared to $3.6 million for the three months ended March 31, 2016. The net change in cash of $13.0 million used in investing activities for the three months ended March 31, 2017 resulted from the purchase of $13.1 million in short term investments offset by a $0.1 million decrease in purchased equipment.

Net cash used in financing activities

Net cash used in financing activities was $0.3 million for the three months ended March 31, 2017 as compared to $1.7 million for the three months ended March 31, 2016. The decrease of $1.4 million used in financing activities is the result of a $1.7 million decrease in cash used in connection with our IPO related activities in 2016 combined with an increase in net cash received of $0.4 million from the exercise of employee stock options offset by the $0.7 million of loan principle payments made during the three months ended March 31, 2017.

The functional currency of our Russian subsidiary is the Russian ruble. The statement of cash flows for our Russian subsidiary is translated using the average translation rate applicable during the period except that all cash and cash equivalents, short term investments and restricted cash at the beginning of the period is translated using the exchange rate as of the beginning balance sheet date, and cash and cash equivalents, short term investments and restricted cash at the end of the period is translated using the exchange rate as of the ending balance sheet date.

Contractual obligations and contingent liabilities

The disclosure of our contractual obligations and commitments was included in our 2016 Annual Report on Form 10-K. There have been no material changes from the contractual commitments and obligations previously disclosed in our 2016 Annual Report on Form 10-K.

OFF-BALANCE SHEET ARRANGEMENTS

As of March 31, 2017, 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

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with United States generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be 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. Actual results may differ from these estimates under different assumptions or conditions.

During the three months ended March 31, 2017, there were no material changes to our critical accounting policies as reported in our 2016 Annual Report on Form 10-K.

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, 2017 and December 31, 2016, we had cash equivalents and short term investments of $68.5 million and $84.1 million, respectively, consisting of non-interest and interest-bearing money market accounts, repurchase agreements, short-term investments of treasuries and government obligations. 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. At March 31, 2017, we held $2.3 million of total cash in Russian banks to support our Russian subsidiary, which includes $2.2 million of cash and cash equivalents and $0.1 million of restricted cash, of which $2.2 million of cash and cash equivalents 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, 2017.

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) during the three months ended March 31, 2017 that have materially affected, or is 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 $15.1 million for the three months ended March 31, 2017 and $36.2 million and $25.2 million for the years ended December 31, 2016 and 2015, respectively. As of March 31, 2017, we had an accumulated deficit of $166.7 million. To date, we have financed our operations primarily through issuances of preferred stock, debt, research grants and a research collaboration. 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. In November 2016 we received written notice from Sanofi that Sanofi had elected to terminate in its entirety our license and research collaboration agreement with Sanofi, or the Sanofi Agreement. As a result of the termination of the Sanofi Agreement, which was effective on May 8, 2017, we will not receive any future payments related to the Sanofi Agreement. We have devoted substantially all of our financial resources and efforts to developing our SVP technology, identifying potential product candidates and conducting preclinical studies and our clinical trials. We are in the early stages of development of our product candidates, and we have not completed development of any SVP 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 SVP technology and discover and develop additional product candidates;
- 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;
- 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 transition to 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 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 U.S. Food and Drug Administration, or 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.

In addition, we have recurring losses and negative cash flows from operations and will require additional capital to fund planned operations. There can be no assurance that we will be able to raise additional capital on reasonable terms, if at all, which could prevent us from continuing 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, 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 research and development programs or any future commercialization efforts.

We believe that our existing cash, cash equivalents and investments, and funding that we expect to receive under our existing collaborations will enable us to fund our operating expenses and capital expenditure requirements into the middle of 2018. 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. Our future capital requirements will depend on many factors, including:

- the progress and results 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. 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 or the commercialization of any product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Revenues from research and development activities in collaboration with Sanofi represented a significant portion of our revenues and the loss of these revenues may adversely affect our business and our liquidity.

Revenues from research and development activities under the Sanofi Agreement were a significant source of revenues in 2016. In November 2016 we received written notice from Sanofi that Sanofi had elected to terminate in its entirety the Sanofi Agreement. The termination of the Sanofi Agreement was effective on May 8, 2017, which was six months from the date of the notice. The loss of revenue derived from research and development activities under the Sanofi Agreement may adversely affect our business and our liquidity. In addition, Sanofi's termination of this agreement could adversely affect our reputation.

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 SVP technology 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. All but one of our product candidates, SEL-212, are still in preclinical development. We completed the patient treatment portion of our Phase 1a clinical trial of pegsiticase, a component of SEL-212, our lead product candidate, but have not yet completed any other clinical trials for SEL-212 or any other product candidates. We initiated our Phase 2 clinical trial of SEL-212 in October 2016, but have not yet 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 and subsidiary's charter 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.

We have a $12.0 million credit facility with Oxford Finance LLC, or Oxford, and Pacific Western Bank, as successor in interest to Square 1 Bank, that is secured by a lien covering substantially all of our personal property, excluding intellectual property. As of March 31, 2017, the outstanding principal balance under the credit facility was $11.3 million. The credit facility contains customary affirmative and negative covenants and events of default applicable to us and our subsidiaries. The affirmative covenants include, among others, covenants requiring us (and us to cause our subsidiaries) to maintain our legal existence and governmental approvals, deliver certain financial reports and notifications, maintain proper books of record and account, timely file and pay tax returns, maintain inventory and insurance coverage, maintain unrestricted cash in a control account equal to or

greater than the lesser of 105% of all outstanding amounts under the credit facility and 100% of the cash and cash equivalents of our company and our wholly-owned subsidiary, Selecta Biosciences Security Corporation, and protect material intellectual property. The negative covenants include, among others, restrictions on us and our subsidiaries transferring collateral, changing businesses, dissolving, liquidating, engaging in mergers or acquisitions, adding new offices or locations, making certain organizational changes, incurring additional indebtedness, encumbering collateral, paying cash dividends or making other distributions, making investments, selling assets, undergoing a change in control, engaging in certain non-ordinary course material transactions with affiliates, and making certain payments or transfers to our subsidiary Selecta (RUS) LLC, or Selecta RUS, in each case subject to certain exceptions. If we default under the credit facility, Oxford, as collateral agent for the lenders, may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse effect as defined under the credit facility, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

In addition, the charter of our subsidiary, Selecta RUS, prohibits distributions to us in violation of Russian law or if, as a result of such distribution, Selecta RUS would be insolvent or its net assets would be less than its charter capital and statutory reserves. Selecta RUS held $2.3 million of total cash in Russian banks as of March 31, 2017, including $2.2 million of cash and cash equivalents and $0.1 million of restricted cash.

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 which 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 this 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.

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

We are very early in our clinical development efforts and may not be successful in our efforts to use our SVP technology to build a pipeline of product candidates and develop marketable drugs.

We are primarily using our SVP technology to improve and enable biologics that treat rare and serious diseases, with an initial focus on developing SEL-212 for the treatment of refractory and chronic tophaceous gout. While we believe our preclinical and clinical data to date have validated our technology to a degree, we are at an early stage of development and our technology has not yet led to, and may never lead to, approvable or marketable drugs. We are developing additional product candidates to address the problem of anti-drug antibodies, or ADAs, and immunogenicity in biologic therapy and to treat cancer and other infectious diseases and conditions that are not responsive to currently available vaccines. We may have problems applying our technologies to these other areas, and our new product candidates may not be as effective as our initial product candidates. Even if we are successful in identifying additional 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:

- completion of preclinical studies and clinical trials with positive results;

- 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 entering 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.

Our product candidates are based on our SVP technology, which is an unproven approach designed to induce antigen-specific immune tolerance to biologic drugs or stimulate the immune system.

All of our product candidates are derived from our SVP technology, which is an unproven approach to inducing antigen-specific tolerance or stimulating the immune system. In addition, SEL-212, our lead product candidate, uses pegsiticase, a biologic, which we source from Shenyang Sunshine Pharmaceutical Co., Ltd., or 3SBio, in China. We have not, nor to our knowledge has any other company, received FDA approval for a therapeutic based on SVP or for a biologic product manufactured in China. In addition, we may use biologics other than pegsiticase with our SVP technology.

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 SVP therapeutics, they may have 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 SVP 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 for SEL-212 or another product and a pre-approval inspection by the FDA of the facilities of 3SBio or any other manufacturer of biologics 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 provider 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 SVP technology to antigen specific immune tolerance for gene therapy involving gene augmentation, replacement or editing. So far no gene therapy product has been approved for a genetic disease in the United States and only two such products have been approved in the European Union.

Our future success depends in part on our successful development of viable gene therapy product candidates utilizing SVP technology. 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 requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory authorities, and the criteria these regulators use to determine the safety and efficacy of a product candidate, vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. 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.

Sponsors of certain clinical studies of cells containing recombinant or synthetic nucleic acid molecules, including human gene transfer studies, must comply with the National Institutes of Health's, or NIH's, Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines"). The NIH Guidelines set forth the principles and requirements for NIH and institutional oversight of research with recombinant or synthetic nucleic acid molecules, including the standards for investigators and institutions to follow to ensure the safe handling and containment of such molecules. In April 2016, modifications to the NIH Guidelines went into effect, pursuant to which only a subset of human gene transfer protocols are subject to review by the NIH Recombinant DNA Advisory Committee, or RAC, a federal advisory committee that provides recommendations regarding research involving recombinant or synthetic nucleic acid molecules. Specifically, under the modified NIH Guidelines, RAC review of the protocol will be required only in exceptional cases where (a) an oversight body such as an Institutional Biosafety Committee, or IBC, which provides local review and oversight of research utilizing recombinant or synthetic nucleic acid molecules, or an IRB determines that the protocol would significantly benefit from RAC review, and (b) the protocol (i) uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience and thus presents an unknown risk, and/or (ii) relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value, and/or (iii) involves a proposed vector, gene construct, or method of delivery associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously. The RAC review proceedings are public, and reports are posted publicly to the website for the NIH's Office of Biotechnology Activities. Although compliance with the NIH Guidelines is mandatory for research 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. Independent of RAC review, the NIH Guidelines also require all human gene transfer protocols subject to the NIH Guidelines to be registered with NIH, with limited exemptions. A study subject to the NIH Guidelines may not begin until the IBC approves the protocol, and the IBC cannot approve the protocol until confirmation from the NIH that such registration is complete. In the event that RAC review is warranted, the protocol registration process cannot be completed until RAC review has taken place.

Although the FDA decides whether individual gene therapy protocols may proceed, the RAC public review process, if undertaken, can delay the initiation of a clinical trial. Conversely, the FDA can delay or prevent the initiation of a clinical study even if the RAC has provided a favorable review the study is not subject to in-depth, public RAC review. In addition, clinical trials involving a gene therapy product candidate must be authorized by an applicable IRB and an IBC, which provides oversight of recombinant DNA research.

In 2012, the European Medicines Agency approved a gene therapy product called Glybera, which is the first gene therapy product approved by regulatory authorities anywhere in the Western world. GlaxoSmithKline plc's Strimvelis and uniQure N.V.'s Glybera, are the only two gene therapy products for a genetic disease that have received marketing authorization from the European Commission. We cannot predict how long it will take or how much it will cost to 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. Regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. Adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to modify the requirements for testing or approval of any of our product candidates. Similarly, 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.

As we advance any gene therapy product candidate, 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 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. 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.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates and are currently principally focused on SEL-212. As a result, we may forego or delay our pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource-allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may not pursue such product candidate, or we may relinquish valuable rights to that product candidate through future collaboration, licensing or other arrangements, in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

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, is currently being evaluated in a Phase 1/2 clinical program that includes a Phase 1a and Phase 1b clinical trial. We initiated the Phase 2 clinical trial in October 2016. Aside from SEL-212, 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. 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.

We had a prior SVP-nicotine product candidate, which entered clinical development after a promising preclinical program. However, results from a Phase 1 clinical trial conducted in smokers and non-smokers with this product candidate showed that nicotine-specific antibodies were induced at sub-therapeutic levels. In this regard, 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. For example, multiple serious adverse events, or SAEs, have occurred in connection with SEL-212's Phase 1/2 clinical program and additional SAEs or similar events could occur during the course of our development of SEL-212 or other product candidates, which could be materially adverse to the success of these programs. 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 our 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 successfully gain approval to market SEL-212 or any of our other product candidates in the United States or other countries. 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. In some situations, evidence from a Phase 2 trial and a Phase 3 trial or from a single Phase 3 trial can be sufficient for FDA approval, such as in cases where the trial or trials provide highly reliable and statistically strong evidence of an important clinical benefit. We expect to conduct more than one Phase 3 trial for SEL-212 in the refractory gout indication in order to gain approval. 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, for various reasons including noncompliance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues such as a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions;

- 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;

- 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 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, 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.

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 50,000 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.

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.

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

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, adverse event reporting, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States, and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing that product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval for, or prevent or limit the commercial use of, such product candidates.

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. 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. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Although the FDA and other regulatory authorities have approved nanotechnology-based therapeutics in the past, they are monitoring whether nanotechnology-based therapeutics pose any specific health and human safety risks. While they have not issued any regulations to date, it is possible that the FDA and other regulatory authorities could issue regulations in the future regarding nanotechnology-based therapeutics that could adversely affect our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

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, although we have not yet applied for or obtained such designation. 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 annually 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 biologics license application, or 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. Our competitors, including Horizon Pharma plc, may seek orphan drug status for the same biologic or drug for the same indication as our product candidates. In this regard, Krystexxa® (pegloticase) previously obtained orphan drug status for chronic refractory gout, although the exclusivity period has lapsed. However, Krystexxa could in the future obtain orphan drug status for chronic tophaceous gout, an indication we plan to pursue.

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.

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 recently 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.

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. The drug-related side effects could 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; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could 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 sole supplier of pegsiticase 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, which could delay, prevent or impair our development or commercialization efforts.

We obtain the biologic pegsiticase, a component of SEL-212, our lead product candidate, from 3SBio in China. Under our license agreement with 3SBio, we are not permitted to manufacture pegsiticase and, as a result, expect to continue to rely on 3SBio for our supply of pegsiticase for the foreseeable future. Although we intend to seek to secure a backup supplier outside of China, we cannot assure you that we will be able to do so on acceptable terms, or at all.

Any disruption in production or inability of 3SBio in China to produce adequate quantities of pegsiticase to meet our needs, whether as a result of a natural disaster 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 of the Chinese government, political unrest or unstable economic conditions in China. 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 pegsiticase 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 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, our 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.

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.

Third-party manufacturers may not be able to comply with current Good Manufacturing Practices, or cGMP, regulations or similar regulatory requirements outside the United States. 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. If our CMOs are is unable to comply with cGMP regulations or if the FDA does not approve their facilities upon a pre-approval inspection, our product candidate may not be approved or may be delayed in obtaining approval. In addition, there are a limited number of manufacturers that operate under cGMP regulations and 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 SVP technology. 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, 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 SVP technology, and such collaborations and licensing arrangements currently represent a significant portion of our product pipeline. Certain of our collaborations also provide us with important funding for some of our development programs and we expect to receive additional funding under collaborations in the future. 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 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;

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

- we currently have, and in the future may have, a limited number of collaborations and the loss of, or a disruption in our relationship with, any one or more of such collaborators may could harm our business.

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. For example, in November 2016, we received written notice from Sanofi that Sanofi had elected to terminate in its entirety the Sanofi Agreement, which was effective on May 8, 2017, and as a result we will not receive any future payments related in the Sanofi Agreement. If we do not receive the funding we expect under these agreements, our continued development of our SVP technology 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 report 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.

We may in the future collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. 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 1/2 clinical trial of SEL-212.

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 regulatory standards, commonly referred to as good clinical practice, or 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. 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 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 also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of such product candidates, producing additional losses and depriving us of potential product revenue.

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 SVP product candidates for preclinical use. We rely on the scale equipment 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. We currently intend to develop our manufacturing capacity in part by expanding our current facility or building additional facilities. This activity will require substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. 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. 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 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.

The research, development and commercialization of our product candidates depends upon our maintaining strong working relationships with the medical community. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and commercialization of our product candidates. If we are unable to maintain our strong relationships with these professionals and continue to receive their advice and input, our products and product candidates may not be developed and marketed in line with such professionals' needs and expectations. Accordingly, the development and commercialization of our products and product candidates could suffer, which could have a material adverse effect on our business and results of operations.

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.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies for our product candidates.

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.

Our product candidates, if approved, may fail to offer material commercial advantages over other treatments.

The therapeutic advantages that we believe may be offered by our product candidates, if approved, may fail to materialize, or may not be recognized by physicians, hospital administrators, patients, caregivers, healthcare payors and others in the medical community. For example, physicians may be skeptical to use SEL-212 for the treatment of refractory and chronic tophaceous gout. Patients may also be skeptical of using a product based on our SVP technology. The therapeutic advantages of our product candidates may not be sufficient to either move market share to us or expand the population of patients using our treatments.

We face substantial competition, 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 protect our products and technologies by filing patent applications in major pharmaceutical markets as well as leading emerging growth markets. We have either been granted patents or filed patent applications covering our SVP technology, our immune tolerance programs and our SEL-212 product candidate. To the extent that our product candidates and technologies are protected by such intellectual property rights, they will be protected from competition for the life of the applicable patents. However, we are aware of a number of large pharmaceutical and biotechnology companies, including Sanofi, Horizon Pharma plc, Pfizer Inc., and Merck & Co., Inc., 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 microbiome therapeutic which 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.

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 harm our business.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. 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. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. 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. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. 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. 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.

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.

We maintain general liability, product liability and umbrella liability insurance. Our existing insurance coverage may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage as our risks of exposure increase, which, for example, would happen if and when we begin selling any product candidate that receives marketing approval. In addition, certain types of insurance coverage are becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of any approved product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

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.

Although we are not currently marketing our product candidates, including to healthcare providers, if and when we do, our relationships with healthcare providers, customers and third-party payors may 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.

Healthcare providers, customers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our future arrangements with third party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations may 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 federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act);

- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties, through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- 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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- 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 manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report 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) and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners; and

- analogous state and foreign 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; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 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. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, some of whom will recommend, purchase and/or prescribe our product candidates, if approved, could be subject to challenge under one or more of such laws.

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, in the United States, in 2010, President Obama signed into law 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;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- 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.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since taking office, President Trump has continued to support the repeal of all or portions of the ACA. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the ACA and permits such legislation to pass with a majority vote in the Senate. President Trump has also recently issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the ACA to the maximum extent permitted by law. There is still uncertainty with

respect to the impact the current presidential administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

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 in 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.

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. For example, the 21st Century Cures Act changed the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain products. Individual states in the United States have become increasingly aggressive in implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Any product candidate for which we obtain marketing approval 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, when and if any of them are approved.

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 ensure 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, problems with manufacturers or manufacturing processes, or failure to comply with regulatory requirements, 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. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. 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 presidential administration may impact our business and industry. Namely, the current presidential 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. 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.

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 harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, 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. 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 candidates. 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 harmed, possibly materially.

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 harm 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, such as trichloroethylene. 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.

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.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to adequately protect our proprietary technology, or obtain and maintain issued patents which 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. Prosecution of our patent portfolio is at a very early stage, and we are just beginning to 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. As those deadlines come due, 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.

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 currently own nine issued U.S. patents. Although we have patent applications pending, we cannot provide any assurances that any of these pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will 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, should they issue.

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, given the early stage of prosecution of our portfolio, it may be some time before we understand how patent offices react 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.

Intellectual property rights do not prevent all potential threats to competitive advantages we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage.

The following examples are illustrative:

- others may be able to make compounds that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;

- we or any of our licensors or collaborators might not have been the first to make the inventions covered by the patents or pending patent applications that we own or have exclusively licensed;

- we or any of our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- the prosecution of our pending patent applications may not result in granted patents;

- granted patents that we own or have licensed may not cover our products or may be held not infringed, invalid or unenforceable, as a result of legal challenges by our competitors;

- with respect to granted patents that we own or have licensed, especially patents that we either acquire or in-license, if certain information was withheld from or misrepresented to the patent examiner, such patents might be held to be unenforceable;

- patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product candidates;

- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates;

- we may not develop additional proprietary technologies that are patentable;

- the patents of others may have an adverse effect on our business; and

- we may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our product candidates.

We 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.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline molecules. We may incorrectly determine that our product candidates are not covered by a third-party patent.

Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of an originator product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect which may negatively impact our ability to develop and market our product candidates.

Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

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.

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

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that one of our patents is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could materially and adversely affect us and our collaborators.

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 significantly harmed.

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. If we were to challenge the validity of an issued U.S. patent in court, such as an issued U.S. patent of potential relevance to some of our product candidates or methods of use, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity.

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. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our product candidates. 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.

In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign or rename some or all of our product candidates, or other brands to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their

greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Any of these risks coming to fruition could harm our business.

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.

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.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, contractors and advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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.

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 need to obtain FDA approval for any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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, including Russia. 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 or Russia. 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.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

If our ability to obtain and, if obtained, enforce our patents to stop infringing activities is inadequate, third parties 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. Accordingly, our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

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.

We may face competition from biosimilars, which may have a material adverse effect on the future commercial prospects of our product candidates.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or biosimilar, to or "interchangeable" with an FDA-approved biological product. This new pathway could allow competitors to reference data from innovative biological products 12 years after the time of approval of the innovative biological product. This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data, and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator's application to support the biosimilar product's approval. In his proposed budget for fiscal year 2017, President Obama proposed to cut this 12-year period of exclusivity down to seven years. He also proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as "evergreening." While President Obama has proposed these measures in previous years without success, it is possible that Congress may take these or other measures to reduce or eliminate periods of exclusivity. The Biologics Price Competition and Innovation Act of 2009 is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. Although it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

RISKS RELATED TO EMPLOYEE MATTERS AND MANAGING GROWTH AND OTHER RISKS RELATED TO OUR BUSINESS

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

We are highly dependent on Werner Cautreels, 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. Cautreels and certain of our 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 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. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

A variety of risks associated with operating in Russia and internationally could adversely affect our business.

In addition to our U.S. operations, we have operations in Russia through our wholly owned subsidiary, Selecta RUS, and may expand international operations in the future, including by conducting clinical trials of our product candidates in countries outside the United States, including Russia and Belgium. We face risks associated with our operations in Russia, 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 in Russia and 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, 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;
- 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.

Sanctions relating to Russia, and Russia's response to those sanctions, could adversely affect our business.

Due to Russia's intervention in Ukraine, the United States and the European Union have imposed sanctions on certain individuals, companies and financial institutions in Russia and additional sanctions could be forthcoming. In response, Russia has imposed entry bans on certain U.S. lawmakers and officials. If the United States and European Union were to impose additional sanctions on Russian businesses, or if Russia were to take retaliatory action against U.S. companies operating in Russia, our research and development activities with respect to our program for HPV-associated cancers currently conducted by Selecta RUS, or any other research and development activities with respect to our other immune stimulation programs conducted by Selecta RUS in the future, could be adversely affected.

Our business and operations would suffer in the event of system failures.

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.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could expose us to liability and hurt our reputation.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include

intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA laws and regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (2) manufacturing standards, (3) healthcare fraud and abuse laws, or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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 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 35% of our outstanding voting stock as of March 31, 2017. 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. Approximately 12.9 million shares of our common stock became eligible to be sold into the market on December 19, 2016, unless held by one of our affiliates, in which case the resale of those securities is subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended, or Rule 144. Moreover, holders of an aggregate of approximately 12.3 million shares of our common stock as of the completion of the initial public offering of our common stock on June 27, 2016 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 and the lock-up agreements.

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 $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations";
- 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. 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 we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the sale of any shares of our common stock at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities

exercisable for or convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

For instance, on December 2, 2016 we entered into a stock purchase agreement, or the Spark SPA, with Spark Therapeutics, Inc., or Spark, in conjunction with a license and option agreement with Spark. Pursuant to the Spark SPA, we issued and sold 197,238 shares of our common stock to Spark for gross proceeds of $5.0 million, which purchase price per share represented a 115.0% premium to the average of the daily volume-weighted average price, or VWAP, of the common stock during the thirty consecutive calendar days ending on, and including, December 1, 2016. Spark has also agreed to make two additional investments of $5.0 million in our common stock, the first between May 1, 2017 and June 1, 2017, and the second between October 1, 2017 and November 1, 2017, in each case at a 115.0% premium, subject to the terms and conditions of the Spark SPA.

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 new 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.

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be 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. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources, engage outside consultants, developed a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 target animal studies 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. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

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.

Our restated certificate of incorporation provides 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 between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

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. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation described above.

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 inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Because we do not expect paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, our credit facility with Oxford and Pacific Western Bank currently prohibits us from paying cash dividends on our equity securities, and any future debt agreements may likewise preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Registered Securities

On June 21, 2016, we completed the initial public offering of our common stock and issued and sold 5,000,000 shares of our common stock at a public offering price of $14.00 per share.

The offer and sale of all of the shares in the offering was registered under the Securities Act pursuant to a registration on Form S-1 (File No. 333-211555), as amended, which was declared effective by the Securities and Exchange Commission (the "SEC") on June 21, 2016, and a registration statement on Form S-1MEF (File No. 333-212162), which was automatically effective upon filing with the SEC on June 21, 2016. On July 25, 2016, we closed the underwriters' over-allotment option, and we sold 289,633 shares at a price to the public of $14.00 per share.

The net proceeds of approximately $64.5 million from our initial public offering have been invested in short-term, investment-grade, interest-bearing instruments and U.S. government securities. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus, dated June 21, 2016, filed with the SEC pursuant to Rule 424(b) relating to our Registration Statement on Form S-1.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

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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 11, 2017

By: /s/ Werner Cautreels, Ph.D.

Werner Cautreels, Ph.D.

President and Chief Executive Officer, and Director

(Principal Executive Officer)

Date: May 11, 2017

By: /s/ David Siewers

David Siewers

Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)

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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†	Patent License Agreement, entered into as of April 27, 2017, by and between the U.S. Department of Health and Human Services, as represented by The National Cancer Institute an Institute or Center of the National Institutes of Health and the Registrant					*
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	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

* Filed herewith.

** Furnished herewith.

† Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.

CERTAIN MATERIAL (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT - *EXCLUSIVE*

This **Agreement** is based on the model Patent License Exclusive Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the **PHS** within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by

The National Cancer Institute

an Institute or Center (hereinafter referred to as the "**IC**") of the

NIH

and

Selecta Biosciences,

hereinafter referred to as the "**Licensee**",

having offices at 480 Arsenal Street, Building One, Watertown, Massachusetts, 02472,

created and operating under the laws of Delaware.

Tax ID No.: 26-1622110

For the **IC** internal use only:

License Number:

License Application Number: A-035-2017

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

Group A (Exclusive Rights)

[***]

Group B (Non-exclusive Rights)

[***]

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention): None

Public Benefit(s): The development of new cancer therapeutics can alleviate pain and suffering for many members of the public who are afflicted with certain cancers, which is collectively the second leading cause of death in the United States.

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options).

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

The **IC** and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the **IC** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **IC** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **IC**.

1.3 The Secretary of **HHS** has delegated to the **IC** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.4 The **IC** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

1.6 All materials required by **Licensee** from **NIH** for the performance of the **Commercial Development Plan** will be obtained by the **Licensee** under a Cooperative Research and Development Agreement (**"CRADA"**). Therefore, no materials will be distributed under the terms and conditions of this **Agreement**. If additional materials are required, they will either be obtained by request and amendment of the **CRADA**, or by request and amendment of this **Agreement**.

2. DEFINITIONS

2.1 **Additional License**" means an exclusive or non-exclusive license that includes the **Licensed Patent Rights** and is granted to a **Third Party** who is responsible for paying a share of patent expenses, and wherein the exclusive or non-exclusive license has a **Licensed Field(s) of Use** directed to therapeutic applications. **Additional License** specifically excludes exclusive or non-exclusive licenses directed solely to evaluation, internal research use or commercialization of research reagents.

2.2 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.3 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.4 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.5 "**Commercially Reasonable Efforts**" means the level of efforts and resources consistent with the efforts and resources normally used by a similarly situated biotechnology company in the exercise of commercially reasonable business discretion relating to the manufacture, development or commercialization of a biopharmaceutical product with similar product characteristics that is of similar market potential at a similar stage of development or commercialization, taking into account issues of efficacy, safety, product profile, anticipated or approved labeling, present and future market potential, competitive market conditions, the proprietary position of the drug substance or product, the regulatory structure involved, and other key technical, legal, scientific, medical or commercial factors, and the profitability of the product.

2.6 "**CRADA"** means a Cooperative Research and Development Agreement.

2.7 "**FDA**" means the Food and Drug Administration.

2.8 "**First Commercial Sale**" means **[***]** by or on behalf of the **Licensee** or its sublicensees of the **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee** or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.9 "**Government**" means the Government of the United States of America.

2.10 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.11 "**Licensed Patent Rights**" shall mean:

a. Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;

b. to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.11(a):

i. continuations-in-part of 2.11(a);

ii. all divisions and continuations of these continuations-in-part;

iii. all patents issuing from these continuations-in-part, divisions, and continuations;

iv. priority patent application(s) of 2.11(a); and

v. any reissues, reexaminations, and extensions of these patents;

c. to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.11(a): all counterpart foreign and U.S. patent applications and patents to 2.11(a) and 2.11(b), including those listed in Appendix A; and

d. **Licensed Patent Rights** shall **[***]**.

2.12 "**Licensed Processes**" means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.13 "**Licensed Products**" means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.14 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.15 "**Net Sales**" means the total gross receipts from **Third Parties** for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of the **Licensee**, its **Affiliates** or its sublicensees, and from leasing, renting, or otherwise making the **Licensed Products** available to **Third Parties** without sale or other dispositions, whether invoiced or not, less **[***]**. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, or sublicensees, and on its payroll, or for the cost of collections. Notwithstanding the foregoing, the following will not be included in **Net Sales**: (a) samples of **Licensed Products** used to promote additional **Net Sales**, in amounts consistent with normal business practices of **Licensee** and (b) disposal or use of **Licensed Products** in clinical studies or under compassionate use, patient assistance, named patient use, test marketing programs or non-registrational studies or other similar programs or studies where the **Licensed Product** is supplied without charge or at the actual manufacturing cost thereof.

2.16 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

2.17 "**Pro Rata Share**" means one of the following:

a. in instances where the **Additional License(s)** granted by **IC** recover a pre-determined percentage of patent costs, one hundred percent (100%) of patent prosecution costs minus the percentage of patent prosecution costs recovered by the **Additional License(s)** which recover a pre-determined percentage of patent costs. For example, if **IC** has granted an **Additional License** which recovers twenty percent (20%) of patent prosecution costs, then the **Pro Rata Share** would be one hundred percent (100%) minus twenty percent (20%), or eighty percent (80%);

b. in instances where the **Additional Licenses** granted by **IC** recover a full **Pro Rata Share** of patent prosecution costs, one (1) minus the value derived from the number of **Additional Licenses** granted by **IC** which recover a full **Pro Rata Share** of patent prosecution costs divided by the total number of licenses granted by **IC** which recover a full **Pro Rata Share** of patent prosecution costs. For example, if **IC** has granted 4 **Additional Licenses** which recover a full **Pro Rata Share** of patent prosecution costs, then the **Pro Rata Share** would be, one (1) minus [four (4) divided by five (5)], or one fifth (1/5); or

c. in instances where the **Additional Licenses** are granted according to the definition of both 2.17(a) and 2.17(b), the **Pro Rata Share** paid by **Licensee** will be the value derived from the **Pro Rata Share** as determined under paragraph 2.17(a) multiplied by the value derived from the **Pro Rata Share** as determined under paragraph 2.17(b). For example, if two (2) **Additional Licenses** are granted wherein one (1) **Additional License** recovers twenty percent (20%) of patent prosecution costs and one (1) **Additional License** recovers a full **Pro Rata Share** of patent prosecution costs, the **Pro Rata Share** would be (one hundred percent (100%) minus twenty percent (20%)) multiplied by (one (1) minus (one (1) divided by two (2))), or eighty percent (80%) multiplied by one half (1/2), equaling forty percent (40%).

2.18 "**Research License**" means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or the **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

2.19 "**Third Party**" means any entity other than (i) the **NIH** or (ii) **Licensee**, its **Affiliates** or its sublicensses.

3. GRANT OF RIGHTS

3.1 The **IC** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license to **Group A** of the **Licensed Patent Rights** and a non-exclusive license to **Group B** of the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Process(es)** in the **Licensed Fields of Use**.

3.2 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **IC** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, **[***]** and which shall not be unreasonably withheld, the **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**. With respect to any proposed sublicense agreement, if the **IC** does not provide the Licensee with written rejection thereof within **[***]**, the **IC** shall be deemed to have given its approval of such sublicense agreement and the **Licensee** shall have the right to enter into such sublicense agreement.

4.2 The **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to the **IC** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. The **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **IC**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **IC** approval and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

4.4 The **Licensee** agrees to **[***]**. To the extent permitted by law, the **IC** agrees to **[***]**.

4.5 The **Licensee** may enter into sublicensing agreements under **Licensed Patent Rights** with **Affiliates** of **Licensee**, and Paragraphs 4.1 and 4.4 of the **Agreement** and Paragraph V in **Appendix C** of the **Agreement** shall not apply to such **Affiliate** sublicense; provided that **Licensee** shall notify **IC** in writing of the **Affiliate** that sublicenses any **Licensed Patent Rights** within **[***]** of effectiveness of each sublicense.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 a. the **IC** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **IC** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **IC** research use; and

b.in the event that the **Licensed Patent Rights** are Subject Inventions made under **CRADA**, the **Licensee** grants to the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice the **Licensed Patent Rights** or have the **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. **[***]**.

5.2 The **Licensee** agrees that products used or sold in the United States embodying the **Licensed Products** or produced through use of the **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **IC**.

5.3 The **Licensee** acknowledges that the **IC** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee [***]** requests for a **Research License** from future collaborators with the **IC** when acquiring these rights is necessary in order to make a **CRADA** project feasible. The **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

a. In addition to the reserved license of Paragraph 5.1, the **IC** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, the **IC** shall consult with the **Licensee** and **[***]** any objections or comments of the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and

a. In exceptional circumstances, and in the event that the **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:

i. the action is necessary to meet health or safety needs that are not reasonably satisfied by the **Licensee**;

ii. the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or

iii. the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B);

b. the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).; and

c. The **IC** acknowledges and agrees that a **Research License** or other right granted pursuant to this Paragraph 5.3 shall only pertain to the **Licensed Patent Rights** and shall not include a right or license to any patent or other intellectual property right solely owned or solely controlled by **Licensee** or its **Affiliates** other than the **Licensed Patent Rights**. Without limiting the foregoing, except as expressly provided herein, nothing contained in this **Agreement** shall be construed as granting, by implication, estoppel or otherwise, any licenses or rights under any patents or other intellectual property rights other than the **Licensed Patent Rights**.

6. ROYALTIES AND REIMBURSEMENT

6.1 The **Licensee** agrees to pay the **IC** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 The **Licensee** agrees to pay the **IC** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 The **Licensee** agrees to pay the **IC** earned royalties as set forth in Appendix C.

6.4 The **Licensee** agrees to pay the **IC** benchmark royalties as set forth in Appendix C.

6.5 The **Licensee** agrees to pay the **IC** sublicensing royalties as set forth in Appendix C.

6.6 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

a. the application has been abandoned and not continued;

b. the patent expires or irrevocably lapses, or

c. the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.8 On sales of the **Licensed Products** made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **IC** prior to the effective date of this **Agreement**, the **Licensee** shall pay the **IC**, as an additional royalty, within **[***]** of the **IC's** submission of a statement and request for payment to the **Licensee**, an amount equivalent to these unreimbursed expenses previously paid by the **IC**.

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **IC** on or after the effective date of this **Agreement**, the **IC**, at its sole option, may require the **Licensee**:

a. to pay the **IC [***]**, within **[***]** of the **IC's** submission of a statement and request for payment, a royalty amount equivalent to a **Pro Rata Share** of these unreimbursed expenses paid during the previous calendar year(s);

b. to pay a **Pro Rata Share** of these unreimbursed expenses directly to the law firm employed by the **IC** to handle these functions. However, in this event, the **IC** and not the **Licensee** shall be the client of the law firm; or

c. in limited circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the **IC** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 The **IC** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **IC** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. The **Licensee** agrees that all information provided by the **IC** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.12 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon **[***]** written notice to the **IC** and owe no payment obligation under Paragraph 6.10 for patent-related expenses paid in that country after **[***]** of the effective date of the written notice.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 Except as otherwise provided in this Article 7, the **IC** agrees to take responsibility for, but to consult with, the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall furnish copies of relevant patent-related documents to the **Licensee**.

7.2 Upon the **IC's** written request, the **Licensee** shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all patent-related documents to the **IC**. In this event, the **Licensee** shall, **[***]**, select registered patent attorneys or patent agents to provide these services on behalf of the **Licensee** and the **IC**. The **IC** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **Licensee** and its attorneys or agents shall consult with the **IC** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** and shall provide the **IC** sufficient opportunity to comment on any document that the **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.3 At any time, the **IC** may provide the **Licensee** with written notice that the **IC** wishes to assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**. If the **IC** elects to reassume these responsibilities, the **Licensee** agrees to cooperate fully with the **IC**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and to provide the **IC** with complete copies of any and all documents or other materials that the **IC** deems necessary to undertake such responsibilities. **[***]**

7.4 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the **Licensed Patent Rights**, **[***]**.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **IC**. These records shall be retained for at least **[***]** following a given reporting period and shall be available during normal business hours for inspection, at the expense of the **IC**, by an accountant or other designated auditor selected by the **IC** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the **IC** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of **[***]** for any **[***]** period, then the **Licensee** shall reimburse the **IC** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within **[***]** of the date the **IC** provides to the **Licensee** notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **IC** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within **[***]** after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacture and status of sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The **IC** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for these differences. In the annual report, the **Licensee** may propose amendments to the **Commercial Development Plan**, **[***]**. The **Licensee** agrees to provide any additional information reasonably required by the **IC** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **IC**. The **IC** **[***]** of any request of the **Licensee** to extend the time periods of this schedule **[***]**. The **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of the **IC** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.

9.3 The **Licensee** shall report to the **IC** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within **[***]** of such occurrences.

9.4 The **Licensee** shall submit to the **IC**, within **[***]** after each **[***]**, a royalty report, as described in the example in Appendix F, setting forth for the preceding **[***]** the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **IC** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.15 to determine **Net Sales** made under Article 6 to determine royalties due. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.

9.5 The **Licensee** agrees to forward **[***]** to the **IC** a copy of these reports received by the **Licensee** from its sublicensees during the preceding **[***]** as shall be pertinent to a royalty accounting to the **IC** by the **Licensee** for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the **[***]**. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to the **IC** at its address for **Agreement** Notices indicated on the Signature Page.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

9.7 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments.

9.8 Additional royalties may be assessed by the **IC** on any payment that is more than **[***]** overdue at the rate of **[***]**. This **[***]** rate may be **[***]**. The payment of any additional royalties shall not prevent the **IC** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **IC** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **IC** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The **Licensee** shall use **Commercially Reasonable Efforts** to bring the **Licensed Products** and the **Licensed Processes** to **Practical Application** to perform the activities set forth in the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D. The efforts of a sublicensee or **Affiliate** shall be considered the efforts of the **Licensee**.

10.2 Upon the **First Commercial Sale**, until the expiration or termination of this **Agreement**, the **Licensee** shall use **Commercially Reasonable Efforts** to make the **Licensed Products** and the **Licensed Processes** reasonably accessible to the United States public.

10.3 The **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of the **Licensed Products** or materials produced through the use of the **Licensed Processes** available to patient assistance programs.

10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 The **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or the **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 The **IC** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.

11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **Licensee** may:

a. bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

b. in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

c. settle any claim or suit for infringement of the **Licensed Patent Rights [***]**; and

d. if the **Licensee** desires to initiate a suit for patent infringement, the **Licensee** shall notify the **IC** in writing. If the **IC** does not notify the **Licensee** of its intent to pursue legal action within **[***]**, the **Licensee** shall be free to initiate suit. The **IC** shall have a continuing right to intervene in the suit. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit, the **Licensee** shall **[***]**. In all cases, the **Licensee** agrees to keep the **IC** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **IC** and **[***]**.

11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against the **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29 or other statutes, the **Licensee** may:

a. defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;

b. in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and

c. settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights-[***]** and shall have a continuing right to intervene in the suit; and

d. if the **IC** does not notify the **Licensee** of its intent to respond to the legal action within **[***]**, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall **[***]**. If the **Licensee** elects not to defend against the declaratory judgment action, the **IC**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **IC** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **IC** and **[***]**.

11.4 In any action under Paragraphs 11.2 or 11.3 **[***]**. The value of any recovery made by the **Licensee** through court judgment or settlement shall, **[***]**.

11.5 The **IC** shall cooperate fully with the **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. The **IC** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by the **Licensee**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The **IC** offers no warranties other than those specified in Article 1.

12.2 The **IC** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 THE **IC** MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 The **IC** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 The **Licensee** shall indemnify and hold the **IC**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

a. the use by or on behalf of the **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights**; or

b. the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, the **IC** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, the **Licensee** shall immediately notify the **IC** in writing.

13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any country or territory by giving the **IC** sixty (60) days written notice to that effect.

13.5 The **IC** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the **IC** determines that the **Licensee**:

a. is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **IC's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;

b. has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

c. has willfully made a false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;

d. has committed a material breach of a covenant or agreement contained in this **Agreement**;

e. is not keeping the **Licensed Products** or the **Licensed Processes** reasonably available to the public after commercial use commences;

f. cannot reasonably satisfy unmet health and safety needs; or
g. cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.

13.6 In making the determination referenced in Paragraph 13.5, the **IC** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **IC** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **IC's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **IC's** concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the **IC's** satisfaction, the **IC** may terminate this **Agreement**.

13.7 When the public health and safety so require, and after written notice to the **Licensee** providing the **Licensee** a **[***]** opportunity to respond, the **IC** shall have the right to require the **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless the **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. The **IC** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the **Licensee**.

13.8 The **IC** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

13.9 Within **[***]** of receipt of written notice of the **IC's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **IC** official or designee. The decision of the designated **IC** official or designee shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be accessible.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

13.10 Within **[***]** of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the **IC** shall **[***]**. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with the **IC** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **IC** or provide the **IC** with certification of the destruction thereof. The **Licensee** may not be granted additional **IC** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by the **Licensee**.

14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, the **Licensed Products** and the **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **IC**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **IC** approves a proposed assignment, the **Licensee** shall **[***]**.

14.8 The **Licensee** agrees in its use of any **IC**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying the **IC**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **IC** of research involving human subjects or clinical trials outside of the United States shall be given no later than **[***]** prior to commencement of the research or trials.

14.9 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. The **IC** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 The **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All the **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **IC's** patent rights in those countries.

14.11 By entering into this **Agreement**, the **IC** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **IC**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **IC**, the **FDA** or the **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **IC**.

14.12 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **IC** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

14.14 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **IC**.

14.15 Paragraphs 4.3, 8.1, 9.5-9.9, 12.1-12.5, 13.9, 13.10, 14.12 and 14.15 of this **Agreement** shall survive termination of this **Agreement**.

14.16 The terms and conditions of this **Agreement** shall, at the **IC's** sole option, be considered by the **IC** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **IC** within **[***]** from the date of the **IC's** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

NIH PATENT LICENSE AGREEMENT - *EXCLUSIVE*

SIGNATURE PAGE

For the **IC**:

/s/ Richard U. Rodriguez 4-14-17
Richard U. Rodriguez, M.B.A. Date
Associate Director
Technology Transfer Center
National Cancer Institute

Mailing Address or E-mail Address for **Agreement** notices and reports:

License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: **[***]**

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

by:

/s/ Werner Caultreels, Ph.D. 4-27-17
Signature of Authorized Official Date

Werner Cautreels, Ph.D.
Printed Name

CEO and Chairman
Title

I. Official and Mailing Address for **Agreement** notices:

David Abraham
General Counsel
Selecta Biosciences
480 Arsenal Street, Building One
Watertown, MA 02472
Phone: (617) 923-1400
E-mail: [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments)

David Siewers
Selecta Biosciences
480 Arsenal Street, Building One
Watertown, MA 02472
Phone: (617) 923-1400
E-mail: [***]

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

APPENDIX A - Patent(s) or Patent Application(s)

Patent(s) or Patent Application(s):

Group A (Exclusive Rights)

[***]

Group B (Non-exclusive Rights)

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

APPENDIX B - Licensed Fields of Use and Territory

I. **Licensed Fields of Use:**

The use of anti-mesothelin targeted immunotoxins for the treatment of mesothelin-expressing cancers, [***].

For purposes of clarity, the immunotoxin [***].

II. **Licensed Territory:**

Worldwide

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

APPENDIX C - Royalties

Royalties:

I. The **Licensee** agrees to pay to the **IC** a noncreditable, nonrefundable license issue royalty in the amount of fifty thousand dollars ($50,000.00) within **[***]** from the effective date of this **Agreement.**

II. The **Licensee** agrees to pay to the **IC** a nonrefundable minimum annual royalty in the amount of **[***]** as follows:

(a) The first minimum annual royalty is due within **[***]** of the effective date of this **Agreement** and may be **[***]**; and

(b) Subsequent minimum annual royalty payments are due and payable on **[***]** of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. The **Licensee** agrees to pay the **IC** earned royalties of **[***]** on **Net Sales** by or on behalf of the **Licensee** and its sublicensees.

IV. **Licensee** agrees to pay **NIH Benchmark** royalties within **[***]** of achieving each **Benchmark** set forth below.

(a) **Benchmark** #1- The first to occur of:

(1) **[***]** upon the **[***]**, or
(2) **[***]** within **[***]**;

(b) **Benchmark** #2- The first to occur of:

(1) **[***]** upon the **[***]**, or
(2) **[***]** within **[***]**;

(c) **Benchmark** #3- **[***]** upon the **[***]**;

(d) **Benchmark** #4- **[***]** upon the **[***]**.

V. **Licensee** agrees to pay **NIH** additional sublicensing royalties in the following manner:

(a) For sublicenses granted **[***]**, a sublicensing royalty in the amount of **[***]** on the fair market value of any consideration received for each sublicense is due no later than **[***]** after **Licensee** receives the consideration for each sublicense;

(b) For sublicenses granted **[***]**, a sublicensing royalty in the amount of **[***]** on the fair market value of any consideration received for each sublicense is due no later than **[***]** after **Licensee** receives the consideration for each sublicense; and

(c) For sublicenses granted **[***]**, a sublicensing royalty in the amount of **[***]** on the fair market value of any consideration received for each sublicense is due no later than **[***]** after **Licensee** receives the consideration for each sublicense.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

APPENDIX D - Benchmarks and Performance

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within **[***]** of achieving a **Benchmark**, shall notify the **IC** that the **Benchmark** has been achieved.

I.	[***]	[***]
II.	[***]	[***]
III.	[***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment has been requested with respect to the omitted portions.

APPENDIX E - Commercial Development Plan

The content of commercial development plan set forth in the document below is incorporated by reference.

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Appendix F - Example Royalty Report

Required royalty report information includes:

- License reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

Appendix G - Royalty Payment Options

The License Number MUST appear on payments, reports and correspondence.

Credit and Debit Card Payments

Credit and debit card payments can be submitted for amounts up to $29,999. Submit your payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443.

Automated Clearing House (ACH) for payments through U.S. banks only

The **IC** encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443. Please note that the IC "only" accepts ACH payments through this U.S. Treasury web site.

Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

[***]

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

[***]

Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

[***]

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health
Office of Technology Transfer
License Compliance and Administration
Royalty Administration
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 31.1

CERTIFICATIONS

I, Werner Cautreels, 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)) 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.)[omitted];

   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 11, 2017

/s/ Werner Cautreels, Ph.D.

Werner Cautreels, Ph.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, David Siewers, 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)) 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.)[omitted];

   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 11, 2017

/s/ David Siewers

David Siewers

Chief Financial Officer and Treasurer

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, Werner Cautreels, 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, 2017 (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 11, 2017

/s/ Werner Cautreels, Ph.D.

Werner Cautreels, Ph.D.
President and Chief 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, David Siewers, 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, 2017 (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 11, 2017

/s/ David Siewers

David Siewers
Chief Financial Officer and Treasurer