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 June 30, 2020
OR

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

Commission File Number: 001-37798

Selecta Biosciences, Inc.

(Exact name of registrant as specified in its charter)

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

(617) 923-1400
(Registrant's telephone number, including area code)

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒
As of July 31, 2020, the registrant had 107,143,410 shares of common stock, par value $0.0001 per share, outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly Report") contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, the plans and objectives of management for future operations and future results of anticipated products, the impact of the novel coronavirus (COVID-19) pandemic on our business and operations and our future financial results, and the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

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

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

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

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

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

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

	June 30, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 59,730	$ 89,893
Restricted cash	278	279
Accounts receivable	—	5,000
Prepaid expenses and other current assets	1,044	1,495
Total current assets	61,052	96,667
Property and equipment, net	1,301	1,222
Right-of-use asset, net	11,474	301
Long-term restricted cash	1,379	1,379
Total assets	$ 75,206	$ 99,569
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,242	$ 500
Accrued expenses	9,308	13,492
Loan payable	8,384	18,905
Lease liability	1,648	372
Deferred revenue	1,928	1,674
Total current liabilities	22,510	34,943
Non-current liabilities:		
Loan payable, net of current portion	6,449	—
Lease liability	10,120	—
Deferred revenue	16,412	14,680
Warrant liabilities	32,767	41,549
Total liabilities	88,258	91,172
Commitments and contingencies (Note 17)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 100,847,810 and 86,325,547 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	10	9
Additional paid-in capital	370,944	348,664
Accumulated deficit	(379,454)	(335,753)
Accumulated other comprehensive loss	(4,552)	(4,523)
Total stockholders' equity (deficit)	(13,052)	8,397
Total liabilities and stockholders' equity (deficit)	$ 75,206	$ 99,569

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

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(Unaudited)			
Grant and collaboration revenue	$ —	$ 13	$ —	$ 23
Operating expenses:				
Research and development	10,730	12,134	25,454	19,487
General and administrative	5,637	4,114	9,735	8,627
Total operating expenses	16,367	16,248	35,189	28,114
Loss from operations	(16,367)	(16,235)	(35,189)	(28,091)
Investment income	13	246	253	523
Foreign currency transaction gain (loss), net	(42)	(10)	40	(40)
Interest expense	(205)	(400)	(478)	(796)
Change in fair value of warrant liabilities	(7,539)	—	(8,385)	—
Other (expense), net	59	5	58	(64)
Net loss	(24,081)	(16,394)	(43,701)	(28,468)
Other comprehensive loss:				
Foreign currency translation adjustment	31	7	(29)	29
Unrealized gain on securities	—	1	—	3
Total comprehensive loss	$ (24,050)	$ (16,386)	$ (43,730)	$ (28,436)
Net loss per share:				
Basic and diluted	$ (0.25)	$ (0.37)	$ (0.46)	$ (0.68)
Weighted average common shares outstanding:				
Basic and diluted	96,785,915	44,855,083	95,754,714	41,668,902

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

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(Amounts in thousands, except share data)

(Unaudited)

	Common stock		Additional paid-in		Accumulated other comprehensive	Stockholders' Equity
	Shares	Amount	capital	Accumulated deficit	loss	(Deficit)
Balance at December 31, 2019	86,325,547	$ 9	$348,664	$ (335,753)	$ (4,523)	$ 8,397
Issuance of common stock under Employee Stock Purchase Plan	78,583	—	114	—	—	114
Issuance of common stock upon exercise of options	5,128	—	3	—	—	3
Issuance of vested restricted stock units	10,937	—	—	—	—	—
Issuance of common stock through at-the-market offering, net	598,977	—	1,141	—	—	1,141
Other financing fees	—	—	(147)	—	—	(147)
Stock-based compensation expense	—	—	1,409	—	—	1,409
Currency translation adjustment	—	—	—	—	(60)	(60)
Net loss	—	—	—	(19,620)	—	(19,620)
Balance at March 31, 2020	87,019,172	$ 9	$351,184	$ (355,373)	$ (4,583)	$ (8,763)
Issuance of common stock upon exercise of options	37,500	—	98	—	—	98
Issuance of vested restricted stock units	10,938	—	—	—	—	—
Issuance of common stock through at-the-market offering, net	470,509	—	967	—	—	967
Issuance of common stock upon exercise of pre-funded warrants	8,342,128	1	—	—	—	1
Issuance of common stock upon exercise of common warrants	4,967,563	—	17,214	—	—	17,214
Stock-based compensation expense	—	—	1,481	—	—	1,481
Currency translation adjustment	—	—	—	—	31	31
Net loss	—	—	—	(24,081)	—	(24,081)
Balance at June 30, 2020	100,847,810	$ 10	$370,944	$ (379,454)	$ (4,552)	$ (13,052)

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

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(Amounts in thousands, except share data)

(Unaudited)

	Common stock		Additional paid-In		Accumulated other	Stockholders' Equity
	Shares	Amount	Capital	Accumulated deficit	comprehensive loss	(Deficit)
Balance at December 31, 2018	22,471,776	$ 3	$279,539	$ (280,403)	$ (4,557)	$ (5,418)
Issuance of common stock under Employee Stock Purchase Plan	11,943	—	20	—	—	20
Issuance of common stock upon exercise of options	115,600	—	145	—	—	145
Issuance of common stock, net of issuance costs	22,188,706	2	30,940	—	—	30,942
Stock-based compensation expense	—	—	1,180	—	—	1,180
Currency translation adjustment	—	—	—	—	22	22
Unrealized gains on securities	—	—	—	—	2	2
Net loss	—	—	—	(12,074)	—	(12,074)
Balance at March 31, 2019	44,788,025	$ 5	$311,824	$ (292,477)	$ (4,533)	$ 14,819
Issuance of common stock through at-the-market offering, net	164,926	—	372	—	—	372
Stock-based compensation expense	—	—	1,251	—	—	1,251
Currency translation adjustment	—	—	—	—	7	7
Unrealized gains on securities	—	—	—	—	1	1
Net loss	—	—	—	(16,394)	—	(16,394)
Balance at June 30, 2019	44,952,951	$ 5	$313,447	$ (308,871)	$ (4,525)	$ 56

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)

	Six Months Ended June 30,	
	2020	**2019**
	(Unaudited)	
Cash flows from operating activities		
Net loss	$ (43,701)	$ (28,468)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	356	355
Amortization of premiums (accretion of discounts) on investments	—	(131)
Non-cash lease expense	602	723
(Gain) Loss on disposal of property and equipment	(35)	76
Stock-based compensation expense	2,890	2,431
Non-cash interest expense	173	267
Warrant liabilities revaluation	8,385	—
Changes in operating assets and liabilities:		
Accounts receivable	5,000	—
Prepaid expenses, deposits and other assets	451	2,189
Accounts payable	735	1,363
Deferred revenue	2,000	(11)
Accrued expenses and other liabilities	(362)	(6,231)
Net cash used in operating activities	(23,506)	(27,437)
Cash flows from investing activities		
Receipts from the maturity of short-term investments	—	4,850
Purchases of short-term investments	—	(18,188)
Sale of short term investments	—	1,992
Purchases of property and equipment	(334)	(5)
Proceeds from the sale of property and equipment	45	77
Net cash used in investing activities	(289)	(11,274)
Cash flows from financing activities		
Repayments of principal on outstanding debt	(4,200)	—
Net proceeds from issuance of common stock	—	30,942
Net proceeds from issuance of common stock- at-the-market offering	2,137	372
Issuance costs paid for December 2019 financing	(4,381)	—
Other financing fees	(147)	—
Proceeds from exercise of pre-funded and common warrants	49	—
Proceeds from exercise of stock options	101	145
Proceeds from issuance of common stock under Employee Stock Purchase Plan	114	20
Net cash (used in) provided by financing activities	(6,327)	31,479
Effect of exchange rate changes on cash	(42)	29
Net change in cash, cash equivalents, and restricted cash	(30,164)	(7,203)
Cash, cash equivalents, and restricted cash at beginning of period	91,551	37,682
Cash, cash equivalents, and restricted cash at end of period	$ 61,387	$ 30,479
Supplement cash flow information		
Cash paid for interest	$ 387	$ 634
Noncash investing and financing activities		
Cashless warrant exercise	$ 17,089	$ —
Reclassification of warrant liability to equity upon exercise of warrants	$ 77	$ —
Purchase of property and equipment not yet paid	$ 111	$ —
Equity offering costs in accrued liabilities	$ 29	$ 14
Unrealized gain on marketable securities	$ —	$ 3

1. Nature of the Business and Basis of Presentation

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

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

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

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements for the three and six months ended June 30, 2020 and 2019 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 12, 2020 (the "Annual Report on Form 10-K"). The unaudited interim financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments that are necessary for a fair statement of the Company's financial position as of June 30, 2020 and consolidated results of operations and cash flows for the six months ended June 30, 2020. Such adjustments are of a normal and recurring nature. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

Liquidity and Management's Plan

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

To date, the Company has financed its operations primarily through the initial public offering of its common stock, a private placement of its common stock, issuances of common and preferred stock, debt, research grants and research collaborations. The Company currently has no source of product revenue, and it does not expect to generate product revenue for the foreseeable future. To date, all of the Company's revenue has been collaboration and grant revenue. The Company has devoted

substantially all of its financial resources and efforts to developing its ImmTOR platform, identifying potential product candidates and conducting preclinical studies and its clinical trials. The Company is in the early stages of development of its product candidates, and it has not completed development of any ImmTOR-enabled therapies.

As of June 30, 2020, the Company's cash, cash equivalents and restricted cash were $61.4 million, of which $1.7 million was restricted cash related to lease commitments and $0.3 million was held by its Russian subsidiary designated solely for use in its operations, and together with the $25 million payment received from Sobi under the Sobi Private Placement and the expected payment from Sobi of $75 million that is due under the Sobi License, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. The Company has incurred losses and negative cash flows from operating activities since inception. As of June 30, 2020 and December 31, 2019, the Company had an accumulated deficit of $379.5 million and $335.8 million, respectively. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates, conducting preclinical studies and clinical trials, and its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy, and the Company will pursue a range of options to secure additional capital.

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

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 June 30, 2020, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Foreign Currency

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

Use of Estimates

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

Segment Information

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

Cash Equivalents, Short-term Investments and Restricted Cash

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

Although available to be sold to meet operating needs or otherwise, securities are generally held through maturity. The cost of securities sold is determined based on the specific identification method for purposes of recording realized gains and losses. During the six months ended June 30, 2020, there were no realized losses on sales of investments, and no investments were adjusted for other than temporary declines in fair value.

As of June 30, 2020, the Company had restricted cash balances relating to secured letters of credit in connection with its Prior Headquarters Lease and Headquarters Lease (as defined in Note 8). The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet that sum to the total of the same such amounts shown in the consolidated statement of cash flows:

	June 30,	
	2020	2019
Cash and cash equivalents	$ 59,730	$ 30,200
Restricted cash	278	279
Long-term restricted cash	1,379	—
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	$ 61,387	$ 30,479

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents, short-term deposits and investments, and accounts receivable. Cash and cash equivalents are deposited with federally insured financial institutions in the United States and may, at times, exceed federally insured limits. Management believes that the financial institutions that hold the Company's deposits are financially creditworthy and, accordingly, minimal risk exists with respect to those balances. Generally, these deposits may be redeemed upon demand and therefore bear minimal interest rate risk. As an integral part of operating its Russian subsidiary, the Company also maintains cash in Russian bank accounts in denominations of both Russian rubles and U.S. dollars. As of June 30, 2020, the Company maintained approximately $0.3 million in Russian bank accounts, all of which was held in U.S. dollars.

The Company did not have any off-balance sheet arrangements as of June 30, 2020 and December 31, 2019.

Fair Value of Financial Instruments

The Company's financial instruments consist mainly of cash equivalents, restricted cash, accounts payable, loans payable, and common warrants. The carrying amounts of cash equivalents, restricted cash, accounts receivable, and accounts payable approximate their estimated fair value due to their short-term maturities. At June 30, 2020, the carrying amount of the Company's loan payable approximates its estimated fair value due to the short-term nature of the instrument.

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

> *Level 1*—Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2—Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term of the asset or liability.

Level 3—Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

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

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, the Company's own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. The Company uses prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may change for many instruments. This condition could cause an instrument to be reclassified within levels in the fair value hierarchy. There were no transfers within the fair value hierarchy during the six months ended June 30, 2020 or the year ended December 31, 2019.

Property and Equipment

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

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In order to determine if assets have been impaired, assets are tested at the lowest level for which identifiable independent cash flows are available, which is at the entity level ("asset group"). An impairment loss is recognized when the sum of projected undiscounted cash flows is less than the carrying value of the asset group. The measurement of the impairment loss to be recognized is based on the difference between the fair value and the carrying value of the asset group. Based on management's evaluation, the fair value of the asset group, measured as the market capitalization of the Company exceeds its carrying value, and for this reason the Company did not recognize any material impairment losses during the six months ended June 30, 2020 and 2019.

Debt Issuance Costs

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

Accumulated Other Comprehensive Income (Loss)

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

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Pursuant to ASC Topic 606, *Revenue from Contracts with Customers (ASC 606)*, a customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i)

identify the contract(s) with a customer; (ii) identify the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. If a promised good or service is not distinct, it is combined with other performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For example, certain performance obligations associated with Spark, AskBio, and Sarepta (see Note 12) will be satisfied over time, and revenue will be recognized using the output method, based on the proportion of actual deliveries to the total expected deliveries over the initial term.

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

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

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

Milestone Payments: At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service. If the milestone payment is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method. The Company also evaluates the milestone to determine whether they are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the

transaction price to be allocated, otherwise, such amounts are constrained and excluded from the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the transaction price. Any such adjustments to the transaction price are allocated to the performance obligations on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation shall be recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

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

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

Research and Development Costs

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

Clinical Trial Costs

Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these costs to third parties. Third party clinical trial expenses include patient costs, clinical research organization costs and costs for data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued clinical trial cost. These third party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future R&D activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. The Company also records accruals for estimated ongoing clinical research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical clinical accrual estimates made by the Company have not been materially different from the actual costs.

Income Taxes

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

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

Warrants

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

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

Stock-Based Compensation

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

Net Loss Per Share

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

Contingent Liabilities

The Company accounts for its contingent liabilities in accordance with ASC No. 450, *Contingencies*. A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. As of June 30, 2020 and December 31, 2019, the Company was not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

Leases

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

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

Recent Accounting Pronouncements

Recently Adopted

In August 2018, 2018-13, *Fair Value Measurement (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13) which changes the fair value measurement disclosure requirements of ASC 820. Entities will no

longer be required to disclose the amount of, and reasons for, transfers between Level 1 and Level 2 of the fair value hierarchy, the policy of timing of transfers between levels of the fair value hierarchy and the valuation processes for Level 3 fair value measurements. The Company adopted the new standard effective January 1, 2020, and there was no impact on its consolidated financial statements.

Not Yet Adopted

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

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

3. Marketable Securities

As of June 30, 2020 and December 31, 2019, the Company did not have marketable securities.

4. Net Loss Per Share

The Company has reported a net loss for the three and six months ended June 30, 2020, and 2019. For this reason basic and diluted net loss per share are the same for all periods presented. Since the shares underlying the 8,342,128 pre-funded warrants were issuable for little or no consideration, they are considered outstanding for both basic and diluted earnings per share. During the second quarter 2020, all 8,342,128 pre-funded warrants were exercised, but had no effect on basic and diluted shares at exercise because all were included in both basic and diluted from the period of issuance. 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net loss attributable to common stockholders	$ (24,081)	$ (16,394)	$ (43,701)	$ (28,468)
Denominator:				
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	96,785,915	44,855,083	95,754,714	41,668,902
Net loss per share attributable to common stockholders —basic and diluted	$ (0.25)	$ (0.37)	$ (0.46)	$ (0.68)

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

	June 30,	
	2020	2019
Stock options to purchase common stock	7,473,613	4,637,463
Unvested restricted stock units	159,375	275,000
Stock warrants to purchase common stock	14,841,100	95,619
Total	22,474,088	5,008,082

5. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The tables below present information about the Company's financial assets and liabilities that are measured and carried at fair value as of June 30, 2020 and December 31, 2019, and indicate the level within the fair value hierarchy where each

measurement is classified. Below is a summary of assets and liabilities measured at fair value on a recurring basis (in thousands):

	June 30, 2020			
	Total	(Level 1)	(Level 2)	(Level 3)
Assets:				
Money market funds	$ 30,574	$ 30,574	$ —	$ —
Total	$ 30,574	$ 30,574	$ —	$ —
Liabilities:				
Warrant liabilities	$ 32,767	$ —	$ —	$ 32,767
Total	$ 32,767	$ —	$ —	$ 32,767

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

At each of June 30, 2020 and December 31, 2019, the money market funds were classified as cash and cash equivalent on the accompanying consolidated balance sheet as they mature within 90 days from the date of purchase.

Assumptions Used in Determining Fair Value of Common Warrants

In December 2019, the Company issued common warrants in connection with a private placement of common shares. Pursuant to the terms of the common warrants, the Company could be required to settle the common warrants in cash in the event of certain acquisitions of the Company and, as a result, the common warrants are required to be measured at fair value and reported as a liability on the balance sheet. The Company recorded the fair value of the common warrants upon issuance using the Black-Scholes valuation model and are required to revalue the common warrants at each reporting date with any changes in fair value recorded in the statement of operations. The valuation of the common warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The change in the fair value of the Level 3 warrant liability is reflected in the statement of operations for the six months ended June 30, 2020.

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

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

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

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

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

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

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

	June 30, 2020
Risk-free interest rate	0.29%
Dividend yield	—
Expected life (in years)	4.48
Expected volatility	94.99%

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

The following table reflects a roll-forward of fair value for the Company's Level 3 warrant liabilities (see Note 10), for the six months ended June 30, 2020 (in thousands):

	Warrant liabilities
Fair value as of December 31, 2019	$ 41,549
Exercises	(17,167)
Change in fair value	8,385
Fair value as of June 30, 2020	$ 32,767

6. Property and Equipment

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

	June 30, 2020	December 31, 2019
Laboratory equipment	$ 4,357	$ 4,836
Computer equipment and software	517	515
Leasehold improvements	—	278
Furniture and fixtures	325	237
Office equipment	164	135
Construction in process	10	2
Total property and equipment	5,373	6,003
Less accumulated depreciation	(4,072)	(4,781)
Property and equipment, net	$ 1,301	$ 1,222

Depreciation expense was $0.2 million for each of the three months ended June 30, 2020 and 2019, respectively. For each of the six months ended June 30, 2020 and 2019, depreciation expense was $0.4 million. The Company recorded accelerated depreciation costs of less than $0.1 million in the reported property and equipment for the six months ended June 30, 2020 relating to the new corporate headquarters move in 2020.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Payroll and employee related expenses	$ 2,112	$ 2,235
Collaboration and licensing	1,350	1,050
Accrued patent fees	492	487
Accrued external research and development costs	4,247	4,379
Accrued professional and consulting services	763	468
Accrued interest	44	82
Issuance costs, December 2019 financing	—	4,381
Other	300	410
Accrued expenses	$ 9,308	$ 13,492

8. Leases

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

480 Arsenal Way Lease

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

75 North Beacon Street Lease

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

65 Grove Street Lease

In July 2019, the Company entered into a lease for 25,078 square feet of laboratory and office space located at 65 Grove Street, Watertown, Massachusetts (the “Headquarters Lease”). The Company estimates that it will incur $0.8 million in non-reimbursable construction costs. The lease began in March 2020, consistent with when the Company took control of the office space and the lease term is 8 years. The discount rate of 8.9% was determined based on the Company’s incremental borrowing rate adjusted for the lease term including any reasonably certain renewal periods. Rent payments began in May 2020, and the base rent for the first year is $0.2 million per month. In connection with the Headquarters Lease, the Company secured a letter of credit from Silicon Valley Bank for $1.4 million which renews automatically each year. The Company recorded the right-of-use asset and operating lease liabilities of $11.8 million during the three months ended March 31, 2020 as control of the premises was transferred to the Company.

Moscow, Russia Lease

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

Summary of All Lease Costs Recognized Under ASC 842

Rent expense for the three months ended June 30, 2020 and 2019 was $0.8 million and $0.6 million, respectively. Rent expense for the six months ended June 30, 2020 and 2019 was $1.4 million and $1.1 million, respectively.

For the three and six months ended June 30, 2020 and 2019 the components of lease costs were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease expense	$ 613	$ 341	$ 1,085	$ 682
Variable lease expense	174	211	373	414
Short-term lease expense	3	3	5	11
Total lease expense	$ 790	$ 555	$ 1,463	$ 1,107

The maturity of the Company's operating lease liabilities as of June 30, 2020 and December 31, 2019 were as follows (in thousands):

Operating leases:	June 30, 2020	December 31, 2019
2020 (remainder)	$ 1,698	$ 375
2021	1,812	—
2022	1,866	—
2023	1,922	—
2024	1,980	—
Thereafter	6,985	—
Total future minimum lease payments	$ 16,263	$ 375
Less imputed interest	4,495	3
Total operating lease liabilities	$ 11,768	$ 372
Included in the condensed consolidated balance sheet:		
Current operating lease liabilities	$ 1,648	$ 372
Non-current operating lease liabilities	10,120	—
Total operating lease liabilities	$ 11,768	$ 372

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

Operating leases:	Six Months Ended June 30, 2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 825	$ 735

Other than the initial recording of the right-of-use asset and lease liability for the Headquarters Lease, which is non-cash, the changes in the Company’s right-of-use asset and lease liability for the six months ended June 30, 2020 are reflected in the non-cash lease expense and accrued expenses and other liabilities, respectively, in the consolidated statements of cash flows.

The following summarizes additional information related to operating leases:

Operating leases:	June 30, 2020	December 31, 2019
Weighted-average remaining lease term	7.9 years	0.3 years
Weighted-average discount rate	8.9%	10.0%

9. Debt

2017 Term Loan

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

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

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

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

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

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

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

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

As of June 30, 2020 and December 31, 2019, the outstanding principal balance under the 2017 Term Loan was $14.0 million and $18.2 million, respectively.

Future minimum principal and interest payments on the 2017 Term Loan as of June 30, 2020 are as follows (in thousands):

2020 (Remainder)		4,390
2021		8,626
2022		2,457
Total minimum debt payments	$	15,473
Less: Amount representing interest		(423)
Less: Debt discount and deferred charges		(217)
Less: Current portion of loan payable		(8,384)
Loan payable, net of current portion	$	6,449

The Company has not been notified of an event of default by SVB as of the date of the filing of this Quarterly Report on Form 10-Q.

During each of the three months ended June 30, 2020 and 2019, the Company recognized $0.2 million and $0.4 million of interest expense related to the 2017 Term Loan. During the six months ended June 30, 2020 and 2019, interest expense was $0.5 million and $0.8 million, respectively.

10. Equity

Equity Financings

August 2017 Shelf Registration Statement

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

“At-the-Market” Offerings

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

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

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

During the six months ended June 30, 2020, the Company sold 1,069,486 shares of its common stock pursuant to the Sales Agreement at an average price of approximately $2.16 per share for aggregate net proceeds of $2.1 million, after deducting commissions and other transaction costs.

December 2019 Financing

On December 18, 2019, the Company entered into a securities purchase agreement (the "2019 Purchase Agreement") with a group of institutional investors and certain members of the board of directors. Pursuant to the 2019 Purchase Agreement, the Company sold an aggregate of 37,634,883 shares of its common stock at a purchase price of $1.46 per share, warrants to purchase an aggregate of 22,988,501 shares of common stock at a purchase price of $0.125 per share underlying each common warrant, and pre-funded warrants to purchase an aggregate of 8,342,128 shares of common stock at a purchase price of $1.46 per share, all with five year terms (the "2019 PIPE"). The closing of the 2019 PIPE occurred on December 23, 2019. The exercise price of the pre-funded warrants is $0.0001 per share and the exercise price for the common warrants is $1.46 per share. In the event of a certain sale of the Company, the terms of the common warrants require us to make a payment to such common warrant holders based on a Black-Scholes valuation (using variables as specified in the warrants). This provision does not apply to the pre-funded warrants. Therefore, the Company is required to account for the common warrants as liabilities and record them at fair value, while the pre-funded warrants met the criteria to be classified as permanent equity.

The Company recorded the fair value of the common warrants of $40.7 million upon issuance using the Black-Scholes valuation model. The common warrants were revalued as of December 31, 2019 at $41.5 million; a charge in fair value of $8.4 million was recorded in the statement of operations for the six months ended June 30, 2020. Issuance costs were allocated between the equity component with an offset to additional paid-in capital and the liability component recorded as expense on a relative fair value basis. Total net proceeds from the equity offering was $65.6 million, after deducting transaction costs and commissions of $4.4 million which was paid in the three months ended March 31, 2020.

On December 23, 2019, in connection with the 2019 PIPE, the Company entered into a registration rights agreement (the “2019 Registration Rights Agreement”), pursuant to which the Company agreed to prepare and file a registration statement with the SEC within 45 days after the closing of the 2019 PIPE for purposes of registering the resale of the shares of common stock issued and sold in the 2019 PIPE, shares of common stock issuable upon exercise of the warrants sold in the 2019 PIPE, and any shares of common stock issued as a dividend or other distribution with respect to the shares of common stock or shares of common stock issuable upon exercise of the warrants. The 2019 PIPE registration statement was declared effective by the SEC on February 6, 2020.

The Company agreed, among other things, to indemnify the investors in the 2019 PIPE, and their officers, directors, members, employees and agents, successors and assigns, under the registration statement from certain liabilities and to pay all fees and expenses (excluding any legal fees of the selling holder(s), and any underwriting discounts and selling commissions) incident to the Company’s obligations under the 2019 Registration Rights Agreement.

June 2017 Financing

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

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

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

The Company agreed to indemnify the Institutional Investors and Dr. Springer, their officers, directors, members, employees and agents, successors and assigns under the registration statement from certain liabilities and to pay all fees and expenses (excluding any legal fees of the selling holder(s), and any underwriting discounts and selling commissions) incident to the Company’s obligations under the 2017 Registration Rights Agreement.

Warrants

During the six months ended June 30, 2020, warrant holders exercised 8,210,180 common warrants on a cashless basis and received 4,934,723 shares of common stock. In addition, warrant holders exercised 32,840 common warrants and 8,342,128 pre-funded warrants, and paid the exercise price in cash.

	Number of Warrants			
	Equity classified	Liability classified	Total	Weighted average exercise price
Outstanding at December 31, 2019	8,437,747	22,988,501	31,426,248	$ 1.12
Exercises	(8,342,128)	(8,243,020)	(16,585,148)	$ 0.73
Outstanding at June 30, 2020	95,619	14,745,481	14,841,100	$ 1.56

Common Stock

As of June 30, 2020, the Company had 200,000,000 shares of common stock authorized for issuance, $0.0001 par value per share, with 100,847,810 shares issued and outstanding. The voting, dividend and liquidation rights of the common stockholders are subject to and qualified by the rights, powers and preferences of the preferred stock. The common stock has the following characteristics:

Voting

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

Dividends

The common stockholders are entitled to receive dividends, if and when declared by the Board of Directors. Through June 30, 2020, no dividends have been declared or paid on common stock.

Liquidation

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

Reserved Shares

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

	Period ending	
	June 30, 2020	**December 31, 2019**
Exercise of common warrants	14,841,100	31,426,248
Shares available for future stock incentive awards	5,283,139	1,765,018
Unvested restricted stock units	159,375	181,250
Outstanding common stock options	7,473,613	6,796,669
Total	27,757,227	40,169,185

11. Stock Incentive Plans

Stock Options

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

On June 7, 2016, the Company’s stockholders approved the 2016 Incentive Award Plan (the “2016 Plan”), which became effective June 21, 2016. The 2016 Plan provides for the granting of incentive and non-qualified stock option, restricted stock and other stock and cash-based awards as determined by the Board. Shares subject to awards that are granted under the 2016 Plan and that expire, lapse or terminate are available for future grants under the 2016 Plan. At inception of the 2016 Plan, a total of 1,210,256 shares of common stock were authorized for future issuance under the 2016 Plan. The number of shares of common stock that may be issued under the 2016 Plan automatically increases on the first day of each calendar year, beginning in 2017 and ending in and including 2026, by an amount equal to the lesser of: (i) 4% of the number of shares of the Company’s common stock outstanding on the last day of the applicable preceding calendar year and (ii) such smaller number of shares as is determined by the Board. During the six months ended June 30, 2020 and 2019, the number of shares of common stock that may be issued under the 2016 Plan was increased by 3,453,022 shares and 898,871 shares, respectively. As of June 30, 2020, 2,651,062 shares remain available for future issuance under the 2016 Plan.

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

The Company’s 2018 Employment Inducement Incentive Award Plan (the “Inducement Incentive Award Plan”), which was adopted by the Board on September 25, 2018 without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules ("Rule 5635(c)(4)"), provides for the grant of equity-based awards in the form of non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock or cash based awards. In accordance with Rule 5635(c)(4), awards under the Inducement Incentive Award Plan may only be made to a newly hired employee who has not previously been a member of the Board, or an employee who is being rehired following a bona fide period of non-employment by the Company, as a material inducement to the employee’s entering into employment with the Company. The Company reserved 1,175,000 shares of its common stock for issuance under the Inducement Incentive Award Plan. On March 25, 2019, the Board approved the amendment and restatement of the Inducement Incentive Award Plan to reserve an additional 2,000,000 shares of the Company’s common stock for issuance thereunder. As of June 30, 2020, there are 1,100,000 shares available for future grant under the Inducement Incentive Award Plan.

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

Employees

Effective June 25, 2020, the Company entered into transition agreements with two executive officers, under which the right to exercise their vested options was extended for a period of two years following their respective separation dates. The subsequent stock based compensation amount recognized in connection with the option modification in the second quarter was less than $0.1 million.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Risk-free interest rate	0.39%	2.18%	1.61%	2.41%
Dividend yield	—	—	—	—
Expected term	5.56	5.87	6.03	6.03
Expected volatility	89.70%	88.71%	88.12%	87.56%
Weighted-average fair value of common stock	$ 2.92	$ 2.48	$ 2.36	$ 2.42

The weighted average grant date fair value of stock options granted to employees during the three and six months ended June 30, 2020 was $2.08, and $1.73, respectively. The weighted average grant date fair value of stock options granted to employees during the three and six months ended June 30, 2019 was $1.83, and $1.78, respectively.

As of June 30, 2020, total unrecognized compensation expense related to unvested employee stock options was $8.1 million, which is expected to be recognized over a weighted average period of 2.3 years.

Non-employees

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Risk-free interest rate	—%	2.07%	—%	2.10%
Dividend yield	—	—	—	—
Expected life (in years)	0	5.49	0	5.50
Expected volatility	—%	88.46%	—%	88.44%
Weighted-average fair value of common stock	$ —	$ 2.04	$ —	$ 2.04

No stock option awards were granted to non-employee consultants during the three and six months ended June 30, 2020. The weighted average grant date fair value of stock options granted to non-employees during the three and six months ended June 30, 2019 was $1.46 and $0.65, respectively. As of June 30, 2020, no unrecognized compensation expense related to unvested non-employee stock options remained.

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

	Number of options	Weighted-average exercise price ($)	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Employee awards				
Outstanding at December 31, 2019	6,323,596	$ 4.91	8.71	$ 1,716
Granted	1,878,309	$ 2.36		
Exercised	(42,628)	$ 2.42		
Forfeited	(1,158,737)	$ 5.84		
Outstanding at June 30, 2020	7,000,540	$ 4.09	8.69	$ 3,736
Vested at June 30, 2020	1,632,355	$ 7.62	7.37	$ 337
Vested and expected to vest at June 30, 2020	6,472,944	$ 4.22	8.64	$ 3,381
Non-employee awards				
Outstanding at December 31, 2019	473,073	$ 5.89	6.23	$ 38
Granted	—	$ —		
Exercised	—	$ —		
Forfeited	—	$ —		
Outstanding at June 30, 2020	473,073	$ 5.89	5.73	$ 72
Vested at June 30, 2020	413,191	$ 5.45	5.37	$ 72
Vested and expected to vest at June 30, 2020	473,073	$ 5.89	5.73	$ 72

Restricted Stock Units

During the second quarter of 2020, the Company entered into a transition agreement with an executive officer under which previously awarded restricted stock units under the Inducement Incentive Award Plan remain eligible to vest in accordance with their terms, notwithstanding the requirement that the executive remain in continuous service with the Company through the applicable vesting date, if the administrator of the Inducement Incentive Award Plan determines the applicable performance conditions are achieved on or prior to December 31, 2020. In accordance with ASC718, the restricted stock units granted were remeasured with a weighted average fair value of $2.92 per share based on the closing price of the Company's common stock on the date the transition agreement was executed. Since the performance condition is probable of achievement, the restricted stock units were re-valued, resulting in additional expense of less than $0.1 million.

Unrecognized compensation expense for the restricted stock units was $0.6 million as of June 30, 2020, which is expected to be recognized over a weighted average period of 2.4 years.

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

	Number of shares	Weighted average grant date fair value ($)
Unvested at December 31, 2019	181,250	$ 5.00
Granted	—	—
Vested	21,875	6.03
Forfeited	—	—
Unvested at June 30, 2020	159,375	$ 5.05

Employee Stock Purchase Plan

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

Under the ESPP, the Company has set two six-month offering periods during each calendar year, one beginning March 1st and the other beginning September 1st of each calendar year, during which employees may elect to have up to 25% of their eligible

compensation deducted on each payday on an after-tax basis for use in purchasing the Company's common stock on the last trading day of each offering period, subject to limits imposed by the Internal Revenue Code. The purchase price of the shares may not be less than 85% of the fair market value on the first or last trading day of the offering period, whichever is lower. The first ESPP offering period began on March 1, 2017.

At inception of the ESPP, a total of 173,076 shares of common stock were authorized and reserved for future issuance under the ESPP. The number of shares of common stock that may be issued under the ESPP will automatically increase on the first day of each calendar year, beginning in 2017 and ending in and including 2026, by an amount equal to the lesser of: (i) 1% of the number of shares of the Company's common stock outstanding on the last day of the applicable preceding calendar year and (ii) such smaller number of shares as is determined by the Company's Board of Directors. During the six months ended June 30, 2020 and 2019, the number of shares of common stock that may be issued under the ESPP was increased by 863,254 shares and 224,717 shares, respectively. During the six months ended June 30, 2020, the Company issued 78,583 shares of common stock under the ESPP. As of June 30, 2020, 1,532,077 shares remain available for future issuance under the ESPP.

For each of the three and six months ended June 30, 2020 and 2019, the Company recognized less than $0.1 million of stock-based compensation expense under the ESPP.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 618	$ 445	$ 1,241	$ 964
General and administrative	863	806	1,649	1,467
Total stock-based compensation expense	$ 1,481	$ 1,251	$ 2,890	$ 2,431

12. Revenue Arrangements

Sarepta Therapeutics, Inc.

Research License and Option Agreement

On June 13, 2020, the Company and Sarepta Therapeutics, Inc., ("Sarepta") entered into a Research License and Option Agreement (the "Sarepta Agreement"). Pursuant to the Sarepta Agreement, the Company agreed to grant Sarepta a license under the Company's intellectual property rights covering the Company's antigen-specific biodegradable nanoparticle encapsulating ImmTOR to research and evaluate ImmTOR in combination with Sarepta's adeno-associated virus gene therapy technology, or gene editing technology, using viral or non-viral delivery, to treat Duchenne Muscular Dystrophy and certain Limb-Girdle Muscular Dystrophy subtypes (the "Indications"). Sarepta will have an option term of 24 months during which it can opt-in to obtain an exclusive license to further develop and commercialize the Product to treat at least one Indication, with a potential to extend the option term for an additional fee. The Company will supply ImmTOR to Sarepta for clinical supply on a cost-plus basis.

Sarepta paid a $2.0 million up-front payment to the Company upon signing of the Sarepta Agreement, and the Company is eligible to receive additional preclinical payments during the option term. If Sarepta opts-in to an exclusive license agreement, the Company could receive option exercise payments per Indication upon execution of the exclusive license, and the Company would be entitled to significant development and commercial milestone payments and tiered royalties ranging from the mid-to-high single digits based on net sales.

Pursuant to the Sarepta Agreement, the Company determined the Sarepta Agreement represents a service arrangement under the scope of ASC 606, with a 24 month contract duration. Given the reversion of the rights under the Sarepta Agreement represents a penalty in substance for a termination by Sarepta, the contract term would remain the stated term of the Sarepta Agreement.

The Company determined that the Sarepta Agreement and Supply Obligation including the delivery of the Research License, the Licensed Know-How, the Manufactured Supply and delivery of materials represent a single promise and performance obligation to be transferred to Sarepta over time due to the nature of the promises in the contract. The delivery of the Manufactured Supply is the predominant promise within the arrangement, as it is essential to the utility of the Licensed intellectual property. As such, consideration in the initial transaction price will be allocated to the single performance obligation based on the contractual price.

In determining the transaction price, the Company concluded the payment associated with all the performance milestones will be fully constrained and only be included in the transaction price when the respective milestone is deemed probable of achievement. Each of these variable consideration items was evaluated under the most likely amount method to determine

whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such study milestones is outside the control of the Company and probability of success criteria is estimated. As of June 30, 2020, all milestones were constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved. The Company will recognize the revenue associated with the upfront payment and combined single performance obligation utilizing the output method, over the 24 month term as the Manufactured Supply is delivered to Sarepta.

The Company also determined the option to enter into a future commercial license agreement and extend the term of the option does not represent a material right since it was not priced at an incremental discount. Sarepta may terminate the Sarepta Agreement for any reason upon 30 days' written notice to the Company. The Sarepta Agreement contains other customary terms and conditions, including representations and warranties, covenants, termination, and indemnification obligations in favor of each party.

As of June 30, 2020, the Company recorded $0.3 million as a short-term contract liability and $1.7 million as a long-term contract liability representing deferred revenue associated with this agreement. No revenue related to the Sarepta Agreement was recognized during the three months ended June 30, 2020 as no deliveries were made during the period.

Asklepios Biopharmaceutical, Inc.

License Agreement for Pompe Disease

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

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

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

The Company determined that the AskBio License Agreement and Supply Obligation represent a single promise and performance obligation. This is because AskBio cannot derive benefit from the license without the simultaneous transfer of the patent protected ImmTOR supply. Therefore, the License Obligation and Supply Obligation represent the only promise in the arrangement and are combined as a single performance obligation (the "AskBio License and Supply Obligation").

In determining the transaction price, the Company concluded that the future development milestones, regulatory milestones, sales milestones, and sales royalties all represent variable consideration. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company. Consideration related to sales-based milestones as well as royalties on net sales upon commercialization by AskBio, will be recognized when the related sales occur, as they were determined to relate predominantly to the intellectual property granted to AskBio and, therefore, have also been excluded from the transaction price in accordance with the royalty recognition constraint. As of June 30, 2020 and December 31, 2019, all milestones were constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

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

As of June 30, 2020 and December 31, 2019, the Company recorded $1.7 million as a short-term contract liability and $5.3 million as a long-term contract liability representing deferred revenue associated with this agreement. Revenue will be recognized over the period in which the particles are delivered. No revenue related to the AskBio License Agreement was recognized during the six months ended June 30, 2020 as no deliveries were made during the period.

Spark Therapeutics, Inc.

Spark License Agreement

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

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

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

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

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

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

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

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

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

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

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

The terms of the Spark Purchase Agreement and the Spark License Agreement were negotiated at the same time between the parties and the terms of the Spark Purchase Agreement are referenced in the Spark License Agreement in multiple sections. The pricing and terms of the agreements are unique and must be considered in contemplation with each other. There are provisions within the Spark License Agreement that link to the Spark Purchase Agreement related to provisions that constitute a material breach of the license agreement. Therefore, the Company concluded that the two agreements must be combined and evaluated

as a single agreement. While the Spark Purchase Agreement and the Spark License agreement are considered to be a single agreement, the Company determined that the purchase of common stock and future acquisition rights are not within the scope of ASC 606. The Company determined that the initial purchase of common stock combined with the embedded future stock Acquisition Rights had a fair value of $2.7 million and this amount was recorded in equity as of the effective date. The remaining $2.3 million of cash received in exchange for the stock and acquisition rights is included in allocable consideration, as this represents the premium paid by Spark on the purchase of common stock, and should be allocated to the remaining performance obligations.

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

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

In determining the transaction price, the Company considered the future development milestones, regulatory milestones, commercial milestones, sales milestone, and sales royalties all represent variable consideration. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company. Separately, any consideration related to sales-based milestones as well as royalties on net sales upon commercialization by Spark, will be recognized when the related sales occur as they were determined to relate predominantly to the intellectual property granted to Spark and, therefore, have also been excluded from the transaction price in accordance with the royalty recognition constraint. As of June 30, 2020, all future milestones are constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

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

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

On December 1, 2019, the term for Spark to exercise additional target options expired; the Company recognized $6.7 million in revenue from deferred revenue as originally allocated. In addition, during the year ended December 31, 2019, there were two deliveries resulting in less than $0.1 million of revenue recognized. No revenue related to the Spark License Agreement was recognized during the six months ended June 30, 2020 as no deliveries were made during the period.

As of June 30, 2020 and December 31, 2019, there was a contract liability of $9.2 million representing deferred revenue presented as non-current associated with this agreement.

Spark Letter Agreement

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

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

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

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

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

Skolkovo Foundation

The Company has received grant funding from the Russia-based Development Fund of New Technologies Development and Commercialization Center ("Skolkovo"). From grant inception through June 30, 2020, the Company received $2.0 million from Skolkovo.

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

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

As of June 30, 2020, a contract liability of $0.1 million remains on the balance sheet and will not be recognized as revenue until the expiration of the three-year audit period, expected April 2021, or sooner, if resolution is reached with Skolkovo or there is a change in the estimate.

Transaction Price Allocated to Future Performance Obligations

Remaining performance obligations represent the transaction price of contracts for which work has not been performed (or has been partially performed). As of June 30, 2020, the aggregate amount of the transaction price allocated to remaining performance obligations was $18.3 million.

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

The following table presents changes in the Company's contract liabilities during the six months ended June 30, 2020 (in thousands):

	Balance at beginning of period	Additions	Deductions	Balance at end of period
Six Months Ended June 30, 2020				
Contract liabilities:				
Deferred revenue	$ 16,354	$ 2,000	$ (14)	$ 18,340
Total contract liabilities	$ 16,354	$ 2,000	$ (14)	$ 18,340

13. Related-Party Transactions

Consulting Services

The Company incurred expenses for consulting services provided by its founders totaling $0.1 million during each of the three months ended June 30, 2020 and 2019, respectively, and $0.1 million and $0.3 million during each of the six months ended June 30, 2020 and 2019, respectively. The Company entered into consulting agreements with its founders to serve on its Scientific Advisory Board, effective January 1, 2020 to December 31, 2021, under which they will be paid quarterly for their services.

14. Collaboration Agreements

Asklepios Biopharmaceutical, Inc.

Feasibility Study and License Agreement

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

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

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

The AskBio Collaboration Agreement is considered to be within the scope of ASC 808, as both parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the AskBio Collaboration Agreement and have identified the following promises in the arrangement (1) conducting research and development activities to develop and commercialize products under the collaboration, (the "R&D Services"), (2) granting a non-exclusive, non-transferable, royalty-free, fully paid up, worldwide license to certain intellectual property of the Company, (the "IP Rights") for the purpose of performing the POC Studies, (the "Research License"), (3) granting an exclusive, nontransferable, worldwide license to the IP Rights for use in certain indications (the" Collaboration License"), (4) providing manufactured supply of preclinical and clinical ImmTOR, (the "Manufactured Supply"), (5) participation on identified steering committees responsible for the oversight of the collaboration, (the "JSC Participation"), and (6) granting an exclusive option to obtain a license under the IP Rights to research, develop and commercialize Licensed Products. The Company determined that the R&D Services, Research License, Collaboration License, Manufactured Supply, and JSC Participation were not capable of

being distinct, and therefore must be combined into a single performance obligation. Therefore, promises (1) through (5) identified above were combined into a single performance obligation. Furthermore, the Company evaluated the Option Agreement and determined that it does not provide AskBio with a material right under ASC 606 as the option was not priced at a discount (see discussion of the Option exercise in Note 12). The Company noted that AskBio did not meet the definition of a customer within the scope of ASC 606 for any distinct performance obligations as the Company concluded that such items were not an output of the Company's ordinary activities. As such, the Company determined that the entire arrangement would be accounted for within the scope of ASC 808.

In accordance with ASC 808, collaboration expenses are recognized within R&D expense and selling, general and administrative expense on the Company's condensed consolidated statements of operations. For the three and six months ended June 30, 2020, the Company recognized $0.8 million and $2.0 million, respectively, of collaboration expense under the AskBio Collaboration Agreement in which actual costs incurred by both parties approximate a 50% cost share.

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

Massachusetts Institute of Technology

On November 25, 2008, the Company entered into an exclusive patent license agreement (the "MIT License") with the Massachusetts Institute of Technology ("MIT"). 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.

On June 12, 2020, the Company entered into a Fifth Amendment (the "MIT Amendment") to the MIT License, which is effective as of May 15, 2020. Pursuant to the MIT Amendment, certain of the Company's diligence obligations were extended, including a diligence obligation to commence a Phase 3 trial for a licensed product by a specific date in the second quarter of 2021. Additionally, certain of the Company's development and regulatory milestones and payments upon achievement of such milestones were adjusted.

As of June 30, 2020, and in connection with the execution of the Spark License Agreement, the Company has made contractual payments pursuant to the MIT License totaling $2.2 million for the sublicense granted to Spark, and $0.4 million relative to the calculated premium paid by Spark for the equity investments made under the Spark Purchase Agreement. The Company made no additional payments during the six months ended June 30, 2020.

Shenyang Sunshine Pharmaceutical Co., Ltd

In May 2014, the Company entered into a license agreement (the "3SBio License") with Shenyang Sunshine Pharmaceutical Co., Ltd. ("3SBio"). The Company has paid to 3SBio an aggregate of $3.0 million in upfront and milestone-based payments under the 3SBio License as of June 30, 2020. The Company is required to make future payments to 3SBio contingent upon the occurrence of events related to the achievement of clinical and regulatory approval milestones of up to an aggregate of $21.0 million for products containing the Company's ImmTOR platform, and up to an aggregate of $41.5 million for products without the ImmTOR platform.

15. Income Taxes

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

For the three and six months ended June 30, 2020 and 2019, the Company did not record a current or deferred income tax expense or benefit.

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

Utilization of the net operating loss and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code due to ownership change limitations that have occurred previously, or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. As of December 31, 2019, the Company completed a Section 382 study, noting that an ownership change occurred during 2017.

However, the Company has determined that all net operating losses would be available in the future. As a result, the deferred tax assets related to the federal and Massachusetts net operating losses and credit carryforwards are not currently limited.

The Company applies ASC 740 to uncertain tax positions. As of the adoption date of January 1, 2010 and through June 30, 2020, the Company had no unrecognized tax benefits or related interest and penalties accrued.

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

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

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

16. Defined Contribution Plan

The Company maintains a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pretax basis. The 401(k) Plan provides for matching contributions on a portion of participant contributions pursuant to the 401(k) Plan's matching formula. All matching contributions vest ratably over 4 years and participant contributions vest immediately. Contributions by the Company totaled less than $0.1 million during each of the three months ended June 30, 2020 and 2019, respectively, and $0.1 million during each of the six months ended June 30, 2020 and 2019.

17. Commitments and Contingencies

As of June 30, 2020, the Company has an operating lease agreement for an office in Watertown, MA. See Note 8 for additional information regarding the Company's leases.

Other

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

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

18. Subsequent Events

Swedish Orphan Biovitrum AB (Publ) License and Development Agreement

On June 11, 2020, the Company and Swedish Orphan Biovitrum AB (Publ), a Swedish corporation ("Sobi"), entered into a license and development agreement (the "Sobi License"). Pursuant to the Sobi License, the Company has agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize the Company's SEL-212 drug candidate, which is currently in development for the treatment of chronic refractory gout. Pursuant to the Sobi License, in consideration of the license, Sobi agreed to pay the Company a one-time, up-front payment of $75 million. Sobi has also agreed to make milestone payments totaling up to $630 million to the Company upon the achievement of various

development and regulatory milestones and sales thresholds for annual net sales of SEL-212, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier.

Pursuant to the Sobi License, the Company has agreed to supply (at cost) quantities of SEL-212 as necessary for completion of the planned Phase 3 program for SEL-212, which includes two planned Phase 3 clinical trials and a crossover study. Sobi has agreed to reimburse the Company for all budgeted costs incurred to complete development of SEL-212, including but not limited to costs incurred while conducting and completing the Phase 3 program for SEL-212, except for any costs of additional development activities required that are related to ImmTOR and that are unrelated to SEL-212. Sobi will have control and responsibility over all regulatory filings, including any INDs, BLAs and MAAs relating to the licensed product.

The consummation of the transactions contemplated by the Sobi License is subject to customary closing conditions, including the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The transactions contemplated by the Sobi License were consummated on July 28, 2020 following the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Sobi may terminate the Sobi License for any reason upon 180 days' written notice to the Company, whereby the rights to the licensed compound would revert to the Company.

Additionally, on June 11, 2020, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with Sobi, pursuant to which the Company agreed to sell to Sobi an aggregate of 5,416,390 shares of its common stock at a purchase price equal to $4.6156 per share, which represented 120% of the 10-day volume-weighted average price of the Company's common stock prior to signing, for aggregate gross proceeds of $25 million (the "Sobi Private Placement"). The closing of the Sobi Private Placement occurred on July 31, 2020, following the closing of the transactions contemplated under the Sobi License. In accordance with ASC 815, this forward sale treatment qualifies as equity classification as the shares are not within the scope of ASC 480. The shares of common stock acquired in the Sobi Private Placement are subject to a one-year lock-up from closing, during which time Sobi is prohibited from selling or otherwise disposing of such shares.

Also on June 11, 2020, the Company entered into a registration rights agreement (the "Sobi Registration Rights Agreement") with Sobi, pursuant to which the Company has agreed to prepare and file a registration statement with respect to the resale of the shares of common stock acquired in the Sobi Private Placement. The Company will be required to file this resale registration statement within 90 days from closing and to have the registration statement declared effective within 120 days from closing (or within 160 days if the SEC reviews the registration statement).

The Sobi Private Placement is exempt from registration pursuant to Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder, as a transaction by an issuer not involving a public offering. Sobi has represented that it will acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends have been affixed to the securities issued in this transaction.

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

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

OVERVIEW

We are a clinical-stage biopharmaceutical company using our proprietary ImmTOR immune tolerance platform with the goal of optimizing the efficacy of biologics, enabling the re-dosing of life-saving gene therapy, and developing novel immunotherapies for autoimmune diseases. Our ImmTOR platform encapsulates an immunomodulator in biodegradable nanoparticles and is designed to mitigate the formation of anti-drug antibodies, or ADAs, by inducing antigen-specific immune tolerance. We have developed a portfolio of proprietary and collaboration-driven applications of ImmTOR, and we plan to continue to pursue opportunistic strategic collaborations, out-licensing, and in-licensing transactions in addition to developing proprietary compounds utilizing ImmTOR.

On June 12, 2020, we announced that we had entered into a license and development agreement, or the Sobi License, with Swedish Orphan Biovitrum AB (Publ), a Swedish corporation, or Sobi, pursuant to which we have agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize the our SEL-212 drug candidate, which is currently in development for the treatment of chronic refractory gout. For a further description of the Sobi License, see "Licenses and Collaborations- Swedish Orphan Biovitrum."

Following our entry into the Sobi License, we are focused on unlocking the full potential of the ImmTOR immune tolerance platform in the following three high-impact areas of unmet need:

- Optimizing the efficacy of biologic therapies. We believe the efficacy and safety of many currently marketed biologic therapies could be improved by utilizing ImmTOR. Additionally, ImmTOR has the potential to enable the development of some biologics that might otherwise have to be abandoned.

- Enabling the re-dosing of life saving AAV gene therapy. AAV gene therapies can typically only be administered once due to the formation of neutralizing antibodies, and therapeutic benefit can wane over time due to cell turnover. Enabling vector re-dosing has the potential to create chronic therapies that patients can use throughout their lifetimes.

- Developing novel immunotherapies for autoimmune diseases. We believe we have demonstrated the ability of ImmTOR to mitigate deleterious immune responses in humans with the SEL-212 program. We intend to leverage our learnings from this program to develop antigen-specific immunotherapies with the goal of re-establishing tolerance to self-antigens in autoimmune diseases.

Our Current Programs

Chronic Refractory Gout

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

In March 2019, we initiated a Phase 2 head-to-head clinical trial of SEL-212 (COMPARE), in which SEL-212 is being compared against the current FDA-approved therapy for chronic refractory gout, KRYSTEXXA, in multiple clinical sites in the United States. We expect to report top-line data in the third quarter of 2020, subject to the impact of the novel coronavirus disease, COVID-19, pandemic on our business. The two-armed, open label trial has enrolled 170 patients with 87 patients receiving KRYSTEXXA (as set forth in the prescribing information) and the other 83 patients receiving six monthly doses of SEL-212 (0.15 mg/kg of ImmTOR and 0.2 mg/kg of pegadricase). The primary endpoint in the study is the percentage of patients in each arm that maintain SUA control below 6.0 mg/dL, for at least 80% of the time during months three and six.

Subject to the impact of the COVID-19 pandemic on our business, we and Sobi plan to commence the two Phase 3 clinical trials of SEL-212 in the third quarter of 2020, at Sobi's expense. The Phase 3 clinical program will consist of two double blinded, placebo-controlled trials of SEL-212. Each trial is expected to enroll 105 patients and have 35 patients receiving 0.1 mg/kg of ImmTOR and 0.2 mg/kg of pegadricase, 35 patients receiving 0.15 mg/kg of ImmTOR and 0.2 mg/kg of pegadricase, and 35 patients receiving placebo. See “Licenses and Collaborations-Swedish Orphan Biovitrum” for further details surrounding the Sobi License.

Gene Therapy

Our lead gene therapy program, which is based on our product candidate SEL-302, is in collaboration with AskBio in methylmalonic acidemia, or MMA, an inherited disorder in which the body is unable to process certain proteins and fats (lipids) properly. Subject to the impact of the COVID-19 pandemic, we plan to file an IND in MMA in the first quarter of 2021 under this collaboration and report initial data by the second half of 2021. See “Licenses and Collaborations-AskBio” for further details surrounding the AskBio collaboration.

Our proprietary gene therapy product candidate, SEL-313, is being developed to treat ornithine transcarbamylase or OTC deficiency and is currently in preclinical development. We have several additional programs in development with our collaborators.

Autoimmune Diseases

We expect that our lead indication in our autoimmune diseases program will be IgA nephropathy, a kidney disease that occurs when an antibody called immunoglobulin A (IgA) accumulates in the kidneys. We plan to file an Investigational New Drug, or IND, application, for this program in 2021 subject to the impact of the COVID-19 pandemic on our business. Our second indication is expected to be primary biliary cholangitis, or PBC, an autoimmune disease that causes progressive destruction of the bile ducts. We believe both diseases have well-defined target antigens, significant unmet medical need, and are well suited to the application of our ImmTOR immune tolerance platform.

Licenses and Collaborations

Swedish Orphan Biovitrum

On June 12, 2020, we announced that we had entered into the Sobi License, pursuant to which we have agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize the our SEL-212 drug candidate, which is currently in development for the treatment of chronic refractory gout. Pursuant to the Sobi License, Sobi has agreed to pay to the Company a one-time, up-front payment of $75 million within 45 days of the closing date of the Sobi License. Sobi has also agreed to make milestone payments totaling up to $630 million to us upon the achievement of various development and regulatory milestones and sales thresholds for annual net sales of SEL-212, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier. The consummation of the transactions contemplated by the Sobi License is subject to customary closing conditions, including the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The transactions contemplated by the Sobi License were consummated on July 28, 2020 following the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Additionally, Sobi agreed to purchase an aggregate of 5,416,390 shares of our common stock at $4.6156 for aggregate gross proceeds of $25 million, which we refer to as the Sobi Private Placement. The closing of the Sobi Private Placement occurred on July 31, 2020, following the closing of the transactions contemplated under the Sobi License.

Under the Sobi License, we will have operational oversight of the two planned Phase 3 clinical trials of SEL-212 expected to commence in the third quarter of 2020, at Sobi's expense.

Sarepta Therapeutics

In June 2020, we entered into a research license and option agreement with Sarepta Therapeutics, or the Sarepta Agreement. Pursuant to the agreement, we agreed to grant Sarepta a license to research and evaluate ImmTOR in combination with Sarepta’s AAV gene therapy or gene editing technology, using viral or non-viral delivery, or the Product, to treat Duchenne Muscular Dystrophy and certain Limb-Girdle Muscular Dystrophy subtypes, or the Indications. Sarepta will have an option term of 24 months during which it can opt-in to obtain an exclusive license to further develop and commercialize the Product to treat at least one Indication, with a potential to extend the option term if Sarepta pays an additional fee to the Company. Sarepta made an up-front payment to us upon signing of the agreement, and we are eligible to receive additional preclinical payments under the option term. If Sarepta opts-in to an exclusive license agreement, we could receive option exercise payments per indication, we would be entitled to significant development and commercial milestone payments and tiered royalties ranging from the mid-to-high single digits based on net sales.

AskBio

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

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

CureCN

In September 2018, we announced a collaboration with the European consortium, CureCN, for an ImmTOR+AAV gene therapy combination product candidate in Crigler-Najjar syndrome.

Spark Therapeutics

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

Impact of Novel Coronavirus

We are closely monitoring how the spread of the novel coronavirus is affecting our employees, business, preclinical studies and clinical trials. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees

continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. Disruptions caused by the COVID-19 pandemic may result in difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials and the incurrence of unforeseen costs as a result of preclinical study or clinical trial delays. While the COVID-19 pandemic has not had a material impact on our clinical programs as of the date of this Quarterly Report on Form 10-Q, it could have an impact on our ability to successfully complete our ongoing COMPARE trial, our ability to commence the Phase 3 clinical program of SEL-212, and our ability to commence preclinical and clinical studies of our gene therapy and autoimmune disease programs, and our ability to obtain supply of both active drug substances and finished drug product as well as efficient execution of the overall supply chain for SEL-212 and our other programs. We have been proactively working with our contract research organization, or CRO, clinical sites, and principal investigators to provide patients with more convenient locations to have their SUA measured for the primary endpoint of the study, such as at local laboratories or their homes, as well as alternative sites to receive infusions of study drug. We are also working with our primary and back-up suppliers for SEL-037 (pegadricase) and SEL-110 (ImmTOR) to ensure that we have adequate supply of our materials for both our clinical and preclinical programs. As of the date of this Quarterly Report on Form 10-Q, we believe we have adequate supply of all material necessary to initiate our Phase 3 clinical program of SEL-212 in chronic refractory gout and to begin our clinical trial in gene therapy under our collaboration with AskBio.

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

FINANCIAL OPERATIONS OVERVIEW

Financial Operations

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

Since inception, we have incurred significant operating losses. We incurred net losses of $43.7 million and $28.5 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $379.5 million. We expect to continue to incur significant expenses and operating losses for at least the next several years as we:

- continue the research and development of our other product candidates as well as product candidates that we may be developing jointly with collaboration partners;

- seek to enhance our ImmTOR platform and discover and develop additional product candidates;

- seek to enter into collaboration, licensing and other agreements, including, but not limited to research and development, and/or commercialization agreements;

- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- potentially establish a sales, marketing and distribution infrastructure and scales-up external manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;

- maintain, expand and protect our intellectual property portfolio, including through licensing arrangements; and

- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operations as a public company.

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

We believe that our existing cash, cash equivalents, investments, and restricted cash as of June 30, 2020, together with the $25 million payment received from Sobi under the Sobi Private Placement and the expected payment from Sobi of $75 million that

is due under the Sobi License, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. 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.

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

Grant and collaboration revenue

To date, we have not generated any product sales. Our revenue consists of grant and collaboration revenue, which includes amounts recognized related to upfront and milestone payments for research and development funding under collaboration and license agreements. In addition, we earn revenue under the terms of government contracts or grants, which require the performance of certain research and development activities. We expect that any revenue we generate will fluctuate from quarter to quarter because of the timing and amount of fees, research and development reimbursements and other payments from collaborators. We do not expect to generate revenue from product sales for at least the next several years. If we or our collaborators fail to complete the development of our product candidates in a timely manner or fail to obtain regulatory approval as needed, our ability to generate future revenue will be harmed, and will affect the results of our operations and financial position. For a further description of the agreements underlying our collaboration and grant-based revenue, see Notes 2 and 12 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Research and development

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

We have incurred a total of $266.2 million in research and development expenses from inception through June 30, 2020, with a majority of the expenses being spent on the development of SEL-212 and a prior nicotine vaccine candidate, and the remainder being spent on our various discovery and preclinical stage product candidate programs and the general expansion of our technology.

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

We expense research and development costs as incurred. Conducting a significant amount of research and development is central to our business model. Product candidates in clinical development generally have higher development costs than those in earlier stages of development, primarily due to the size, duration and cost of clinical trials. The successful development of our clinical and preclinical product candidates is highly uncertain. Clinical development timelines, the probability of success and development costs can differ materially from our expectations. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently expect will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time to complete any clinical development.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development expenses (key projects and initiatives):				
SEL-212	$ 5,969	$ 8,454	$ 14,933	$ 11,315
AskBio collaboration	598	—	1,574	—
SELA-070	—	—	—	51
Discovery and preclinical stage product candidate programs, collectively	195	11	480	300
Other internal research and development expenses	3,968	3,669	8,467	7,821
Total research and development expenses	$ 10,730	$ 12,134	$ 25,454	$ 19,487

General and administrative

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

Investment income

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

Interest expense

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

Other income (expense)

Other income (expense) was de minimis during each of the three and six months ended June 30, 2020, and 2019.

Change in fair value of warrant liabilities

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

Foreign currency transaction gain (loss)

The functional currency of our Russian subsidiary is the Russian ruble. In addition to holding cash denominated in Russian rubles, our Russian bank accounts also hold cash balances denominated in U.S. dollars to facilitate payments to be settled in U.S. dollars or other currencies. As of June 30, 2020 and December 31, 2019, we maintained cash of $0.3 million and $0.4 million, respectively, in Russian banks, all of which was denominated in U.S. dollars. The amounts denominated in U.S. dollars and used in transacting the day-to-day operations of our Russian subsidiary are subject to transaction gains and losses, which are reported as incurred.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended June 30, 2020 and 2019

Revenue

The following is a comparison of revenue for the three months ended June 30, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended June 30,		Increase	
	2020	2019	(decrease)	
Collaboration revenue	$ —	$ 13	$ (13)	—%

During the three months ended June 30, 2020, we did not recognize revenue. During the three months ended June 30, 2019, we recognized less than $0.1 million of revenue for a shipment under our collaboration agreement with Spark.

Research and development

The following is a comparison of research and development expenses for the three months ended June 30, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended June 30,		Increase	
	2020	2019	(decrease)	
Research and development	$ 10,730	$ 12,134	$ (1,404)	(12)%

During the three months ended June 30, 2020, our research and development expenses decreased by $1.4 million, or 12%, as compared to 2019. The decrease in costs was primarily the result of reduced expense for our Phase 2 COMPARE trial for SEL-212 offset by increases for our gene therapy program in collaboration with AskBio, and salaries and benefits.

General and administrative

The following is a comparison of general and administrative expenses for the three months ended June 30, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended June 30,		Increase	
	2020	2019	(decrease)	
General and administrative	$ 5,637	$ 4,114	$ 1,523	37%

During the three months ended June 30, 2020, our general and administrative expenses increased by $1.5 million, or 37%, as compared to 2019. The increase in costs was the result of expenses incurred for salaries, legal and professional fees offset by decreased travel expense.

Investment income

Investment income was less than $0.1 million and $0.2 million, respectively during the three months ended June 30, 2020 as compared to 2019. The decrease reflects reduced interest rates.

Foreign currency transaction gain (loss)

We recognized minimal foreign currency losses of less than $0.1 million during each of the three months ended June 30, 2020 and 2019, respectively.

Interest expense

Interest expense was $0.2 million and $0.4 million for the three months ended June 30, 2020 and 2019, respectively, representing interest expense and amortization of the carrying costs of our credit facilities.

Change in fair value of warrant liabilities

For the three months ended June 30, 2020, we recognized a $7.5 million charge for the increase in the fair value of warrant liabilities utilizing a Black-Scholes valuation methodology. The increase in value was primarily driven by an increase in the share price and volatility, offset by a decreased discount rate this quarter (see Note 5 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Other income (expense)

Other (expense) income was de minimis for each of the three months ended June 30, 2020 and 2019.

Net Loss

Net loss for the three months ended June 30, 2020 was $24.1 million compared to $16.4 million for the three months ended June 30, 2019.

Comparison of the Six Months Ended June 30, 2020 and 2019

Revenue

The following is a comparison of revenue for the six months ended June 30, 2020 and 2019 (in thousands, except percentages):

	Six Months Ended June 30,		Increase	
	2020	2019	(decrease)	
Collaboration revenue	$ —	$ 23	$ (23)	—%

During the six months ended June 30, 2020, we did not recognize revenue. During the six months ended June 30, 2019, we recognized less than $0.1 million of revenue for two shipments under our collaboration agreement with Spark.

Research and development

The following is a comparison of research and development expenses for the six months ended June 30, 2020 and 2019 (in thousands, except percentages):

	Six Months Ended June 30,		Increase	
	2020	2019	(decrease)	
Research and development	$ 25,454	$ 19,487	$ 5,967	31%

During the six months ended June 30, 2020, our research and development expenses increased by $6.0 million, or 31%, as compared to 2019. The increase in cost was primarily the result of expenses incurred for the preparation of the Phase 3 clinical

trial for SEL-212, the continuation of our Phase 2 COMPARE trial for SEL-212, salaries and benefits, and for our gene therapy program in collaboration with AskBio.

General and administrative

The following is a comparison of general and administrative expenses for the six months ended June 30, 2020 and 2019 (in thousands, except percentages):

	Six Months Ended June 30,		Increase	
	2020	2019	(decrease)	
General and administrative	$ 9,735	$ 8,627	$ 1,108	13%

During the six months ended June 30, 2020, our general and administrative expenses increased by $1.1 million, or 13%, as compared to 2019. The increase in costs was the result of expenses for legal, professional fees and stock compensation expense offset by consulting fees.

Investment income

Investment income was $0.3 million and $0.5 million, respectively during the six months ended June 30, 2020 as compared to 2019. The decrease reflects reduced interest rates.

Foreign currency transaction gain (loss)

We recognized minimal foreign currency gains of less than $0.1 million and minimal losses of less than $0.1 million during each of the six months ended June 30, 2020 and 2019, respectively.

Interest expense

Interest expense was $0.5 million and $0.8 million for the six months ended June 30, 2020 and 2019, respectively, representing interest expense and amortization of the carrying costs of our credit facilities.

Change in fair value of warrant liabilities

For the six months ended June 30, 2020, we recognized an $8.4 million charge for the increase in the fair value of warrant liabilities utilizing a Black-Scholes valuation methodology. The increase in value was primarily driven by an increase in the share price and volatility, offset by a decreased discount rate this quarter (see Note 5 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Other income (expense)

Other (expense) income was de minimis for each of the six months ended June 30, 2020 and 2019.

Net Loss

Net loss for the six months ended June 30, 2020 was $43.7 million compared to $28.5 million for the six months ended June 30, 2019.

LIQUIDITY AND CAPITAL RESOURCES

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

From our inception through June 30, 2020, we have raised an aggregate of $425.0 million to fund our operations, which includes $118.5 million from the sale of preferred stock, $11.1 million in government grant funding, $25.3 million from borrowings under our credit facility, $53.3 million from our collaborations and license agreements, $64.5 million in combined net proceeds from our initial public offering, $149.3 million in combined net proceeds from private placements and follow-on offerings of our common stock, and $3.0 million in aggregate net proceeds from "at-the-market" offerings of our common stock.

Collaborations

On June 13, 2020, we entered into the Sarepta Agreement. We received a $2.0 million upfront payment.

On June 11, 2020, we entered into the Sobi License. Upon closing of the Sobi Private Placement, Selecta received $25 million for Sobi’s purchase of our common stock at $4.6156 per share and we expect payment from Sobi of $75 million that is due under the Sobi License. We are eligible to receive $630 million in milestone payments upon the achievement of various development and regulatory milestones and sales thresholds for annual net sales of SEL-212, and tiered royalty payments

ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier. Additionally, Sobi has agreed to fund the planned Phase 3 clinical program of SEL-212, which is expected to substantially reduce Selecta's annual operating expenses.

On December 17, 2019, we entered into the AskBio License Agreement. Pursuant to the AskBio License Agreement, AskBio has exercised its option to exclusively license intellectual property rights covering ImmTOR to research, develop, and commercialize certain AAV gene therapy products utilizing ImmTOR, and targeting the GAA gene, or derivatives thereof, to treat Pompe Disease. We received $7.0 million of upfront fees pursuant to the AskBio License Agreement and are eligible to receive $237 million in milestone payments, and royalties on net sales ranging from the mid-to-high single digits.

Financings

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

From August 11, 2017, the date we entered into the Sales Agreement, to December 31, 2019, we sold 615,453 shares of our common stock pursuant to the Sales Agreement at an average price of approximately $1.84 per share for aggregate net proceeds of $1.0 million, after deducting commissions and other transaction costs. During the six months ended June 30, 2020, we sold 1,069,486 shares of our common stock pursuant to the Sales Agreement at an average price of approximately $2.16 per share for aggregate net proceeds of $2.1 million, after deducting commissions and other transaction costs.

As of June 30, 2020, our cash, cash equivalents, and restricted cash were $61.4 million, of which $1.7 million was restricted cash related to lease commitments and $0.3 million was held by our Russian subsidiary designated solely for use in its operations. Our Russian subsidiary cash is consolidated for financial reporting purposes.

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

Indebtedness

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

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

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

Plan of operations and future funding requirements

As of the date of this Quarterly Report on Form 10-Q, we have not generated any product sales. We do not know when, or if, we will generate revenue from product sales. We will not generate significant revenue from product sales unless and until we obtain regulatory approval and commercialize one of our current or future product candidates. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses, and general overhead costs. We expect that

we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to risks in the development of our products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect that we will need substantial additional funding to support our continuing operations.

As of June 30, 2020 and December 31, 2019, we had an accumulated deficit of $379.5 million and $335.8 million, respectively. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of our product candidates, conducting preclinical studies and clinical trials, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital.

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

We believe that our existing cash, cash equivalents, and restricted cash as of June 30, 2020, together with the $25 million payment received from Sobi under the Sobi Private Placement and the expected payment from Sobi of $75 million that is due under the Sobi License, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. Subject to the impact of the COVID-19 pandemic on our business, we and Sobi plan to commence the Phase 3 clinical program for SEL-212 in the third quarter of 2020. Additionally, while the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital as and when needed. 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 number of product candidates that we pursue;
- our collaboration agreements remaining in effect, our entering into additional collaboration agreements and our ability to achieve milestones under these agreements;
- the cost of manufacturing clinical supplies of our product candidates;
- our headcount growth and associated costs;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

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

Summary of Cash Flows

(In thousands)	Six Months Ended June 30, 2020	2019
Cash provided by (used in):		
Operating activities	$ (23,506)	$ (27,437)
Investing activities	(289)	(11,274)
Financing activities	(6,327)	31,479
Effect of exchange rate changes on cash	(42)	29
Net change in cash, cash equivalents, and restricted cash	$ (30,164)	$ (7,203)

Operating activities

Net cash used in operating activities for the six months ended June 30, 2020 was $23.5 million compared to $27.4 million in the same period in 2019, a decrease of $3.9 million. The decrease in net cash used in operating activities was primarily due to the collection of $5.0 million in accounts receivable, a $5.9 million change in accrued expenses and other liabilities when compared to the prior year, an increase of $2.0 million in deferred revenue, offset by $2.4 million changes in prepaid expenses and accounts payable when compared to the prior year and a $6.8 million increase in recorded net loss after adjusting for non-cash charge of $8.4 million for the warrant liability.

Investing activities

Net cash used in investing activities for the six months ended June 30, 2020 was $0.3 million compared to net cash used in investing activities of $11.3 million in the same period in 2019. The net cash used in investing activities in 2020 was to purchase property and equipment. During the six months ended June 30, 2019, the net cash used by investing was the result of purchases of short-term investments of $18.2 million, offset by $6.8 million in sales and maturities of short-term investments.

Financing activities

Net cash used in financing activities for the six months ended June 30, 2020 was $6.3 million compared to net cash provided by financing activities of $31.5 million in the same period in 2019. The net cash used in financing activities in 2020 was the result of $4.4 million of issuance costs paid for December 2019 financing, $4.2 million principal payment on outstanding debt, offset by $2.1 million net proceeds from "at-the-market" offerings. The net cash provided by financing activities in 2019 was due to $30.9 million net proceeds from the issuance of common stock under the January 2019 Public Offering, $0.4 million net proceeds from "at-the-market' offerings and $0.1 million from the exercise of employee stock options.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

As of June 30, 2020, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

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

Clinical Trial Costs

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

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

Revenue Recognition

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

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

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

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

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

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

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

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

Warrant Liabilities

In December 2019, we issued common warrants in connection with the 2019 Purchase Agreement. Pursuant to the terms of these common warrants, we could be required to settle the common warrants in cash in the event of certain acquisitions of the Company and, as a result, the common warrants are required to be measured at fair value and reported as a liability on the balance sheet. We recorded the fair value of the common warrants of $40.7 million upon issuance using the Black-Scholes valuation model, and are required to revalue the common warrants at each reporting date with any changes in fair value recorded on our statement of operations. Inputs used to determine estimated fair value of the common warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. As of June 30, 2020, the fair value of the common warrants of $32.8 million was recorded as a long-term liability on our balance sheet, which resulted in a charge in fair value of $8.4 million for the six months ended June 30, 2020.

Stock-Based Compensation

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

Emerging Growth Company Status

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

Smaller Reporting Company

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of June 30, 2020 and December 31, 2019, we had cash, cash equivalents, restricted cash and investments of $61.4 million and $91.6 million, respectively, consisting of non-interest and interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term and the low risk profile of our money market accounts and investments, and our current plan to hold investments to maturity, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents or short-term investments.

In addition, we are subject to currency risk for balances held in Russian rubles in our foreign subsidiary. We hold portions of our funds in both U.S. dollars and Russian rubles. The exchange rate between the U.S. dollar and Russian ruble changes from period to period. As of June 30, 2020, we held cash and cash equivalents totaling $0.3 million in Russian banks to support our Russian subsidiary, all of which were denominated in U.S. dollars. We do not hedge against foreign currency risks. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Limitations on effectiveness of controls and procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2020.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that occurred during the three months ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings

On August 3, 2020, a putative stockholder of the Company filed a shareholder derivative action purportedly on behalf of the Company and against certain current and former members of the Company's Board of Directors, as well as one affiliated company owned by a current board member, in the Court of Chancery of the State of Delaware, namely Franchi v. Barabe, et al. The complaint alleges that the individual defendants breached their fiduciary duties and committed corporate waste when they approved the private placement transaction, announced on December 18, 2019, at a price allegedly below fair value. The complaint further alleges that the four defendant directors who participated in the private placement were unjustly enriched in connection with the transaction, because they had material non-public information which allegedly caused the stock price to increase when it was made public one day after the private placement was announced. The Company expects to file a motion to dismiss.

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 $43.7 million for the six months ended June 30, 2020, and $55.4 million and $65.3 million for each of the years ended December 31, 2019 and 2018, respectively. As of June 30, 2020, we had an accumulated deficit of $379.5 million. To date, we have financed our operations primarily through the public offering and private placements of our securities, funding received from research grants and collaboration arrangements and our credit facility. We currently have no source of product revenue, and we do not expect to generate product revenue for the foreseeable future. All of our revenue to date has been collaboration and grant revenue. We have devoted substantially all of our financial resources and efforts to developing our ImmTOR platform, identifying potential product candidates and conducting preclinical studies and our clinical trials. We are in the early stages of development of most of our product candidates, and we have not completed development of any ImmTOR-enabled therapies. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses will increase substantially as we:

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

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval and securing reimbursement for these product candidates, manufacturing, marketing and selling any products for which we

may obtain regulatory approval, and establishing and managing our collaborations at various stages of a product candidate's development. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations.

We will need substantial additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

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

We believe that our existing cash, cash equivalents and restricted cash as of June 30, 2020, together with the $25 million payment received from Sobi under the Sobi Private Placement and the expected payment from Sobi of $75 million that is due under the Sobi License, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. 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 scope, progress, results and costs of our clinical trials;
- the number of product candidates that we pursue;
- our collaboration agreements remaining in effect, our entering into additional collaboration agreements and our ability to achieve milestones under these agreements;
- the cost of manufacturing clinical supplies of our product candidates;
- our headcount growth and associated costs;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether

equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

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

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

We commenced active operations in 2007, and our operations to date have been limited to developing and researching our ImmTOR platform and related products and programs, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. Other than SEL-212, which we have agreed to license to Sobi (except as to Greater China), our product candidates are still in preclinical development. While we have completed our early development clinical trials and a Phase 2 clinical trial for SEL-212, we have not completed a clinical trial for any other product candidate, nor have we demonstrated our ability to successfully complete any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

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

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

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

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

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

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

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

All of our product candidates are derived from our ImmTOR platform, which is an unproven approach to induce antigen-specific immune tolerance and to mitigate the immunogenicity of biologic therapies currently being implemented to treat patients. We are primarily developing our ImmTOR platform to improve and enable activity in biologics that are designed to treat rare and serious diseases.

We are developing two gene therapy product candidates for rare inborn errors of metabolism. Our lead gene therapy program, known as SEL-302, is a potential gene therapy product candidate for methylmalonic acidemia, or MMA. In August 2019, we entered into a feasibility study and license agreement with AskBio, or the AskBio Collaboration Agreement, pursuant to which we and AskBio agreed to conduct proof of concept studies to potentially validate the use of our ImmTOR platform in conjunction with an adeno-associated virus, or AAV, gene therapy for the treatment of MMA, based on SEL-302, to mitigate the formation of neutralizing anti-AAV capsid antibodies. If the proof of concept studies are successful, we will proceed with a collaboration to pursue the development and commercialization of AAV gene therapy product candidates utilizing ImmTOR for the treatment of certain agreed serious rare and orphan genetic diseases. Our proprietary gene therapy product candidate, SEL-313, is being developed to treat OTC deficiency and is currently in preclinical development. We have several additional programs in development with our collaborators. In September 2018, we announced a collaboration with the European consortium, CureCN, for an ImmTOR+AAV gene therapy combination product candidate in Crigler-Najjar syndrome.

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

- design, initiation and completion of preclinical studies and clinical trials with positive results;
- reliance on third parties (including but not limited to collaborators, licensees, clinical research organizations and contract manufacturing organizations);
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities, or establishing such capabilities ourselves;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;

- our existing collaboration agreements remaining in effect and our ability to enter into new collaborations throughout the development process as appropriate, from preclinical studies through to commercialization;

- acceptance of our products, if and when approved, by patients and the medical community;

- effectively competing with other therapies;

- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved;

- protecting our rights in our intellectual property portfolio;

- operating without infringing or violating the valid and enforceable patents or other intellectual property of third parties;

- maintaining an acceptable safety profile of our products following approval; and

- maintaining and growing an organization of scientists and business people who can develop and commercialize our product candidates and technology.

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

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

- due to the unproven nature of our ImmTOR therapeutics, there may be different efficacy and safety rates in various indications;

- the FDA or other regulatory agencies may lack experience in evaluating the efficacy and safety of products based on ImmTOR 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.

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

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

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

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

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

Additionally, under the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional

biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

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

The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to evaluate the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates created with novel genome editing technology such as ours can be more lengthy, rigorous and expensive than the process for other better known or more extensively studied product candidates and technologies. Since we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or comparable regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. This may be a particularly significant risk for many of the genetically defined diseases for which we may develop product candidates alone or with collaborators due to small patient populations for those diseases, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome editing technology in a timely manner or under technically or commercially feasible conditions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

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

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

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

Our product candidate, SEL-212, which has been licensed to Sobi (except as to Greater China), was evaluated in a Phase 2 clinical program that was initiated in October 2016 and the final patient's last visit occurred in January 2019. In March 2019, we initiated COMPARE, a Phase 2 clinical trial designed to directly compare the safety, efficacy and tolerability of SEL-212 to the currently FDA-approved uricase therapy, KRYSTEXXA, for the treatment of patients with chronic refractory gout, and completed our targeted enrollment of the COMPARE trial in December 2019. Under the Sobi License, we will have operational oversight of the two planned Phase 3 clinical trials of SEL-212 expected to commence in the third quarter of 2020, at Sobi's expense. For a further description of the Sobi License, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Licenses and Collaborations- Swedish Orphan Biovitrum.”

Aside from SEL-212, which has been licensed to Sobi (except as to Greater China), our product candidates are in preclinical development. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical development is costly and inherently uncertain. For example, we have invested significant resources in our preclinical gene therapy program, which has demonstrated the potential for treatment of rare inborn errors of metabolism. Early preclinical results may not be predictive of future results, however, if our technology proves to be ineffective or unsafe as a result of, among other things, adverse side effects, pre-existing anti-drug antibodies that can neutralize the viral vector and block gene transfer, or cellular immune response to the transduced cells, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the clinical development and commercialization of our product candidates.

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

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

In addition, we cannot be certain as to what type and how many clinical trials the FDA will require us to conduct before we may gain regulatory approval to market any of our product candidates in the United States or other countries, if any. Prior to approving a new therapeutic product, the FDA generally requires that safety and efficacy be demonstrated in two adequate and well-controlled clinical trials. We expect that we and Sobi will need to conduct more than one Phase 3 trial for SEL-212 for a chronic refractory gout indication in order to gain approval from the FDA. Even if we and Sobi conduct more than one Phase 3 trial for SEL-212, the FDA may not accept the data, and may delay, limit or deny approval of SEL-212, which could have an impact on the timing of development milestone payments owed to us by Sobi.

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

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

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

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

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

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

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

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

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

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

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

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

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

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

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, or if we are forced to delay or abandon certain clinical trials or other testing in order to conserve capital resources, we may:

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

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

- not obtain marketing approval at all;

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

- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

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

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

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or

comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

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

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

For example, SEL-212, which has been licensed to Sobi (except as to Greater China), is being developed for the treatment of chronic refractory gout, which affects approximately 160,000 patients in the United States. Accordingly, there is a limited number of patients who could enroll in our clinical studies for SEL-212.

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

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

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

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

In December 2019, a novel strain of coronavirus, which causes COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States, where we have planned or ongoing preclinical studies and clinical trials. On March 11, 2020, the World Health Organization declared the outbreak of

COVID-19 as a global pandemic. On March 23, 2020, the governor of Massachusetts ordered the closure of all non-essential businesses effective March 24, 2020. On May 18, 2020, the governor issued an order outlining the phased reopening of workplaces and imposing workplace safety measures to address COVID-19. Because of the nature of our operations, we have been considered to be an essential business so, to date, our operations have only been partially affected by the orders. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our principal executive office with our administrative employees continuing their work outside of our office and limited the number of staff in any given research and development laboratory. If the COVID-19 coronavirus continues to spread in the United States and elsewhere, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;

- delays or difficulties in enrolling patients in our clinical trials;

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, such as ImmTOR including interruption in global shipping that may affect the transport of clinical trial materials;

- changes in local regulations as part of a response to the COVID-19 coronavirus pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals and clinics serving as our clinical trial sites and hospital and clinic staff supporting the conduct of our clinical trials;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, or the closing of clinical trial sites due to the virus, the occurrence of which could affect the integrity of clinical trial data;

- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, or will withdraw from the clinical trial due to concerns over COVID-19, which could impact the results of the clinical trial, including by increasing the number of observed adverse events, or reducing the statistical power of the clinical trials;

- interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facility;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- refusal of the FDA to accept data from clinical trials in affected geographies;

- changes to the clinical endpoints, statistical analysis plan, or enrollment plans for ongoing clinical trials due to limitations in patients, resources, or sites due to COVID-19;

- interruption or delays to our sourced discovery and clinical activities; and

- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical studies;
- the FDA's or the applicable foreign regulatory agency may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

Gene therapy remains a novel technology. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target and prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Our product candidates, including our products that utilize

viral delivery systems, could produce adverse events. Adverse events in our clinical trials or following approval of any of our product candidates, even if not ultimately attributable to our product candidates, could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES AND MANUFACTURING

We rely on 3SBio in China as our primary supplier of pegadricase and on other third parties for the manufacture of our product candidates for preclinical and clinical testing, and expect to continue to do so for the foreseeable future. Our reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such

quantities may not be available at an acceptable cost, or in compliance with regulatory requirements, which could delay, prevent or impair our development or commercialization efforts.

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

Any disruption in production or inability of 3SBio in China to produce adequate quantities of pegadricase to meet our needs, whether as a result of a natural disaster, public health emergency, such as the COVID-19 pandemic, failure to comply with regulatory requirements or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our future product candidates. Furthermore, since 3SBio is located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies, laws, rules and regulations of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, trade tensions between the United States and China have been escalating in recent years. Most notably, several rounds of U.S. tariffs have been placed on Chinese goods being exported to the United States. Each of these U.S. tariff impositions against Chinese exports were followed by a round of retaliatory Chinese tariffs on U.S. exports to China. Pegadricase is subject to, and any other components we purchase from China may be subject to these tariffs, which could increase our manufacturing costs and could make our products, if successfully developed and approved, less competitive than those of our competitors whose inputs are not subject to these tariffs.

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

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

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

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

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

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

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

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

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

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

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing application to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or suppliers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, there are a limited number of manufacturers that operate under cGMP regulations that might be capable of manufacturing our products. Therefore, our product candidates and any future products that we may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the clinical development, marketing approval and commercialization of our product candidates.

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

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

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

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

- collaborators may not perform their obligations as expected;

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

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

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

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

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

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

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

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

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

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

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

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

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business in the business and financial communities, and our stock price, could be adversely affected. In addition, we have a limited number of collaborations and if our relationship with any one or more of such collaborators were to cease, our business would be harmed as a result.

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

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

We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials, including our Phase 2 and planned Phase 3 clinical trials of

SEL-212, which we have agreed to continue to run on behalf of Sobi and for our other product candidates. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials.

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

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

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

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

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

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

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

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

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

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an

adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. For example, even if the statistical results from our Phase 2 head-to-head (COMPARE) trial vs. KRYSTEXXA favor SEL-212 and SEL-212 receives marketing approval, the drug may fail to gain market acceptance from physicians, patients, third-party payors and others in the medical community who may continue to favor KRYSTEXXA.The degree of market acceptance of our product candidates, if any, will depend on a number of factors, including:

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

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

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

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

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

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

The development and commercialization of new drug and biologic products and technologies is highly competitive and is characterized by rapid and substantial technological development and product innovations. We are aware that pharmaceutical and biotechnology companies, including Horizon Pharma plc, offer or are pursuing the development of pharmaceutical

products or technologies that may address one or more indications that our product candidates target, as well as smaller, early-stage companies, that offer or are pursuing the development of pharmaceutical products or technologies that may address one or more indications that our product candidates target. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

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

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

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

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

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

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

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

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

Obtaining and maintaining adequate reimbursement for our products may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our products by third-party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and

are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. Some third-party payors may require pre-approval of coverage for new and innovative therapies, such as our product candidates, before they will provide reimbursement. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

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

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

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

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

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

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

- substantial monetary awards to patients or other claimants;

We maintain general liability, product liability and umbrella liability insurance. Our existing insurance coverage may not fully cover potential liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent. Private individuals (e.g., whistleblowers) can bring these actions on behalf of the government; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

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

- the federal Physician Payments Sunshine Act, which requires applicable manufacturers of certain products for which payment is available under a federal healthcare program to report annually to the government information related to certain payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists

and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- litigation involving patients taking our products;

- restrictions on such products, manufacturers or manufacturing processes;

- restrictions on the labeling or marketing of a product;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

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

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

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

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued that protect our technology or

products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

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

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

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

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security

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

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

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

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

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

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

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

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

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

We are aware of numerous patents and pending applications owned by third parties, and we monitor patents and patent applications in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until

patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

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

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

Even if we are successful in such proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. There could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

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

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we do not have sufficient patent life to protect our product candidates, proprietary technologies and their uses, our business and results of operations will be adversely affected.

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

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

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

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

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

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

We may also be unable to maintain third-party intellectual property rights. For example, MIT may terminate the MIT License if we fail to meet our diligence obligations under the agreement.

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

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

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

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

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. In this regard, in addition to the United States, we also seek to protect our intellectual property rights in other countries. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For all of the patent families in our portfolio, including the families that may provide coverage for our lead product candidate, the relevant statutory deadlines have not yet expired. Therefore, for each of the patent families that we believe provide coverage for our lead product candidate, we will need to decide whether and where to pursue additional protection outside the United States. In addition, the laws of some foreign countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, for our existing patent rights outside the United States and any foreign patent rights we may decide to pursue in the future, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

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

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

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

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

RISKS RELATED TO OUR OPERATIONS

Our new corporate strategy may not be successful.

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

On June 11, 2020, we entered into the license agreement with Sobi. Pursuant to the license agreement, we have agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize our SEL-212 drug candidate, which is currently in development for the treatment of chronic refractory gout. Pursuant to the license agreement, in consideration of the license, Sobi has agreed to pay us a one-time, up-front payment of $75 million within 45 days of the effective date of the agreement. Sobi has also agreed to make milestone payments totaling up to $630 million to us upon the achievement of various development and regulatory milestones and sales thresholds for annual net sales of SEL-212, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier. Pursuant to the license agreement, we will supply (at cost) quantities of SEL-212 as necessary for completion of the planned Phase 3 program for SEL-212, which includes two planned Phase 3 clinical trials and a crossover study. Sobi has agreed to reimburse us for all budgeted costs incurred to complete development of SEL-212, including but not limited to costs incurred while conducting and completing the Phase 3 program for SEL-212, except for any costs of additional development activities required that are related to ImmTOR and that are unrelated to SEL-212. Sobi will have control and responsibility over all regulatory filings, including any INDs, BLAs and MAAs relating to the licensed product.

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

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

Recruiting and retaining qualified scientific, clinical, manufacturing, technology and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement

of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

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

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

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

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

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

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

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

- failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries;

- additional potentially relevant third-party patent rights;

- complexities and difficulties in obtaining protection of and enforcing our intellectual property rights;

- difficulties in staffing and managing foreign operations;

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

- limits on our ability to penetrate international markets;

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

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

- changes in diplomatic and trade relationships;

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

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

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

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

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

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

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

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

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

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

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

- unexpected liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- inability to develop a sales force for any additional product candidates.

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

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

RISKS RELATED TO OUR COMMON STOCK

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

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

- the success of competitive products or technologies;
- results or progress, or changes in approach or timelines, of clinical trials of our product candidates or those of our competitors;
- failure or discontinuation of any of our development programs;
- commencement of, termination of, or any development related to any collaboration or licensing arrangement;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our collaborators 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 18.6% of our outstanding voting stock as of June 30, 2020. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. . Pursuant to our fifth amended and restated investors’ rights agreement, holders of an aggregate of approximately 1.9 million shares of our common stock as of June 30, 2020 have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the investors’ rights agreement between us and such holders. We have also registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

In addition, on June 27, 2017, we issued and sold in a private placement 3,088,791 shares of our common stock (of which approximately 0.3 million shares have continuing registration rights as of June 30, 2020) and a warrant to purchase 79,130 shares of our common stock, including to certain of our affiliates. Pursuant to a registration rights agreement entered into with the investors in the private placement, on July 13, 2017, we filed a Registration Statement on Form S-3 to register the shares of common stock sold in the private placement and the shares of common stock issuable upon exercise of the warrant. As a result, these shares can be freely sold in the public market.

Similarly, on December 23, 2019, we issued and sold in a private placement 37,634,883 shares of our common stock (of which approximately 19.1 million shares have continuing registration rights as of June 30, 2020) and warrants to purchase 31,330,629 shares of our common stock (of which approximately 16.5 million shares have continuing registration rights as of June 30, 2020), including to certain of our affiliates. Pursuant to a registration rights agreement entered into with the investors in the private placement, on January 29, 2019, we filed a Registration Statement on Form S-3 to register the shares of common stock sold in the private placement and the shares of common stock issuable upon exercise of the warrants. As a result, these shares can be freely sold in the public market.

Additionally, on June 11, 2020, we entered into a stock purchase agreement with Sobi, pursuant to which we agreed to sell to Sobi an aggregate of 5,416,390 shares of common stock. The closing of the Sobi Private Placement occurred on July 31, 2020, following the closing of the transactions contemplated under the Sobi License. The shares of common stock to be sold in the private placement will be subject to a one-year lock-up from closing, during which time Sobi is prohibited from selling or otherwise disposing of such shares. Also on June 11, 2020, we entered into a registration rights agreement with Sobi, pursuant to which we have agreed to prepare and file a registration statement with respect to the resale of the shares of common stock to be sold in the private placement. We are required to file this resale registration statement within 90 days from closing and to have the registration statement declared effective within 120 days from closing (or within 160 days if the SEC reviews the registration statement). Once the registration statement is declared effective, the shares of common stock to be sold in the private placement with Sobi can be freely sold in the public market.

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

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

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of the initial public offering of our common stock. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.07 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. We have, historically, relied on these exemptions, and we may continue to do so until they are no longer available to us. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

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

Provisions in our restated certificate of incorporation and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our restated bylaws, which became effective upon the closing of the initial public offering of our common stock may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors.

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

Furthermore, our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum

litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be applicable or unenforceable in such action.

We could be subject to securities class action litigation.

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

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

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation of Selecta Biosciences, Inc.	8-K	001-37798	3.1	6/29/2016	
3.2	Amended and Restated By-laws of Selecta Biosciences, Inc.	8-K	001-37798	3.2	6/29/2016	
4.1	Registration Rights Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)					*
10.1†	Fifth Amendment to Exclusive Patent License Agreement, dated as of May 15, 2020, by and between the Registrant and the Massachusetts Institute of Technology					*
10.2†	License and Development Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)					*
10.3	Stock Purchase Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)					*
10.4	Transition Agreement and Release, dated June 25, 2020, between Selecta Biosciences, Inc. and Stephen Smolinski	8-K	001-37798	10.1	6/25/2020	
10.5	Transition Agreement and Release, dated June 25, 2020, between Selecta Biosciences, Inc. and Elona Kogan	8-K	001-37798	10.2	6/25/2020	
31.1	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.					***
101.SCH	Inline XBRL Taxonomy Extension Schema Document					***
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					***
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					***
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					***

101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	***
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	***

* Filed herewith.

** Furnished herewith.

*** Submitted electronically herewith.

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

SIGNATURES

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

SELECTA BIOSCIENCES, INC.

Date: August 6, 2020

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

Carsten Brunn, Ph.D.

President and Chief Executive Officer, and Director

(Principal Executive Officer)

Date: August 6, 2020

By: /s/ Bradford D. Dahms

Bradford D. Dahms

Chief Financial Officer

(Principal Financial Officer)

Exhibit 4.1

REGISTRATION RIGHTS AGREEMENT

THIS REGISTRATION RIGHTS AGREEMENT (this "Agreement"), dated as of June 11, 2020, is entered into by and between Selecta Biosciences, Inc., a Delaware corporation (the "Company"), and the "Purchaser" named in that certain Share Purchase Agreement, dated as of June 11, 2020, by and between the Company and Purchaser (the "Purchase Agreement"). Capitalized terms used herein have the respective meanings ascribed thereto in the Purchase Agreement unless otherwise defined herein.

WHEREAS, the Company and the Purchaser have entered into the Purchase Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement and the Purchase Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Purchaser agree as follows:

SECTION 1. DEFINITIONS.

In addition to the terms defined elsewhere in this Agreement, the following terms have the meanings set forth in this Section 1:

"Prospectus" means (i) the prospectus included in any Registration Statement, as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by such Registration Statement and by all other amendments and supplements to the prospectus, including post-effective amendments and all material incorporated by reference in such prospectus, and (ii) any "free writing prospectus" as defined in Rule 405 under the Securities Act.

"Public Offering" means the offer and sale of Registrable Securities for cash pursuant to an effective Registration Statement under the Securities Act (other than a Registration Statement on Form S-4 or Form S-8 or any successor form).

"Purchaser" means the Purchaser identified in the Purchase Agreement and any affiliate or permitted transferee of any Purchaser who is a subsequent holder of Registrable Securities.

"Register," "registered" and "registration" refer to a registration made by preparing and filing a Registration Statement or similar document in compliance with the Securities Act, and the declaration or ordering of effectiveness of such Registration Statement or document.

"Registrable Securities" means (i) the Shares and (ii) all securities directly or indirectly issued with respect to the Shares by way of a stock dividend or stock split, or in connection with a combination of shares, recapitalization, merger, consolidation or other reorganization. As to any particular Registrable Securities, such securities shall cease to be Registrable Securities when (w) a Registration Statement with respect to the sale of such securities shall have become effective under the Securities Act and such securities shall have been disposed of in accordance with such Registration Statement, (x) such securities shall have been transferred pursuant to Rule 144, (y) such holder is able to immediately sell such securities under Rule 144 without any restrictions on transfer (including without application of paragraphs (c), (d), (e), (f) and (h) of Rule 144), as reasonably determined by the Company, upon the advice of counsel to the Company, or (z) such securities shall have ceased to be outstanding.

"Registration Statement" means any registration statement of the Company under the Securities Act that covers the resale of any of the Registrable Securities pursuant to the provisions of this Agreement,

amendments and supplements to such Registration Statement, including post-effective amendments, all exhibits and all material incorporated by reference in such Registration Statement.

"SEC" means the U.S. Securities and Exchange Commission.

"Underwritten Public Offering" means an underwritten Public Offering, including any bought deal or block sale to a financial institution conducted as an underwritten Public Offering.

SECTION 2. REGISTRATION.

(a) Registration Statement.

(i) Promptly following the Closing Date but no later than ninety (90) days after the Closing Date (the "Filing Deadline"), the Company shall prepare and file with the SEC one Registration Statement covering the resale of all of the Registrable Securities. Each Registration Statement filed hereunder shall be on Form S-3 and for an offering to be made on a continuous basis pursuant to Rule 415 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance herewith, subject to the provisions of Section 2(d)) and, subject to any SEC comments, such Registration Statement shall include the plan of distribution attached hereto as Exhibit A; provided, however, that Purchaser shall not be named as an "underwriter" in such Registration Statement without Purchaser's prior written consent. Such Registration Statement also shall cover, to the extent allowable under the Securities Act and the rules promulgated thereunder (including Rule 416), such indeterminate number of additional shares of Common Stock resulting from stock splits, stock dividends or similar transactions with respect to the Registrable Securities. Such Registration Statement (and each amendment or supplement thereto) shall be provided in accordance with Section 3(c) to Purchaser prior to its filing or other submission.

(ii) Piggy-Back Registrations. If, at any time during the Effectiveness Period (as defined below), there is not an effective Registration Statement covering all of the Registrable Securities and the Company shall determine to prepare and file with the SEC a registration statement relating to an offering for its own account or the account of others under the Securities Act of any of its equity securities, other than on Form S-4 or Form S-8 (each as promulgated under the Securities Act) or their then equivalents relating to equity securities to be issued solely in connection with any acquisition of any entity or business or equity securities issuable in connection with the Company's stock option or other employee benefit plans, then the Company shall deliver to Purchaser a written notice of such determination and, if within fifteen (15) business days after the date of the delivery of such notice, Purchaser shall so request in writing, the Company shall include in such registration statement all or any part of such Registrable Securities that the Purchaser requests to be registered (a "Piggyback Registration"); provided, however, that the Company shall not be required to register any Registrable Securities pursuant to this Section that are eligible for resale pursuant to Rule 144 (without volume restrictions or current public information requirements) promulgated by the SEC pursuant to the Securities Act or that are the subject of a then effective Registration Statement that is available for resales or other dispositions by the Purchaser. If the managing underwriter or underwriters of any proposed offering of Registrable Securities included in a Piggyback Registration informs the Company and the Purchaser in writing that, in its or their opinion, the number of securities that the Purchaser and any other Persons intend to include in such offering exceeds the number that can be sold in such offering without being likely to have a significant adverse effect on the price, timing or distribution of the securities offered or the market for the securities offered, then the securities to be included in such Registration Statement shall be (i) first, one hundred percent (100%) of the securities that the Company proposes to sell, and (ii) second, and only if all the securities referred to in clause (i) have been included, the number of Registrable Securities

requested to be sold by Purchaser that, in the opinion of such managing underwriter or underwriters, can be sold without having such adverse effect, and (iii) third, and only if all of the Registrable Securities referred to in clause (ii) have been included in such Registration Statement, any other securities eligible for inclusion in such Registration Statement. The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 2(a)(ii) prior to the effectiveness of such registration whether or not the Purchaser has elected to include securities in such registration.

(b) Expenses. All expenses incident to the Company's performance of or compliance with this Agreement (excluding any underwriting discounts and selling commissions, which shall be borne solely by the Purchaser) shall be paid by the Company, including (i) all registration and filing fees, and any other fees and expenses associated with filings required to be made with the SEC or FINRA, (ii) all fees and expenses in connection with compliance with any securities or "Blue Sky" laws, (iii) all printing, duplicating, word processing, messenger, telephone, facsimile and delivery expenses (including expenses of printing certificates for the Registrable Securities in a form eligible for deposit with The Depository Trust Company and of printing prospectuses), (iv) all fees and disbursements of counsel for the Company and of all independent certified public accountants or independent auditors of the Company and any subsidiaries of the Company (including the expenses of any special audit and comfort letters required by or incident to such performance), (v) Securities Act liability insurance or similar insurance if the Company so desires, (vi) all fees and expenses incurred in connection with the listing of the Registrable Securities on any securities exchange or quotation of the Registrable Securities on any inter-dealer quotation system, (vii) all reasonable fees and expenses of any other Persons retained by the Company in connection with any Registration Statement or sale, and (viii) all of the Company's internal expenses (including all salaries and expenses of its officers and employees performing legal or accounting duties). To the extent that underwriting discounts and selling commissions are incurred in connection with the sale of Registrable Securities in an Underwritten Public Offering hereunder, such underwriting discounts and selling commissions shall be borne solely by the Purchaser. The Company shall not be responsible for legal fees, broker or similar commissions or any other costs incurred by the Purchaser in connection with the performance of its rights and obligations under this Agreement.

(c) Effectiveness.

(i) The Company shall use reasonable efforts to have any Registration Statement declared effective as soon as practicable after the filing. The Company shall respond promptly to any and all comments made by the staff of the SEC on any Registration Statement, and shall submit to the SEC, within two (2) business days after the Company learns that no review of the Registration Statement will be made by the staff of the SEC or that the staff of the SEC has no further comments on such Registration Statement, as the case may be, a request for acceleration of the effectiveness of such Registration Statement to a time and date not later than two (2) business days after the submission of such request. The Company shall notify the Purchaser by facsimile or e-mail as promptly as practicable, and in any event, within twenty-four (24) hours, after any such Registration Statement is declared effective and shall, upon request, provide the Purchaser with copies of any related Prospectus to be used in connection with the sale or other disposition of the securities covered thereby.

(ii) If, with respect to any Registration Statement covering the Registrable Securities:

(A) such Registration Statement covering the Registrable Securities is not filed with the SEC on or prior to the Filing Deadline,

(B) such Registration Statement covering the Registrable Securities is not declared effective by the SEC prior to earlier of: (x) ten (10) Business Days after the SEC informs the Company that no review of such Registration Statement will be made or that the SEC has no further comments on such Registration Statement, (y) the 120th calendar day following the Closing Date, or (z) in the event of a "review" by the SEC, the 160th calendar day following the Closing Date (as applicable, the "Effectiveness Deadline"), or

(C) after a Registration Statement has been declared effective by the SEC, sales cannot be made pursuant to such Registration Statement for any reason (including without limitation by reason of a stop order, or the Company's failure to update such Registration Statement), but excluding any Allowed Delay (as defined below) or, if the Registration Statement is on Form S-1, for a period of twenty (20) days following the date on which the Company files a post-effective amendment to incorporate the Company's Annual Report on Form 10-K (a "Maintenance Failure"),

then the Company will make pro rata payments to each Purchaser then holding Registrable Securities, as liquidated damages and not as a penalty, in an amount equal to 1% of the aggregate amount paid pursuant to the Purchase Agreement by such Purchaser for such Registrable Securities then held by such Purchaser for each 30-day period or pro rata for any portion thereof following the date by which such Registration Statement should have been effective (the "Blackout Period"). Such payments shall constitute the Purchaser's exclusive monetary remedy for such events, but shall not affect the right of the Purchaser to seek injunctive relief. The amounts payable as liquidated damages pursuant to this paragraph shall be paid no later than five (5) Business Days after each such 30-day period following the commencement of the Blackout Period until the termination of the Blackout Period (the "Blackout Payment Date"). Such payments shall be made to each Purchaser in cash. Interest shall accrue at the rate of 1% per month on any such liquidated damages payments that shall not be paid by the Blackout Payment Date until such amount is paid in full.

(iii) Notwithstanding anything to the contrary contained herein, the Company may, upon written notice to any holder of Registrable Securities included in a Registration Statement, suspend the use of any Registration Statement, including any Prospectus that forms a part of a Registration Statement, if the Company (X) determines that it would be required to make disclosure of material information in the Registration Statement that the Company has a bona fide business purpose for preserving as confidential, (Y) the Company determines it must amend or supplement the Registration Statement or the related Prospectus so that such Registration Statement or Prospectus shall not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the case of the Prospectus in light of the circumstances under which they were made, not misleading or (Z) the Company has experienced or is experiencing some other material non-public event, including a pending transaction involving the Company, the disclosure of which at such time, in the good faith judgment of the Company, would adversely affect the Company; provided, however, in no event shall holders of Registrable Securities be suspended from selling Registrable Securities pursuant to the Registration Statement for a period that exceeds 30 consecutive Trading Days or 60 total Trading Days in any 360-day period (any such suspension contemplated by this Section 2(c)(ii), an "Allowed Delay"). Upon disclosure of such information or the termination of the condition described above, the Company shall provide prompt notice to holders whose Registrable Securities are included in the Registration Statement, and shall promptly terminate any suspension of sales it has put into effect and shall take such other reasonable actions to permit registered sales of Registrable Securities as contemplated hereby.

(d) If Form S-3 is not available for the registration of the resale of Registrable Securities hereunder, the Company shall (i) register the resale of the Registrable Securities on another appropriate form and (ii) undertake to register the Registrable Securities on Form S-3 as soon as such form is available,

provided that the Company shall maintain the effectiveness of the Registration Statement then in effect until such time as a Registration Statement on Form S-3 covering the Registrable Securities has been declared effective by the SEC.

(e) Rule 415; Cutback. If at any time the SEC takes the position that the offering of some or all of the Registrable Securities in a Registration Statement is not eligible to be made on a delayed or continuous basis under the provisions of Rule 415 under the Securities Act, the Company shall (i) remove from the Registration Statement such portion of the Registrable Securities (the "Cut Back Shares") and/or (ii) agree to such restrictions and limitations on the registration and resale of the Registrable Securities as the SEC may require to assure the Company's compliance with the requirements of Rule 415 (collectively, the "SEC Restrictions"); provided, however, that the Company shall not agree to name Purchaser as an "underwriter" in such Registration Statement without the prior written consent of Purchaser. No liquidated damages shall accrue as to any Cut Back Shares until such date as the Company is able to effect the registration of such Cut Back Shares in accordance with any SEC Restrictions applicable to such Cut Back Shares (such date, the "Restriction Termination Date"). From and after the Restriction Termination Date applicable to any Cut Back Shares, all of the provisions of this Section 2 (including the Company's obligations with respect to the filing of a Registration Statement and its obligations to use reasonable best efforts to have such Registration Statement declared effective within the time periods set forth herein and the liquidated damages provisions relating thereto) shall again be applicable to such Cut Back Shares; provided, however, that the Filing Deadline for the Registration Statement including such Cut Back Shares shall be (20) business days after such Restriction Termination Date.

(f) Other Limitations. Notwithstanding any other provision herein or in the Purchase Agreement, (i) the Filing Deadline and each Effectiveness Deadline for a Registration Statement shall be extended and any Maintenance Failure shall be automatically waived by no action of the Purchaser, in each case, without default by or liquidated damages payable by the Company hereunder in the event that the Company's failure to make such filing or obtain such effectiveness or a Maintenance Failure results from the failure of an Purchaser to timely provide the Company with information requested by the Company and necessary to complete a Registration Statement in accordance with the requirements of the 1933 Act (in which case any such deadline would be extended, and a Maintenance Failure waived, with respect to all Registrable Securities until such time as the Purchaser provides such requested information) and (ii) in no event shall the aggregate amount of liquidated damages (or interest thereon) paid hereunder exceed, in the aggregate, 8% of the aggregate purchase price of the Shares purchased by the Purchaser under the Purchase Agreement.

SECTION 3. COMPANY OBLIGATIONS.

The Company will use reasonable best efforts to effect the registration of the Registrable Securities in accordance with the terms hereof, and pursuant thereto the Company will, as expeditiously as possible:

(a) use reasonable best efforts to cause each such Registration Statement to become effective and to remain continuously effective until such time as the earlier of: (i) there are no longer Registrable Securities held by the Purchaser, or (ii) the Registrable Securities can be sold pursuant to Rule 144 without regard to the volume-of-sale limitations imposed under Rule 144(e) (the "Effectiveness Period") and advise the Purchaser promptly in writing when the Effectiveness Period has expired;

(b) prepare and file with the SEC such amendments and post-effective amendments to such Registration Statement and the related Prospectus as may be necessary to keep such Registration Statement

effective for the Effectiveness Period and to comply with the provisions of the Securities Act and the Exchange Act with respect to the distribution of all of the Registrable Securities covered thereby;

(c) provide copies to the Purchaser and permit the Purchaser's legal counsel to review each Registration Statement and all amendments and supplements at least three (3) business days in advance of their filing with the SEC; provided that the Company shall duly consider any comments received no later than two (2) business days prior to the filing of such Registration Statement, amendment or supplement, but shall not be required to accept any such comments to which it reasonably objects;

(d) furnish to the Purchaser and its legal counsel (i) immediately after the same is prepared and publicly distributed, filed with the SEC, or received by the Company (but not later than twenty-four (24) hours after the filing date, receipt date or sending date, as the case may be) one (1) copy of any Registration Statement and any amendment thereto, each preliminary prospectus and Prospectus and each amendment or supplement thereto, and each letter written by or on behalf of the Company to the SEC or the staff of the SEC, and each item of correspondence from the SEC or the staff of the SEC, in each case relating to such Registration Statement (other than any portion of any thereof which contains information for which the Company has sought confidential treatment or it reasonably believes would constitute material and non-public information) and (ii) such number of copies of a Prospectus, including a preliminary prospectus, and all amendments and supplements thereto and such other documents as the Purchaser may reasonably request in order to facilitate the disposition of the Registrable Securities owned by the Purchaser that are covered by the related Registration Statement;

(e) use reasonable best efforts to (i) prevent the issuance of any stop order or other suspension of effectiveness and, (ii) if such order is issued, obtain the withdrawal of any such order at the earliest possible moment and to notify the Purchaser of the issuance of such order and the resolution thereof;

(f) use reasonable best efforts to register or qualify (unless an exemption from the registration or qualification exists) or cooperate with the Purchaser and its counsel in connection with the registration or qualification of such Registrable Securities for offer and sale under the securities or "Blue Sky" laws of such domestic jurisdictions as are reasonably requested by the Purchaser and do any and all other reasonable acts or filings necessary or advisable to enable a distribution in such jurisdictions of the Registrable Securities covered by the Registration Statement; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to (i) qualify to do business in any jurisdiction where it would not otherwise be required to qualify but for this Section 3(f), (ii) subject itself to general taxation in any jurisdiction where it would not otherwise be so subject but for this Section 3(f), or (iii) file a general consent to service of process in any such jurisdictions;

(g) use reasonable best efforts to cause all Registrable Securities covered by a Registration Statement to be listed on each securities exchange, interdealer quotation system or other market on which similar securities issued by the Company are then listed;

(h) promptly notify the Purchaser, at any time prior to the end of the Effectiveness Period, upon discovery that, or upon the happening of any event as a result of which, the Prospectus includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in light of the circumstances then existing, and as promptly as reasonably possible prepare, file with the SEC and furnish to such holder a supplement to or an amendment of such Prospectus as may be necessary so that such Prospectus shall not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading in light of the circumstances then existing;

(i) otherwise use reasonable best efforts to comply with all applicable rules and regulations of the SEC under the Securities Act and the Exchange Act, including, without limitation, Rule 172 under the Securities Act, file any final Prospectus, including any supplement or amendment thereof, with the SEC pursuant to Rule 424 under the Securities Act, promptly inform Purchaser in writing if, at any time during the Effectiveness Period, the Company does not satisfy the conditions specified in Rule 172 and, as a result thereof, Purchaser is required to deliver a Prospectus in connection with any disposition of Registrable Securities and take such other actions as may be reasonably necessary to facilitate the registration of the Registrable Securities hereunder;

(j) with a view to making available to the Purchaser the benefits of Rule 144 (or its successor rule) and any other rule or regulation of the SEC that may at any time permit Purchaser to sell shares of Common Stock to the public without registration, the Company covenants and agrees to: (i) make and keep public information available, as those terms are understood and defined in Rule 144, until the earlier of (A) six (6) months after such date as all of the Registrable Securities may be sold without restriction by the holders thereof pursuant to Rule 144 or any other rule of similar effect or (B) such date as all of the Registrable Securities shall have been resold; (ii) file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act; and (iii) furnish to Purchaser upon request, as long as Purchaser owns any Registrable Securities, (A) a written statement by the Company that it has complied with the reporting requirements of the Exchange Act, (B) a copy of the Company's most recent Annual Report on Form 10-K or Quarterly Report on Form 10-Q, and (C) such other information as may be reasonably requested in order to avail Purchaser of any rule or regulation of the SEC that permits the selling of any such Registrable Securities without registration;

(k) if requested by an Purchaser, cooperate with such Purchaser to facilitate the timely preparation and delivery of certificates representing Registrable Securities to be delivered to a transferee pursuant to an effective Registration Statement, which certificates shall be free, to the extent permitted by the Purchase Agreement and applicable law, of all restrictive legends, and to enable such certificates to be in such denominations and registered in such names as any such Purchaser may request.

SECTION 4. OBLIGATIONS OF THE PURCHASER.

(a) The Purchaser shall furnish in writing to the Company such information regarding itself, the Registrable Securities held by it and the intended method of disposition of the Registrable Securities held by it, as shall be reasonably required to effect the registration of such Registrable Securities and shall execute such documents in connection with such registration as the Company may reasonably request. At least five (5) business days prior to the first anticipated filing date of any Registration Statement, the Company shall notify the Purchaser of the information the Company requires from the Purchaser if the Purchaser is to have any of the Registrable Securities included in such Registration Statement. The Purchaser shall provide such information to the Company at least two (2) business days prior to the first anticipated filing date of such Registration Statement if the Purchaser is to have any of the Registrable Securities included in such Registration Statement. If the Purchaser fails to provide to the Company the information required by this Section 4(a) by such date, the Company shall not be obligated to include the Purchaser's Registrable Securities in such Registration Statement and shall not be obligated to pay the Purchaser liquidated damages with respect to the lack of registration of such Registrable Securities under this Agreement.

(b) The Purchaser, by its acceptance of the Registrable Securities, agrees to cooperate with the Company as reasonably requested by the Company in connection with the preparation and filing of a Registration Statement hereunder, unless the Purchaser has notified the Company in writing of its election to exclude all of its Registrable Securities from such Registration Statement.

SECTION 5. INDEMNIFICATION.

(a) Indemnification by the Company. The Company will indemnify and hold harmless the Purchaser and its officers, directors, members, employees and agents, successors and assigns, and each other person, if any, who controls, or is alleged to control, the Purchaser within the meaning of the Securities Act, against any losses, claims, damages or liabilities, joint or several, to which they may become subject under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement or omission or alleged omission of any material fact contained in any Registration Statement, any preliminary Prospectus or final Prospectus, or any amendment or supplement thereof (it being understood that the Purchaser has approved Exhibit A hereto for this purpose); and the Company will reimburse the Purchaser, and each officer, director or member and each such controlling person for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case if and to the extent that any such loss, claim, damage or liability arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission so made in conformity with information furnished by the Purchaser or any such controlling person in writing specifically for use in such Registration Statement or Prospectus or to the extent that such information relates to the Purchaser's proposed method of distribution of Registrable Securities and was reviewed and expressly approved in writing by the Purchaser expressly for use in such Registration Statement or Prospectus (it being understood that the Purchaser has approved Exhibit A hereto for this purpose), and provided further that the foregoing indemnity shall not apply to amounts paid in settlement of any loss, claim, damage, liability or expense if such settlement is effected without the consent of the Company.

(b) Indemnification by the Purchaser. The Purchaser, for any Registration Statement in which it is named as a selling stockholder, agrees to indemnify and hold harmless, to the fullest extent permitted by law, the Company, its directors, officers, employees, stockholders and each person who controls the Company (within the meaning of the Securities Act) against any losses, claims, damages or liabilities resulting from any untrue statement of a material fact or any omission of a material fact required to be stated in the Registration Statement or Prospectus or preliminary Prospectus or amendment or supplement thereto or necessary to make the statements therein not misleading, to the extent, but only to the extent that such untrue statement or omission is contained in any information furnished in writing by the Purchaser to the Company specifically for inclusion in such Registration Statement or Prospectus or amendment or supplement thereto and has not been corrected in a subsequent writing prior to the sale of the Registrable Securities thereunder, or to the extent that such information relates to the Purchaser's or the Purchaser's proposed method of distribution of Registrable Securities and was reviewed and expressly approved in writing by the Purchaser expressly for use in the Registration Statement or Prospectus or amendment or supplement thereto (it being understood that the Purchaser has approved Exhibit A hereto for this purpose); provided, however, that the foregoing indemnity shall not apply to amounts paid in settlement of any loss, claim, damage, liability or expense if such settlement is effected without the consent of the Purchaser. In no event shall the liability of the Purchaser be greater in amount than the dollar amount of the proceeds (net of all expense paid by the Purchaser in connection with any claim relating to this Section 5 and the amount of any damages the Purchaser has otherwise been required to pay by reason of such untrue statement or omission) received by the Purchaser upon the sale of the Registrable Securities included in the Registration Statement giving rise to such indemnification obligation.

(c) Conduct of Indemnification Proceedings. Any person entitled to indemnification hereunder shall (i) give prompt notice to the indemnifying party of any claim with respect to which it seeks indemnification and (ii) permit such indemnifying party to assume the defense of such claim with counsel

reasonably satisfactory to the indemnified party; provided that any person entitled to indemnification hereunder shall have the right to employ separate counsel and to participate in the defense of such claim, but the fees and expenses of such counsel shall be at the expense of such person unless (a) the indemnifying party has agreed to pay such fees or expenses, (b) the indemnifying party shall have failed to assume the defense of such claim and employ counsel reasonably satisfactory to such person or (c) in the reasonable judgment of any such person, based upon written advice of its counsel, a conflict of interest exists between such person and the indemnifying party with respect to such claims (in which case, if the person notifies the indemnifying party in writing that such person elects to employ separate counsel at the expense of the indemnifying party, the indemnifying party shall not have the right to assume the defense of such claim on behalf of such person); and provided, further, that the failure of any indemnified party to give notice as provided herein shall not relieve the indemnifying party of its obligations hereunder, except to the extent that such failure to give notice shall materially adversely affect the indemnifying party in the defense of any such claim or litigation. It is understood that the indemnifying party shall not, in connection with any proceeding in the same jurisdiction, be liable for fees or expenses of more than one separate firm of attorneys at any time for all such indemnified parties. No indemnifying party will, except with the consent of the indemnified party, which shall not be unreasonably withheld or conditioned, consent to entry of any judgment or enter into any settlement that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect of such claim or litigation.

(d) Contribution. If for any reason the indemnification provided for in the preceding paragraphs (a) and (b) is unavailable to an indemnified party or insufficient to hold it harmless, other than as expressly specified therein, then the indemnifying party shall contribute to the amount paid or payable by the indemnified party as a result of such loss, claim, damage or liability in such proportion as is appropriate to reflect the relative fault of the indemnified party and the indemnifying party, as well as any other relevant equitable considerations. Relative fault shall be determined by reference to whether any alleged untrue statement or omission relates to information provided by the Company or by a holder of Registrable Securities. No person guilty of fraudulent misrepresentation within the meaning of Section 11(f) of the Securities Act shall be entitled to contribution from any person not guilty of such fraudulent misrepresentation. In no event shall the contribution obligation of a holder of Registrable Securities be greater in amount than the dollar amount of the proceeds (net of all expenses paid by such holder in connection with any claim relating to this Section 5 and the amount of any damages such holder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission) received by it upon the sale of the Registrable Securities giving rise to such contribution obligation.

SECTION 6. MISCELLANEOUS.

(a) Amendments and Waivers. This Agreement may be amended only by a writing signed by the Company and the Purchaser. The Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company shall have obtained the written consent to such amendment, action or omission to act, of the Purchaser.

(b) Notices. All notices and other communications provided for or permitted hereunder shall be made as set forth in the Purchase Agreement.

(c) Assignments and Transfers by the Purchaser. The provisions of this Agreement shall be binding upon and inure to the benefit of the Purchaser and its respective successors and assigns. The Purchaser may transfer or assign, in whole or from time to time in part, to one or more persons its rights hereunder in connection with the transfer of Registrable Securities by the Purchaser to such person, provided that the

Purchaser complies with all laws applicable thereto and provides written notice of assignment to the Company promptly after such assignment is effected.

(d) Assignments and Transfers by the Company. This Agreement may not be assigned by the Company (whether by operation of law or otherwise) without the prior written consent of the Purchaser; provided, however, that in the event that the Company is a party to a merger, consolidation, share exchange or similar business combination transaction in which the Common Stock is converted into the equity securities of another Person, from and after the effective time of such transaction, such Person shall, by virtue of such transaction, be deemed to have assumed the obligations of the Company hereunder, the term "Company" shall be deemed to refer to such Person and the term "Registrable Securities" shall be deemed to include the securities received by the Purchaser in connection with such transaction unless such securities are otherwise freely tradable by the Purchaser after giving effect to such transaction.

(e) Benefits of the Agreement. The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective permitted successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

(f) Counterparts; Faxes. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may also be executed via facsimile, which shall be deemed an original.

(g) Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

(h) Severability. Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof but shall be interpreted as if it were written so as to be enforceable to the maximum extent permitted by applicable law, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the parties hereby waive any provision of law which renders any provisions hereof prohibited or unenforceable in any respect.

(i) Further Assurances. The parties shall execute and deliver all such further instruments and documents and take all such other actions as may reasonably be required to carry out the transactions contemplated hereby and to evidence the fulfillment of the agreements herein contained.

(j) Entire Agreement. This Agreement is intended by the parties as a final expression of their agreement and intended to be a complete and exclusive statement of the agreement and understanding of the parties hereto in respect of the subject matter contained herein. This Agreement supersedes all prior agreements and understandings between the parties with respect to such subject matter.

(k) Governing Law; Consent to Jurisdiction; Waiver of Jury Trial. This Agreement will be governed by and construed in accordance with the laws of the State of Delaware without regard to any choice of laws or conflict of laws provisions that would require the application of the laws of any other jurisdiction. The parties hereby irrevocably and unconditionally consent to submit to the exclusive jurisdiction of Delaware Court of Chancery and any state appellate court therefrom within the State of Delaware (or, if the Delaware Court of Chancery declines to accept jurisdiction over a particular matter, any state or federal court within the State of Delaware) for any actions, suits or proceedings arising out of or relating to this Agreement and

the transactions contemplated hereby. Each party to this Agreement hereby irrevocably waives any defense in any such action, suit or proceeding that it is not personally subject to the jurisdiction of the above named courts and to the fullest extent permitted by applicable law, that the action, suit or proceeding in any such court is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT AND THE OTHER TRANSACTION DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY AND THEREBY.

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IN WITNESS WHEREOF, the parties have executed this Agreement or caused their duly authorized officers to execute this Agreement as of the date first above written.

SELECTA BIOSCIENCES, INC.

COMPANY:

By: /s/ Carsten Brunn, Ph.D.
Name: Carsten Brunn, Ph.D.
Title: *President and Chief Executive Officer*

SWEDISH ORPHAN BIOVITRUM AB (PUBL)

PURCHASER:

By: /s/ Guido Oelkers
Name: Guido Oelkers
Title: *CEO*

By: /s/ Torbjörn Hallberg
Name: Torbjörn Hallberg
Title: *General Counsel*

EXHIBIT A

Plan of Distribution

The selling stockholder, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from the selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of its shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholder may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the date the registration statement of which this Prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholder to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

The selling stockholder may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by it and, if it defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholder to include the pledgee, transferee or other successors in interest as selling stockholder under this prospectus. The selling stockholder also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short

sales of the common stock in the course of hedging the positions they assume. The selling stockholder may also sell shares of our common stock short and deliver these securities to close out its short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholder may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholder from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. The selling stockholder reserves the right to accept and, together with its agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholder also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that it meets the criteria and conform to the requirements of that rule.

The selling stockholder and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be “underwriters” within the meaning of Section 2(a)(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. If the selling stockholder is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act, it will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholder, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholder that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholder and its affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholder for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholder may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholder against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholder to keep the registration statement of which this prospectus constitutes a part effective until such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with such registration statement.

Exhibit 10.1

FIFTH AMENDMENT

This Fifth Amendment, effective as of the date set forth above the signatures of the parties below ("Amendment Effective Date"), amends the Exclusive Patent License Agreement effective November 25, 2008, as amended by a First Amendment dated January 12, 2010, a Second Amendment dated August 29, 2013, a Third Amendment dated November 18, 2016, and a Fourth Amendment dated December 13, 2019 (the "License Agreement") between the Massachusetts Institute of Technology, a Massachusetts corporation having its principal office at 77 Massachusetts Avenue, Cambridge, Massachusetts 02139 ("MIT"), and Selecta Biosciences, Inc., a Delaware corporation, with a principal place of business at 65 Grove Street, Watertown, MA 02472 ("COMPANY").

WHEREAS, COMPANY has requested that the diligence provisions of the License Agreement be amended to account for ongoing development of LICENSED PRODUCTS.

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein, the parties hereby agree as follows:

1. Section 3.1, Diligence Requirements, of the License Agreement is hereby amended to delete Sections 3.1(j) and 3.1(k) in their entirety and replace them with the following Section 3.1(j):

(j) COMPANY or an AFFILIATE or SUBLICENSEE shall achieve either: (i) the diligence milestones set forth in Table A for a LICENSED PRODUCT that is in clinical development as of the Amendment Effective Date; or (ii) the diligence milestones set forth in Table B for a LICENSED PRODUCT that is in preclinical development as of the Amendment Effective Date.

TABLE A	
Diligence Milestone	Due Date
A.1 [***] for a LICENSED PRODUCT	[***]
A.2 [***] for a LICENSED PRODUCT	[***]
A.3 [***] of a LICENSED PRODUCT and/or [***] of a LICENSED PROCESS	[***]

TABLE B	
Diligence Milestone	Due Date
B.1 [***] for a LICENSED PRODUCT	[***]
B.2 [***] of a LICENSED PRODUCT	[***]
B.3 [***] for a LICENSED PRODUCT	[***]

2. COMPANY shall have no further obligations under Section 3.1(h) or 3.1(i). In addition, the existing section identified in the License Agreement prior to amendment as Section 3.1(l) shall be renumbered as Section 3.1(k).

3. Section 4.1(d), Milestone Payments, of the License Agreement is hereby amended to delete Section 4.1(d)(i) in its entirety and replace it with the following:

(i) COMPANY shall pay to M.I.T. the following amounts upon the first achievement of the following milestones, whether by COMPANY or any of its AFFILIATES or SUBLICENSEES:

TABLE A	
Milestone Event	Payment
[***] in accordance with Section 3.1(j) Table A.1	[***]
[***] in accordance with Section 3.1(j) Table A.3	[***]

TABLE B	
Milestone Event	Payment
[***] in accordance with Section 3.1(j) Table B.1	[***]
[***] in accordance with Section 3.1(j) Table B.2	[***]
[***] in accordance with Section 3.1(j) Table B.3	[***]

COMPANY shall make such non-refundable, non-creditable milestone payments within [***] days after achievement of each of the milestones. Notwithstanding the foregoing: (i) any milestone payments made to MIT with respect to the milestone events set forth in TABLE A above may be credited against any milestone payments subsequently due under TABLE B and vice versa; and (ii) if all of the milestone events set forth in TABLE A above are achieved prior to the milestone events in TABLE B, then the milestone payments set forth in TABLE B shall no longer be due, and vice versa; such that the maximum payments payable under this Section 4.1(d)(i) shall be [***].

4. The parties acknowledge and agree prior to the Amendment Effective Date that COMPANY paid M.I.T [***] for milestone events that are deleted from Section 4.1(d)(i) by this Fifth Amendment and that such payments are non-refundable and non-creditable.

5. The License Agreement, as amended hereby, is hereby ratified and confirmed in all respects, and except as expressly amended by this Fifth Amendment, all terms and conditions of the License Agreement shall continue in full force and effect. All capitalized terms used herein shall have the meanings ascribed to such terms in the License Agreement. The License Agreement shall, together with this Fifth Amendment, be read and construed as a single instrument.

{Signature page follows}

IN WITNESS WHEREOF, the parties have caused this Fifth Amendment to be executed under seal by their duly authorized representatives.

The Effective Date of this Fifth Amendment is May 15, 2020.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY		**SELECTA BIOSCIENCES, INC.**	
By:	/s/ Lesley Millar-Nicholson	By:	/s/ Carsten Brunn
Name:	Lesley Millar-Nicholson	Name:	Carsten Brunn
Title:	Director, TLO	Title:	President and CEO

Exhibit 10.2

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

LICENSE AND DEVELOPMENT AGREEMENT

by and between

SELECTA BIOSCIENCES, INC.

and

SWEDISH ORPHAN BIOVITRUM AB (PUBL)

June 11, 2020

SEL-212

CONTENTS

LICENSE AND DEVELOPMENT AGREEMENT

THIS LICENSE AND DEVELOPMENT AGREEMENT ("Agreement") dated as of June 11, 2020 (the "Execution Date") is by and between **SELECTA BIOSCIENCES, INC.,** a Delaware corporation having its principal place of business at 65 Grove Street, Watertown, MA 02472 ("Licensor") and **SWEDISH ORPHAN BIOVITRUM AB (publ)**, a Swedish public company having its principal place of business at SE-112 76 Stockholm, Sweden ("Licensee"). Licensor and Licensee are referred to in this Agreement individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Licensee is a biopharmaceutical company focused on developing and commercializing therapies for rare diseases;

WHEREAS, Licensor is the owner of all right, title and interest in, or otherwise has the right to license, the Licensed Technology (as hereinafter defined); and

WHEREAS, Licensor desires to grant, and Licensee desires to accept, a License (as hereinafter defined) under such Licensed Technology to Develop, Manufacture and Commercialize the Products in the Field in the Territory (each as hereinafter defined) on the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, for and in consideration of the above-described recitals, the mutual promises and covenants of the parties hereinafter contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the Parties, the Parties hereto, intending to be legally bound, enter into the agreements contained herein.

1. DEFINITIONS

1.1 Defined Terms. For purposes of this Agreement, the following terms shall have the meanings set forth below:

"3SBio" shall mean Shenyang Sunshine Pharmaceutical Co., Ltd.

"3SBio Agreements" shall mean the 3SBio License Agreement and the 3SBio Supply Agreement.

"3SBio Breach Notice" shall have the meaning set forth in Section 2.2.13.

"3SBio License Agreement" shall mean the Amended and Restated License Agreement between Licensor and 3SBio dated 31 May 2017.

"3SBio Supply Agreement" shall mean the Commercial Supply Agreement between Licensor and 3SBio dated 1 August 2019.

"AAA" shall have the meaning set forth in Section 17.2.7(a).

"Accounting Standards" shall mean, with respect to Licensor, GAAP, with respect to Licensee, IFRS (International Financial Reporting Standards), and, with respect to Sublicensees, IFRS or GAAP, as applicable, in each case as generally and consistently applied throughout the Party's or Sublicensee's organization. Each Party will promptly notify the other Party if such Party changes the Accounting Standards pursuant to which its records relating to this Agreement are maintained; provided, however, that each Party may only use internationally recognized accounting principles (e.g., IFRS or US GAAP).

"Acquisition Entity" shall mean, collectively, (a) with respect to the acquisition of a Party by a Third Party, a Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than the applicable Party in the definition of Change of Control and such Party's Affiliates (determined as of immediately prior to the closing of such Change of Control), and (b) with respect to the acquisition by a Party of a Third Party (whether by a merger, consolidation, recapitalization, reorganization, sale or other transfer of voting securities, or sale or other transfer of substantially all of such Third Party's and its controlled Affiliates' assets), such Third Party and its Affiliates, other than the applicable acquiring Party, and such Party's Affiliates (determined as of immediately prior to the closing of such acquisition transaction).

"Acting Party" shall have the meaning set forth in Section 7.3.2

"Additional Compound Development Activities" shall have the meaning set forth in Section 4.3.2.

"Additional ImmTOR Development Activities" shall have the meaning set forth in Section 4.3.2.

"Adverse Event" shall mean any untoward medical occurrence in a patient or clinical investigation subject temporally associated with the use of the Compound, ImmTOR or a Product whether or not considered related to the Compound, ImmTOR and / or Product.

"Affiliate" shall mean, with respect to either Party, any person or entity which, directly or indirectly, controls, is controlled by, or is under common control with, the specified Party. For the purposes of this definition, the term "control", as applied to any person or entity (including, with correlative meaning, the terms "controlled by" and "under the common control"), means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Party, whether by the ownership of more than fifty percent (50%) of the voting stock of such Party, by contract or otherwise.

"Agreement" shall have the meaning set forth in the introduction to this document.

"Annual Net Sales" [***]

"Bankruptcy Code" shall have the meaning set forth in Section 9.10.1.

[***]

[***]

[***]

"Biosimilar Product" shall mean, with respect to a Product in a country, a biologic product that (a) is marketed for sale in such country by a Third Party (including an Acquisition Entity of Licensor) (not licensed, supplied, or otherwise permitted by Licensee, its Affiliates or its Sublicensees); (b) contains (i) the active pharmaceutical ingredient or biologic of the Compound or a substantial equivalent to the active pharmaceutical ingredient or biologic of the Compound as an active pharmaceutical ingredient or biologic in such country, together with (ii) the active pharmaceutical ingredient or biologic of ImmTOR or a substantial equivalent to the active pharmaceutical ingredient or biologic of ImmTOR and (c) for which its Regulatory Approval in such country references or relies on safety and efficacy clinical data submitted by Licensor or any of its Affiliates or (sub)licensees to obtain Regulatory Approval for such Product in such country.

"BLA" shall mean a Biologic License Application for a Product requesting permission to place a biological product on the market in accordance with 21 C.F.R. Part 601, and all supplements or

amendments thereto, filed pursuant to the requirements of the FDA, or an equivalent application in the event that the FDA determines that a New Drug Application (NDA) rather than a BLA is the appropriate mechanism for requesting such approval.

"Business Day" shall mean a day other than a Saturday, Sunday or a bank or other public holiday in Massachusetts or New York in the United States or in Stockholm in Sweden.

"Cell Bank" shall mean a cell bank of a characterized bank of cells expressing the Compound.

"cGMP" shall mean the requirements of applicable Laws governing the Manufacture of biological and pharmaceutical products, including as provided for (and amended from time to time) in 21 C.F.R. Parts 210 and 211 *et seq.*, European Commission Directive 2003/94/EC and guidelines issued from time to time by the ICH, as amended and supplemented from time to time, or equivalent Laws in other jurisdictions.

"Change of Control" shall mean, with respect to a Party, (a) a merger, consolidation, recapitalization, or reorganization of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger, consolidation, recapitalization, reorganization, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets or (d) entry into such other arrangement or agreement whereby the current shareholders of such Party no longer have the actual power, either directly or indirectly, to appoint a majority of the board of directors. Notwithstanding the foregoing, any transaction or series of transactions effected for the purpose of financing the operations of the applicable Party (such as an initial public offering or other offering of equity securities to non-strategic investors) will not be deemed a "Change of Control" for purposes of this Agreement.

"Chronic Refractory Gout" shall mean the treatment of chronic gout in adult patients refractory to conventional therapy.

"Claim" shall mean any charge, allegation, civil, criminal or administrative claim, demand, complaint, cause of action, suit, or Proceeding.

"CMC Activities" shall mean chemistry manufacturing controls and related activities in support of Regulatory Filings and Regulatory Approvals for the Product.

"Combination Product" shall mean, on a Product-by-Product basis, (a) any biological or pharmaceutical product that contains or comprises (i) such Product and (ii) at least one other active pharmaceutical or biologic ingredient, either co-formulated or packaged together or otherwise sold as a single unit for a single price, (b) a Product that is sold for a single price together with any (i) delivery device or component therefor, (ii) diagnostic product, process, service, or therapy, or (iii) product, process, service, or therapy other than such Product, or (c) a Product that is defined as a "combination product" by the FDA pursuant to 21 C.F.R. § 3.2(e) or its foreign equivalent.

"Commercialization" shall mean any and all activities directed to the launch of, offering for sale of or sale of a Product, including activities related to marketing, promoting, detailing, distributing, importing, exporting, offering to sell or selling such Product, interacting with Regulatory Authorities regarding any of the foregoing and seeking pricing or reimbursement approvals (as applicable). When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

"Commercially Reasonable Efforts" shall mean (a) with respect to efforts to be expended by a Party to achieve an agreed objective, except as provided for in clause (b), such reasonable, diligent and good faith efforts as [***].

"Competitive Infringement" shall have the meaning set forth in Section 9.4.1.

"Compound" shall mean (a) the compound SEL-037, known as Pegadricase (formerly known as Pegsiticase), as further defined in Annex B, a recombinant uricase derived from Candida Utilis and pegylated with 20kDA mPEG, and (b) any back-up compounds or any other forms thereof, including uricase, monomeric uricase, aggregated uricase, mixtures of monomeric and aggregated uricase, uricase of alternative natural or modified amino acid sequence, uricase with incorporation of non-natural amino acid(s) or amino acid derivatives or analogs; (c) any compounds from any of those identified in clauses (a) or (b) conjugated with any linker or linked to any other molecular entity, including those compounds linked to the same or other PEG molecules; (d) any salts, prodrugs, esters, amides, active metabolites, solvates, intermediates, fragments, derivatives (including pegylated versions and any linkers thereof), analogs and polymorphs of any compounds covered by the foregoing clauses (a), (b), (c) or this clause (d), and (e) any improvements to any of the foregoing covered by the foregoing clauses (a), (b), (c), (d) or this clause (e).

"Compound Know-How" shall mean (a) all Know-How licensed to Licensor pursuant to any of the 3SBio Agreements; and (b) all Know-How solely related to the Compound and reasonably necessary or reasonably useful for the Exploitation of the Product in the Field in the Territory, in the case of (b) to the extent such Know-How is Controlled by Licensor or its Affiliates as of immediately prior to the Effective Date or during the Term and is not otherwise covered by (a).

"Compound Patents" shall mean (a) all Patents licensed to Licensor pursuant to any of the 3SBio Agreements; and (b) all Patents solely related to the Compound and reasonably necessary or reasonably useful for the Exploitation of the Product in the Field in the Territory, in the case of (b) to the extent such Patents are Controlled by Licensor or its Affiliates as of immediately prior to the Effective Date or during the Term and are not otherwise covered by (a). Compound Patents existing as of the Execution Date are set forth in Annex A-1.

"Confidential Information" of a Party shall mean all Know-How, unpublished patent applications, and other information and data of a financial, commercial, business, operational, scientific or technical nature of such Party that is: (a) disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, whether made available orally, in writing, or in electronic form or (b) learned by the other Party pursuant to this Agreement. The terms and conditions of this Agreement are the Confidential Information of both Parties. Notwithstanding anything to the contrary in this Agreement, as between the Parties, all Development and Commercialisation plans are the Confidential Information of the Licensee.

"Confidentiality Period" shall have the meaning set forth in Section 10.1.1.

"Control" or "Controlled" shall mean, with respect to any Know-How, Patents, Trademarks or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license, or otherwise) to grant a license, sublicense, access, or other right (as applicable) under such Know-How, Patents, Trademarks or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case (a) without breaching the terms of any agreement of such Party with any Third Party (including a Third Party which becomes any Acquisition Entity of Licensor) existing at the time such Party would be required hereunder to grant the other Party such license, sublicense, access, or other use right and (b) without being obligated to pay to any Third Party (including a Third Party which becomes any Acquisition Entity of Licensor) any royalties or other consideration therefor except for (i) any intellectual property right (including any Patents or Know-How) in-licensed by Licensor

under an Existing Upstream Agreement; and (ii) any intellectual property right (including any Patents or Know-How) in-licensed by Licensor under a New Upstream Agreement under which Licensee elects to take a sublicense and, where Licensee is obliged to reimburse associated In-Licensor Payments, Licensee agrees to reimburse the associated In-Licensor Payments pursuant to Section 2.7.3 which, in each case of (i) and (ii) shall be considered under the Control of Licensor. Notwithstanding anything in this Agreement to the contrary, a Party will be deemed not to Control any intellectual property right (including any Patents or Know-How) that are owned or in-licensed by an Acquisition Entity, except (A) with respect to any intellectual property right (including any Patents or Know-How) arising out of or in connection with the conduct of activities under this Agreement after such Change of Control or acquisition (as applicable), (B) to the extent that any intellectual property right (including any Patents or Know-How) are included in or used in furtherance of the conduct of activities under this Agreement by the relevant Party, its Affiliates or such Acquisition Entity after such Change of Control or acquisition (as applicable), (C) for intellectual property rights (including any Patents or Know-How) constituting improvements (or improvements to such improvements) to the Licensed Technology in existence prior to such Change of Control or acquisition (as applicable) in each case, conceived by any employees or consultants of or otherwise by or on behalf of such Acquisition Entity; or (D) for intellectual property rights (including any Patents or Know-How) which comprise, include or were conceived, discovered, developed, reduced to practice or otherwise made using the Confidential Information of the other Party.

[***]

"Data Protection Laws" shall mean all applicable data protection, data security, data breach notification or privacy laws, rules, regulations, declarations, decrees, directive, legislative enactments, court orders, standards and other similar instruments, whether international, federal, state, or local, including but not limited to EU Data Protection Law, United States Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA"), the California Consumer Privacy Act of 2018 ("CCPA") and any supranational or national legislation relating to privacy and data protection, direct marketing or the interception or communication of electronic messages, in each case as amended, consolidated, re-enacted or replaced from time to time, and any relevant law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding instrument which implements, replaces, adds to, amends, extends, reconstitutes or consolidates such laws from time to time, in each case as amended, consolidated, re-enacted or replaced from time to time.

"Data Subject" shall mean a natural person who is an identified or identifiable natural person to whom the Personal Data relates. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

"Development" shall mean all drug development activities, including those related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, assay development, cell line development, formulation development, drug substance and drug product process development, product and process characterization, qualification and validation of processes and test methods, quality assurance/quality control, clinical studies, statistical analysis and report writing, the preparation, submission and prosecution of BLAs and MAAs, regulatory affairs with respect to the foregoing, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval, including any post-marketing development commitments. When used as a verb, "Develop" means to engage in Development.

"Development Budget" shall mean a budget agreed mutually by the Parties covering the Development of the Products in accordance with the Development Plan, which budget is split into (a) an annual development budget covering activities for a given calendar year and (b) a long term development

budget covering successive [***] year periods, including a payment schedule for payments by Licensee to Licensor to reimburse Licensor for the conduct of the Existing Pivotal Trials and, as applicable, the Additional Compound Development Activities and the Additional ImmTOR Development Activities.

"Development Cost" shall mean, with respect to a Product, those costs and expenses incurred directly in connection with the performance of any Development activities for such Product in accordance with the applicable Development Plan and Development Budget, including [***].

"Development Milestone Event" shall have the meaning set forth in Section 6.2.1.

"Development Milestone Payment" shall have the meaning set forth in Section 6.2.1.

"Development Plan" shall mean a plan mutually agreed by the Parties covering the global Development of the Products, including the Additional Compound Development Activities and the Additional ImmTOR Development Activities, if any, and the Existing Pivotal Trials, and the strategy for, preparation and submission of Regulatory Filings and interactions with Regulatory Authorities for the Products, [***]. The Development Plan will specify which Party is to conduct a given activity. [***].

"Dispute" shall have the meaning set forth in Section 17.2.1.

"DOJ" shall have the meaning set forth in Section 18.1.

"Drug Pricing Transparency Laws" shall have the meaning set forth in Section 11.1.

"EEA" shall mean the European Economic Area.

"Effective Date" shall mean (a) in the event that the Parties determine pursuant to Section 18 that HSR filings are required, the HSR Clearance Date, (b) in the event that the Parties determine prior to the Execution Date that no HSR filings are required, the Execution Date, or (c) in the event that the Parties determine after the Execution Date that no HSR filings are required, the date that is [***] days from the date the Parties make such mutual.

"EMA" shall mean the European Medicines Agency and any successor Governmental Authority having substantially the same function.

[***].

"Encumbrance" shall mean any lien, pledge, security interest, right of first refusal, option, title defect, Claim, license, restriction, or other interest or encumbrance of any kind or nature whatsoever, whether or not perfected, including any restriction on use, transfer, receipt of income or exercise of any other attribute of ownership.

"EU Data Protection Law" shall mean the GDPR and any relevant law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding instrument which implements, replaces, adds to, amends, extends, reconstitutes or consolidates such laws from time to time, in each case as amended, consolidated, re-enacted or replaced from time to time, including for clarity, the UK Data Protection Act 2018.

"Exclusive" shall mean in relation to a Party (subject to any retained rights set forth in this Agreement of the other Party), exclusive even as to the other Party and its Affiliates.

"Execution Date" shall have the meaning set forth in the introduction to this document.

"Executive Officer" shall mean for Licensor, its Chief Executive Officer, and for Licensee, its Chief Executive Officer or a direct report of its Chief Executive Officer, or, in each case, another senior executive officer who is a direct report to such Party's Chief Executive Officer (but for each Party, other than an existing member of the JSC) with appropriate responsibilities, seniority, and decision making authority; provided that any of the foregoing individuals may designate the Chief Financial Officer as his/her designee for financial related matters. In the event that the position of any of the Executive Officers identified in this definition no longer exists due to a Change of Control, corporate reorganization, corporate restructuring, or the like that results in the elimination of the identified position, then the applicable Party will replace the applicable Executive Officer with another executive officer with responsibilities and seniority comparable to the eliminated Executive Officer prior to such Change of Control.

"Existing 212 Patents" shall mean that subset of the Licensed Patents that relate solely to SEL-212. Existing 212 Patents existing as of the Execution Date are set forth in Annex A-2.

"Existing Pivotal Trials" shall mean Licensor's current planned [***] Pivotal Clinical Trial [***] as included in the agreed Development Plan and Development Budget.

"Existing Upstream Agreements" shall mean [***] and any other license agreement pursuant to which Licensor Controls any Licensed Technology existing as of the Effective Date, including [***].

"Expedited Arbitration" shall have the meaning set forth in Section 17.2.7.

"Expedited Dispute" shall have the meaning set forth in Section 17.2.7.

"Exploit", "Exploiting" or "Exploitation" shall mean to make, have made, import, use, sell or offer for sale, including to Develop, Commercialize, Manufacture, and have Manufactured.

[***].

"FDA" shall mean the U.S. Food and Drug Administration of the U.S. Department of Health and Human Services and any successor Governmental Authority having substantially the same function.

"FFDCA" shall mean the United States Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

"Field" shall mean all diagnostic, prophylactic and therapeutic uses.

"Financial Transparency Laws" shall have the meaning set forth in Section 11.1.

"First Commercial Sale" shall mean, with respect to a Product, the date of the first commercial sale in a country by Licensee or any of its Affiliates or Sublicensees to a Third Party for end use or consumption of such Product approved by a Regulatory Authority in such country and, with respect to the European Union, separate pricing and reimbursement approval. For clarity, First Commercial Sale does not include the supply or transfer of Product to an Affiliate or Sublicensee or for clinical trials or compassionate use.

"Force Majeure Event" shall mean any acts or events beyond a Party's reasonable control, including strikes or other labor disturbances, lockouts, insurrections, riots, quarantines, epidemics, pandemics and other communicable disease outbreaks, government actions, acts of God, embargoes, wars, acts of war (whether war be declared or not), acts of terrorism, fires, earthquakes, floods or storms.

"FTC" shall have the meaning set forth in Section 18.1.

"FTE" shall mean one (1) person (or the equivalent of one (1) person) employed by Licensor or any of its Affiliates on a full time basis, which for the purposes hereof shall be one thousand eight hundred and eighty (1,880) hours per year, and assigned to perform work in connection with this Agreement.

"FTE Cost" shall mean the FTE Rate multiplied by the applicable number of FTEs who perform a specified activity pursuant to this Agreement.

"FTE Rate" shall mean the actual, documented fully burdened direct cost of the relevant FTE working full time for one (1) year in performing the relevant activity (comprising of such FTE's salary, benefits, all Taxes related to such FTE, but excluding overtime payments to such employee unless otherwise agreed in writing in advance between the Parties) provided that, the FTE Rate for any FTE who devotes less than [***] hours per year in performing the relevant activity shall be determined on a pro rata basis based upon the actual number of hours spent divided by [***].

"Full Enrolment" shall mean, with respect to either Existing Pivotal Trials, the close of enrolment following completion of accrual of patients into such clinical study such that the inclusion of the protocol-defined number of patients into such clinical study has been successfully achieved.

"GAAP" shall mean generally accepted accounting principles as practiced in the United States, as consistently applied.

"GCP" shall mean the current standards for clinical studies for pharmaceuticals, as set forth in the ICH guidelines and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by the FDA, EMA and other Regulatory Authorities in countries in which a Product is intended to be sold.

"GDPR" shall mean Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

"GLP" shall mean all applicable good laboratory practice standards, including, as applicable, (i) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and (ii) the equivalent applicable Law in any relevant country, each as may be amended and applicable from time to time.

"Governmental Authority" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities, agencies, commissions or bodies.

"Greater China" shall mean mainland China, Hong Kong, Macau and Taiwan.

"HSR Act" shall have the meaning set forth in Section 18.1.

"HSR Clearance Date" means the earlier of: (a) the date on which the FTC or DOJ shall notify the Parties of early termination of the waiting period under the HSR Act, or (b) the date on which the applicable waiting period under the HSR Act expires.

"ICH" shall mean the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and any successor council having substantially the same function.

"ImmTOR" shall mean: (a) the Licensor's proprietary tolerogenic ImmTOR platform, also known as SEL-110, as further defined in Annex B, which acts to modulate the immune response to "compound" in humans by potentially inducing immune tolerance by encapsulating an immunomodulator rapamycin, and [***].

"ImmTOR Manufacturing Process" means the process for manufacturing ImmTOR described in IND 124184 for ImmTOR.

"ImmTOR Trademarks" shall mean the Trademark ImmTOR™ and any other related Trademark or service mark containing the word "ImmTOR" and any other Trademark that Licensor or its Affiliates use on or with ImmTOR, for each of the foregoing that are Controlled by Licensor or its Affiliates.

"In-Licensor Payments" shall have the meaning set forth in Section 2.7.1.

"IND" shall mean any investigational new drug application, clinical trial application, clinical trial exemption, or similar or equivalent application filed with the applicable Regulatory Authority of a country of the Territory for approval to conduct clinical testing of a biological or pharmaceutical product in humans in such country.

"Indemnifying Party" shall have the meaning set forth in Section 14.3.2.

"Indemnitee" shall have the meaning set forth in Section 14.3.2.

"Indication" shall mean a separate and distinct disease, disorder, or medical condition for which a Product can be used to diagnose, treat, or prevent, which use is the subject of a separate BLA or MAA approval for a distinct labeling supported by data from at least one Pivotal Clinical Trial not previously submitted to the applicable Regulatory Authority. For clarity, subpopulations or patients with a primary disease, disorder or condition, however stratified, shall not be deemed to be separate

"Indications" for the purposes of this Agreement, including stratification by stages or progression (including precursor condition), particular combinations of symptoms associated with the primary disease, disorder or condition, prior treatment courses, response to prior treatment, different lines of treatment, family history, clinical history, phenotype, age (e.g. adult and pediatric) or other stratification.

"Insolvency Proceeding" shall mean any proceeding commenced by or against any Person under any provision of Title 11 of the United States Code (as in effect from time to time) or under any other state or federal bankruptcy or insolvency law, or proceedings seeking reorganization, arrangement, or other similar relief.

"JSC" shall have the meaning set forth in Section 3.1.1.

"Know-How" shall mean all commercial, technical, scientific, and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, composition of matter, analytical reference standards, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know how, including regulatory data, study designs, and protocols), and cells, cell lines, assays, animal models, and other physical, biological, or chemical materials, in all cases, whether or not confidential, proprietary, patentable, in written, electronic or any other form now known or hereafter developed, but excluding all Patents.

"Law" shall mean any federal, state, local or supranational law, statute or ordinance, or any rule, regulation, or published guidelines promulgated by any Governmental Authority or any similar provision having the force or effect of law, together with the requirements of any Governmental Authority.

"License" shall mean the licenses set forth in Section 2.1 of this Agreement.

"Licensed Know-How" shall mean (a) all Compound Know-How and (b) all Know-How Controlled by Licensor or its Affiliates (i) in existence as of immediately prior to the Effective Date or (ii) arising during the Term, [***].

"Licensed Patents" shall mean (a) all Compound Patents and (b) all Patents Controlled by Licensor or its Affiliates (i) in existence as of immediately prior to the Effective Date or (ii) arising during the Term, [***]. Licensed Patents existing as of the Execution Date are set forth in Annex A.

"Licensed Technology" shall mean (a) the Licensed Patents, and (b) the Licensed Know-How.

"Licensee" shall have the meaning set forth in the introduction to this document.

"Licensee CMO Agreement" shall have the meaning set forth in Section 13.4.1.

"Licensee Indemnitee" shall have the meaning set forth in Section 14.1.

"Licensor" shall have the meaning set forth in the introduction to this document.

"Licensor Acquisition" shall have the meaning set forth in Section 2.10.3.

"Licensor Acquisition Program" shall have the meaning set forth in Section 2.10.3.

"Licensor COC Program" shall have the meaning set forth in Section 2.10.2.

"Licensor Development Activities" shall mean the Existing Pivotal Trials and, if any, the Additional Compound Development Activities and the Additional ImmTOR Development Activities.

"Licensor Development Breach" shall have the meaning set forth in Section 4.3.1.

"Licensor Indemnitee" shall have the meaning set forth in Section 14.2.

"Licensor Permitted Activities" shall mean (a) the Exploitation of products other than the Products in the Field in the Territory; (b) the Exploitation of the Product outside the Field outside the Territory; and (c) the exercise of the Licensor Retained Rights.

"Licensor Retained Rights" shall have the meaning set forth in Section 2.5.

"Litigation Costs" shall have the meaning set forth in Section 14.1.

"Loss of Market Exclusivity" shall mean an event where or circumstances where, with respect to any Product in any country: (a) one or more Biosimilar Product(s) are being marketed in such country; [***].

"Losses" shall have the meaning set forth in Section 14.1.

"MAA" shall mean a Marketing Authorization Application or other application or submission submitted to the EMA, pursuant to the centralized approval procedure or, if such centralized approval procedure is not used, to the applicable Regulatory Authority of a country in the EU with respect to the mutual recognition, de-centralised or any other national approval, for approval to commercially sell a Product in that country or in that group of countries or equivalent foreign applications to a Regulatory Authority for approval to commercially sell a Product in any country or jurisdiction in the Territory other than an NDA or BLA.

"Manufacture" and "Manufacturing" shall mean all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of Product, including process qualification and validation, scale-up, clinical and commercial manufacture, stability testing, quality assurance and quality control.

"Materials" shall have the meaning set forth in Section 2.8.4.

"Minimum Floor" shall have the meaning set forth in Section 6.5.4.

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"New Upstream Agreement" shall have the meaning set forth in Section 2.7.3.

"Non-Acting Party" shall have the meaning set forth in Section 7.3.2.

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"Order" means any order, judgment, injunction, award, decree, ruling, stipulation, determination, or writ of any Governmental Authority.

"Opted-In New Upstream Agreement" shall have the meaning set forth in Section 2.7.3.

"Other Joint New IP" shall have the meaning set forth in Section 9.2.2.

"Other Joint New IP Patents" shall mean any and all Patents claiming Other Joint New IP.

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"Out of Pocket Costs" shall mean, with respect to certain activities for a Product hereunder, specifically identifiable direct expenses paid or payable by either Party or its Affiliates to Third Parties incurred to conduct such activities, including payments to contract personnel (including contractors, consultants, and subcontractors).

"Patent(s)" shall mean all patents and patent applications (including all provisional applications, priority applications, substitutions, divisionals, continuations, continuations in part), any patent issued

with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal, or extension (including any patent term adjustment, patent term extension, supplemental protection certificate, or the equivalent thereof) of any such patent, any confirmation patent or registration patent or patent of addition based on any such patent, and any inventor's certificates, and all equivalents and counterparts thereof in any country.

"Patent Challenge" shall have the meaning set forth in Section 16.4.

"Permitted Encumbrance" shall mean any (a) statutory Encumbrances for Taxes that are not yet due and payable or which are being contested in good faith through proper proceedings, in each case, with sufficient reserves maintained in accordance with GAAP; (b) statutory Encumbrances arising out of operation of Law with respect to a liability incurred in the ordinary course of business with respect to any amounts not yet due and payable; (c) Encumbrances, other than liens securing indebtedness for borrowed money, that, individually and in the aggregate, (i) do not and would not reasonably be expected to detract from the value or impair the Exploitation of the Product and (ii) do not conflict with any rights granted to Licensee and its Affiliates and Sublicensees hereunder; (d) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like Encumbrances and security obligations incurred in the ordinary course of business with respect to any amounts not yet due and payable; and (d) Encumbrances created or required by this Agreement in favor of Licensee and its Affiliates and Sublicensees.

"Person" shall mean any individual, corporation, partnership, limited liability company, association, joint venture, trust or any other entity or organization, including any Governmental Authority.

"Personal Data" shall mean any information regulated by any applicable Data Protection Laws, including any information relating to an identifiable Data Subject.

"Personal Data Breach" shall mean a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data which has been transferred by one Party to the other Party, whether by physical or electronic means, pursuant to this Agreement (if any).

"Phase I Clinical Trial" shall mean, as to the Product, a study in humans of the metabolism, tolerability and safety of such Product, which is prospectively designed to generate sufficient data (if successful) to commence a Phase II Clinical Trial of such Product, as further defined in Federal Regulation 21 C.F.R. 312.21(a), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. A Phase I Clinical Trial shall be deemed initiated upon the dosing of the first subject.

"Phase II Clinical Trial" shall mean, as to the Product, a study, conducted in diseased humans, of the feasibility, safety, dose ranging and efficacy of such Product, that is prospectively designed to generate sufficient data (if successful) to commence a Phase III Clinical Trial of such Product, as further defined in 21 C.F.R. 312.21(b), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. For the avoidance of doubt, a Phase II Clinical Trial requires enrollment of patients with the applicable disease or condition and is aimed to provide a measure of efficacy in addition to short-term tolerability. A Phase II Clinical Trial shall be deemed initiated upon the dosing of the first patient.

"Phase III Clinical Trial" shall mean, as to the Product, a study in humans performed to gain evidence of the efficacy of such Product in a target population, and to obtain expanded evidence of safety for such Product that is needed to evaluate the overall benefit-risk relationship of such Product and provide an adequate basis for physician labeling, as described in 21 C.F.R. 312.21(c), as amended from time to

time, or the corresponding regulation in jurisdictions other than the United States. A Phase III Clinical Trial shall be deemed initiated upon the dosing of the first patient.

"PHSA" shall mean the United States Public Health Services Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

"Pivotal Clinical Trial" shall mean adequate and well-controlled clinical trials (as defined in 21 C.F.R. § 314.126, as amended from time to time, or corresponding regulations in jurisdictions other than the United States) that are designed to demonstrate the effectiveness of a Product in certain Indications and are intended to form the primary basis for a Regulatory Filing seeking Regulatory Approval, including clinical trials which prove substantial evidence of effectiveness and have the ability to generate product labelling that defines an appropriate patient population and provides adequate information to enable safe and effective use of the Product, regardless of whether such trials are captioned as a Phase II Clinical Trial, Phase IIb Clinical Trial, Phase II/III Clinical Trial or Phase III Clinical Trial, but excluding a Phase I Clinical Trial.

"Proceeding" shall mean any action, arbitration, audit (to the knowledge of such Party), hearing, investigation (to the knowledge of such Party), litigation or suit (whether civil, criminal, administrative, investigative or informal) commenced, brought, conducted or heard by or before, or otherwise involving any Governmental Authority or arbitrator.

"Processing" and "Process" shall mean any operation or set of operations that is performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

"Products" shall mean (a) SEL-212, (b) any pharmaceutical composition containing a combination of the Compound with ImmTOR, whether or not such combination is the sole active ingredient or biologic, and (c) all forms, presentations, formulations and dosage forms of the product or compositions of clause (a) and (b) respectively. For clarity, a Product includes any Combination Product.

"Proposal" shall have the meaning set forth in Section 17.2.7(b).

"Prosecution" or "Prosecute" shall have the meaning set forth in Section 9.3.1(a).

"Quality Agreements" shall mean the agreements between the Parties on standard terms and conditions for the pharmaceutical industry which outlines the operational responsibilities of each Party with respect to quality assurance and quality control of the Compound, ImmTOR and/or Products supplied under this Agreement.

"Regulatory Approval" shall mean all approvals by Regulatory Authorities necessary for the Exploitation of a pharmaceutical or biologic product for one or more Indications in a country or regulatory jurisdiction (including pricing and reimbursement approvals).

"Regulatory Authority" shall mean any Governmental Authority involved in granting Regulatory Approvals in the applicable country in the Territory, including the FDA in the United States, the EMA and the European Commission in the European Union, and the Japanese Ministry of Health, Labour, and Welfare and the Pharmaceuticals and Medical Devices Agency in Japan.

"Regulatory Exclusivity Period" shall mean, with respect to each Product in any country in the Territory, any period of data, market or other regulatory exclusivity (other than Patent exclusivity) granted or afforded by Law or by a Regulatory Authority in such country that confers exclusive marketing rights

with respect to such Product in such country or prevents another party from using or otherwise relying on any data supporting the approval of a BLA or MAA or supporting the Regulatory Approval for such Product without the prior written consent of the BLA-holder, MAA-holder or Regulatory Approval-holder, as applicable, such as reference product exclusivity for biological products under Section 351(k)(7) of the PHSA, new chemical entity exclusivity, new use or Indication exclusivity, new formulation exclusivity, orphan drug exclusivity, non-patent related pediatric exclusivity or any other applicable marketing or data exclusivity, including any such periods listed in the FDA's Orange Book or Purple Book or any such periods under national implementations in the EU of Article 10 of Directive 2001/83/EC, Article 14(11) of Parliament and Council Regulation (EC) No. 726/2004, Parliament and Council Regulation (EC) No. 141/2000 on orphan medicines, Parliament and Council Regulation (EC) No. 1901/2006 on medicinal products for pediatric use and all international equivalents of any of the foregoing.

"Regulatory Filing" shall mean any filing, application or submission with a Regulatory Authority relating to or to permit or request, as applicable, the clinical evaluation or Regulatory Approval of a pharmaceutical or biologic product in a particular country or jurisdiction. Regulatory Filings include without limitation INDs, BLAs and MAAs.

"Regulatory Materials" shall mean any and all regulatory applications, submissions, notifications, communications, correspondences, registrations, and other filings made to, received from, or otherwise conducted with a Regulatory Authority in order to or in connection the Exploitation of a pharmaceutical or biologic product in a particular country or jurisdiction, including all Regulatory Filings and Regulatory Approvals.

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"Royalty" shall have the meaning set forth in Section 6.4.1.

"Royalty Reporting Quarter" shall have the meaning set forth in Section 6.6.1.

"Royalty Term" shall mean, on a Product-by-Product and country-by-country basis, the period starting on the First Commercial Sale of such Product in such country and ending on the later to occur of: (a) [***] years from the First Commercial Sale of such Product in such country; (b) the expiration of the last-to-expire Valid Claim of a Licensed Patent covering such Product in such country; and (c) the expiry of all Regulatory Exclusivity Periods for such Product in such country.

"Safety Agreement" shall mean the agreement between the Parties relating to the sharing of safety data Controlled by each Party and its Affiliates related to the Compound, ImmTOR and / or the Products.

"Sales Milestone Event" shall have the meaning set forth in Section 6.3.1.

"Sales Milestone Payment" shall have the meaning set forth in Section 6.3.1.

"Second Source Supplier" shall have the meaning set forth in Section 13.4.1.

"Securitization Transaction" shall have the meaning set forth in Section 19.5.2.

"SEL-212" shall mean Licensor's proprietary SEL-212 product described on Annex B.

[***].

"Selecta-Controlled Patents" shall mean that subset of the Licensed Patents that exist as of the Execution Date and are Controlled by Selecta [***].

"Significant Trial" means, with respect to the Product, a new human clinical trial that, at the time of commencement, is reasonably expected to (a) cost in excess of [***] and / or (b) involve the enrollment of more than [***] patients.

"Specifications" shall mean the Manufacturing specifications set forth in the Regulatory Approvals for the Products, together with mutually agreed specifications set forth in the Quality Agreement for the Product.

"Sublicense" shall have the meaning set forth in Section 2.3.

"Sublicensee" shall mean any person or entity other than an Affiliate of Licensee that is granted a Sublicense by Licensee.

"Supply Agreement" shall mean the agreement relating to the supply of Product by or on behalf of Licensor to Licensee or its Affiliates or Sublicensees entered into by the Parties pursuant to Section 13.2.

"Supply Price" shall mean, as applicable, the fully allocated cost of manufacturing nude vials of the Product, as calculated in accordance with GAAP, including costs incurred by Licensor to obtain active ingredients, raw materials, components, containers and labeling and the direct costs of production, packaging, analytical and stability testing, quality control and quality assurance, reasonable supervision, reasonable material variance, reasonable yield variance, reasonable investigations, serialisation as required by applicable Law, but excluding any mark-up or overhead. For clarity, where Licensor acquires any of the foregoing from any of its Affiliates, the Supply Price shall include the fully allocated cost of such Affiliate and not the purchase price applied between companies. [***], unless the actual cost of Manufacturing the same decreases during such period, in which case the Supply Price for such period will be the actual cost of Manufacturing. For clarity, the Supply Price does not include any allocation of royalty or other amounts payable to Licensor's licensors.

"Tax Action" shall have the meaning set forth in Section 7.3.2.

"Taxes" shall mean all taxes of any kind, and all charges, fees, customs, levies, duties, imposts, required deposits or other assessments, including all federal, state, local or foreign net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social security, worker's compensation, unemployment, occupation, capital stock, transfer, gains, windfall profits, net worth, asset, transaction and other taxes, and any interest, penalties or additions to tax with respect thereto, imposed upon any Person by any Governmental Authority under applicable Laws, whether disputed or not.

"Technology Transfer" shall have the meaning set forth in Section 13.4.6.

"Term" shall have the meaning set forth in Section 16.1.

"Territory" shall mean, subject to Section 2.2.11, all countries of the world, excluding Greater China.

"Third Countries" shall mean all countries outside of the scope of the data protection laws of the EEA, excluding countries approved as providing adequate protection for Personal Data by the European Commission from time to time, which at the date of this Agreement include Andorra, Argentina, Canada, Faroe Islands, Guernsey, Isle of Man, Israel, Japan, Jersey, New Zealand, Switzerland and Uruguay.

"Third Party" shall mean any Person other than Licensor, Licensee, or their respective Affiliates.

"Third Party Infringement Claim" shall have the meaning set forth in Section 9.5.1.

"Third Party Payments" shall mean the aggregate of all payments (including for royalties, lump sum payments, upfront payments, costs, damages, judgements and awards) which Licensee, its Affiliates or its Sublicensees pay to a Third Party (including any Third Party which later becomes an Acquisition Entity of Licensor but excluding any Sublicensee) for a license under Patents or Know-How owned or controlled by such Third Party (including any Acquisition Entity of Licensor) that are reasonably necessary or reasonably useful for the Exploitation of the Products in the Field in the Territory.

"Trademark" shall mean any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing, whether registered or unregistered.

"Transferred Data" shall mean the Personal Data transferred by one Party to the other Party, whether by physical or electronic means, pursuant to this Agreement (if any) in respect of which EU Data Protection Law applies.

[***].

"Transparency Laws" shall have the meaning set forth in Section 11.1.

"United States" or "U.S." shall mean the United States of America and its territories, commonwealths, possessions (including the District of Columbia and the Commonwealth of Puerto Rico) and its military bases.

"Up-Front Payment" shall have the meaning set forth in Section 6.1.

"Upstream Agreements" shall mean, collectively, the Existing Upstream Agreements and the Opted-In New Upstream Agreements.

"Valid Claim" shall mean: (a) any claim of an issued and unexpired Patent, that shall not have been withdrawn, lapsed, abandoned, revoked, canceled or disclaimed, or held invalid or unenforceable by a court, Governmental Authority, national or regional patent office or other appropriate body that has competent jurisdiction in a decision being final and unappealable or unappealed within the time allowed for appeal; and (b) a claim of a pending patent application that is filed and being prosecuted in good faith and that has not been finally abandoned or finally rejected and which has been pending for no more than [***] years from the date of filing of the earliest patent application to which such pending patent application claims priority. (For clarity, a claim of an issued patent that ceased to be a Valid Claim before it issued because it had been pending for more than [***] years from the date of filing of the earliest patent application to which such pending patent application claims priority, but subsequently issued and is otherwise described by clause (a) of the foregoing sentence shall again be considered to be a Valid Claim once it issues. The same principle shall apply in similar circumstances such as if, for example (but without limitation), a final rejection of a claim is overcome).

"Withholding Taxes" shall have the meaning set forth in Section 7.3.1.

1.2 Interpretation. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms "hereof," "herein," "hereby," and derivative or similar towards refer to this entire Agreement and not merely to the particular provision in which such words appear; (d) the terms "Section" or "Annex" refer to the specified Section or Annex of this Agreement; (e) the term "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase, "and/or"; (f) the term "including" means "including, without limitation"; (g) the word "shall" will be construed to have the same meaning and effect as the word "will"; (h) any definition of

or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (i) any reference herein to any Person will be construed to include the Person's successors and assigns; (j) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; (k) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging); (l) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then current amendments thereto or any replacement or successor law, rule or regulation thereof, (m) "days" refers to calendar days; and (n) the Annexes form part of the operative provisions of this Agreement and references to this Agreement shall include references to the Annexes. All accounting terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Accounting Standards. All references to "$" amounts hereunder shall be deemed to be U.S. Dollars.

2. GRANT OF RIGHTS; NON-COMPETE

2.1 License Grant.

2.1.1 Subject to the terms and conditions of this Agreement (including Section 2.5), Licensor hereby grants to Licensee an Exclusive, sublicensable (in accordance with Section 2.3) and assignable (in accordance with Section 19.5) license under the Licensed Technology to Exploit the Products in the Field in the Territory (the "License"). Upon the expiration of the Royalty Term for a Product in a country of the Territory, the foregoing license shall be rendered fully paid-up, royalty-free and non-terminable for such Product in such country.

2.2 Additional Obligation of Licensor. Licensor:

2.2.1 shall, as soon as reasonably practicable, and in any event no later than the [***] calendar day, following receipt of notice from Licensee requesting the same, [***];

2.2.2 shall [***] not materially breach or be in material default under any of its obligations under any Upstream Agreement or take any other action, or omit or fail to take any action (including making necessary payments unless such payment breach or default is the result of Licensee failing to reimburse In-Licensor Payments in accordance with Section 2.7.3), which might reasonably be expected to result in an early termination of any Upstream Agreement or otherwise have an adverse effect in any material respect on the rights of Licensee hereunder;

2.2.3 [***] shall immediately (and in any event within [***] Business Days) notify Licensee if Licensor receives notice (whether written or otherwise) from 3SBio alleging that Licensor is in breach of its obligations under the 3SBio License Agreement and shall promptly take all reasonable steps to remedy such breach, unless and to the extent such breach is caused by Licensee's failure to comply with its obligations under this Agreement, in which case Licensor shall promptly notify Licensee of such alleged Licensee breach in reasonable detail;

2.2.4 shall [***] not terminate any Upstream Agreement in a manner that would terminate or have an adverse effect on the rights of Licensee hereunder;

2.2.5 shall [***] promptly notify Licensee upon Licensor becoming aware of any alleged, threatened or actual breach of an Upstream Agreement (other than the 3SBio License Agreement which is the subject of Section 2.2.3) by Licensor where termination of such Upstream Agreement is

being or reasonably could be sought by the counterparty and such termination would terminate or have an adverse effect on the rights of Licensee hereunder;

2.2.6 shall [***] use Commercially Reasonable Efforts to enforce the terms of [***] the Upstream Agreements (other than the 3SBio License Agreement which is the subject of Section 2.2.3) in the case of a breach by any counterparty to such agreements, and shall keep Licensee reasonably informed in connection therewith, including providing prompt notice of any breach by the counterparty thereto;

2.2.7 subject to Section 2.2.14, shall, in respect of the 3SBio License Agreement, provide Licensee with reasonable notice, information and opportunity to comment regarding any decisions to be taken by the joint steering committee constituted pursuant to that agreement which could have an adverse effect on the rights of Licensee hereunder [***];

2.2.8 shall [***], not agree, consent or acquiesce to any amendment, supplement or other modification to the Upstream Agreements that would reasonably be expected to have an adverse effect on the rights or expand the obligations of Licensee under this Agreement, unless and until Licensee has consented in writing to the same (such consent, not to be unreasonably withheld, conditioned or delayed);

2.2.9 shall [***] not assign, novate or otherwise transfer [***] any Upstream Agreement, to a Third Party without Licensee's consent if such assignment, novation or other transfer would have an adverse effect on the rights of Licensee hereunder, except in connection with a permitted assignment of this Agreement in accordance with Section 19.5;

2.2.10 shall, during the Term, [***];

2.2.11 [***]

2.2.12 shall, as soon as reasonably practicable and in any event no later than the [***] calendar day following the Effective Date, commence discussions with 3SBio, and shall use Commercially Reasonable Efforts until the first anniversary of the Effective Date, to:

(a) obtain 3SBio's agreement as soon as reasonably practicable (and, upon Licensee's request, to facilitate direct discussion between Licensee and 3SBio [***]; and

(b) [***];

2.2.13 if a Party reasonably believes that 3SBio is in breach of its obligations under the 3SBio License Agreement, such Party shall promptly notify the other in writing, providing reasonable details of such breach (a "3SBio Breach Notice"). Upon receiving Licensee's 3SBio Breach Notice or upon Licensee's request following Licensee's receipt of Licensor's 3SBio Breach Notice, Licensor (a) shall promptly notify 3SBio of such breach and use Commercially Reasonable Efforts to promptly enforce the terms of the 3SBio License Agreement and to have 3SBio cure such breach, (b) shall, upon Licensee's request, promptly facilitate direct discussion between Licensee and 3SBio to have 3SBio cure such breach, and (c) if 3SBio refuses to cure such breach, fails to cure such breach within the time period specified under Section 12.2 of the 3SBio License Agreement or fails to cure such breach to the reasonable satisfaction of Licensee, then, if so requested by Licensee, with Licensee bearing Licensor's out of pocket costs associated therewith (provided Licensor shall provide Licensee with monthly updates regarding legal fees accrued to date and estimates of legal fees to completion), (i) shall promptly bring, and shall use Commercially Reasonable Efforts to pursue, an action against 3SBio to enforce the terms of the 3SBio License Agreement using counsel chosen by Licensee and allowing Licensee to decide and direct the enforcement strategy for such action with Licensor implementing such strategy, and (ii) shall keep Licensee informed and provide copies of all communications of all developments in connection with any

such action, and shall implement any changes to the strategy Licensee has instructed Licensor to take for such action.

2.2.14 Without limiting Licensor's obligations under Section 2.2.13, if:

(a) [***]; and

(b)

(i) Licensee has provided Licensor with a 3SBio Breach Notice regarding the 3SBio License Agreement and 3SBio has not remedied the relevant breach within [***] Business Days following the date of Licensor's notice delivered in accordance with Section 2.2.13 (a); or

(ii) Licensor has received notice (whether written or otherwise) from 3SBio alleging that Licensor is in breach of its material obligations under the 3SBio License Agreement and Licensor has not remedied the same within [***] Business Days (in the case of a failure to make payment) or [***] Business Days (in the case of any other breach), in each case, of Licensor's receipt of such notice, provided that such breach is not caused by Licensee's failure to comply with its obligations hereunder,

[***].

2.3 Right to Sublicense. Licensee shall have the right to grant sublicenses (or licenses, or further rights of reference, as applicable), [***], under the License (individually, a "Sublicense") to its Affiliates and Third Parties [***], [***].

2.4 Disclosure of Licensed Know-How. Promptly following the Effective Date (or as otherwise requested by Licensee) and for no additional consideration, Licensor shall promptly disclose to Licensee, or provide Licensee with copies (both in print and, where available, electronic copies) of the Licensed Know-How relating to the Compound and / or SEL-212 [***] existing as of the date of such transfer in reasonably sufficient detail in order for a reasonably-skilled person to practice such Licensed Know-How solely within the scope of the License. Licensor shall update such Licensed Know-How previously transferred to Licensee on as frequent and regular a basis as is reasonably required by Licensee. Without limiting the foregoing, such transfer of such Licensed Know-How shall include:

2.4.1 transfer of copies of the results of and data from all clinical trials and pre-clinical studies (including the Existing Pivotal Trials, when the same have been completed) conducted prior to and as of the Effective Date relating to the Compound and /or the SEL-212 (including all clinical data, pre-clinical data, hard-copy case report forms and reports to the extent disclosure thereof to Licensee is not prohibited by applicable Laws outside the Territory);

2.4.2 transfer of copies of the data and results of all CMC Activities relating to the Compound and /or SEL-212 [***];

2.4.3 transfer copies of all Development reports and summaries relating to the Compound and/or SEL-212 [***]; and

2.4.4 transfer of copies of all documents supporting technical transfer received from a Third Party manufacturer or development of Compound of Licensor or its Affiliates;

2.4.5 providing Licensee with reasonable access to Licensor personnel with relevant expertise to explain such Licensed Know-How transferred hereunder.

For clarity, in no event shall any transfer of Licensed Know-How to Licensee pursuant to this Section 2.4 include Licensed Know-How related solely to the Manufacture of ImmTOR.

2.5 Reservation of Rights. Notwithstanding anything in this Agreement to the contrary, Licensor shall, as between the Parties, retain for itself (and its Affiliates and (sub)licensees) the right under the Licensed Technology, with the right to grant licenses through multiple tiers, to:

2.5.1 Manufacture and supply the Products [***] for the Licensee, its Affiliates and its Sublicensees pursuant to Section 13;

2.5.2 Manufacture and supply the Products [***] for the purposes of conducting the Licensor Development Activities; and

2.5.3 conduct and perform the Licensor Development Activities in accordance with Section 4.3.

(collectively, the foregoing, the "Licensor Retained Rights").

2.6 Combination Products. Notwithstanding any other provision of this Agreement, for purposes of the License with respect to any Product that is a Combination Product, such License will not include any claims in any Licensed Patents which specifically claim only the additional active ingredient or biologic (*i.e.* the additional active ingredient or biologic which is not the Compound) but will include any claims in any Licensed Patents which include within their scope the combination of such additional active ingredient agent or biologic with the Compound or with the Compound and ImmTOR.

2.7 Upstream Agreements.

2.7.1 Subject to Section 2.7.2, Licensor agrees that all upfront, milestone, royalty, and other payments to any Third Party (including to any Third Party which becomes any Acquisition Entity of Licensor and including in relation to any sales by Licensee, its Affiliates or Sublicensees) (collectively, "In-Licensor Payments") with respect to any Existing Upstream Agreements [***] will be the sole responsibility of Licensor.

2.7.2 Licensee agrees that, [***].

2.7.3 In the event that, after the Effective Date, Licensor in-licenses Licensed Technology that would be deemed Controlled for purposes of the License but for Licensor owing In-Licensor Payments under the agreement for such in-licensed Licensed Technology (each such agreement, a "New Upstream Agreement") on account of any sublicense granted thereunder to Licensee or its Affiliates or its Sublicensees, Licensor will notify Licensee of the existence of and anticipated amounts of such In-Licensor Payments attributable to the Product (based on Licensee's, its Affiliates' and its Sublicensees' pro rata share of the total amount thereof) and Licensee will have the right to decline a sublicense to such in-licensed Licensed Technology or take such sublicense (a New Upstream Agreement for which Licensee elects a sublicense, an "Opted-In New Upstream Agreement"), in which case Licensee agrees to comply with any obligations under such Opted-In New Upstream Agreement that apply to Licensee, its Affiliates and its Sublicensees and of which Licensee is informed by Licensor and to reimburse Licensor for such In-Licensor Payments. In the event Licensee elects to take such sublicense and is required to reimburse Licensor for In-Licensor Payments thereunder, Licensee will make such payments to Licensor within [***] days of receiving an invoice from Licensor for the same and shall be entitled to offset such payments against the royalties otherwise due under Section 6.4 as a "Third Party Payment" in accordance with Section 6.5.3.

2.7.4 [***].

2.7.5 Licensee shall be free, without the consent of the JSC or the Licensor, at any time during the Term, to obtain licenses to Third Party intellectual property rights.

2.8 ImmTOR Trademarks License.

2.8.1 Licensor hereby grants to Licensee an Exclusive, sublicensable (in accordance with Section 2.3) and assignable (in accordance with Section 19.5) license under the ImmTOR Trademarks in the Field and Territory solely in connection with the Commercialization of the Product. The foregoing license shall be rendered non-terminable upon the expiration of the Royalty Term. For clarity, nothing in this Section 2.8.1 shall prevent Licensor from using or licensing to a Third Party the ImmTOR Trademarks for use in relation to the Commercialization of a product in the Field in the Territory other than a Product.

2.8.2 Licensee acknowledges the validity of Licensor's right, title and interest in and to the ImmTOR Trademarks. Licensee shall not have, assert or acquire any right, title or interest in or to any of the ImmTOR Trademarks or the goodwill pertaining thereto, except as otherwise explicitly provided in this Agreement, and Licensee's use of the ImmTOR Trademarks shall inure to the benefit of Licensor for the purpose of the ImmTOR Trademarks and trade name ownership, registration, enforcement, and maintenance.

2.8.3 Licensee shall, and shall cause its Affiliates and Sublicensees to, include all notices, markings and legends as are or may be required by applicable Laws in order to give appropriate notice of ownership of and rights to the ImmTOR Trademarks. Licensee shall, and shall cause its Affiliates and Sublicensees to, use the ImmTOR Trademarks in accordance with all applicable federal, state and local Laws and with Licensor's reasonable trademark usage policies and guidelines which may be in effect from time to time as provided to Licensee by Licensor in writing.

2.8.4 Upon Licensor's reasonable request, Licensee shall provide, and shall cause its Affiliates and Sublicensees to provide, Licensor with representative samples of any materials bearing the ImmTOR Trademarks, including business forms, marketing materials, and advertising materials ("Materials"). In the event that Licensor notifies Licensee within [***] Business Days of receipt of such Materials that, in the reasonable opinion of Licensor, such Materials materially deviate from the standards of quality set forth in Section 2.8.3, Licensee shall use Commercially Reasonable Efforts to correct such deviations.

2.8.5 Licensee shall not (a) challenge the validity of Licensor's ownership of the ImmTOR Trademarks or any registration or application for registration thereof, or (b) seek its own registration of the ImmTOR Trademarks, or any name or mark confusingly similar to, or dilutive of, the ImmTOR Trademarks.

2.8.6 Licensee shall notify Licensor in writing, as promptly as practicable, should it become aware of activity by a Third Party that constitutes an unauthorized use, infringement, or dilution of any of the ImmTOR Trademarks. Licensor shall have the sole right to take, and to determine whether or not to take, [***], any action(s) it deems appropriate with respect to any unauthorized use, infringement, or dilution of the ImmTOR Trademarks, and Licensee shall, at [***], cooperate with Licensor in connection with any such action. [***] retain all recovery in the form of monetary damages or settlement from any such action.

2.9 No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party or any of its Affiliates, as a result of this Agreement, obtain any ownership interest, license or other right (whether by implication, estoppel or otherwise) in or to any Know-How, Patents or other intellectual property rights of the other Party or any of such other Party's Affiliates, including tangible or intangible items owned, controlled or developed by the other Party or any of such

other Party's Affiliates, or provided by the other Party or any of its Affiliates to the receiving Party or any of its Affiliates at any time, pursuant to this Agreement. Neither Party nor any of its Affiliates will use or practice any Know-How or Patents licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

2.10 Non-Compete.

2.10.1 During the Term, neither Licensor nor any of its Affiliates shall, directly or indirectly, [***]

2.10.2 [***]

2.10.3 [***]

2.11 [***]. [***]. Each of the Parties hereto recognizes that the restrictions contained in, and the terms of, this Section 2.11 are required for the protection of Licensor's Royalties hereunder, and agree that if any provision in this Section 2.11 is determined by any court to be unenforceable by reason of its extending for too great a period of time or over too great a geographic area, or by reason of its being too extensive in any other respect, such covenant shall be interpreted to extend only for the longest period of time and over the greatest geographic area, and to otherwise have the broadest application as shall be enforceable under applicable Law.

3. GOVERNANCE

3.1 Joint Steering Committee

3.1.1 General. Within [***] days after the Effective Date, the Parties shall establish a joint steering committee (the "JSC"), composed of an equal number of representatives of each Party including at least two (2) senior representatives of each Party. The JSC may, from time to time, elect to establish sub-committees to perform its functions. Each Party may replace its JSC representatives at any time upon prior written notice to the other Party. Licensee shall have the right to designate the chairperson of the JSC. The JSC shall have the right to set up subcommittees as required, comprised of equal numbers of appropriate representatives from each Party which shall not be voting committees.

3.1.2 Responsibility. The JSC will have the following responsibilities:

(a) review and discuss the initial Development Plan and Development Budget, and determine whether to approve the portions of each of such Development Plan and Development Budget that relate to the Licensor Development Activities;

(b) review and discuss any amendments or updates to the Development Plan and Development Budget (in each case, whether initial or subsequent versions), and determine whether to approve any amendments or updates to the portions of each of such Development Plan and Development Budget that relate to the Licensor Development Activities (including whether to include any Additional Compound Development Activities or Additional ImmTOR Development Activities, and any changes to the protocols for (including any endpoints) and whether to terminate, disband or otherwise discontinue, any of the Existing Pivotal Trials);

(c) supervise Licensor's conduct of the Existing Pivotal Trials and determine whether there has occurred a Licensor Development Breach and whether to transfer the conduct of the Existing Pivotal Trials to Licensee pursuant to a Licensor Development Breach as permitted pursuant to Section 4.3.1;

(d) review and determine whether to approve Licensee's reimbursement of Licensor for amounts incurred in excess of the payment schedule and budget set out in the Development Budget for any of the Additional Compound Development Activities and the Existing Pivotal Trials pursuant to Section 4.2.2;

(e) review and determine whether to approve Licensor bearing Development Costs in excess of those set out in the Development Budget for any of the Additional ImmTOR Development Activities pursuant to Section 4.2.3;

(f) oversee and review the Development of the Products and provide a forum for Licensee to share information on the Development activities for the Products performed by Licensee, its Affiliates or its Sublicensees;

(g) provide a forum for Licensor to share information on the performance of the Licensor Development Activities;

(h) provide a forum to facilitate Licensee sharing information on the overall strategy regarding Regulatory Approval of the Products in the Territory and, more specifically, the supporting, obtaining and maintaining Regulatory Approvals for the Products in the Territory;

(i) provide a forum for Licensee to share information on the Commercialization activities for the Products in the Territory performed by Licensee, its Affiliates or its Sublicensees;

(j) facilitate the Licensed Know-How transfer contemplated under Section 2.4 and any additional transfers by Licensor to Licensee of Licensed Know-How pursuant to Section 2.4;

(k) facilitate the Know-How transfer to the Second Source Supplier contemplated under Section 13.4.6;

(l) review, discuss and determine whether to approve Licensor's right to step-in under Section 9.4.2(c) to bring an action to abate a Competitive Infringement where Licensee has not;

(m) review, discuss and determine whether to approve a Second Source Supplier as contemplated under Section 13.4.1; and

(n) provide a forum for the Parties to share information on patent prosecution matters and other intellectual property matters, and to facilitate coordination between the Parties in accordance with Section 9.

3.1.3 Meetings. Unless otherwise agreed between the Parties, the JSC shall meet in person or via teleconference or video link at least quarterly until all payments under Section 6.2 have been paid and thereafter at least annually, on such dates and at such times and places as agreed to by the JSC representatives. The first JSC meeting shall be held within [***] days of the Effective Date. The JSC shall be disbanded, on Licensee's election, upon a Change of Control of Licensor, provided that, if Licensor is performing Licensor Development Activities at such time, the JSC will be disbanded after the completion of such activities unless Licensee instructs Licensor to terminate such activities early, in which case, Licensor, at Licensee's cost, shall promptly handover responsibility for, sponsorship of (to the extent relevant) and the conduct of the same to Licensee (or its nominated Affiliate or Third Party) in a smooth, efficient and timely manner. Each Party's advisors may be permitted to attend meetings of the JSC as the JSC determines as non-voting representatives of such Party, subject to such advisors agreeing to keep confidential the subject matter of, and any Confidential Information disclosed by the

other Party at, such meeting. Each Party shall be responsible for its own expenses for participating in the JSC. Meetings of the JSC shall be effective only if at least [***] of each Party is present or participating. The JSC chairperson may also call a special meeting of the JSC (in person or via teleconference or video link) if the JSC chairperson reasonably believes that a significant matter must be addressed prior to the next scheduled meeting of the JSC. The JSC chairperson shall be responsible for (a) preparing and circulating an agenda for each meeting, and (b) appointing a secretary for such meeting from one of the attendees of such meeting who shall be responsible for the preparation and circulation of minutes of the meeting within [***] Business Days after each JSC meeting, and endeavoring to finalize such minutes within [***] days after each JSC meeting.

3.2 Decision Making. The JSC shall serve as a decision-making and dispute resolution body solely with respect to the matters set forth in Sections [***], and decisions relating thereto shall be made by consensus. If the JSC cannot reach a consensus decision on any of the foregoing matters, either Party may instruct the JSC to refer such matter to the Executive Officers for resolution. If any such Party does so, then each Party will submit in writing its respective position to each of the Executive Officers. Such Executive Officers will use good faith efforts to resolve such matter within [***] Business days after the JSC's submission of such matter to such Executive Officers, which good faith efforts will include at least one (1) meeting between such Executive Officers. If the Executive Officers are unable to reach unanimous agreement on any such matter within such [***] Business Day period, then:

3.2.1 if the matter relates to [***] then the matter will be decided by Licensee, [***];

3.2.2 if the matter relates solely to [***], then the matter will be decided by Licensor, [***];

3.2.3 if the matter relates to [***], then the matter will be decided by Licensee;

3.2.4 if the matter relates to [***], then the Executive Officers or their designees will submit their respective positions on such matter to be resolved by Expedited Arbitration, provided however that if Licensee agrees to pay the excess costs associated with Licensee's position in relation to such matter, then the matter will be decided by Licensee; and

3.2.5 if the matter relates to [***], then the Executive Officers or their designees will submit their respective positions on such matter to be resolved by Expedited Arbitration.

3.3 Limitations on Decisions. Notwithstanding anything herein to the contrary, without the other Party's prior written consent, no exercise of a Party's decision-making authority on any matters may [***].

3.4 Good Faith. In conducting themselves on the JSC, and in exercising their rights under Section 3.2, all representatives of both Parties will consider diligently, reasonably and in good faith all input received from the other Party, and will use reasonable efforts to reach unanimous agreement on all matters before them.

3.5 General JSC Authority. The JSC has solely the powers expressly assigned to it in this Section 3. The JSC will not have any power to amend, modify, or waive compliance with this Agreement. It is expressly understood and agreed that the control of decision-making authority by Licensor or Licensee, as applicable, pursuant to Section 3.2, so as to resolve a disagreement or deadlock of the JSC for any matter, will not authorize either Party to perform any function or exercise any decision-making right not delegated to the JSC or such Party, and that neither Licensor nor Licensee has any right to unilaterally modify, amend, or waive its own compliance with the terms of this Agreement.

4. DEVELOPMENT

4.1 Overview of Development, Diligence.

4.1.1 Subject to the oversight of the JSC and to Sections 4.2.3 and 4.3, Licensee shall solely control, assume all responsibility for and fund (including all Development Costs) the Development of the Products in the Field for the Territory.

4.1.2 Licensee shall use Commercially Reasonable Efforts to Develop and obtain and maintain Regulatory Approval for a Product for Chronic Refractory Gout in [***]. The Parties acknowledge that Licensee shall not be in breach of its obligations set forth in this Section 4.1.2 or Section 4.1.3 to the extent such breach is due to Licensor and / or its Affiliates' failure to comply with its obligations under this Agreement, including Sections 4.3, 13, 8.2, 8.3 and 8.4.

4.1.3 Licensee (a) shall use Commercially Reasonable Efforts to conduct, or cause to be conducted, the Development of the Products under Section 4.1.2 in compliance with the Development Plan and the Development Budget, and (b) shall conduct, or cause to be conducted, the Development of the Products under Section 4.1.2 in material compliance with all applicable Law, including GCPs and GLPs, and all applicable Data Protection Laws.

4.1.4 Each Party (but for Licensor until completion of the Licensor Development Activities) will report to the JSC in writing, on a quarterly basis, an update regarding the Development activities for the Products in the Field for the Territory conducted, and planned to be conducted during [***], by such Party, its Affiliates or, in the case of Licensee, its Sublicensees. Each such report will contain sufficient detail to enable the other Party to assess the progress of the Development of the Products in the Field for the Territory.

4.2 Development Plan, Development Budget, Reimbursement.

4.2.1 The Parties shall agree in good faith, acting via the JSC (or its delegated subcommittee, if any), on a Development Plan and Development Budget for the Products [***] days following the Effective Date. The Parties, acting via the JSC (or its delegated subcommittee, if any), shall review and, if deemed necessary, shall update the Development Plan and Development Budget, on an annual basis (or more frequently as required by Licensee or reasonably requested by Licensor). Licensee shall design the Development activities set forth in the Development Plan to be in material compliance with all applicable Laws and professional and ethical standards customary in the pharmaceutical industry.

4.2.2 Licensee shall reimburse the Development Costs incurred by Licensor, in accordance with the payment schedule and budget set out in the Development Budget, upon the completion of each of the Existing Pivotal Trials and for performance of any Additional Compound Development Activities and, subject to Section 4.2.3, any Additional ImmTOR Development Activities, provided that Licensee shall have no obligation to reimburse Licensor for amounts incurred in excess of such payment schedule and budget set out in the Development Budget for any of the foregoing studies or activities which have not been approved by Licensee through the JSC.

4.2.3 Licensor shall bear the Development Costs for any portion of any Additional ImmTOR Development Activities [***].

4.2.4 Except as provided by Section 4.2.3, Licensee will bear all Development Costs for the Product.

4.3 Development Activities.

4.3.1 Licensor shall retain responsibility for, sponsor and conduct (or ensure the conduct by its relevant Affiliates or permitted Third Parties) the Existing Pivotal Trials (including any

follow-up treatment of patients therein following the conclusion or termination of such trials), each as included in the Development Plan and in accordance with the Development Plan. In the event of either (a) on Licensee's request upon a Change of Control of Licensor or (b) subject to Section 19.9 and a determination by the JSC, a breach by Licensor of its obligation to diligently perform the Existing Pivotal Trials (a "Licensor Development Breach), Licensor, at Licensee's cost, shall promptly handover responsibility for, sponsorship of and the conduct of the Existing Pivotal Trials to Licensee (or its nominated Affiliate or Third Party) in a smooth, efficient and timely manner, and as directed by the JSC.

4.3.2 Licensor shall perform such additional Development activities in relation to ImmTOR as are reasonably necessary to support Development of Products capable of attaining Regulatory Approval in the Territory and approved by the JSC ("Additional ImmTOR Development Activities"). In addition, Licensor shall perform such additional Development activities in relation to the Compound as are reasonably necessary to support Development of Products capable of attaining Regulatory Approval in the Territory or Exploitation of Products in the Territory, and approved by the JSC ("Additional Compound Development Activities"). Licensee shall have the right to unilaterally terminate the provision of the Additional ImmTOR Development Activities and the Additional Compound Development Activities upon notice to the Licensor via the JSC. Upon receipt of such notice, Licensor, at Licensee's cost, shall promptly handover responsibility for, sponsorship of (to the extent relevant) and the conduct of the same to Licensee (or its nominated Affiliate or Third Party) in a smooth, efficient and timely manner, and as directed by the JSC.

4.3.3 Licensor shall conduct the Licensor Development Activities promptly, using reasonable skill and care and in a professional and diligent manner, at least to the same degree of accuracy, completeness, efficiency, quality, responsiveness and timeliness as Licensor would utilize in performing similar activities for the Development of its own products that are at a similar stage of Development and have similar market potential for Licensor, in accordance with sound and ethical business and scientific practices, and in compliance with the Development Plan, the Development Budget, all applicable Law, including GCPs and GLPs, and all applicable Data Protection Laws.

4.3.4 Licensor shall be permitted to utilize the services of its Affiliates or its material Third Party subcontractors listed on Annex E or other Third Party subcontractors to which Licensee gives its prior written approval (such approval not to be unreasonably withheld, conditioned or delayed) in the performance of the Licensor Development Activities, provided that Licensor shall remain at all times fully liable for the performance of the Licensor Development Activities in compliance with this Agreement. In all cases, the rights granted to any subcontractor shall be subject and subordinate to the applicable terms and conditions of this Agreement. Licensor shall oversee the performance by its subcontractors of the subcontracted Licensor Development Activities in a manner that would be reasonably expected to result in their timely and successful completion of such activities, and Licensor shall remain responsible and primarily and fully liable for the performance of such activities in accordance with this Agreement. Licensor hereby expressly waives any requirement that Licensee exhaust any right, power or remedy, or proceed against such subcontractor for any obligation or performance hereunder, prior to proceeding directly against Licensor. Licensor shall ensure compliance with the applicable terms of this Agreement by any such subcontractor, including with respect to provisions on confidentiality and intellectual property ownership and compliance with legal requirements. Without limiting the foregoing, to the extent that Licensor uses a subcontractor to perform Licensor Development Activities, Licensor shall ensure that such subcontractors are obligated to assign rights to any Inventions made by such subcontractors so that such rights can be conveyed in accordance with the terms and conditions of this Agreement.

4.3.5 Licensor shall not use in any capacity, in connection with its performance of the Licensor Development Activities, any Person who has been debarred pursuant to Section 306 of the FFDCA (or similar applicable Law outside of the U.S.), or who is the subject of a conviction described in such section, and shall inform Licensee in writing promptly if it or any Person who is performing

services for Licensor hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCA (or similar applicable Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to Licensor's knowledge, is threatened, relating to the debarment of Licensor or any Person used in any capacity by Licensor in connection with its performance of the Licensor Development Activities.

4.3.6 Licensor shall maintain (and cause each of its Affiliates and subcontractors to maintain) complete, current and accurate hard and electronic records of all Licensor Development Activities conducted by it and all data and other information resulting from such work (which records shall include, as applicable, books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof (e.g., samples of materials and other graphic or written data generated in connection with the Licensor Development Activities)). Such records shall properly reflect all work done and results achieved in the performance of the Licensor Development Activities in sufficient detail and in good scientific manner appropriate for regulatory and patent purposes. Licensor shall (and shall cause each of its Affiliates and subcontractors to) document all preclinical studies and clinical trials to be conducted in formal written study reports according to applicable national and international (e.g., ICH, GCP and GLP) guidelines. Licensee shall have the right to receive and retain a copy of all such records and to review them in person upon written notice to Licensor, during regular business hours. Licensee shall also have the right to conduct reasonable quality assurance inspections and audits with respect to all facilities, operations and laboratories (and any records related thereto) operated by Licensor, its Affiliates and subcontractors where Licensor Development Activities are conducted, as is reasonably necessary for the purposes of verifying Licensor's compliance with this Agreement and all applicable Law, including GCPs and GLPs, and all applicable Data Protection Laws. All audits initiated by Licensee will be at Licensee's sole expense, upon written notice to Licensor, during regular business hours.

4.3.7 [***], Licensor shall Manufacture, supply (or have Manufactured and supplied) and have delivered the Product for the purposes of conducting the Licensor Development Activities. [***].

4.3.8 Licensee shall not use in any capacity in connection with the Exploitation of the Products, any Person who has been debarred pursuant to Section 306 of the FFDCA (or similar applicable Law outside of the U.S.), or who is the subject of a conviction described in such section. Licensee shall inform Licensor in writing promptly if it or any Person who is performing services for Licensee hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCA (or similar applicable Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to Licensee's knowledge, is threatened, relating to the debarment of Licensee or any Person used in any capacity by Licensee in connection with its Exploitation of the Product.

4.3.9 Licensee shall (and shall cause each of its Affiliates and its Sublicensees engaged in the Development of the Products to) maintain current and accurate records of all Development activities conducted by it and all data and other information resulting from such work (which records shall include, as applicable, books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof (e.g., samples of materials and other graphic or written data generated in connection therewith)). Such records shall properly reflect all work done and results achieved in the performance of such Development activities in sufficient detail and in good scientific manner appropriate for regulatory and patent purposes. Licensee shall, and shall cause each of its Affiliates and its Sublicensees engaged in the Development of the Products to, document all preclinical studies and clinical trials to be conducted in formal written study reports according to applicable national and international (e.g., ICH, GCP and GLP) guidelines.

5. COMMERCIALIZATION

5.1 Diligence.

5.1.1 Licensee shall solely control and assume all responsibility, at its sole cost, for conducting all Commercialization activities within the Territory relating to the Products, including marketing, promotion, sales detailing and any other activities relating to the Commercialization of the Products or Sublicense of Commercialization rights to the Products.

5.1.2 Licensee shall use Commercially Reasonable Efforts to Commercialize a Product for Chronic Refractory Gout in [***].

5.2 Trademark Use. Licensee may, in its sole discretion, package, label, market, promote and sell the Product in the Territory under any Trademark. The fees and expenses incurred in connection therewith will be the sole responsibility of Licensee.

5.3 Commercialization Updates. Licensee will report to the JSC in writing, on an annual basis in the first calendar quarter of each calendar year beginning with the calendar year following the first Regulatory Approval of a Product in the Field in the Territory (for the period ending December 31 of the prior calendar year), summarizing in reasonable detail Licensee's and, if applicable, its Affiliates' and its Sublicensees', Commercialization activities for the Products performed to date (or updating such report for activities performed since the last such report was given hereunder, as applicable) and those planned to be performed during the upcoming calendar year. Each such report will contain sufficient detail to enable Licensor to assess the progress of Commercialization of the Products in the Territory. Licensee will keep the JSC reasonably informed of Licensee's, and, if applicable, its Affiliates' and its Sublicensees', Commercialization activities with respect to the Product in the Territory.

6. PAYMENTS

6.1 Up-Front Payment. In partial consideration of the rights granted hereunder and subject to the terms and conditions stated herein, Licensee shall pay to Licensor a non-refundable and non-creditable up-front payment of seventy-five million U.S. dollars (U.S.$75,000,000) (the "Up-Front Payment") within forty-five (45) days of the Effective Date.

6.2 Development and Regulatory Milestone Payments.

6.2.1 In partial consideration of the rights granted hereunder and subject to the terms and conditions stated herein, Licensee shall make the following non-refundable and non-creditable payments (each, a "Development Milestone Payment") to Licensor upon the first occurrence of the corresponding milestone events specified below by Licensee or any of its Affiliates or Sublicensees (each a "Development Milestone Event"):

	Development Milestone Event	**Development Milestone Payment:**
1.	[***]	[***] U.S. dollars (U.S.$[***])
2.	[***]	[***] U.S. Dollars (U.S.$[***])
3.	[***]	[***] U.S. dollars (U.S.$[***])
4.	[***]	[***] U.S. Dollars (U.S.$[***)
5.	[***]	[***] U.S. Dollars (U.S.$[***])
6.	[***]	[***] U.S. Dollars (U.S.$[***])

6.2.2 Such Development Milestone Payments shall be paid only once on the first occurrence of such Development Milestone Event by Licensee or any of its Affiliates or Sublicensees, notwithstanding the potential Development of multiple Products hereunder which may involve separate clinical trials or Regulatory Approvals and regardless of how many times such Development Milestone Event is achieved and/or the number of Products that achieve such Development Milestone Event; provided, however, that if such first Product fails to achieve all Development Milestone Events, Licensee will owe Licensor the Development Milestone Payments corresponding to the achievement by the next most advanced Product of all Development Milestone Events not previously achieved by such first Product, and so forth with each next most advanced Product until all Development Milestone Payments corresponding to achieved Development Milestone Events have been paid to Licensor.

6.2.3 Licensee shall promptly, and in any event within [***] Business Days, notify Licensor following the first occurrence of a Development Milestone Event. Following receipt of such notice, Licensor shall issue an invoice for the corresponding Development Milestone Payment which shall be paid by Licensee, or its designated Affiliate, to Licensor within [***] days after receipt of an invoice from Licensor.

6.3 Sales Milestone Payments.

6.3.1 In partial consideration of the rights granted hereunder and subject to the terms and conditions stated herein, Licensee shall make the following non-refundable and non-creditable payments to Licensor (each, a "Sales Milestone Payment") when Annual Net Sales by Licensor, its Affiliates or its Sublicensees of all Products across all Indications in the Territory first reach the threshold values indicated below during the Term (each a "Sales Milestone Event"):

Sales Milestone Event	**Milestone Payment**
Annual Net Sales of all Products in the Territory first exceeds [***] US Dollars (U.S.$[***])	[***] US Dollars (U.S.$[***])
Annual Net Sales of all Products in the Territory first exceeds [***] US Dollars (U.S.$[***])	[***] US Dollars (U.S.$[***])
Annual Net Sales of all Products in the Territory first exceeds [***] US Dollars (U.S.$[***])	[***] US Dollars (U.S.$[***])
Annual Net Sales of all Products in the Territory first exceeds [***] US Dollars (U.S.$[***])	[***] US Dollars (U.S.$[***])
Annual Net Sales of all Products in the Territory first exceeds [***] US Dollars (U.S.$[***])	[***] US Dollars (U.S.$[***])
Annual Net Sales of all Products in the Territory first exceeds [***] US Dollars (U.S.$[***])	[***] US Dollars (U.S.$[***])
Annual Net Sales of all Products in the Territory first exceeds [***] US Dollars (U.S.$[***])	[***] US Dollars (U.S.$[***])

6.3.2 Such Sales Milestone Payments shall be paid by Licensee, or its designated Affiliate, to Licensor within [***] days after receipt of an invoice from Licensor, such invoice to be issued concurrently with the invoice issued under Section 6.6.1 for the relevant Royalty Reporting Quarter in which the first occurrence of the Sales Milestone Event set forth above takes place. Such Sales Milestone Payments shall be paid only once, regardless of how many times such Sales Milestone Event is achieved and/or the number of Products that achieve such Sales Milestone Event; provided, however, that if multiple Sales Milestone Events are achieved in a single calendar year, all corresponding Sales Milestone Payments will be made in such calendar year (e.g., Annual Net Sales of Products of U.S.$[***] in a calendar year would result in payment of a U.S.$[***] Sales Milestone Payment (U.S.$[***] plus U.S.$[***] plus U.S.$[***])).

6.3.3 Annual Net Sales in a given country shall not be considered for the purposes of the calculation of the Sales Milestone Events in this Section 6.3 following expiration of the Royalty Term in a such country.

6.4 Royalty.

6.4.1 In partial consideration of the rights granted hereunder and subject to the terms and conditions stated herein, during the Royalty Term, Licensee shall pay to Licensor a royalty ("Royalty") on worldwide aggregate Annual Net Sales of Products in the Territory by Licensee, its Affiliates and its Sublicensees in a given calendar year at the royalty rate calculated in accordance with the following table, subject to reduction as set forth in Section 6.5 below:

(a) [***] percent ([***]%) on the first [***] U.S. dollars (U.S.$[***]) in Annual Net Sales within the Territory;

(b) [***] percent ([***]%) on Annual Net Sales greater than [***] U.S. dollars (U.S.$[***]) up to and including [***] U.S. dollars (U.S.$[***]) in Annual Net Sales within the Territory;

(c) [***] percent ([***]%) on Annual Net Sales greater than [***] U.S. dollars (U.S.$[***]) up to and including [***] U.S. dollars (U.S.$[***]) within the Territory; and

(d) [***] percent ([***]%) on Annual Net Sales in excess of [***] U.S. dollars (U.S.$[***]) within the Territory.

6.4.2 No multiple royalties will be payable under this Section 6.4 regardless of the number of Valid Claims in any Licensed Patent covering a Product.

6.4.3 Licensee's obligation to pay royalties pursuant to this Section 6.4 for a Product in any given country shall expire on the expiration of the Royalty Term for such Product in such country.

6.5 Royalty Reductions.

6.5.1 Subject to Section 6.5.4, if during the Royalty Term, on a country-by-country and Product-by-Product basis, such Product ceases to be covered by a Valid Claim of a Licensed Patent in such country of sale, [***] then the Royalties payable under Section 6.4 shall be reduced by [***] percent ([***]%) for such Product in such country from the first calendar quarter in which this Section 6.5.1 applies through the remainder of such Royalty Term.

6.5.2 Subject to Section 6.5.4, in the event that during the Royalty Term, on a country-by-country and Product-by-Product basis:

(a) there occurs a Loss of Market Exclusivity with respect to such Product in such country, then from the first calendar quarter this Section 6.5.2(a) applies, the Royalties payable under Section 6.4 for such Product in such country shall be reduced by [***] percent ([***]%) [***]; or

(b) [***].

6.5.3 Subject to Section 6.5.4, if during the Royalty Term, Licensee or any of its Affiliate pays Third Party Payments with respect to a Product, Licensee may credit [***] percent ([***]%) of such Third Party Payments paid in a given calendar quarter against the Royalties otherwise due to Licensor on the Annual Net Sales of such Product in such calendar quarter under Section 6.4, provided, however that the Royalties paid to Licensor on Annual Net Sales of such Product in such calendar quarter after application of such credit shall not be less than [***] percent ([***]%) of those otherwise due under Section 6.4 without such credit. [***].

6.5.4 In no event will the Royalties otherwise due to Licensor on the Annual Net Sales of any Product in any calendar quarter under Section 6.4 be reduced in any such calendar quarter by more than [***] percent ([***]%) of the amount that otherwise would have been due and payable to Licensor in such calendar quarter but for the reductions set forth in Sections 6.5.1, 6.5.2(a), 6.5.2(b) and 6.5.3 (the "Minimum Floor**"**).

6.6 Payment and Reports.

6.6.1 Within (a) [***] days after the end of each of the first three calendar quarters of each year during the Royalty Term, or (b) the later of (i) [***] days after the end of the final quarter of each calendar year during the Royalty Term and (ii) the date of [***], but, in no event for this clause (b), later than [***] days after the end of the final quarter of each calendar year during the Royalty Term (each such quarter in (a) and (b), a "Royalty Reporting Quarter"), Licensee shall provide Licensor with a written

report setting forth (A) the number of units of each Product sold by Licensee, its Affiliates or its Sublicensees on which Royalties are owed to Licensor, (B) the gross amount received for such sales in clause (A), (C) the Annual Net Sales during such Royalty Reporting Quarter, including any deductions taken as permitted under such definition, (D) the amount of any credits or reductions, if any, taken or made pursuant to Section 6.5, (E) the calculation of the Royalty payable to Licensor for such Annual Net Sales pursuant to Section 6.4, and (F) the computations for any applicable currency conversions pursuant to Section 6.6.3. Upon receipt of such report, Licensor shall promptly issue an invoice for an amount equal to the total Royalty due, if any, to Licensor pursuant to this Section 6. All payments shall be made to Licensor within [***] days of receipt of Licensor's invoice, in United States Dollars.

6.6.2 All payments to be made between the Parties under this Agreement will be made in United States dollars. Each payment to be made to Licensor under this Agreement will be made by bank wire transfer in immediately available funds to such bank account as may be designated in writing by Licensor from time to time.

6.6.3 Sales made in currencies other than United States Dollars shall be converted to United States Dollars using the exchange rates published by Swedish Central Bank, on the last day of the calendar quarter in which the applicable sales were made.

6.6.4 In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for Licensee to transfer, or have transferred on its behalf, payments owed Licensor hereunder, then Licensee will promptly notify Licensor of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Licensor in a recognized banking institution designated by Licensor or, if none is designated by Licensor within a period of [***] days, in a recognized banking institution selected by Licensee and identified in a written notice given to Licensor.

6.6.5 In addition, Licensee shall within [***] days after the end of each calendar year during the Term provide Licensor, at least annually during the Royalty Term, with reports of the Annual Net Sales by Licensee, its Affiliates and its Sublicensees during the prior calendar year.

6.7 Other Amounts Payable. Within (a) [***] days after the end of each of the first three calendar quarters of each year during the Term, or (b) the later of (i) [***] days after the end of the final quarter of each calendar year during the Term and (ii) the date of [***], but, in no event for this clause (b), later than [***] days after the end of the final quarter of each calendar year during the Term, each Party will invoice the other Party for any amounts owed by the other Party under this Agreement that are not otherwise accounted for in this Section 6, including payments by Licensee to Licensor under the Development Plan and Development Budget in accordance with Section 4.2.2, and payments made on account of costs, expenses, damages or recoveries pursuant to Sections 9.3, 9.4, and 9.5. The owing Party will pay any undisputed amounts within [***] days of receipt of the invoice, and any disputed amounts owed by a Party will be paid within [***] days of resolution of the dispute pursuant to Section 17.2.1.

7. RECORD KEEPING, AUDIT RIGHTS

7.1 Record Keeping. Each Party shall (and shall ensure that its Affiliates and its Sublicensees) keep, complete, true and accurate books of accounts of record to permit verification of payments made hereunder. Such records shall be maintained for the period equal to the later of (i) [***] years from the date on which they were generated, or (ii) as required by applicable Law.

7.2 Audit Rights. Each Party (the "auditing Party") shall have the right to have an independent third party nationally-recognized accounting firm (the "Auditor") reasonably acceptable to the other Party (the "audited Party") access the books and records of the audited Party and its Affiliates solely to the extent necessary to verify the accuracy of the reports and payments made hereunder, provided that, where

Licensor is the auditing Party, it shall have the right to require Licensee to permit Licensor's auditor to accompany Licensee when Licensee exercises its audit rights (or, if Licensee does not intend to exercise its right to audit such Sublicensee within the relevant calendar year, to require Licensee to exercise such right) under any Sublicenses that have been granted as of the date of such audit to permit the Auditor to have access to the books and records of the corresponding Sublicensees. Such audit shall be conducted upon at least [***] days advanced written notice to the audited Party and shall commence on a date reasonably acceptable to both Parties, not to be later than [***] calendar days after the auditing Party's notice. Such audit shall only be during the audited Party's normal business hours. [***]. The Auditor shall be required to sign a confidentiality agreement for the benefit of, and in a form reasonably acceptable to, the audited Party. The audited Party shall be provided the opportunity to discuss any discrepancies found during such audit with the Auditor prior to such Auditor issuing its final report. In addition, the Auditor shall redact any Confidential Information disclosed in the proposed final report reasonably identified by the audited Party as confidential and not necessary for purposes of calculating the Royalty or the milestones owed. The final report shall be shared with both of the Parties. If any audit discloses any underpayments by the audited Party to the auditing Party, then unless contested by the audited Party, such underpayment, shall be paid by the audited Party to the auditing Party within [***] calendar days of it being so disclosed. If any audit discloses any overpayments by the audited Party to the auditing Party, then unless contested by the auditing Party, the audited Party shall have the right to credit the amount of the overpayment against each subsequent quarterly Royalty payment due to the auditing Party until the overpayment has been fully applied. If the overpayment is not fully applied prior to the final quarterly payment of Royalties due hereunder, the auditing Party shall promptly refund an amount equal to any such remaining overpayment. If the auditing Party's audit demonstrates an underpayment of more than [***] percent ([***]%) of the total payments due to the auditing Party hereunder during the audited period, the audited Party shall be liable for the auditing Party's reasonable out of pocket expenses, including the Auditor's fees and expenses, in connection with the audit that discovered such underpayment. Otherwise, the auditing Party shall solely bear the costs of such audits. Any contested amounts shall be subject to the dispute resolution procedures set forth in Section 17.2.1.

7.3 Taxes.

7.3.1 Where required to do so by applicable Law or order of a Governmental Authority, Licensee shall be permitted to withhold Taxes required to be paid to a taxing authority in connection with any and all payments to Licensor hereunder ("Withholding Taxes"), and, upon request of Licensor, Licensee shall furnish Licensor with satisfactory evidence of such withholding and payment. To the extent permitted by Law, Licensor shall provide Licensee any Tax forms requested by Licensee that may be reasonably necessary in order for Licensee to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty. Licensor shall use reasonable efforts to provide any such Tax forms to Licensee in advance of the due date. The Parties acknowledge and agree that no Withholding Taxes are expected to be deducted or withheld from payments under this Agreement.

7.3.2 Notwithstanding anything to the contrary in this Agreement, in the event a Party (i) undertakes a "redomiciliation" (as defined below), (ii) assigns, delegates or otherwise transfers this Agreement or all or any portion of its rights and obligations hereunder (including for sake of clarification the assignment or delegation of any payment obligations under this Agreement) to another Person, including pursuant to Section 19.5, other than at the request of the other Party or (iii) adopts a Tax reporting position that Swedish Withholding Taxes are applicable to payments made to Licensor under this Agreement (other than as a result of a change in Law after the date of this Agreement) (each, a "Tax Action" and such Party, the "Acting Party"), and as a result of such Tax Action the amount of Withholding Taxes required to be withheld under this Section 7.3 in respect of a payment to the other Party (the "Non-Acting Party") is greater than the amount of such Withholding Taxes that would have been required to have been withheld absent such Tax Action, then any such amount payable to the Non-Acting Party shall be adjusted to take into account such Withholding Taxes as may be necessary so that, after making all required withholdings, the Non-Acting Party receives an amount equal to the sum it would have received

had no such increased withholding been made. The obligation to adjust payments pursuant to the preceding sentence shall not apply, however, to the extent such increased Withholding Tax (a) would not have been imposed but for a Tax Action taken by the Non-Acting Party pursuant to the preceding sentence or (b) is attributable to a the failure of the Non-Acting Party to comply with the requirements of this Section 7.3. To the extent the Non-Acting Party receives additional amounts under this Section 7.3.2 and the Non-Acting Party (or its Affiliates), taken as a whole, actually realizes an overall reduction in cash Taxes otherwise due in any taxable period ending before the termination of this Agreement (determined on a with and without basis and taking into account the overall Tax liability of the Non-Acting Party (and its Affiliates)) as a result of a foreign Tax credit or a Tax refund attributable to such Withholding Taxes in respect of which the Non-Acting Party received additional amounts pursuant to this Section 7.3.2 (such reduction, a "Tax Benefit"), the Non-Acting Party shall pay to the Acting Party an amount equal to such Tax Benefit, net of all reasonable out-of-pocket expenses incurred by the Non-Acting Party in connection with the obtaining or receipt of such Tax Benefit. For purposes of this Section 7.3, a "redomiciliation" shall include a reincorporation or other action resulting in a change in Tax residence of the applicable Party, its assignee or any Person making a payment on behalf of such Party, or the formation of a branch of any such Party or Person in a jurisdiction other than Sweden, in the case of Licensee, or the United States, in the case of Licensor, but only to the extent that a payment under this Agreement is made by such branch.

7.4 Late Payments. Any milestone payments or Royalties due to Licensor under this Agreement or any portion thereof which are not paid when due, shall bear interest at a per-annum rate of prime (as reported in *The Wall Street Journal* (U.S., Eastern Edition)) plus [***] percentage points ([***]%) or the maximum rate allowable by applicable Law, whichever is less.

8. REGULATORY

8.1 Regulatory Matters.

8.1.1 Licensee shall solely control and assume all responsibility, [***], for submitting all Regulatory Filings for the Products in the Territory (including pricing and reimbursement approvals) and obtaining and maintaining all Regulatory Approvals and for all interactions with Regulatory Authorities for the Products in the Territory, including any and all INDs, BLAs and MAAs, provided however that Licensor shall continue to control, hold in its name and remain responsible for the IND for SEL-212 (including any updates thereto) which is required to be submitted and held by Licensor in connection with the performance of its obligations under Section 4.3.1 [***] prior to transfer of the same under Section 8.2.

8.1.2 Subject to Section 8.1.1, during the Term, all Regulatory Filings relating to the Products shall be submitted and all Regulatory Approvals shall be held solely in the name of Licensee, its Affiliates or its Sublicensees.

8.1.3 Licensor shall have [***] Business Days (or, in the event the relevant Regulatory Authority requires an urgent response, such time period as is reasonable in the circumstances) to review and comment on Regulatory Filings for the Products to the extent pertaining to ImmTOR prior to the filing thereof with a Regulatory Authority and Licensee shall reasonably consider all such comments; provided, however, that, with respect to such timely comments provided by Licensor regarding any statement Licensee proposes to make that specifically concern ImmTOR, Licensee will consider in good faith such Licensor comments, provided, that notwithstanding the foregoing, if the intended statement is consistent with a previous statement made publicly by Licensor regarding ImmTOR in its Regulatory Filings, Licensee shall be permitted to make such statement regardless of Licensor's comments.

8.1.4 Licensee shall exclusively own:

(a) subject to Section 8.1.1, all Regulatory Filings for the Products;

(b) all information and data (including clinical and non-clinical data) generated by or on behalf of Licensee in connection with the Products, including clinical data generated in connection with the Existing Pivotal Trials;

(c) subject to Section 8.1.1, any and all (pre-) INDs, BLAs, MAAs, and other similar Regulatory Approvals filed or awarded in any jurisdiction in the Territory related to the Products; and

(d) all Confidential Information of Licensee.

8.2 Regulatory Transfer.

8.2.1 [***], Licensor shall, as promptly as reasonably practicable, but in no event later than [***] days following the Effective Date, transfer to Licensee (a) all Regulatory Filings and Regulatory Approvals related to SEL-212 (other than the IND for SEL-212 which is required to be held by Licensor in connection with the performance of its obligations under Sections 4.3.1 and 4.3.2), (b) all other Regulatory Materials, including copies of all written communications with the FDA and other Regulatory Authorities in the Territory (including for clarity, all eCTD sequences and source documents referenced therein), and (c) the minutes of any meetings with the FDA and any such other Regulatory Authority, in each case of (a), (b) and (c), relating to the Compound and /or SEL-212 and including all ownership and rights thereto and including all eCTD sequences and source documents referenced therein.

8.2.2 [***], Licensor shall, as promptly as reasonably practicable after the date of completion of treatment and follow up (day [***] of the final treatment period) for the last patient enrolled in the last of the Existing Pivotal Trials (unless the Parties agree via the JSC that Licensor should continue to hold the IND in connection with any ongoing Additional Compound Development Activities or Additional ImmTOR Development Activities, in which case the Parties will agree via the JSC an appropriate transfer date), but in no event later than [***] days following such completion, transfer to Licensee the IND for SEL-212 (including all ownership and rights thereto) which was required to be held by Licensor in connection with the performance of its obligations under Sections 4.3.1 and 4.3.2, unless Licensee otherwise requests its earlier transfer, in which case, the transfer shall be made as promptly as reasonably practicable, but in no event later than [***] days following Licensee's request therefor, and in such case Licensor's obligations under Sections 4.3.1 and 4.3.2 to perform the Licensor Development Activities for which such IND for SEL-212 is required to be held by Licensor will terminate as of the effective date of such transfer.

8.2.3 In support of the transfers contemplated by Sections 8.2.1 and 8.2.2 and without affecting the cost allocation specified thereunder for such transfers, Licensor, [***], shall execute all additional documents and take all additional actions, including any additional filings with the relevant Regulatory Authorities, as are necessary or otherwise reasonably requested by Licensee to vest all ownership and rights to such Regulatory Filings and Regulatory Approvals with Licensee and to reflect Licensee as the holder of all such Regulatory Filings and Regulatory Approvals.

8.3 Regulatory Support.

8.3.1 Licensor shall provide all reasonable assistance and support to Licensee, on Licensee's reasonable request, to enable Licensee, its Affiliates and/or Sublicensees to prepare and submit Regulatory Filings for the Products in the Territory, which services will be provided at the FTE Rate and subject to a mutually agreed budget. Within [***] days of the end of every [***] month period following the Effective Date, Licensor shall issue invoices, along with supporting documentation, of all costs

incurred in providing the agreed assistance and support in accordance with this Section 8.3 in such [***] month period. Licensee shall, within [***] days of receipt of an invoice and supporting documentation from Licensor, reimburse Licensor the FTE Cost for all agreed assistance and support provided in accordance with this Section 8.3.

8.4 Licensee Access. Without limiting its obligations under this Agreement, as promptly as reasonably practicable, but in no event later than [***] days following the Effective Date or at Licensee's request, Licensor shall (and shall ensure that its Affiliates and (sub)licensees):

(a) give Licensee the right to use and reference all Development work product, Regulatory Materials, Regulatory Filings and Regulatory Approvals (including all data and information referenced therein) to the extent: (i) Controlled by Licensor or its Affiliates or its (sub)licensees during the Term; and (ii) related to the Compound; and

(b) provide the FDA or any other Regulatory Authority in the Territory with information necessary for purposes of assisting Licensee with obtaining Regulatory Approvals for the Products in the Territory through a right to reference, all Development work product, Regulatory Materials, Regulatory Filings and Regulatory Approvals (including all data and information referenced therein) related to ImmTOR to the extent: (i) Controlled by Licensor, its Affiliates or (sub)licensees as of the Effective Date or during the Term, and (ii) related to the Product or reasonably necessary or reasonably useful to Licensee's exercise of the License,

in each case, for use solely by and for the benefit of Licensee and its Affiliates and Sublicensees in connection with the Exploitation of the Products, at no cost to Licensee and provided that Licensor may redact any information or data not related to the Product. Notwithstanding the foregoing, neither Licensee nor any of its Affiliates shall give access or other rights with respect to such Development work product, Regulatory Materials, Regulatory Filings and Regulatory Approvals (including all data and information referenced therein) to any of their Sublicensees, unless Licensee's Sublicense with such Sublicensee permits Licensee the right to provide equivalent rights to Licensor to those set out in Section 8.5 in respect of such Sublicensee's Development work product, Regulatory Materials, Regulatory Filings and Regulatory Approvals (including all data and information referenced therein).

8.5 Licensor Access. Licensee shall (and shall ensure that its Affiliates and Sublicensees), at no cost to Licensor, give Licensor the right to use and reference all Development work product, Regulatory Materials, Regulatory Filings and Regulatory Approvals (including all data and information referenced therein) to the extent:

8.5.1 Controlled by Licensee or its Affiliates or its Sublicensees during the Term; and

8.5.2 related to ImmTOR (but not the Compound and/or the Products),

in each case for use solely by and for the benefit of Licensor and its Affiliates and (sub)licensees in connection with their Exploitation of ImmTOR, whether alone or in combination (but not in combination with the Compound and/or in the form of the Products), and provided that Licensee may redact any information or data not related to ImmTOR. Notwithstanding the foregoing, neither Licensor nor any of its Affiliates shall give access or other rights with respect to such Development work product, Regulatory Materials, Regulatory Filings and Regulatory Approvals (including all data and information referenced therein) to any of their (sub)licensees, unless Licensor's license agreement with such (sub)licensee permits Licensor the right to provide equivalent rights to Licensee to those set out in Section 8.4 in respect of such (sub)licensee's Development work product, Regulatory Materials, Regulatory Filings and Regulatory Approvals (including all data and information referenced therein).

8.6 Adverse Event Reporting, Safety Agreement. To the extent permitted by and in compliance with applicable Data Protection Laws, Licensor shall notify Licensee of all information coming into its possession concerning any Adverse Event relating to the Compound, ImmTOR or the Product, and, to the extent permitted by and in compliance with applicable Data Protection Laws, Licensee shall notify Licensor of all information coming into its possession concerning any Adverse Event related to ImmTOR or the Product (to the extent relevant to ImmTOR). Without prejudice to the foregoing, the Parties will use good faith efforts to negotiate and enter into the Safety Agreement on or before the date that is [***] days after the Effective Date or such longer period as may be mutually agreed by the Parties. The Parties acknowledge and agree that the Safety Agreement will govern all technical safety matters relating to the Compound, ImmTOR and/or the Products arising as a result of entry into and implementation of this Agreement as more particularly set out therein. If there is a conflict between this Agreement and the Safety Agreement, the Safety Agreement shall govern in relation to technical safety issues only. Each Party shall comply with its respective agreements, covenants and other obligations set forth in the Safety Agreement.

8.7 Regulatory Action Letters. Without limiting Section 8.4, Licensor shall promptly, but in no event later than [***] Business Days, notify Licensee in writing of the receipt of any action letters from any Regulatory Authority in connection with safety or quality issues concerning the Compound, ImmTOR and / or the Product, enclosing a copy thereof. Without limiting Section 8.5, Licensee shall promptly, but in no event later than [***] Business Days, notify Licensor in writing of the receipt of any action letters from any Regulatory Authority in connection with safety or quality issues concerning ImmTOR and/or the Product (to the extent relevant to ImmTOR) enclosing a copy thereof.

8.8 Regulatory Meetings. Licensor shall have the right to receive advance notice, but in no event less than [***] calendar days advance notice, of meetings and calls with Regulatory Authorities related to ImmTOR, unless such meeting or call is scheduled by the Regulatory Authority on less than [***] days' notice, in which case Licensee shall notify Licensor as soon as reasonably practicable. Licensee shall use Commercially Reasonable Efforts to obtain the right for Licensor to participate in such meetings and calls.

8.9 Global Safety Database. Licensee shall control, and be responsible for maintaining, the global safety database for the Product from the date that is [***] months following the date on which the IND for SEL-212 is transferred to Licensee in accordance with Section 8.2.2 and Licensor shall control and be responsible for the maintenance of the global safety database until such date.

9. INTELLECTUAL PROPERTY RIGHTS

9.1 Inventorship.

9.1.1 Inventorship for all inventions first conceived under this Agreement shall be determined in accordance with the rules of inventorship under United States patent laws.

9.1.2 Notwithstanding anything in this Agreement to the contrary, each Party will have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2) (c)(3) (the "CREATE Act") when exercising its rights under this Agreement, but only with the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. In the event that a Party intends to invoke the CREATE Act, it will notify the other Party and, if invoking the CREATE Act is agreed to by the other Party, the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

9.2 Ownership.

9.2.1 As between the Parties, Licensee shall solely and exclusively own all right, title and interest in and to [***]. Notwithstanding the foregoing, in the event that, nonetheless, Licensor, is Affiliates or its (sub)licensees, pursuant to the exercise of its rights and performance of its obligations hereunder, holds any right, title, or interest in and to any [***], then Licensor, on behalf itself and its Affiliates and its (sub)licensees, hereby does, and agrees to, assign any and all such right, title and interest to any such [***] to Licensee together with the right to file and own applications for any Patent and any Patent issuing thereon.

9.2.2 As between the Parties, Licensor shall solely and exclusively own all right, title and interest in and to [***]. Notwithstanding the foregoing, in the event that, nonetheless, Licensee, its Affiliates or its Sublicensees, pursuant to the exercise of its rights and performance of its obligations hereunder, holds any right, title, or interest in any [***], then Licensee, on behalf of itself and its Affiliates and its Sublicensees, hereby does, and agrees to, assign any and all such right, title and interest to any such [***] to Licensor together with the right to file and own applications for any Patent and any Patent issuing thereon.

9.2.3 [***] or (c) jointly owned by both Parties if first invented jointly by the Parties or their Affiliates jointly (the "Other Joint New IP"). [***]. Except to the extent restricted by the licenses and other rights granted to other Party under this Agreement, each Party, as joint owners, shall be entitled to practice, license, assign, and otherwise exploit its undivided interest in the Other Joint New IP without the duty of accounting or seeking consent from the other Party, provided, however, that the foregoing shall not be construed as granting or conveying to either Party any license or other rights to the other Party's other intellectual property rights, unless otherwise expressly set forth in this Agreement. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Other Joint New IP.

9.2.4 Licensor will promptly disclose to Licensee all [***], but in no event later than [***] days after Licensor's intellectual property department receives notice of such invention. Licensee will promptly disclose to Licensor all [***], but in no event later than [***] days after Licensee's intellectual property department receives notice of such invention. Licensee will promptly disclose to Licensor all patent applications it proposes to make in respect of [***], but in no event later than [***] days after Licensee's intellectual property department makes such determination.

9.2.5 Each Party shall provide the other Party ([***]) with all further reasonable cooperation to give effect to the allocation of ownership, as between the Parties, of [***] and Other Joint New IP (including with respect to rights of priority), in each case as contemplated by this Section 9.2, including executing and delivering further assignments, consents, releases and other commercially reasonable documentation, and providing good faith testimony by affidavit, declaration, deposition, in person or other proper means and otherwise assisting the other Party in support of its efforts to establish, perfect, defend, or enforce its rights in its respective intellectual property.

9.3 Patent Prosecution and Maintenance.

9.3.1 Licensee.

(a) As between the Parties, Licensee shall have the primary right and obligation, [***], using patent counsel of Licensee's choice reasonably acceptable to Licensor (unless the Parties mutually agree to continue using Licensor's existing patent prosecution counsel as of the Effective Date [***]), to conduct and control prosecution, maintenance, extension, applications for supplementary protection certificates related thereto, including any related interference, re-issuance, re-examination and opposition proceedings with respect thereto (collectively, "Prosecution" or "Prosecute") with respect to [***].

(b) As between the Parties, Licensee shall have the sole right, at [***], to conduct and control Prosecution of [***].

(c) Promptly after the Effective Date, and unless the Parties mutually agree to continue using Licensor's existing patent prosecution counsel as of the Effective Date, [***].

(d) Licensee shall keep Licensor reasonably informed of Licensee's intellectual property and Prosecution strategy with respect to [***], including furnishing to Licensor, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and documents received from patent counsel in the course of Prosecuting [***], and copies of documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such [***], and such other material documents related to the Prosecution of such [***] in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by Licensor. Licensee shall consider in good faith the reasonable requests and suggestions of Licensor with respect to the Prosecution of, and Licensee's intellectual property strategy for, [***] received no later than [***] Business Days prior to any filing deadline; provided, however, that, with respect to such timely comments provided by Licensor regarding any statement Licensee proposes to make in connection with the Prosecution of [***], Licensor will have final say and Licensee will implement such Licensor comments, provided, that notwithstanding the foregoing, if the intended statement is consistent with a previous statement made publicly in Prosecution by Licensor regarding ImmTOR, Licensee shall be permitted to make such statement regardless of Licensor's comments.

(e) Licensee shall notify Licensor of any decision to cease Prosecution of [***] in any country in the Territory. Licensee shall provide such notice in writing at least [***] days prior to any filing or payment due date, or any other due date that requires action, in connection with such [***]. In such event, upon Licensor's request, Licensee shall transfer the Prosecution of such [***] in such country to Licensor (or Licensor's licensor, as applicable), and thereafter Licensor (or Licensor's licensor, as applicable) shall have the right to continue Prosecution of such [***], as applicable, in such country [***].

(f) Licensor shall promptly (and in any event within [***] Business Days) provide Licensee with copies of correspondence or materials received from any Governmental Authority in the Territory to the extent they relate to [***].

(g) Licensee shall have lead responsibility regarding strategy for making all filings with Regulatory Authorities in the Territory with respect to [***], including as required or allowed (i) in the United States, in the FDA's Orange Book or Purple Book, and (ii) in the European Union, under the national implementations of Section 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents, provided Licensee shall consult with Licensor regarding [***].

9.3.2 Licensor.

(a) As between the Parties, Licensor shall have the primary right and obligation, [***], to conduct and control Prosecution of the Selecta-Controlled Patents, [***].

(b) Licensor shall keep Licensee reasonably informed of Licensor's intellectual property and prosecution strategy with respect to the Selecta-Controlled Patents, [***], including furnishing to Licensee, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and documents received from patent counsel in the course of Prosecuting the Selecta-Controlled Patents, [***], and copies of documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such Selecta-Controlled Patents, [***], and such other material documents related to the Prosecution of such Selecta-Controlled Patents, [***], in sufficient time prior to filing such document or making any payment due thereunder to allow

for review and comment by Licensee. Licensor shall consider in good faith the reasonable requests and suggestions of Licensee with respect to the Prosecution of, and Licensee's intellectual property strategy for, the Selecta-Controlled Patents, [***].

(c) Licensor shall notify Licensee of any decision to cease Prosecution of the Selecta-Controlled Patents, [***] in any country in the Territory. Licensor shall provide such notice in writing at least [***] days prior to any filing or payment due date, or any other due date that requires action, in connection with such Selecta-Controlled Patents, [***]. In such event, upon Licensee's request, Licensor shall transfer the Prosecution of such Selecta-Controlled Patents, [***] in such country to Licensee, and thereafter Licensee shall have the right to continue Prosecution of such Selecta-Controlled Patents, [***] in such country [***].

(d) Licensee shall promptly (and in any event within [***] Business Days) provide Licensor with copies of correspondence or materials received from any Governmental Authority in the Territory to the extent they relate to the Selecta-Controlled Patents [***].

(e) As between the Parties, Licensor shall have the right in its good faith determination to make all filings with Regulatory Authorities in the Territory with respect to the Selecta-Controlled Patents, [***] pertaining to any pharmaceutical products, including as required or allowed (i) in the United States, in the FDA's Orange Book or Purple Book and (ii) in the European Union, under the national implementations of Section 10.1.2(a)(iii) of Directive 2001/EC/83 or other international equivalents, provided Licensor shall consult with Licensee regarding such Selecta-Controlled Patents, [***].

9.3.3 Parties Jointly.

(a) Licensee and Licensor shall jointly decide the intellectual property and prosecution strategy for the Other Joint New IP Patents, and Licensee shall be responsible for the implementation of such strategy for the Prosecution of such Other Joint New IP Patents, using patent counsel of Licensee's choice reasonably acceptable to Licensor. [***].

(b) Licensee shall furnish to Licensor, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and documents received from patent counsel in the course of Prosecuting the Other Joint New IP Patents, and copies of documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such Other Joint New IP Patents, and such other material documents related to the Prosecution of such Other Joint New IP Patents, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by Licensor. Licensee shall implement Licensor's reasonable requests and suggestions with respect to the Prosecution of the Other Joint New IP Patents.

(c) In the event [***] with the Prosecution of any of the Other Joint New IP Patents in any country in the Territory (the "Relinquishing Party"), the Relinquishing Part shall provide such notice in writing to the other Party (i) at least [***] days prior to any filing or payment due date, or any other due date that requires action, in connection with such Other Joint New IP Patent, where Licensee is the Relinquishing Party, or (ii) promptly, where Licensor is the Relinquishing Party. In such event, (A) where Licensee is the Relinquishing Party, Licensee shall transfer the Prosecution of such Other Joint New IP Patent, and thereafter Licensor shall have the right to continue the Prosecution of such Other Joint New IP Patent in such country [***], and (B) where Licensor is the Relinquishing Party, Licensee shall assume sole control of the Prosecution of such Other Joint New IP Patent in such country [***], and Licensor shall no longer have review and comment rights as to the Prosecution of such Other Joint New IP Patent pursuant to Section 9.3.3(b).

(d) Each Party shall promptly (and in any event within [***] Business Days) provide to the other copies of correspondence or materials received from any Governmental Authority in the Territory to the extent they relate to the Other Joint New IP Patents.

9.3.4 Support, Reimbursement.

(a) The non-prosecuting Party shall, and shall cause its Affiliates or, in the case of Licensee, its Sublicensees, including its, its Affiliate's and its Sublicensees' employees, contractors, and/or agents, to, assist and cooperate with the prosecuting Party, as the prosecuting Party may reasonably request from time to time, in the preparation, filing and Prosecution of Patents as permitted under this Section 9.3, including that the non-Prosecuting Party shall, and shall ensure that its Affiliates, (a) offer its comments, if any, promptly and in any event no less than [***] Business Days before any applicable due date that requires action, and (b) provide access to relevant documents and other evidence and make its employees available at reasonable business hours; provided, however, that neither Party shall be required to provide legally privileged information with respect to such intellectual property unless and until procedures reasonably acceptable to such Party are in place to protect such privilege; and provided, further, that the Prosecuting Party shall reimburse the non-Prosecuting Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection with the non-Prosecuting Party's obligations under this Section 9.3.4(a).

(b) Any costs and expenses under this Section 9.3 to be reimbursed by one Party to the other shall be paid by the owing Party within [***] days of receipt of evidence that such costs and expenses have been incurred.

9.3.5 Patent Term Extension. As between the Parties and with respect to the Products, Licensee will have lead responsibility and final decision making authority, in consultation with Licensor for [***] to apply for and obtain any patent term extension or related extension of rights, including supplementary protection certificates and similar rights, for [***] anywhere in the Territory. Licensor shall provide reasonable assistance to Licensee in connection with obtaining any such extensions for [***] consistent with such strategy. To the extent reasonably and legally required in order to obtain any such extension in a particular country, Licensor will make available to Licensee a copy of the necessary documentation to enable Licensee to use the same for the purpose of obtaining the extension in such country. With respect to products other than the Products, Licensor will have the sole right to apply for and obtain any patent term extension or related extension of rights, including supplementary protection certificates and similar rights, for [***].

9.4 Infringement or misappropriation of Licensed Technology [***].

9.4.1 Notification. If either Party should become aware of: on a Product-by-Product and country-by-country basis (a) the making, use, offer for sale, sale or import by any Third Party (other than any Sublicensee or authorized purchaser or transferee of such Product) of any pharmaceutical or biologic product in such country constituting infringement or misappropriation or alleged or threatened infringement or misappropriation of the Licensed Technology [***] in such country or (b) any certification filed under the Hatch-Waxman Act claiming that any of the Licensed Patents are invalid or unenforceable, or claiming that any of the Licensed Patents would not be infringed by the making, use, offer for sale, sale or import of any pharmaceutical or biologic product for which an application under the Hatch-Waxman Act is filed or any notice under the Biologics Price Competition and Innovation Act, or any equivalent or similar certification or notice in any other jurisdiction, that references data for a Product that was submitted to a Regulatory Authority to obtain approval to market such Product, (each of (a) and (b) a "Competitive Infringement"), it shall promptly notify the other Party in writing and provide any information available to that Party relating to such alleged Competitive Infringement.

9.4.2 Licensee.

(a) As between the Parties, Licensee shall have the sole right to bring or control, at its own expense, any enforcement action to abate any actual or alleged Competitive Infringement of [***], including as a defense or counterclaim in connection with any Third Party Infringement Claim.

(b) As between the Parties, Licensee shall have the initial right (but not the obligation) to bring or control, at its own expense, any enforcement action to abate any actual or alleged Competitive Infringement of [***], including as a defense or counterclaim in connection with any Third Party Infringement Claim. Licensee shall keep Licensor reasonably informed of Licensee's strategy for such enforcement action, including furnishing to Licensor, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents received from counsel in the course of such enforcement action, and copies of material documents filed with or received from the relevant court or material communications with other party to such enforcement action, and such other material documents related to such enforcement actions in sufficient time prior to filing such document or sending such document to the other party to allow for review and comment by Licensor. Licensee shall consider in good faith the reasonable comments of Licensor with respect to such enforcement action received no later than [***] Business Days prior to any filing deadline; provided, however, that, with respect to such timely comments provided by Licensor regarding any statement Licensee proposes to make in connection with the enforcement of [***], Licensor will have final say and Licensee will implement such Licensor comments, provided, that notwithstanding the foregoing, if the intended statement is consistent with a previous statement made publicly in Prosecution or any enforcement action by Licensor regarding ImmTOR, Licensee shall be permitted to make such statement regardless of Licensor's comments. Licensor shall (and shall ensure that its Affiliates) reasonably cooperate, and Licensor shall use Commercially Reasonable Efforts to ensure that its licensors cooperate, in any such enforcement action, including being joined as a party to such enforcement action if reasonably necessary to establish or maintain standing and making its employees reasonably available, [***]. If Licensor is so joined, then, in the absence of any conflict of interest, the Parties shall use Commercially Reasonable Efforts to utilize the same legal counsel.

(c) In the event that Licensee does not file an enforcement action against or commence and conclude settlement negotiations with the Third Party responsible for a Competitive Infringement of [***] within [***] days of receipt of a written demand from Licensor that Licensee bring such an enforcement action, or within [***] days of either Party's receipt of a notice that an applicant is seeking licensure pursuant to the Hatch Waxman Act, then Licensor shall have the right to submit the matter to the JSC for the JSC to determine whether a reasonably prudent licensee would bring an action to enforce [***], as applicable in question, in light of [***].

(d) Any costs, expenses or damages under this Section 9.4.2 to be reimbursed by one Party to the other shall be paid by the owing Party within [***] days of receipt of evidence that such costs, expenses or damages have been incurred.

9.4.3 [***]. As between the Parties, [***] shall have the sole and exclusive right (but not the obligation) to bring or control[***], any enforcement action to abate any actual or alleged Competitive Infringement of a Selecta-Controlled Patent, [***], including as a defense or counterclaim in connection with any Third Party Infringement Claim.

9.4.4 Parties Jointly. Licensee and Licensor shall jointly decide the enforcement strategy for the Other Joint New IP Patents, and shall bring as joint party-plaintiffs any enforcement action to abate any actual or alleged Competitive Infringement of an Other Joint New IP Patent, including as a defense or counterclaim in connection with any Third Party Infringement Claim. [***] the costs and expenses of any such action [***] all amounts received for damages upon the final judgment or settlement

of any such action. In the absence of any conflict of interest, the Parties shall use Commercially Reasonable Efforts to utilize the same legal counsel.

9.4.5 Settlement. With respect to any infringement or defensive action identified in Section 9.4.2 or Section 9.5, the Party controlling such action shall have the right to settle or otherwise dispose of such action on such terms as such Party shall determine in its sole discretion, including, in the case of Licensee, by granting a license or sublicense to a Third Party under the rights granted to Licensee under the License in accordance with the sublicensing terms of Section 2.3, as applicable. Notwithstanding the foregoing, no such settlement or other disposition will (a) impose any monetary restriction or obligation on or admit fault of the other Party or (b) adversely affect the other Party's rights under this Agreement to any Patent then being enforced or defended, in each case ((a) and (b)), without the prior written consent of the other Party, not to be unreasonably withheld, conditioned, or delayed.

9.4.6 Recoveries. Unless otherwise agreed by the Parties, any monetary damages recovered upon the final judgment or settlement of any action described in Section 9.4.2 shall be used first to reimburse the Party that brought the enforcement action (the "Controlling Party") for its costs and expenses (including reasonable attorneys' fees) incurred from the action, and any remaining amount will be distributed as follows [***].

9.5 Third Party Infringement Claims.

9.5.1 If the Exploitation of a Product results in a claim, suit or proceeding alleging patent infringement against either Party (or its Affiliates, licensees or Sublicensees) (a "Third Party Infringement Claim"), including any defense or counterclaim in connection with a Competitive Infringement initiated in connection with Section 9.4.2, such Party shall promptly notify the other Party hereto in writing.

9.5.2 [***].

9.5.3 Licensor shall, and shall cause its Affiliates to, use Commercially Reasonable Efforts to ensure that its licensors assist and cooperate with Licensee, as Licensee may reasonably request from time to time, in connection with its activities set forth in this Section 9.5, including where necessary, being joined as a party plaintiff if reasonably necessary to establish standing for such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that [***] shall reimburse [***] and its Affiliates and its licensors for their reasonable and verifiable out-of-pocket costs, damages and expenses, including reasonable attorneys' fees (further provided the Parties shall have used Commercially Reasonable Efforts to utilize the same legal counsel) that such entity may incur in connection with such assistance or joinder, including any award of costs against it.

9.5.4 Licensee shall keep Licensor reasonably informed of all material developments in connection with any such Third Party Infringement Claim; provided, however, that, with respect to such comments provided by Licensor and received no later than [***] Business Days prior to any filing deadline regarding any statement Licensee proposes to make in connection with the enforcement of the [***], Licensee will implement such Licensor comments, provided further, that notwithstanding the foregoing, if the intended statement is consistent with a previous statement made publicly in Prosecution or any enforcement action by Licensor regarding ImmTOR, Licensee shall be permitted to make such statement regardless of Licensor's comments.

9.5.5 Any damages or awards, including royalties, awarded to the party alleging patent infringement under any Third Party Infringement Claim defended under this Section 9.5 shall be borne by [***]. For clarity, if [***] is required to make any payment to a Third Party (including any Third

Party which becomes an Acquisition Entity of Licensor) to settle such Third Party Infringement Claim, such Third Party Payment shall be a Third Party Payment for the purposes of Section 6.5.3.

9.6 Defense. To the extent either Party receives notice by counterclaim, or otherwise, alleging the invalidity or unenforceability of any Licensed Patent, it will bring such fact to the attention of the other Party, including all relevant information related to such claim. Where such allegation is made in an opposition, reexamination, interference, post-grant proceeding or other patent office proceeding, the provisions of Section 9.3 will apply. Where such allegation is made in a declaratory judgment action, a counterclaim to a suit or other action brought under Section 9.4, the provisions of Section 9.4 will apply.

9.7 Common Interest. All information exchanged between the Parties regarding the Prosecution, and enforcement and defense, of Patents under this Section 9 will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such Prosecution, and enforcement and defense of Patents under this Section 9, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning Patents under this Section 9, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Section 9 is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

9.8 Third Party Patent Rights. If, at any time during the Term, in the reasonable opinion of Licensee, it is reasonably necessary to obtain rights to a Patent of a Third Party (including any Third Party which becomes an Acquisition Entity of Licensor) for Licensee or its Affiliates or its or their Sublicensees to Exploit the Products in the Field in any country in the Territory (such right, a "Third Party Patent Right"), then, as between the Parties, [***], Licensee shall have the right, but not the obligation, to negotiate and obtain a license from such Third Party (including any Third Party which becomes an any Acquisition Entity of Licensor) to such Third Party Patent Right as necessary for Licensee or its Affiliates or its or their Sublicensees to Exploit the Products in the Field in such country; provided that subject to Section 6.5.3, as between the Parties, Licensee shall bear all expenses incurred in connection therewith, including any royalties, milestones or other payments including In-Licensor Payments, incurred under any such license.

9.9 Personnel Obligations. Prior to beginning work under this Agreement relating to any Development or Commercialization of a Product, each employee, agent or independent contractor of Licensee or Licensor or of either Party's Affiliates, Sublicensees or (sub)licensees will be bound by non-disclosure and invention assignment obligations which are consistent with the obligations of Licensee or Licensor, as appropriate, in this Section 9, to the extent permitted by applicable Law, including: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to Licensee or Licensor, as appropriate, all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property right; (c) in the case of employees, agents, or independent contractors working in the United States, taking actions reasonably necessary to secure patent protection; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) abiding by the obligations of confidentiality and non-use set forth in Section 10. It is understood and agreed that such non-disclosure and invention assignment agreement need not reference or be specific to this Agreement.

9.10 Rights in Bankruptcy.

9.10.1 Licenses in Bankruptcy. All licenses granted by Licensor to Licensee under this Agreement are and shall otherwise be deemed to be, for purposes of Title 11, United States Code or foreign equivalent laws (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined in Section 101 of the Bankruptcy Code. Licensee shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code with respect to this Agreement and any agreement supplementary hereto in accordance with Section 365(n) of the Bankruptcy Code, including the obligations of the Parties under Sections 365(n)(2), (n)(3), and (n)(4) of the Bankruptcy Code. Licensor agrees that such intellectual property is subject to Section 365(n) of the Bankruptcy Code notwithstanding the jurisdiction of such intellectual property. Upon the bankruptcy of Licensor, Licensee shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such shall be promptly delivered or made available to Licensee, unless an order approving assumption of this Agreement and any agreement supplementary hereto that is reasonably acceptable to Licensee is entered and takes effect within [***] days of the bankruptcy commencement by or against Licensor. Upon rejection of this Agreement in an Insolvency Proceeding of Licensor, Licensor or any bankruptcy trustee shall comply with the provisions of Section 16.8 and not interfere with the rights of Licensor provided in this Agreement or any other agreement supplementary hereto to licensed or transferred pursuant to Section 16.8.

9.10.2 No termination or Rejection. Licensor will not move for, or consent to, the termination of or rejection of this Agreement in any Insolvency Proceeding involving Licensor, notwithstanding any right Licensor may have at law to do so. In the event that this covenant is breached and the License is terminated in whole or in part, the Parties acknowledge and agree that Licensee will suffer irreparable harm.

9.10.3 Negative Covenant. Licensor covenants that it will not, during the Royalty Term, create, or permit to subsist, any Encumbrance (except for Permitted Encumbrances) on any of the Licensed Technology.

10. CONFIDENTIAL INFORMATION

10.1 Confidentiality.

10.1.1 Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the Term of this Agreement and for [***] years thereafter (or, with respect to Confidential Information that is a trade secret of the disclosing Party, until such trade secret no longer qualifies as a trade secret under applicable Law) (the "**Confidentiality Period**"), it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information of the other Party. Each Party shall promptly notify the other upon becoming aware of the occurrence of any unauthorized use or disclosure of the other Party's Confidential Information.

10.1.2 The foregoing obligation of Section 10.1.1 shall not apply to Confidential Information which:

(a) (other than the Licensed Know-How in the case of Licensor as disclosing Party) prior to receipt thereof from one Party was in the possession of the recipient Party without restriction, as can be demonstrated by the recipient Party through written evidence;

(b) is subsequently disclosed to the recipient Party without obligations of confidence to the disclosing Party by a third party who has not derived it directly or indirectly from the disclosing Party;

(c) is or becomes generally available to the public through no act or default of the recipient Party or its Affiliates, employees, contractors, agents, or Sublicensees;

(d) (other than the Licensed Know-How in the case of Licensor as disclosing Party) is independently Developed by the receiving Party independently and without the benefit of any disclosure hereunder, as demonstrated by documented evidence prepared contemporaneously with such independent Development.

10.1.3 During the Confidentiality Period:

(a) all Confidential Information obtained by the receiving Party from the disclosing Party shall be used or disclosed by the receiving Party solely as required to (i) perform its obligations or exercise or enforce its rights and remedies under this Agreement, (ii) in the case of Licensee, for the Exploitation of the Product in the Field in the Territory, or (iii) in the case of Licensor, the Licensor Permitted Activities; and

(b) Licensor and its Affiliates shall continue to protect the Licensed Know-How using the same degree of care and in accordance with the same internal processes and safeguards that it applied to the Licensed Know-How immediately prior to the Execution Date, but in any event using no less than reasonable care.

10.1.4 Notwithstanding Sections 10.1.1 or 10.1.3, Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by applicable Law, including by reason of filing with securities regulators or rules of an applicable securities exchange; provided, however, that the receiving Party shall first where practicable have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that such disclosing Party's Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that the Confidential Information disclosed in response to such court or governmental order or made in such filing shall be limited to that information which is legally required to be disclosed in response to such court or governmental order or made in such filing;

(b) made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval as permitted under this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law, and, further provided that, the Parties acknowledge that any submissions of Regulatory Filings for the Products in the Field in the Territory shall be made by Licensee, its Affiliates or Sublicensees and not by Licensor;

(c) made by or on behalf of the receiving Party to any patent office or similar authority as may be reasonably necessary or desirable for purposes of filing, prosecuting, obtaining, maintaining or enforcing its Patents as permitted under this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent practicable and consistent with applicable Law;

(d) made by or on behalf of the receiving Party in connection with prosecuting or defending litigation under this Agreement;

(e) made by or on behalf of the receiving Party or its Affiliate to Affiliates, employees, directors, agents, consultants, advisors, collaborators, actual or potential Sublicensees, (sub)licensees, subcontractors, manufacturers, who, in each case, have a need to know such information

in order to perform Exploitation activities under this Agreement or otherwise perform such Party's obligations or exercise such Party's rights under this Agreement;

(f) made or on behalf of a Party or its Affiliate to the counterparty to an Upstream Agreement, solely to the extent necessary to enable Licensor to comply with its obligations thereunder, provided, however, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 10 and provided, further, that the Confidential Information so disclosed shall be limited to that information which is strictly required to be disclosed to enable compliance with such Upstream Agreement; or

(g) made by or on behalf of the receiving Party to *bona fide* potential or actual sources of financing, investors, strategic partners, acquirers and other financial and commercial partners, and their respective attorneys, accountants, banks, investors and advisors as may be necessary in connection with their evaluation of such potential or actual investment, debt transaction, partnership, collaboration, or acquisition; provided, however, that in each case of clauses (e) and (g), such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 10.

10.1.5 Each Party shall procure that all its employees, directors, agents, consultants, advisors, collaborators, contractors, Affiliates, Sublicensees and licensees, who have access to any information of the other Party to which the obligations of this Section 10.1 apply, shall be made aware of, subject to, and comply with the above obligations.

10.1.6 The Mutual Confidential Disclosure Agreement by and between Licensor and Licensee dated January 24, 2020 (as amended, the "Confidentiality Agreement") is hereby superseded and replaced by this Agreement, and information disclosed pursuant to such Confidentiality Agreement prior to the Effective Date will be protected as Confidential Information under this Section 10.1 of this Agreement.

10.1.7 Notwithstanding the provisions of this Section 10.1, each Party shall comply with the obligations of Licensor pursuant to Section 10.1 of the 3SBio License Agreement.

10.2 Publicity. The Parties have agreed on the language of their respective press releases announcing this Agreement, which are attached hereto as Annex D, to be issued by the Parties promptly after the Effective Date. Subject to the foregoing, the Parties have agreed that neither Party shall issue any public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure as is, in the opinion of the disclosing Party's counsel, required by applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 10.2; provided that such information remains true and accurate as of such time.

10.3 Equitable Relief. Each Party acknowledges that a breach of this Section 10 may not reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. Therefore, each Party agrees that the other Party

shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of the obligations relating to Confidential Information set forth in this Agreement.

11. TRANSPARENCY, DATA PROTECTION.

11.1 Transparency. Each Party acknowledges that the other Party is subject to applicable Laws related to: (i) the collection and reporting of any payments or transfers of value to certain HCPs and teaching hospitals (collectively, "Financial Transparency Laws"), which include, without limitation, relevant provisions of the U.S. Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h) and its implementing regulations along with similar laws and regulations in other countries; and (ii) the collection and reporting requirements, and the processing of any applicable rebate, chargeback or adjustment, under applicable rules and regulations relating to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the Public Health Service Act (42 U.S.C. § 256b), the VA Federal Supply Schedule (38 U.S.C. § 8126) or under any state pharmaceutical assistance program or U.S. Department of Veterans Affairs agreement, and any successor government programs, as well as any registration, notification and reporting requirements under any state drug pricing transparency laws, and its implementing regulations, respectively, along with similar laws and regulations in other countries (collectively, "Drug Pricing Transparency Laws", and together, with the Financial Transparency Laws, the "Transparency Laws"). Each Party shall reasonably cooperate with the other Party in its compliance in all material respects with Transparency Laws and promptly provide any information requested by such other Party in connection with this Agreement in a mutually agreed upon format that is necessary or reasonably useful for such other Party to comply with its obligations under the Transparency Laws. With respect to the Financial Transparency Laws, each Party shall have the right to allocate payments or other transfers of value in connection with this Agreement in any required reporting under such laws in accordance with its normal business practices.

11.2 Data Protection. Each Party shall fully comply with its obligations under applicable Data Protection Laws in the performance of its obligations hereunder. Without limiting the foregoing:

11.2.1 to the extent a Party is the sponsor of each clinical trial, each Party shall ensure that all patient authorizations and consents required under applicable Data Protection Laws are obtained and permit the sharing of data and information by the Parties under this Agreement. Where safety information is received outside the conduct of a clinical trial by a Party and that Party subsequently shares such safety information with the other Party under this Agreement, the disclosing Party shall ensure that all patient authorizations and consents required under applicable Data Protection Laws permit such sharing of safety information by the Parties;

11.2.2 Each Party shall, at the other Party's expense, provide the other with such assistance as may be reasonably requested to ensure that each Party complies with their obligations under applicable Data Protection Laws. For clarity, such assistance may include, but is not limited to cooperating in response to requests from data subjects and notifying the other Party of the receipt of such requests.

11.2.3 Each Party acknowledges that each Party is under an obligation to ensure that the Personal Data they Process in connection with this Agreement and which the disclosing Party discloses in connection with this Agreement is limited to only that which is necessary for the purposes of the Processing, therefore the disclosing Party shall, notwithstanding any other provision of this Agreement, use Commercially Reasonable Efforts to transfer only that Transferred Data which is required to facilitate the performance of this Agreement. If the receiving Party reasonably believes that additional Personal Data is required to be disclosed to enable the performance of this Agreement, the receiving Party shall notify the disclosing Party and the Parties shall discuss in good faith whether such additional Personal Data will be disclosed by the disclosing Party, taking into account each Party's obligations under applicable

Data Protection Laws, the potential for the provision of anonymized data in place of the requested Personal Data, and any actions which are required to be taken by either Party in connection with such requested disclosure.

11.2.4 each Party (on behalf of itself, its Affiliates and its Sub-Licensees and contractors) agrees and acknowledges that (wherever possible whilst meeting the objectives of this Agreement) it:

(a) shall ensure that the Confidential Information transferred under this Agreement cannot be used by the receiver to identify a Data Subject and does not constitute Personal Data in respect of which EU Data Protection Law applies;

(b) shall ensure that the Confidential Information transferred under this Agreement does not constitute personally identifiable information or equivalent information under any applicable Data Protection Laws; and

(c) shall not provide the receiver with any additional information (if any), including any key codes or any other mechanism or data, that may enable the receiving Party to attribute the Information to any identified or identifiable natural person,

and, notwithstanding the foregoing, if either Party (i) transfers Personal Data in connection with this Agreement in respect of which EU Data Protection Law applies, each Party will comply with its respective obligations as set out in Annex C, and (ii) with respect to any other Personal Data or personally identifiable information transferred or received under this Agreement, each Party shall comply with any applicable obligations under applicable Data Protection Laws, including, but not limited, to imposing the same confidentiality and security requirements as outlined in this Agreement; and

11.2.5 The Parties agree to negotiate and agree in good faith modifications to this Agreement (including Annex C) to the extent required for the Parties to transfer or Process any Personal Data or other personally identifiable information (if any) transferred or received under this Agreement in compliance with applicable Data Protection Laws or to address the legal interpretation of Data Protection Laws. Without limiting the foregoing, to the extent Licensor will Process Personal Data on behalf of Licensee, the Parties shall enter into a separate data processing agreement covering, at a minimum, the requirements of Article 28 GDPR.

11.2.6 Personal Data Breach. In the event of a Personal Data Breach, to the extent required by applicable Data Protection Laws, the affected Party shall notify the other Party without delay upon, but no later than 48 hours after the affected Party, or any Affiliate, sublicensee or data processor, becomes aware of a Personal Data Breach and each Party shall comply with its obligations under applicable Data Protection Laws and shall provide reasonable assistance to the other Party to enable the other Party to comply with its obligations under applicable Data Protection Laws, which may include providing such reasonable information, on the other Party's reasonable request, as is required to enable such other Party to meet any obligations (including timelines) to report or inform Data Subjects of the Personal Data Breach under the applicable Data Protection Laws. Additionally, each Party shall use Commercially Reasonable Efforts to promptly and thoroughly investigate all incidents of unauthorized access to, use, or disclosure of Personal Data.

12. REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1 Mutual Representations and Warranties. As of the Execution Date, each Party hereto represents and warrants to the other Party that:

12.1.1 it is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

12.1.2 the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (i) such Party's charter documents, bylaws or other organizational documents; (ii) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (iii) any requirement of any applicable Law; or (iv) any Order presently in effect applicable to such Party;

12.1.3 this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

12.1.4 it is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would materially impede the fulfilment of its obligations hereunder; and

12.1.5 neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates has used or will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA (or similar applicable Law outside of the U.S.) or who is the subject of a conviction described in such section; and it will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in such Section 306 of the FFDCA (or similar applicable Law outside of the U.S.) or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder; and

12.1.6 it is entitled to claim the benefits of the income tax treaty between the United States and Sweden both generally as a "resident" of such jurisdiction (within the meaning of Article 4 thereof) and under the Limitation on Benefits article (Article 17, as amended).

12.2 Additional Representations and Warranties of Licensor. As of the Execution Date, Licensor further represents and warrants to Licensee that:

12.2.1 Annex A sets forth a true, complete and accurate list of all Licensed Patents existing as at the Effective Date;

12.2.2 it exclusively owns or Controls pursuant to an Upstream Agreement the Licensed Technology, without Encumbrance (except for Permitted Encumbrances);

12.2.3 it has the right to grant the License as purported to be granted hereunder;

12.2.4 [***], neither Licensor nor any of its Affiliates is a party to an Upstream Agreement pursuant to which Licensor or such Affiliate in-licenses any Patents or Know-How that are necessary or reasonably useful for the Exploitation of SEL-212 as contemplated by Licensor or its Affiliates as of the Execution Date;

12.2.5 (a) the Upstream Agreements are valid, binding, enforceable and in full force and effect, (b) neither Licensor nor, to Licensor's knowledge, the counterparty to any such Upstream Agreement is in material breach thereof, and, to Licensor's knowledge, no circumstances or grounds exist

that would reasonably be expected to give rise to a claim of material breach or right of rescission, termination, revision, or amendment of any of the Upstream Agreements, including the execution, delivery and performance of this Agreement, and (c) Licensor has not received any written notice that it is in default (or with the giving of notice or lapse of time or both, would be in material default) under any Upstream Agreement;

12.2.6 to Licensor's knowledge, the master Cell Bank for the Compound owned or controlled by 3SBio as of the Execution Date, and each working Cell Bank for the Compound Controlled by Licensor or owned or controlled by 3SBio, respectively, as of the Execution Date, were generated under cGMP standards and in accordance with applicable Laws, and have been stored in a manner consistent with cGMP and industry standards;

12.2.7 it has performed or had performed cGMP runs to generate material for use in human clinical trials;

12.2.8 the Licensed Patents existing as of the Execution Date are, to Licensor's knowledge, valid and enforceable;

12.2.9 all registrations with and applications to Governmental Authorities in respect of the Licensed Patents or to Regulatory Authorities in respect of the Compound, ImmTOR or SEL-212 required to be made by Licensor or its Affiliates in connection with the Exploitation of the Products, or made at its or its Affiliates' direction and under its or its Affiliates' control, in connection with the Exploitation of the Product, are in full force and effect and Licensor or its relevant Affiliate has taken all actions required to maintain their validity, and (a) effectiveness (in the case of such registrations with and applications to Regulatory Authorities) or (b) enforceability (in the case of such registrations with and applications to Governmental Authorities in respect of the Licensed Patents);

12.2.10 it has taken commercially reasonable measures to protect the secrecy, confidentiality and value of the Licensed Know-How and, to Licensor's knowledge, no event has occurred which has resulted in the unauthorized use or disclosure of any Licensed Know-How or which otherwise resulted in any Licensed Know-How falling into the public domain;

12.2.11 it has not received any written Claim alleging that Licensor's or its Affiliates' or licensee's use of the Licensed Technology or Development of the Compound, ImmTOR and/or Product infringes or misappropriates any intellectual property rights of any Third Party (including any written Claim that Licensor must license or refrain from using any intellectual property rights of any Third Party in order to Exploit the Compound, ImmTOR and/or Product);

12.2.12 to Licensor's knowledge: (a) no Third Party has infringed upon, misappropriated, or otherwise violated the Licensor's rights in Licensed Technology; and (b) no facts exist as of the Execution Date which would form a reasonable basis for any claim of such infringement, misappropriation, or other violation;

12.2.13 no Claim is pending or, to Licensor's knowledge, is threatened which challenges the legality, validity, enforceability, use, or ownership of any owned Licensed Technology or, to Licensor's knowledge, in-licensed Licensed Technology;

12.2.14 except for routine patent prosecution proceedings in patent offices throughout the world, there is no pending or, or to Licensor's knowledge, threatened, re-examination, opposition, interference, or litigation against or involving, or any written communication alleging that, any owned Licensed Patent, or, to Licensor's knowledge, in-licensed Licensed Patent, is invalid or unenforceable anywhere in the world;

12.2.15 to Licensor's knowledge, there are no facts existing as of the Execution Date which would form a reasonable basis for any Claim of infringement, misappropriation, or other violation of any intellectual property rights of any Third Party existing as of the Execution Date related to the Licensed Technology or the Exploitation of the Compound, ImmTOR and / or the Product as contemplated by Licensor or its Affiliates as of the Execution Date;

12.2.16 to Licensor's knowledge, having made reasonable inquiry, (a) the Development and Manufacture of the Compound, ImmTOR, and the Product (in the formulation in which it exists as of the Execution Date) in the Territory does not, and (b) the Exploitation of the Product (in the formulation in which it exists as of the Execution Date) in the Territory as contemplated by Licensor or its Affiliates as of the Execution Date will not, in each case ((a) and (b)) infringe upon or misappropriate, any intellectual property rights of any Third Party existing as of the Execution Date;

12.2.17 ImmTOR [***] conform to the statements in Annex G ([***]);

12.2.18 Licensor holds such Regulatory Approvals, and other permits, licenses, franchises, authorizations and clearances issued by the FDA or any other Regulatory Authority as are required in connection with the Development conducted to date by Licensor or its Affiliates of the Compound, ImmTOR or Product;

12.2.19 neither Licensor nor any of its Affiliates has received any warning letters or written correspondence from the FDA or any other Regulatory Authority requiring the termination, suspension or material modification of any clinical or pre-clinical studies or tests with respect to the Compound, ImmTOR or Product;

12.2.20 Licensor and its Affiliates have complied in all material respects with all applicable Law, including GCPs and GLPs, and all applicable Data Protection Laws, in connection with the Development conducted to date by Licensor or its Affiliates of the Compound, ImmTOR and the Product;

12.2.21 Licensor has provided Licensee with a complete and accurate copy of the most current version of the IND for SEL-212 held by Licensor;

12.2.22 the IND and all other Regulatory Filings filed by Licensor with respect to the Product were, at the time of filing, true, complete, and accurate in all material respects;

12.2.23 Licensor has disclosed all facts required to be disclosed with respect to the Compound, ImmTOR and Product to each applicable Regulatory Authority, and Licensor has filed with the applicable Regulatory Authority all required notices, reports, and other Regulatory Materials with respect to the IND held by Licensor for SEL-212;

12.2.24 Licensor has not received any notice from any Regulatory Authority or other Governmental Authority commencing or threatening withdrawal of any active IND for SEL-212 held by Licensor;

12.2.25 all Compound, ImmTOR and / or Product for clinical studies has been Manufactured and stored in material compliance with cGMP and all applicable Law;

12.2.26 Licensor is not as of the Execution Date in material dispute with any Third Party supplier responsible for the supply of the Compound, ImmTOR and / or SEL-212;

12.2.27 Licensor has not initiated a voluntary proceeding under any applicable bankruptcy code; and

12.2.28 there is no involuntary proceeding under any applicable bankruptcy code pending against Licensor as of the Execution Date.

13. SUPPLY

13.1 Supply for Existing Pivotal Trials.

13.1.1 Subject to Section 4.3.7, if applicable, Licensor shall Manufacture and supply (or ensure the Manufacture and supply of) quantities of Product as necessary for the completion of the Licensor Development Activities.

13.1.2 Licensor shall ensure that,

(a) at the time of delivery of Product, [***] and ImmTOR, [***], in each case to the trial site for the Existing Pivotal Trials or relevant location:

(i) the Product or ImmTOR, as applicable, shall have sufficient shelf life as is required to meet the requirements of the Existing Pivotal Trials until [***], the Product or ImmTOR, as applicable, shall have at least [***] months remaining shelf life, or such greater remaining shelf life as is required to meet the requirements of the Existing Pivotal Trials;

(ii) the Product or ImmTOR, as applicable shall have been Manufactured, released, stored and supplied (for clarity, including all packaging and labelling) in compliance with: (i) the applicable Specifications; (ii) the relevant Quality Agreement; and (iii) all applicable Law, cGMP and GCP,

(iii) it shall be solely responsible for obtaining and maintaining (or for ensuring that its relevant contract manufacturers obtain and maintain) all approvals of Regulatory Authorities that are required to Manufacture, release, store and supply the Product or ImmTOR, as applicable, in compliance with applicable Law and cGMP, for the Existing Pivotal Trials, and

(iv) it shall be solely responsible for all Manufacturing, release, acceptance and release testing of the Product or ImmTOR, as applicable, for the Existing Pivotal Trials, and the subsequent handling, storage, transportation, warehousing and distribution thereof; and

(b) without limiting the foregoing, at the time of delivery of Product to the trial site for the Existing Pivotal Trials, such Product shall have been packaged, labelled and released and stored (subject to Licensee's obligation under Section 4.3.7 regarding the Compound, if applicable) in compliance with: (i) the applicable Specifications; (ii) the Licensor's quality agreement with its relevant subcontractor(s); and (iii) all applicable Law, cGMP and GCP.

13.2 Supply Agreement. Without limiting Section 13.1, the Parties shall use good faith efforts to negotiate and enter into a Supply Agreement on the terms set out on Annex F on or before [***] days after the Effective Date or such longer period as may be mutually agreed by the Parties, pursuant to which, Licensor shall Manufacture, release and supply (or procure the Manufacture and supply of) commercial (and if required, clinical) quantities of ImmTOR or Product [***] (in accordance with all applicable Law, cGMP and GCP) to Licensee, its Affiliates and / or its Sublicensees in each case solely for use to Exploit the Product in accordance with the License.

13.3 Supply Price. Without limiting Section 13.2, the Parties agree that Product, [***] and, [***] ImmTOR, in each case, supplied for the Existing Pivotal Trials or under the Supply Agreement

shall be supplied at the Supply Price therefor. Licensor shall solely bear all royalties and other amounts payable to Third Parties (other than under the Transferring Agreements following transfer to Licensee) in connection with its supply obligations under this Section 13, and Licensor warrants that the Supply Price accurately reflects the cost of manufacturing and supplying the Product and does not include any allocation of royalty or other amounts payable to Licensor's licensors. Licensor shall use Commercially Reasonable Efforts to decrease the Supply Price over time.

13.4 Second Source Supplier; Technology Transfer.

13.4.1 Notwithstanding Sections 13.1 and 13.2, at any time during the Term, Licensee may request in writing that the Parties discuss and mutually agree in good faith (each acting reasonably) via the JSC upon a Third Party contract manufacturer as a second source of supply of ImmTOR to Licensee solely for Licensee's, its Affiliates' and its Sublicensees' Exploitation of the Products in the Field in the Territory as permitted under this Agreement (the "Second Source Supplier"). Each Party hereby agrees not to unreasonably withhold, delay or condition its approval right in the mutual selection of the Second Source Supplier.

13.4.2 If a Second Source Supplier is selected in accordance with Section 13.4.1, at Licensee's reasonable cost (provided Licensor shall provide Licensee with monthly updates regarding legal fees accrued to date and estimates of legal fees to completion), Licensor shall, in consultation with, and subject to prior approval by, Licensee, promptly enter into a commercially reasonable written agreement with such Second Source Supplier that:

(a) will provide for the qualification by Licensor of the Second Source Supplier to Manufacture commercial quantities of ImmTOR under applicable Laws (including validation of the facility/ies of such Second Source Supplier) for Licensee, its Affiliates and its Sublicensees solely for Exploitation of the Products in the Field in the Territory as permitted under this Agreement;

(b) will be dedicated to Manufacturing and supplying ImmTOR to Licensee, its Affiliates and its Sublicensees solely for Exploitation of the Products in the Field in the Territory as permitted under this Agreement and no other licensees of Licensor; and

(c) [***],

(such agreement, the "Licensee CMO Agreement").

13.4.3 Licensor shall keep Licensee reasonably informed as to the status of the Licensee CMO Agreement negotiations and give Licensee reasonable opportunity to comment on drafts (with Licensee being responsible for all costs and expenses it incurs with its review and comment).

13.4.4 [***], Licensor will engage and at all times manage in all respects the engagement of the Second Source Supplier, at Licensee's cost.

13.4.5 Licensor shall not materially breach or be in material default under any of its obligations under the Licensee CMO Agreement or take any other action, or omit or fail to take any action (including making necessary payments) that would result in early termination thereof or otherwise have an adverse effect on supply of ImmTOR to Licensee, its Affiliates and its Sublicensees solely for Exploitation of the Products in the Field in the Territory as permitted under this Agreement.

13.4.6 At any time after the execution of the Licensee CMO Agreement, Licensee may request in writing that Licensor complete, at Licensee's cost, a Manufacturing technology transfer to the Second Source Supplier of the ImmTOR Manufacturing Process, which shall include Licensor cooperating with, and providing (or causing its relevant Affiliates or subcontractors to provide) all reasonable assistance, to the Second Source Supplier, including providing copies of all Licensed Know-

How which is reasonably necessary to manufacture ImmTOR (including, for clarity, all reference standards, reagents and other materials reasonably necessary for such Manufacturing) in accordance with the specifications of ImmTOR as set forth in the Quality Agreement therefor and Regulatory Approval for the Product, and in compliance with cGMP and applicable Laws solely for Licensee's, its Affiliates' and its Sublicensees' Exploitation of the Products in the Field in the Territory as permitted under this Agreement (the "Technology Transfer").

13.4.7 If Licensee makes a request for a Technology Transfer, Licensor will, (a) promptly complete the Technology Transfer to the Second Source Supplier, (b) provide (or cause to be provided by its relevant Affiliates or subcontractors) to the Second Source Supplier a reasonable level of technical assistance and consultation to support such Technology Transfer and provide reasonable assistance with the qualification of the Second Source Supplier's Manufacturing facility/ies with applicable Regulatory Authorities, and (c) without limiting clause (b), provide for a certain percentage of the supply of ImmTOR solely for Licensee's, its Affiliates' and its Sublicensees' Exploitation of the Products in the Field in the Territory as permitted under this Agreement to be supplied under the Supply Agreement via such Second Source Supplier. In addition to qualifying the Second Source Supplier, Licensor shall be solely responsible for ensuring that the Second Source Supplier maintains all approvals of Regulatory Authorities that are required to Manufacture, store and supply ImmTOR, as applicable, in compliance with applicable Law and cGMP for Licensee, its Affiliates and its Sublicensees solely for Exploitation of the Products in the Field in the Territory as permitted under this Agreement. Licensee shall reimburse Licensor's costs of such Technology Transfer at the FTE Rate and subject to a mutually agreed budget, provided that if Licensor plans, at the time of such Technology Transfer, to use (or does, within the [***] years following such Technology Transfer, so use) the Second Source Supplier to supply ImmTOR to Licensor, its Affiliates or other of its licensees, Licensee shall bear only (or shall be reimbursed) its pro rata share of such costs.

13.4.8 [***]

(a) [***].

(b) [***].

13.5 Cell Bank. On Licensee's request, Licensor shall transfer the working Cell Bank Controlled by the Licensor for the Manufacture of Compound to Licensee within [***] days following the date of Licensee's request, and shall maintain (or have maintained) the same until such transfer, provided that Licensor may retain a sufficient part of the working Cell Bank as is required to be held by or on behalf of Licensor to enable Licensor to comply with its ongoing supply obligations hereunder.

13.6 Quality Agreements. The Parties will use good faith efforts to negotiate and enter into the Quality Agreements (including a Quality Agreement for ImmTOR on the terms set out on Annex F) on or before the date that is [***] days after the Effective Date or such longer period as may be mutually agreed by the Parties. The Parties acknowledge and agree that the Quality Agreements will govern all technical and quality matters relating to the Existing Pivotal Trials and the Manufacture and supply of clinical and commercial quantities of Product pursuant to the Supply Agreement as more particularly set out therein. If there is a conflict between this Agreement and the Quality Agreements, the relevant Quality Agreement shall govern in relation to technical quality issues only.

14. INDEMNIFICATION

14.1 Indemnification by Licensor. Licensor shall indemnify, defend and hold harmless Licensee and its Affiliates, Sublicensees and each of their respective employees, officers, directors and agents (each a "Licensee Indemnitee") from and against any and all liabilities, losses and damages ("Losses") that result from any Claim made or brought against a Licensee Indemnitee by or on behalf of

a Third Party, and any direct out-of-pocket costs and expenses (including reasonable attorneys' fees) ("Litigation Costs") incurred by a Licensee Indemnitee while investigating or conducting the defense of such Third Party Claim, in either case, solely to the extent such Claim is based on or arises out of:

14.1.1 [***]

14.1.2 [***]

14.1.3 [***]

14.1.4 [***]

14.1.5 [***]

provided, however, that in the case of Sections 14.1.1 to 14.1.4 (inclusive), such indemnification right shall not apply to any Claims, Losses or Litigation Costs (a) to the extent directly attributable to the gross negligence or willful misconduct of a Licensee Indemnitee or Licensee's breach of this Agreement, or (b) for which Licensee is obligated to indemnify Licensor under Section 14.2.

14.2 Indemnification by Licensee. Licensee shall indemnify, defend and hold harmless Licensor and its Affiliates and each of their respective employees, officers, directors and agents (each an "Licensor Indemnitee") from and against any and all Losses that result from any Claim made or bought against an Licensor Indemnitee by or on behalf of such Third Party, and any Litigation Costs incurred by an Licensor Indemnitee while investigating or conducting the defense of such Third Party Claim, in either case, solely to the extent such Claim is based on or arises out of:

14.2.1 [***]

14.2.2 [***]

14.2.3 [***];

provided, however, that such indemnification right shall not apply to any Claims, Losses or Litigation Costs (a) to the extent directly attributable to the gross negligence or willful misconduct of a Licensor Indemnitee or Licensor's breach of this Agreement, or (b) for which Licensor is obligated to indemnify Licensee under Section 14.1.

14.3 Indemnification Procedures.

14.3.1 All indemnification claims in respect of a Licensor Indemnitee shall be made solely by Licensor and all indemnification claims in respect of a Licensee Indemnitee shall be made solely by Licensee.

14.3.2 Subject to Section 14.3.1, promptly after receipt by a Party seeking indemnification under this Section 14 (an "Indemnitee") of notice of any pending or threatened Claim against it by a Third Party, such Indemnitee shall give written notice thereof to the Party from whom the Indemnitee is entitled to seek indemnification pursuant to this Section 14 (the "Indemnifying Party"); provided that the failure so to notify the Indemnifying Party shall not relieve it of any liability that it may have to any Indemnitee hereunder, except to the extent the Indemnifying Party demonstrates that it is materially prejudiced thereby, and in no event shall the Indemnifying Party be liable for any Losses to the extent resulting from any delay of the Indemnitee in providing such notice.

14.3.3 The Indemnitee:

(a) shall not at any time admit liability or otherwise settle or compromise, or attempt to settle or compromise, any such matter (or any aspect of it) except on the Indemnifying Party's express written instructions;

(b) shall give the Indemnifying Party sole conduct of the defense, negotiation or settlement of any such matter upon request (except that the Indemnitee can participate in such defense or consent to such settlements as and to the extent described below) at the Indemnifying Party's sole cost;

(c) may participate, if the Indemnifying Party assumes such defense, in any such matter through counsel of its own choice at such Indemnitee's sole cost and expense; provided, however, that the Indemnifying Party shall pay the fees and expenses of such separate counsel if the interests of the Indemnified Party and Indemnitee with respect to any such matter are sufficiently adverse to prohibit the representation by the same counsel of both the Indemnifying Party and the Indemnitee under applicable Laws, ethical rules, or equitable principles;

(d) shall act in accordance with the Indemnifying Party's reasonable instructions, and give the Indemnifying Party such assistance as it may reasonably require in the conduct of any defense, negotiation or settlement of any such matter, and the Indemnifying Party shall reimburse the reasonable and verifiable out-of-pocket costs and expenses incurred by the Indemnitee; and

(e) shall take all reasonable steps to mitigate any Losses which it may incur as a result of such matter.

14.3.4 The Indemnifying Party shall not agree to any settlement of, or the entry of any judgment arising from, any indemnification claim without the prior written consent of the Indemnitee (such consent not to be unreasonably withheld, delayed or conditioned); provided, however, that the consent of the Indemnitee shall not be required with respect to any such settlement or judgment if the Indemnifying Party or its insurer agrees in writing to pay or cause to be paid any amounts payable pursuant to such settlement or judgment and includes a full release of the Indemnitee from further liability or if such settlement or judgment imposes no admission of liability by or other obligation on the Indemnitee that will not be assumed and performed in full by the Indemnifying Party.

14.4 Insurance. Each of Licensor and Licensee shall have and maintain such type and amounts of liability insurance covering its activities under this Agreement as is normal and customary in the pharmaceutical industry generally for parties similarly situated. Each Party shall, upon request of the other Party, provide the requesting Party with a copy of the foregoing policies of insurance, along with any amendments and revisions thereto.

15. LIMITATION OF LIABILITY

15.1 LIMITS. [***] AND SOLELY TO THE EXTENT PERMITTED BY APPLICABLE LAWS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY UNDER ANY CIRCUMSTANCES OR ANY LEGAL OR EQUITABLE THEORY, WHETHER IN CONTRACT, STRICT LIABILITY OR OTHERWISE, FOR ANY LOST PROFITS OR SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OR ANY LIMITED REMEDY.

15.2 KNOWLEDGE. THE RIGHTS OF LICENSEE TO INDEMNIFICATION OR ANY OTHER REMEDY UNDER THIS AGREEMENT SHALL NOT BE AFFECTED, LIMITED OR DEEMED WAIVED BY REASON OF ANY KNOWLEDGE THAT LICENSEE (OR ANY OF ITS AFFILIATES OR REPRESENTATIVES) MAY HAVE ACQUIRED, OR COULD HAVE ACQUIRED

THAT ANY SUCH REPRESENTATION OR WARRANTY IS, WAS OR MIGHT BE INACCURATE, WHETHER BEFORE OR AFTER THE EXECUTION DATE, NOR BY ANY INVESTIGATION OR DILIGENCE BY LICENSEE (OR ANY OF ITS AFFILIATES OR REPRESENTATIVES). LICENSOR HEREBY ACKNOWLEDGES THAT, REGARDLESS OF ANY INVESTIGATION MADE (OR NOT MADE) BY OR ON BEHALF OF LICENSEE (OR ANY OF ITS AFFILIATES OR REPRESENTATIVES), AND REGARDLESS OF THE RESULTS OF ANY SUCH INVESTIGATION, THE LICENSEE HAS ENTERED INTO THIS AGREEMENT IN EXPRESS RELIANCE ON THE REPRESENTATIONS AND WARRANTIES OF THE LICENSOR MADE IN THIS AGREEMENT.

16. TERM AND TERMINATION

16.1 Term. The term of this Agreement shall begin upon the Effective Date and shall continue in full force and effect, unless terminated as hereinafter provided in this Section 16, on a Product-by-Product basis until the date on which the Royalty Term has expired in each country in the Territory for such Product and will finally expire upon the expiration of the last-to-expire Royalty Term (the "Term").

16.2 Termination of Agreement for Material Breach. Either Party may terminate this Agreement for material breach of this Agreement by the other Party by giving [***] days' written notice to the breaching Party (specifying in reasonable detail the basis for such termination), unless the breaching Party has cured such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within such cure period even with the use of Commercially Reasonable Efforts, the non-breaching Party's right to termination shall be suspended only if and for so long as the breaching Party has provided to the non-breaching Party a reasonable written plan, calculated to effect a cure of such breach, and the breaching Party commits to and is diligently performing such plan.

16.3 Termination of Agreement for Bankruptcy. Either Party may terminate this Agreement upon the occurrence of one or more of the following:

16.3.1 immediately upon written notice to the other Party in the event the other Party initiates a voluntary proceeding under any applicable bankruptcy code; or

16.3.2 immediately upon written notice to the other Party in the event the other Party becomes the subject of an involuntary proceeding under any applicable bankruptcy code and such proceeding is not dismissed or stayed within [***] days of its commencement.

16.4 Termination of Agreement for Patent Challenge. If Licensee or any of its Affiliates brings, or actively supports a Third Party's efforts to bring, an action challenging the validity, patentability or enforceability of any Licensed Patents (a "Patent Challenge"), Licensor may terminate this Agreement by giving [***] days' written notice to Licensee, unless Licensee has filed a motion to dismiss with prejudice such action or caused such action to be dismissed with prejudice within [***] days following receipt of such notice. Provided, however, that the foregoing shall not apply to situations where (a) Licensee or such Affiliate is to participate in such patent challenge pursuant to a subpoena or court order or participates in a proceeding that is initiated by a patent office and not at the instigation of Licensee or such Affiliate, (b) any assertion by Licensee or such Affiliate relating to validity, patentability, priority, construction, non-infringement, inventorship, ownership or enforceability as a defense in any legal proceeding, administrative proceeding or arbitration brought by Licensor or 3SBio or their licensees or assignees asserting infringement against Licensee or such Affiliate, or (c) any challenge brought by a Third Party which subsequently becomes an Affiliate of Licensee provided such challenge was initiated at least one (1) month before the signing of the definitive document(s) whereby such Third Party became an Affiliate of Licensee and the Licensee causes such Third Party to file a motion to dismiss with prejudice such challenge within [***] days after such Third Party becomes an Affiliate of Licensee. For clarity, this Section 16.4 shall not apply to arguments made by Licensee or its Affiliates that distinguish the

inventions claimed in Licensed Patents from those claimed in the patent applications owned or controlled by Licensee or any of its Affiliates in the ordinary course of ex parte prosecution of such patent applications.

16.5 Termination of Agreement by Licensee. Licensee may terminate this Agreement upon not less than one hundred and eighty (180) days' written notice to Licensor for convenience.

16.6 Effects of Termination by Licensor for Cause or by Licensee for Convenience. Upon termination of this Agreement by Licensor pursuant to Section 16.2, 16.3 or 16.4, or by Licensee pursuant to Section 16.5, which shall apply as a lead-in to each of the subsections of this Section 16.6 below:

16.6.1 Termination of License. The License and any rights of use or access granted to Licensee under this Agreement will terminate.

16.6.2 [***].

(a) At Licensor's request delivered no later than [***] days after the effective date of termination, effective upon such effective date of termination of this Agreement, Licensee [***].

(b) LICENSOR AGREES AND ACKNOWLEDGES THAT [***] ITS AND THEIR SUBLICENSEE'S [***].

(c) [***].

(d) [***].

16.6.3 [***].

16.6.4 Right to Sell-Off. Licensee and its Affiliates and Sublicensees shall have the non-exclusive right to sell off any Product within their Control for a period not to exceed [***] months from the date of termination, subject to payment of all applicable Royalty obligations under Section 6.4.

16.6.5 Cooperation. Without limiting either Party's obligations under this Section 16.6, the Parties will reasonably cooperate to effect a smooth transition following the effective date of termination of this Agreement.

16.6.6 Continuation of Supply. [***].

16.6.7 [***].

16.6.8 [***].

16.6.9 Return of Confidential Information. [***], each Party will promptly destroy or return to the other Party all of such other Party's Confidential Information that was provided by or on behalf of such other Party hereunder that is in the possession or control of such Party (or any of its Affiliates), except that such Party will have the right to retain copies of Confidential Information of such other Party to the extent required for legal and archival purposes.

16.6.10 [***].

16.6.11 Dissolution of JSC. The JSC and, if applicable, any subcommittees it formed will be dissolved as of the effective date of such termination, provided that, for any surviving provisions requiring action or decision by the JSC or any such subcommittees or an Executive Officer, each Party

will appoint representatives to act as its JSC and subcommittee members or Executive Officer, as applicable.

16.6.12 Termination of Rights and Obligations. Except as set forth in this Section 16.6 and Section 16.9, as of the effective date of such termination, all rights and obligations of the Parties under this Agreement will terminate.

16.6.13 Future Assurances. Each Party will execute all documents, or cause to be executed all documents, and take, or cause to be taken, all such further actions as may be reasonably requested by the other Party in order to give effect to the foregoing clauses.

16.7 Effect of Termination by Licensee for Cause. Upon termination of this Agreement by Licensee pursuant to Section 16.2 or Section 16.3, which shall apply as a lead-in to each of the subsections of this Section 16.7 below:

16.7.1 Continuation of License. At Licensee's option, exercised by providing written notice to Licensor prior to the effective date of such termination (the exercise of which Licensee may revoke at any time thereafter by providing written notice to Licensor), the License and other rights of use or access granted by Licensor to Licensee under the Licensed Technology will remain in effect in accordance with their respective terms and become perpetual and irrevocable, subject to, (a) if Licensee terminates pursuant to Section 16.3, (i) Licensee's continued compliance with its diligence obligations set forth in Sections 4.1.2 and 5.1.2 and (ii) Licensee's continuing obligation to make milestone and royalty payments under Section 6 in the amounts payable as of the effective date of such termination (subject to any right of set-off under Section 6.5), or (b) [***], and, in each case of (a) and (b), to pay any payments owed to Licensor's licensors under any Upstream Agreements.

16.7.2 Return of Confidential Information. Except in the case of Licensee for any Confidential Information of Licensor that is the subject of its continuing license pursuant to Section 16.7.1, each Party will promptly destroy or return to the other Party all of such other Party's Confidential Information that was provided by or on behalf of such other Party hereunder that is in the possession or control of such Party (or any of its Affiliates), except that such Party will have the right to retain copies of Confidential Information of such other Party to the extent required for legal and archival purposes.

16.7.3 Dissolution of JSC. The JSC and, if applicable, any subcommittees it formed will be dissolved as of the effective date of such termination, provided that, for any surviving provisions requiring action or decision by the JSC or any such subcommittees or an Executive Officer, each Party will appoint representatives to act as its JSC and subcommittee members or Executive Officer, as applicable.

16.7.4 Termination of Rights and Obligations. Except as set forth in this Section 16.7 and Section 16.9, as of the effective date of such termination, all rights and obligations of the Parties under this Agreement will terminate.

16.7.5 Further Assurances. Licensor will execute all documents, or cause to be executed all documents, and take, or cause to be taken, all such further actions as may be reasonably requested by Licensee in order to give effect to the foregoing clauses.

16.8 Licensor's Insolvency. Except to the extent that Licensor is subject to a case under the Bankruptcy Code and the following conflicts with Section 365(n) of the Bankruptcy Code, upon Licensor entering into any voluntary or involuntary bankruptcy, insolvency or restructuring proceeding during the Term of this Agreement, and notwithstanding any attempted termination of this Agreement by any trustee, administrator or executor of Licensor or an applicable bankruptcy court: (i) all rights and licenses herein granted to Licensee shall continue in full force and effect in perpetuity provided Licensee continues to comply with its diligence obligations set forth in Sections 4.1.2 and 5.1.2 and to pay any milestone

payments and Royalties otherwise due hereunder (subject to any right of set-off hereunder); and (ii) Licensor shall have, to the extent required by applicable bankruptcy laws in order to maintain Licensee' license rights hereunder, no further obligations under this Agreement other than to not interfere with Licensee's license rights hereunder. The Parties agree that the terms of this Agreement are fair and reasonable and have been negotiated in an arms-length transaction between unrelated parties with each Party represented by legal counsel. If any provision herein is deemed onerous or otherwise unenforceable by any applicable bankruptcy court, the Parties shall use good faith efforts to amend the Agreement (*e.g.*, removing such onerous provision) so as to avoid any consequences thereof under applicable bankruptcy laws.

16.9 Survival. In addition to any provisions expressly stated to survive expiration or early termination of this Agreement and except as expressly provided herein, Sections 1, 2.2.2 through 2.2.14 (in each case of 2.2.2 through 2.2.14 solely in case of Licensee electing to retain the License pursuant to Section 16.7.1 [***]), 2.3 (solely in case of Licensee electing to retain the License pursuant to Section 16.7.1), 2.6 (solely in case of Licensee electing to retain the License pursuant to Section 16.7.1), 2.8 (except in the case of termination by Licensor pursuant to Section 16.2, 16.3 or 16.4 or by Licensee pursuant to Section 16.5, and in each case following expiry of the period set forth in Section 16.6.4), 2.9, 2.11 [***], 4.3.6 (only until the expiry of the period required by applicable Law), 4.3.9 (only until the expiry of the period required by applicable Law), 6.6, 6.7, 7 (only to the extent stated therein with respect to Section 7.1 and 7.2), 8.4 (solely in case of Licensee electing to retain the License pursuant to Section 16.7.1), 8.6 (until the longer of the expiry of the period required by applicable Law and the expiry or earlier termination of the Safety Agreement), 8.7, 9.1 and 9.2 (in each case 9.1 and 9.2 solely: (i) [***], or (ii) in case of Licensee electing to retain the License pursuant to Section 16.7.1), 9.4 (only in the case of (i) expiration of this Agreement or (ii) Licensee electing to retain the License pursuant to Section 16.7.1 and for each ((i) and (ii)) in respect of pending or contemplated (at the time of such expiration or termination) litigation), 9.5 (only in the case of (i) expiration of this Agreement Licensee electing to retain the License pursuant to Section 16.7.1 and (ii) in respect of pending Third Party Infringement Claims), 9.6 (only in the case of Licensee electing to retain the License pursuant to Section 16.7.1), 9.7, 9.8 (only in the case of Licensee electing to retain the License pursuant to Section 16.7.1), 9.10, 10, (only to the extent stated therein), 11, 13.4.8 (only to the extent stated therein), 14, 15, 16.6, 16.7, 16.8, 16.9, 17 and 19, and Section 6 (to the extent any accrued rights to payment arose prior to, or are intended to, survive any expiration or early termination of this Agreement).

17. DISPUTE RESOLUTION

17.1 Governing Law. This Agreement shall be governed by and construed in accordance with the applicable Laws of the State of New York, excluding any conflicts or choice of applicable Laws rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive applicable Laws of another jurisdiction.

17.2 Dispute Resolution.

17.2.1 Resolution by Executive Officers. Subject to Section 19.6 and except as otherwise expressly set forth in this Agreement, including Section 3.2, in the event of any disagreement, controversy, dispute or claim arising out of, in connection with, or in relation to the interpretation, performance, or alleged breach of this Agreement (the "Dispute"), prior to instituting any proceeding on account of such Dispute, the Parties shall attempt in good faith to settle such Dispute first by referral of such matters to the JSC. After attempted resolution of any Dispute by the JSC in accordance, the Dispute shall be referred to the Executive Officers of the Parties in writing by either Party, who will use good faith efforts to resolve such matter within [***] days after the JSC's submission of such matter to such Executive Officers, which good faith efforts will include at least one (1) meeting between such Executive Officers within [***] Business Days after such submission. Any final decision mutually agreed to by the Executive Officers shall be set forth in writing and be conclusive and binding on the Parties. In the

event said Executive Officers are unable to resolve such Dispute or agree upon a mechanism to resolve such Dispute within [***] days of the first written request for dispute resolution under this Section 17.2.1, then the Parties shall resolve all such Disputes in accordance with Section 17.2.2.

17.2.2 Litigation. Except in relation to a matter expressly stated to be referred to Expedited Arbitration hereunder, any unresolved Dispute that was subject to Section 17.2.1 shall be brought exclusively in a court of competent jurisdiction, federal or state, located in New York, New York, and in no other jurisdiction.

17.2.3 Jurisdiction; Waiver of Trial by Jury. Subject to Section 19.6, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE THEIR RIGHT TO A JURY TRIAL IN CONNECTION WITH ANY LITIGATION ARISING OUT OF OR RELATING TO THIS PARTICIPATION AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

17.2.4 Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or in the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

17.2.5 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 19.8 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

17.2.6 Confidentiality. Any and all non-public activities conducted under Section 17.2, including any and all non-public proceedings and decisions under Section 17.2.2, shall be deemed Confidential Information of each of the Parties, and shall be subject to the terms of Section 10.

17.2.7 Expedited Arbitration. If a Party exercises its rights under this Agreement to refer a Dispute to expedited arbitration (an "Expedited Dispute"), then the Parties will follow the expedited dispute resolution process in this Section 17.2.7 (and not the dispute resolution process in Section 17.2.1 of this Agreement) ("Expedited Arbitration"). The Parties agree and acknowledge that any good faith dispute under Expedited Arbitration will not be deemed to be a material breach of this Agreement. The Expedited Dispute will be submitted to fast track, binding arbitration in accordance with the following:

(a) An Expedited Arbitration shall be administered by the American Arbitration Association ("AAA") in accordance with its International Arbitration Rules, as amended by this Section 17.2.7, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The place of arbitration shall be New York, New York. The award shall be rendered within [***] Business Days after the appointment of the arbitrator, unless the arbitrator determines that the interest of justice requires that such limit be extended. The language of the arbitration shall be English. There shall be one (1) arbitrator. If the Parties are unable to agree on an arbitrator within [***] Business Days from the initiation of the arbitration, then the Parties will request that the AAA select the arbitrator. The arbitrator shall have at least ten (10) years of experience in disputes involving the pharmaceutical and life sciences industries, including the valuation of biopharmaceutical intellectual property and the conduct of research, development, and commercialization collaborations. The cost of the arbitration will be borne equally by the Parties, and each Party shall bear its own costs

and attorney's and witnesses' fees and associated costs and expenses. Except in a proceeding to enforce the results of the arbitration or as otherwise required by applicable Laws, neither Licensee nor Licensor nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written agreement of Licensee and Licensor.

(b) Within [***] Business Days after the appointment of the arbitrator, each Party will provide the arbitrator with a proposal and written memorandum in support of its position regarding the Expedited Dispute, as well as any documentary evidence it wishes to provide in support thereof (not to exceed thirty (30) pages) (each a "Proposal") and the arbitrator will provide each Party's Proposal to the other Party after it receives it from both Parties.

(c) Within [***] Business Days after a Party submits its Proposal, the other Party will have the right to submit a rebuttal memorandum (not to exceed fifteen (15) pages), if any, to the arbitrator and the other Party. If requested by the arbitrator, the Parties will make oral submissions to the arbitrator based on such Party's Proposal.

(d) Within [***] Business Days after the receipt by the arbitrator of both Parties' written submissions (or expiration of the [***] Business Day period if any Party fails to submit a response), the arbitrator will issue a final award in writing, stating its reasoning, provided that the arbitrator will select one of the Parties' Proposals. The decision of the arbitrator will be the sole, exclusive, binding and non-appealable remedy between them regarding the dispute referred to Expedited Arbitration.

17.2.8 Tolling. The Parties agree that all applicable statutes of limitation and time based defenses (such as estoppel and laches), as well as all time periods in which a Party must exercise rights or perform obligation hereunder, will be tolled once the dispute resolution procedures set forth in this Section 17.2 have been initiated and for so long as they are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result. In addition, during the pendency of any Dispute under this Agreement initiated before the end of any applicable cure period, including under Section 16.2, (a) this Agreement will remain in full force and effect, (b) the provisions of this Agreement relating to termination for material breach with respect to such Dispute will not be effective, (c) the time periods for cure under Section 16.2 as to any termination notice given prior to the initiation of arbitration will be tolled, (d) any time periods to exercise rights or perform obligations will be tolled, and (e) neither Party will issue a notice of termination pursuant to this Agreement based on the subject matter of the arbitration, until the arbitral tribunal has confirmed the material breach and the existence of the facts claimed by a Party to be the basis for the asserted material breach; provided that if such breach can be cured by (i) the payment of money, then the defaulting Party will have an additional [***] calendar days within its receipt of the arbitral tribunal's decision to pay such amount, or (ii) the taking of specific remedial actions, then the defaulting Party will have a reasonably necessary period to diligently undertake and complete such remedial actions within such reasonably necessary period or any specific timeframe established by such arbitral tribunal's decision before any such notice of termination can be issued. Further, with respect to any time periods that have run during the pendency of the Dispute, the applicable Party will have a reasonable period of time or any specific timeframe established by such arbitral tribunal's decision to exercise any rights or perform any obligations affected by the running of such time periods.

18. HSR FILINGS AND CLOSING

18.1 HSR Filings. If required by Applicable Laws, after the execution of this Agreement, both Parties shall promptly, and in no less than [***] Business Days, file, the appropriate notices under the Hart Scott Rodino Antitrust Improvements Act ("HSR Act"). The Parties shall promptly make required filings to obtain clearance under the HSR Act for the consummation of this Agreement and the transactions contemplated hereby, use reasonable efforts to obtain such clearance, and shall keep each other apprised of the status of any communications with, and any inquiries or requests for additional information from, the United States' Federal Trade Commission ("FTC") and Department of Justice ("DOJ") and shall

comply promptly with any such inquiry or request; provided, however, neither Party shall be required to consent to the divestiture or other disposition of any of its assets or the assets of its Affiliates or to consent to any other structural or conduct remedy, and each Party and its Affiliates shall have no obligation to contest, administratively or in court, any ruling, order or other action of the FTC or DOJ or any Third Party with respect to the transactions contemplated by this Agreement. Each Party shall be responsible for paying its own costs and expenses (including legal and consultants' fees) incurred in connection with obtaining clearance of the transactions contemplated hereby from the FTC and the DOJ [***]. Each of the Parties hereto will furnish to the other such necessary information and reasonable assistance as the other may request in connection with the preparation of any required filings or submissions and will cooperate in responding to any inquiry from the FTC or DOJ and to any requests for additional information at the earliest practicable date, including promptly informing the other Party of such inquiry, consulting in advance before making any presentations or submissions to the FTC or DOJ, and supplying each other with copies of all material correspondence, filings or communications between either party and either the FTC or DOJ with respect to this Agreement. Such information can be shared on an outside counsel basis or subject to other restrictions to the extent deemed necessary or advisable by counsel for the disclosing Party. To the extent practicable and as permitted by the FTC or DOJ, each Party hereto shall permit representatives of the other Party to participate in material substantive meetings (whether by telephone or in person) with the FTC or DOJ. Neither Party shall commit to or agree with the FTC or DOJ to withdraw its filing and refile under the HSR Act without the prior written consent of the other (such consent not to be unreasonably withheld, conditioned or delayed). In the event the Parties determine that HSR filings are required, the Effective Date shall not be deemed to have occurred and this Agreement (other than this Section 18 and Section 10) shall not be binding until the HSR Clearance Date. Notwithstanding any other provisions of this Agreement to the contrary, either Party may terminate this Agreement effective upon notice to the other Party if the HSR Clearance Date has not occurred on or before the date that is one hundred and eighty (180) days after the Parties make their respective HSR filings.

19. MISCELLANEOUS

19.1 No Benefit to Third Parties. Except under Section 14, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

19.2 Relationship of the Parties. It is expressly agreed that Licensor, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship between the Parties under this Agreement shall not constitute a partnership, joint venture or agency. Neither Licensor, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other Party without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

19.3 Unenforceability. If any provision of this Agreement is held or determined to be illegal, invalid, void or unenforceable under any present or future applicable Laws by a final decision of a court of competent jurisdiction on the merits from which no appeal can be taken, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, void or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, void or unenforceable provision or by its severance therefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid, void or unenforceable provision as may be possible and reasonably acceptable to the Parties.

19.4 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Laws or otherwise available except as expressly set forth herein.

19.5 Assignment; Securitization.

19.5.1 Assignment.

(a) Except as expressly provided hereunder, neither Party may assign, delegate or otherwise transfer this Agreement or its rights and obligations hereunder except with the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either Party shall have the right to assign this Agreement (in whole or in part) without the other Party's prior written consent to any of its Affiliates, successors in interest or acquirers of all or substantially all of its assets relating to the Licensed Technology or the Product, including any successor in interest by way of any merger, sale of assets, reincorporation or other reorganization; provided that such Affiliate, successor in interest or acquirer assumes in writing all of such Party's obligations under this Agreement or part hereof. An assignment to an Affiliate shall terminate, and all rights so assigned will revert to the assigning Party, if and when such Affiliate ceases to be an Affiliate of the assigning Party.

(b) Licensor covenants and agrees that it shall not assign any of the Licensed Technology to any Third Party unless the obligations under this Agreement are also assigned to and assumed by such Third Party in writing and, absent a novation agreed and executed by the Parties, the assigning Party shall continue to be liable to the non-assigning Party for any breaches of this Agreement by the Affiliate, successor in interest or acquirer.

(c) Any attempted assignment, delegation or transfer of this Agreement or any rights or obligations hereunder by either Party without the prior written consent of the other Party, other than in accordance with this Section 19.5.1, shall be void and of no effect. Subject to the preceding sentence, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns, provided that the assigning Party shall remain responsible for all of its obligations hereunder notwithstanding any such assignment.

19.5.2 Securitization. Notwithstanding anything to the contrary in this Section 19.5 or elsewhere in this Agreement, Licensor may assign to a Third Party which is not in the business of exploiting pharmaceutical products the right to receive the milestone payments under Sections 6.2 and 6.3 and the Royalty payments under Section 6.4 (such assignment, a "Securitization Transaction") without the prior written consent of Licensee, provided that upon making such assignment: (a) such Third Party shall not have any rights or benefits directly under this Agreement, including any right to directly enforce its terms with Licensee; (b) Licensee shall have no obligation to pay amounts due hereunder to more than one Person, (c) Licensee's right pursuant to Section 19.4 to waive the terms of this Agreement will not be subject to the consent of such Third Party, and (d) Licensor shall as soon as reasonably practicable following the completion of such Securitization Transaction provide Licensor with a copy of the agreement executed by Licensor with the relevant Third Party (which copy may be redacted to remove provisions which are not necessary to ensure compliance with this Section 19.5.2). In connection with a contemplated or consummated Securitization Transaction, Licensor may disclose to such Third Party the royalty reports contemplated under Section 6.6 and, to the extent milestone payments are proposed to be included in the Securitization Transaction, the notices on achievement of Development Milestone Events contemplated

under Section 6.2, without the prior written consent of Licensee, to the extent reasonably necessary to enable such Third Party to evaluate the Securitization Transaction opportunity and to allow such Third Party to exercise its rights with respect to such Securitization Transaction (provided that such Third Party is under obligations of confidentiality and non-use with respect to Confidential Information included in such reports that are no less stringent than the terms of Section 10).

19.6 Injunctive Relief. Each of the Parties agrees that if certain obligations under this Agreement are not performed in accordance with their specific terms or are otherwise breached, (a) severe and irreparable damage would occur, (b) no adequate remedy at law would exist, and (c) damages would be difficult to determine. Each of the Parties agrees that, in such case, the injured Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, as well as any other relief permitted by applicable law, and the breaching Party hereby waives: (i) any requirement that such Party post bond as a condition for obtaining any such relief and (ii) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

19.7 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

19.8 Notices. Every notice, election, demand, consent, request, approval, report, offer, acceptance, certificate, or other communication required or permitted under this Agreement or by applicable Law shall be in writing and shall be deemed to have been delivered and received (a) when personally delivered, (b) on the fifth (5^{th}) Business Day after which sent by registered or certified mail, postage prepaid, return receipt requested, (c) on the date on which transmitted by email as a PDF attachment (with transmission confirmed) (provided that, on that same date, a copy of such notice is sent by registered or certified mail, postage prepaid, return receipt requested), or (d) on the third (3^{rd}) Business Day after the Business Day on which deposited with a regulated public carrier (e.g., Federal Express) for overnight delivery (receipt verified), freight prepaid, addressed to the Party for whom intended at the mailing address or email set forth below, or such other mailing address or facsimile number, notice of which is given in a manner permitted by this Section 19.8.

For Licensor:

Selecta Biosciences Inc.

65 Grove Street
Watertown, MA 02472
Attn: General Counsel
[***]

With a copy to (which shall not constitute notice):

Gibson, Dunn & Crutcher LLP
555 Mission Street
San Francisco, CA 94105
Attention: Ryan Murr and Karen Spindler
[***]

For Licensee:

Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm, Sweden
Attn: General Counsel
[***]

With a copy to (which shall not constitute notice):

Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92130
[***]

19.9 Force Majeure. If and to the extent that either Party is prevented, delayed or materially hindered by a Force Majeure Event from performing any of its obligations under this Agreement and promptly so notifies the other Party, specifying the matters constituting the Force Majeure Event, then the Party so affected shall be relieved of liability to the other for failure to perform or for delay in performing such obligations (as the case may be), but shall nevertheless use Commercially Reasonable Efforts to resume full performance thereof. The affected Party shall undertake Commercially Reasonable Efforts necessary to cure or to mitigate the effects of such Force Majeure Event. In addition, neither Licensor nor Licensee shall be obligated to make any payments for any part of any services not performed as a result of any Force Majeure Event.

19.10 Headings. The captions to the Sections hereof are not a part of this Agreement and shall not be used to inform interpretation of this Agreement, but are merely guides or labels to assist in locating and reading the several Sections hereof.

19.11 Set Off. Notwithstanding anything to the contrary in this Agreement, Licensee shall have a right to set-off any Royalties or other amounts due under this Agreement to Licensor against any damages incurred by Licensee and/or its Affiliates and awarded pursuant to an Order relating to Licensor's breach of this Agreement.

19.12 Costs and Expenses. Except as otherwise expressly set forth in this Agreement, each Party shall bear its own costs and expenses in performing its obligations under this Agreement.

19.13 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

19.14 Amendment. No amendments, changes, modifications, supplementation, waivers or alterations of the terms and conditions of this Agreement shall be binding upon either Party hereto unless in writing and executed by both Parties.

19.15 Counterparts. This Agreement may be executed in counterparts and each such counterpart shall be deemed an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

19.16 Entire Agreement. This Agreement, together with the Annexes and Schedules hereto and the other agreements and documents delivered in connection with the transactions contemplated hereby, contain the entire understanding between the Parties relating to the subject matter hereof and

supersedes any and all prior agreements, understandings and arrangements, whether written or oral, between the Parties hereto relating to such subject matter and to the extent relating to the Products.

[*SIGNATURE PAGE FOLLOWS*]

IN WITNESS WHEREOF, the Parties hereto have executed this **LICENSE AND DEVELOPMENT AGREEMENT** as of the Execution Date.

SELECTA BIOSCIENCES INC.

By:	/s/ Carsten Brunn, Ph.D.
Name:	Carsten Brunn, Ph.D.
Title:	*President and Chief Executive Officer*

SWEDISH ORPHAN BIOVITRUM AB (PUBL)

By:	/s/ Guido Oelkers
Name:	Guido Oelkers
Title:	*CEO*

By:	/s/ Torbjörn Hallberg
Name:	Torbjörn Hallberg
Title:	*General Counsel*

[***]

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Exhibit 10.3

STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "Agreement"), dated as of June 11, 2020, is entered into by and between Selecta Biosciences, Inc., a Delaware corporation (the "Company"), and Swedish Orphan Biovitrum AB (publ), a Swedish public limited liability company (the "Purchaser").

RECITALS

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to an exemption from the registration requirements of Section 5 of the Securities Act of 1933, as amended (the "Securities Act") contained in Section 4(a)(2) thereof and/or Regulation D promulgated thereunder, the Company desires to issue and sell to the Purchaser, and the Purchaser desires to purchase from the Company, 5,416,390 shares (the "Shares") of the Company's common stock, par value $0.0001 per share (the "Common Stock").

WHEREAS, in connection with the consummation of the purchase and sale of the Shares, the Company and the Purchaser shall execute and deliver the Registration Rights Agreement, in the form attached hereto as Appendix II (the "Registration Rights Agreement").

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Purchaser agree as follows:

SECTION 1. DEFINITIONS

In addition to the terms defined elsewhere in this Agreement, the following terms have the meanings set forth in this Section 1:

"Affiliate" means, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. For the purposes of this Agreement, in no event shall the Purchaser or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Purchaser or any of its Affiliates.

"Business Day" means any day except Saturday, Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in New York City are authorized or required by law or other governmental action to close.

"Change of Control" means, with respect to a Person, any of the following events: (i) any other Person is or becomes the beneficial owner (as such term is defined in Rule 13d-3 under the Exchange Act, except that a Person shall be deemed to have beneficial ownership of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately

or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all shares of such Person's outstanding capital stock; (ii) such Person consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into such Person, other than (A) a merger or consolidation which would result in the voting securities of such Person outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of such Person or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of such Person (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of a majority of the total voting power of all shares of capital stock of such Person, or (iii) such Person conveys, transfers or leases all or substantially all of its assets, to any Person other than a wholly owned Affiliate of such Person.

"Closing" means the purchase and sale of the Shares pursuant to this Agreement.

"Closing Date" means the Trading Day when all of the Transaction Documents and the License Agreement have been executed and delivered by the applicable parties thereto, and all of the conditions set forth in Section 2, Section 3 and Section 6 hereof are satisfied or waived, as the case may be, or such other date as the parties may agree, provided that in no event shall the Closing Date be earlier than July 1, 2020.

"Closing Purchase Amount" means the aggregate amount to be paid for the Shares purchased hereunder as set forth on Exhibit A hereto in United States Dollars and in immediately available funds.

"Commission" means the U.S. Securities and Exchange Commission.

"Common Stock" has the meaning set forth in the recitals to this Agreement.

"Common Stock Equivalents" means any securities of the Company which would entitle the holder thereof to acquire at any time shares of Common Stock, including, without limitation, any debt, preferred shares, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, shares of Common Stock.

"Company" has the meaning set forth in the recitals to this Agreement.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

"Intellectual Property" means all patents, patent applications, trademarks, trademark applications, service marks, trade names, copyrights, trade secrets, licenses, domain names, information and proprietary rights and processes.

"License Agreement" means the license agreement, dated as of June 11, 2020, by and between the Company and Purchaser.

"Material Adverse Effect" means a material adverse effect on (i) the assets, liabilities, results of operations, financial condition or business of the Company and its subsidiaries taken as a whole, (ii) the legality or enforceability of any of the Transaction Documents or (iii) the ability of the Company to perform its obligations under the Transaction Documents; provided, however, that in no event shall any of the following occurring after the date hereof, alone or in combination, be deemed to constitute, or be taken into account in determining whether a Material Adverse Effect has occurred: (1) changes or conditions generally affecting the industries in which the Company operates, or the economy or the financial, debt, banking, capital, credit or securities markets, in the United States, including effects on such industries, economy or markets resulting from any regulatory and political conditions or developments in general, (2) the outbreak or escalation of war or acts of terrorism or any natural disasters, acts of God or comparable events, epidemic, pandemic or disease outbreak (including the COVID-19 virus), (3) changes in applicable law or GAAP, or the interpretation or enforcement thereof after the date of this Agreement, or (4) any change, in and of itself, in the market price or trading volume of the Company's securities (it being understood that the facts or occurrences giving rise to or contributing to such change may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a Material Adverse Effect, to the extent permitted by this definition and not otherwise excepted by a clause of this proviso).

"Nasdaq Stock Market" means The Nasdaq Global Market or such other tier of Nasdaq on which the Common Stock is listed or quoted for trading on the date in question.

"Per Share Purchase Price" has the meaning set forth in Section 2.1.

"Person" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein, including any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"Permitted Transferee" means an Affiliate of the Purchaser that is owned, directly or indirectly, by the Purchaser; it being understood that for purposes of this definition "owned" shall mean an Affiliate in which the Purchaser owns, directly or indirectly, at least fifty percent (50%) of the outstanding capital stock or ownership interests of such Affiliate.

"Registration Rights Agreement" has the meaning set forth in the recitals to this Agreement.

"SEC Documents" has the meaning set forth in Section 4.5.

"Securities Act" has the meaning set forth in the recitals to this Agreement.

"Shares" has the meaning set forth in the recitals to this Agreement.

"Short Sales" means, all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include the location and/or reservation of borrowable shares of Common Stock).

"Third Party" shall mean any Person (other than a governmental authority) other than the Purchaser, the Company or any Affiliate of the Purchaser or the Company.

"Trading Day" means a day on which the Common Stock is listed or quoted and traded on the Nasdaq Stock Market.

"Transaction Documents" means this Agreement and the Registration Rights Agreement, all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer" means any (i) offer, pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock or Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (ii) swap, hedge, derivative instrument, or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock or Common Stock Equivalents, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

SECTION 2. PURCHASE AND SALE OF THE SHARES

2.1 **Purchase and Sale.** On the Closing Date, upon the terms and subject to the conditions set forth herein, the Company will issue and sell to the Purchaser, and the Purchaser will purchase, the number of Shares set forth on Exhibit A attached hereto, at a price per Share equal to $4.6156 (the "Per Share Purchase Price").

2.2 **Compliance with Rules of Principal Market.** The Company shall not issue any Shares pursuant to this Agreement if such issuance would reasonably be expected to result in (i) a violation of the Securities Act or (ii) a breach of the rules and regulations of the Nasdaq Stock Market.

2.3 **Adjustments for Stock Dividends and Splits.** In the event of any stock dividend, stock split, combination or other similar recapitalization affecting the Common Stock after the effectiveness of this Agreement and prior to the Closing, as the case may be, the number of shares of Common Stock to be sold to the Purchaser in the Closing and the Per Share Purchase Price shall be appropriately adjusted and Exhibit A attached hereto shall be updated accordingly.

SECTION 3. CLOSING AND DELIVERY.

3.1 **Closing.**

(a) Subject to the terms and conditions set forth herein, the Closing of the purchase and sale of the Shares shall take place at the offices of Latham & Watkins LLP, 650 Town Center Drive, 20th Floor, Costa Mesa, CA 92626, on the Closing Date or at such other locations or remotely by facsimile transmission or other electronic means as the parties may mutually agree.

(b) On the Closing Date, the Purchaser shall deliver or cause to be delivered to the Company the Closing Purchase Amount via wire transfer of immediately available funds pursuant to the wire instructions delivered to the Purchaser by the Company on or prior to the Closing Date.

3.2 **Issuance and Delivery.**

(a) On the Closing Date, the Company shall issue and deliver, or cause to be delivered, to the Purchaser, subject to adjustment as provided in Section 2.3, evidence satisfactory to the Purchaser of book-entry Shares registered in the name of the Purchaser, in an amount equal to the number of Shares set forth on Exhibit A attached hereto.

(b) The name in which the Shares are to be issued to the Purchaser is set forth in the Stockholder Notice and Questionnaire in the form attached hereto as Appendix I (the "Selling Stockholder Questionnaire"), which shall be provided to the Company no later than the date hereof.

3.3 **Delivery of the Registration Rights Agreement and License Agreement.** On or before the date hereof, the Company and the Purchaser shall execute and deliver (i) the Registration Rights Agreement, pursuant to which the Company will agree to provide certain registration rights in respect of the resale by the Purchaser of the Shares under the Securities Act, and the rules and regulations promulgated thereunder, and (ii) the License Agreement.

SECTION 4. REPRESENTATIONS AND WARRANTIES OF THE COMPANY.

Except as set forth on the Schedule of Exceptions delivered to the Purchaser concurrently with the execution of this Agreement (the "Schedule of Exceptions") (it being agreed that disclosure of any item in any part or subpart of the Schedule of Exceptions shall be deemed disclosure with respect to any other part or subpart to which the relevance of such item is reasonably apparent) or as otherwise described in the SEC Documents (as defined below), which qualify these representations and warranties in their entirety, the Company hereby represents and warrants, as of the date hereof and the Closing Date (except for the representations and warranties that speak as of a specific date, which shall be made as of such date), as follows:

4.1 **Organization.** The Company and each of its subsidiaries are duly organized, validly existing as a corporation or other legal entity and in good standing (or the foreign equivalent thereof) under the laws of their respective jurisdictions of organization. The Company and each of its subsidiaries are duly licensed or qualified as a foreign corporation or other legal entity for transaction of business and in good standing under the laws of each other jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate power and authority necessary to own or hold their respective properties and to conduct their respective businesses in which they are engaged as described in the SEC Documents (as defined below), except where the failure to be so qualified or in good standing or have such power or authority would not have or would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

4.2 **Subsidiaries.** Except as set forth in the SEC Documents, the Company owns, directly or indirectly, all of the equity interests in each of its subsidiaries free and clear of any lien, charge, security interest, encumbrance, right of first refusal or other restriction, and all the equity interests of the subsidiaries are validly issued and are fully paid, nonassessable and free of preemptive and similar rights.

4.3 **Corporate Power; Authorization.** The Company has all requisite corporate power, and has taken all requisite corporate action, to execute and deliver the Transaction Documents, sell and issue the Shares as contemplated by the Transaction Documents and carry out and perform all of its obligations under the Transaction Documents. Each Transaction Document constitutes the legal, valid and binding obligation of the Company and, assuming due execution and delivery by each of the other parties thereto, enforceable in accordance with its terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification provisions of the Registration Rights Agreement may be limited by federal or state securities laws, rules, regulations, or public policy considerations in respect thereof.

4.4 **Issuance and Delivery of the Shares.** The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of any pledge, lien, encumbrance, security interest or other claim, including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights, except for restrictions on transfer set forth in the Transaction Documents or imposed by applicable securities laws, and, assuming the accuracy of the representations made by the Purchaser in Section 5, will be delivered in compliance with all applicable federal and state securities laws. Assuming the accuracy of the representations made by the Purchaser in Section 5, the offer and sale by the Company of the Shares is exempt from registration under the Securities Act.

4.5 **SEC Documents.** The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the one year preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the "SEC Documents"). At the time of filing thereof, the SEC Documents complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as applicable, and, as of their respective dates, did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading.

4.6 **Financial Statements.** The financial statements of the Company, together with the related notes and any supporting schedules thereto, included in the SEC Documents (the "Financial Statements") present fairly, in all material respects, the consolidated financial condition, results of operations and cash flows of the Company and each of its subsidiaries as of and at the dates indicated and the results of their operations and cash flows for the periods specified as of the dates and for the periods indicated. The Financial Statements and any supporting schedules have been prepared in conformity with generally accepted accounting principles as applied in the United States ("GAAP") applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. Ernst & Young LLP, who have audited certain financial statements of the Company included in or incorporated by reference into the SEC Documents, is an independent registered public accounting firm with respect to the Company within the meaning of Article 2-01 of Regulation S-X and the Public Company Accounting Oversight Board (United States).

4.7 **Capitalization.** The authorized capital stock of the Company consists of 200,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, par value $0.0001 (the "Preferred Stock"). There are no other shares of any other class or series of capital stock of the Company issued or outstanding. The Company has not issued any capital stock since the date of its most recently filed SEC Document other than to reflect stock option and warrant exercises and vesting of restricted stock units that do not, individually or in the aggregate, have a material effect on the issued and outstanding capital stock, options and other securities. As of March 31, 2020, there were (i) 87,019,172 shares of the Company's Common Stock issued and outstanding and no shares of the Preferred Stock issued and outstanding; (ii) options to purchase 7,745,936 shares of the Company's Common Stock outstanding; (iii) 170,313 unvested restricted stock units and (iv) warrants to purchase 31,426,248 shares of the Company's Common Stock outstanding. Except as stated above, there are no existing options, warrants, calls, subscriptions or other rights, agreements, arrangements or commitments relating to the issued or unissued capital stock of the Company, obligating the Company to issue, transfer, sell, redeem, purchase, repurchase or otherwise acquire or cause to be issued, transferred, sold, redeemed, purchased, repurchased or otherwise acquired any capital stock of the Company or securities or rights convertible into or exchangeable for such shares or equity interests or obligations of the Company to grant, extend or enter into any such option, warrant, call, subscription or other right, agreement, arrangement or commitment. Except as provided in the Registration Right Agreement, the issuance of Shares pursuant to any provision of this Agreement will not give rise to any preemptive rights or rights of first refusal on behalf of any Person or result in the triggering of any anti-dilution rights, and, other than as set forth in the SEC Documents, there are no agreements or arrangements under which the Company or any of its subsidiaries is obligated to register the sale of any of their securities under the Securities Act, in each case except as have been duly and validly waived.

4.8 **Litigation.** There are no actions, suits or proceedings by or before any governmental authority pending, nor, to the Company's knowledge, any audits or investigations by or before any governmental authority, to which the Company or a subsidiary is a party or to which any property of the Company or any of its subsidiaries is the subject that, individually or in the aggregate, if determined adversely to the Company or any of its subsidiaries, would have a Material Adverse Effect and, to the Company's knowledge, no such actions, suits, proceedings, audits or investigations are threatened or contemplated by any governmental authority or threatened by others. There are no current or pending audits, investigations, actions, suits or proceedings by or before any governmental authority that are required under the Securities Act to be described in the SEC Documents that are not so described.

4.9 **Consents.** No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state, or local governmental authority on the part of the Company is required in connection with the consummation of the transactions contemplated by the Transaction Documents except for (a) the filing of a Form D with the Commission under the Securities Act, (b) the approval by the Nasdaq Stock Market of the listing of the additional shares, (c) the filing of one or more registration statements and all amendments thereto with the Commission as contemplated by the Registration Rights Agreement or (d) where failure to obtain such consents, approval or authorizations, or to make such filings, would not impair the ability of the Company to issue and sell the Shares or to consummate the transactions contemplated by this Agreement.

4.10 **No Violation or Default.** Neither the execution, delivery nor performance of the Transaction Documents by the Company nor the consummation of any of the transactions contemplated thereby (including, without limitation, the issuance and sale by the Company of the Shares) conflict with, result in a breach or violation of, or imposition of, or constitute a default or a Debt Repayment Triggering Event (as defined below) under, or result in the imposition of any lien, charge or encumbrance

upon any property or assets of the Company or each of its subsidiaries pursuant to, (i) the charter, by-laws or similar organizational documents of the Company or each of its subsidiaries, (ii) any statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Company or any of its subsidiaries or any of their properties (including, without limitation, the U.S. Food and Drug Administration ("FDA")), or (iii) any agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the properties of the Company or any of its subsidiaries is subject, except in the case of each of clauses (ii) and (iii), where such breaches, violations, defaults, liens, charges or encumbrances would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. A "Debt Repayment Triggering Event" means any event or condition that gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture, or other evidence of indebtedness (or any Person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

4.11 **No Material Adverse Change.** Since March 31, 2020, except as specifically set forth in a subsequent SEC Documents, there has not been:

(a) any material change in the authorized capital, assets, liabilities, financial condition, business or operations of the Company and its subsidiaries taken as a whole from that reflected in the financial statements included in the Company's most recently filed SEC Document;

(b) any declaration or payment by the Company of any dividend, or any authorization or payment by the Company of any distribution, on any of the capital stock of the Company, or any redemption or repurchase by the Company of any securities of the Company;

(c) any change or amendment to the Company's certificate of incorporation or by-laws, or material change to any material contract or arrangement by which the Company is bound or to which any of its assets or properties is subject;

(d) any action taken by the Company or a subsidiary of the Company to seek protection pursuant to any law or statute relating to bankruptcy, insolvency, reorganization, receivership, liquidation or winding up, nor does the Company have any knowledge that any of the creditors of the Company or a subsidiary of the Company intend to initiate involuntary bankruptcy proceedings, nor has the Company or any subsidiary of the Company received any notice from any such creditor threatening any such action;

(e) any material transaction entered into by the Company other than in the ordinary course of business;

(f) the loss of the services of any executive officer (as defined in Rule 405 under the Securities Act) of the Company;

(g) any material change in the Company's accounting policies or in the Company's internal controls over financial reporting; or

(h) any other event or condition of any character that has had or would reasonably be expected to have a Material Adverse Effect.

4.12 **Intellectual Property.** The Company and its subsidiaries own, possess, license or have other rights to use, the patents and patent applications, copyrights, trademarks, service marks, trade names, service names and trade secrets as necessary or material for use in connection with its businesses

as described in the SEC Documents (collectively, the "Intellectual Property Rights"), and to the Company's knowledge, there are no material liens, security interests or encumbrances that have been filed against any of these Intellectual Property Rights. No actions, suits, proceedings or claims are pending, or to the Company's knowledge, asserted or threatened against the Company or its subsidiaries alleging infringement of a patent or other intellectual property right of others. To the Company's knowledge, there is no existing infringement by another Person of any of the Intellectual Property Rights that would materially affect the use thereof by the Company. To the Company's knowledge, the Company is not liable for infringement with respect to any of the Company's product candidates. To the Company's knowledge, the development, manufacture, sale, and any currently proposed use of any of the products, proposed products or processes of the Company referred to in the SEC Documents, in the current or proposed conduct of the business of the Company, do not currently, and will not upon commercialization, to the Company's knowledge, infringe any right or valid patent claim of any third party. To the Company's knowledge, there are no ownership rights of third parties to any Intellectual Property Rights in any field of use that is exclusively licensed to the Company, other than any licensor to the Company of such Intellectual Property Rights. To the Company's knowledge, no action, suit, claim or other proceeding, except for routine patent and trademark prosecution proceedings in patent offices throughout the world, is pending or threatened challenging the validity, enforceability, scope, registration, ownership or use of any of the Intellectual Property Rights. To the Company's knowledge, no action, suit, claim or other proceeding is pending or threatened, challenging the Company's rights in or to any Intellectual Property Rights. The Company and its subsidiaries have security procedures to protect the secrecy, confidentiality and value of their Intellectual Property Rights. To the Company's knowledge, no employee is in or has been in violation in any material respect of any term of any employment contract, invention assignment agreement, non-competition agreement, or nondisclosure agreement with a former employer, executed prior to such employee's employment where the basis of such violation relates to such employee's employment and such violation occurred while employed and while the contract was valid and in effect. All material licenses or other material agreements under which the Company is granted rights to Intellectual Property are, to the Company's knowledge, in full force and effect and, to the Company's knowledge, there is no material default by any other party thereto. To the Company's knowledge, the licensors under material licenses and other material agreements had all requisite power and authority to grant the rights to the Intellectual Property purported to be granted thereby. To the Company's knowledge, the consummation of the transactions contemplated hereby and by the other Transaction Documents will not result in the alteration, loss, impairment of or restriction on the Company's or any of its subsidiaries' ownership or right to use any Intellectual Property that is material to the conduct of the Company's business as now conducted.

4.13 **Clinical Studies.** The studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company were and, if still pending, are being, conducted in all material respects in accordance with the protocols submitted to the FDA or any foreign governmental body exercising comparable authority, procedures and controls pursuant to, where applicable, good clinical practice, informed consent and all applicable laws, regulations and requirements. The Company has filed with the FDA or other appropriate governmental entity all material required notices, and annual or other reports, including notices of adverse experiences and reports of serious and unexpected adverse experiences, related to the use of its product candidates in clinical trials. The descriptions of the studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company, contained in the SEC Documents are accurate and complete in all material respects; the Company is not aware of any other studies, tests or preclinical and clinical trials, the results of which call into question the results described in the SEC Documents; and the Company has not received any notices or correspondence from the FDA, any foreign, state or local governmental body exercising comparable authority or any Institutional Review Board requiring the termination, suspension, material

modification or clinical hold of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA and any other governmental entity. The Company has not been informed by the FDA or any other governmental entity that the FDA or any other governmental entity will prohibit the testing, distribution, marketing, sale, license or use of any product proposed to be developed, produced, tested, distributed or marketed by the Company. Neither the Company nor, to the Company's knowledge, any of its officers or employees has committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (Sept. 10, 1991) and any amendments thereto. Neither the Company nor, to the Company's knowledge, any officer or employee of the Company has been convicted of any crime or engaged in any conduct that has resulted in or would reasonably be expected to result in (i) debarment under 21 U.S.C. Section 335a or any similar state law or (ii) exclusion under 42 U.S.C. Section 1320a-7 or any similar state law or regulation.

4.14 **Properties and Assets.** The Company and its subsidiaries have good and marketable title in fee simple to all items of real property owned by them, good and valid title to all personal property owned by them that are material to the businesses of the Company or such subsidiary, in each case free and clear of all liens, encumbrances and claims, except those matters that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and any of its subsidiaries or (ii) would not, individually or in the aggregate, have a Material Adverse Effect. Any real or personal property leased by the Company and any of its subsidiaries is held by them under valid, existing and enforceable leases, except those that (A) do not materially interfere with the use made or proposed to be made of such property by the Company or any of its subsidiaries or (B) would not be reasonably expected, individually or in the aggregate, to have a Material Adverse Effect.

4.15 **Possession of Licenses and Permits.** Except in such cases that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, the Company and its subsidiaries (i) possess, and are in compliance with the terms of, all adequate certificates, authorizations, franchises, licenses and permits ("Licenses") from, and have made all declarations, filings, listings, registrations, reports and submissions with, the appropriate federal, state, local or foreign governmental or regulatory authorities including, without limitation, from the FDA and equivalent foreign regulatory authorities, in each case that are necessary or material to the conduct of the business now conducted, (ii) have not received any notice of proceedings relating to the revocation or modification of any Licenses, and (iii) are not in material violation of, or in default under, any such License.

4.16 **Taxes.** The Company and each of its subsidiaries have filed all federal, state, local and foreign tax returns which have been required to be filed and paid all taxes shown thereon through the date hereof, to the extent that such taxes have become due and are not being contested in good faith, except where the failure to so file or pay would not have a Material Adverse Effect, and no tax deficiency has been determined adversely to the Company or any of its subsidiaries which has had, or would have, individually or in the aggregate, a Material Adverse Effect. The Company has no knowledge of any federal, state or other governmental tax deficiency, penalty or assessment which has been asserted or threatened against it which would have a Material Adverse Effect.

4.17 **Investment Company.** Neither the Company nor any of its subsidiaries is, and, after giving effect to the offering and sale of the Shares, will not be, required to register as an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940 (the "Investment Company Act").

4.18 **Insurance.** The Company and its subsidiaries maintain insurance covering their respective properties, operations, personnel and businesses as the Company reasonably deems adequate; the Company reasonably believes such insurance insures against such losses and risks in accordance with customary industry practice to protect the Company and the subsidiaries and their respective businesses and which is commercially reasonable for the current conduct of their respective businesses; to the Company's knowledge, all such insurance is fully in force on the date hereof.

4.19 **Compliance with Nasdaq Requirements.** The Company is in compliance with applicable rules of the Nasdaq Stock Market, including the continued listing requirements thereunder. There are no proceedings pending or, to the Company's knowledge, threatened against the Company relating to the continued listing of the Common Stock on the Nasdaq Stock Market and the Company has not received any notice of, nor to the Company's knowledge is there any reasonable basis for, the delisting of the Common Stock from the Nasdaq Stock Market.

4.20 **Internal Control over Financial Reporting; Sarbanes-Oxley Matters.** The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15(c) and 15d-15(e) of the Exchange Act) for the Company and designed such disclosure controls and procedures to ensure that material information relating to the Company and required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is made known to the certifying officers by others within the Company. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset and liability accountability, and (iii) access to assets or incurrence of liabilities is permitted only in accordance with management's general or specific authorization. The Company's certifying officers have evaluated the effectiveness of the Company's controls and procedures as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the end of the Company's most recent audited fiscal year, to the Company's knowledge, there have been no significant deficiencies or material weakness detected in the Company's internal control over financial reporting (whether or not remediated) and no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal controls over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company maintains a standard system of accounting established and administered in accordance with GAAP and the applicable requirements of the Exchange Act.

4.21 **Labor Disputes.** No labor disturbance by or dispute with employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is threatened which would result in a Material Adverse Effect.

4.22 **Brokers and Finders.** No Person will have, as a result of the transactions contemplated by the Transaction Documents, any valid right, interest or claim against or upon the Company or the Purchaser for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Company, other than pursuant to the Company's engagement of Cantor Fitzgerald as the Company's financial advisor, the fees of which are payable by the Company. The Purchaser shall not have any obligation with respect to any fees, or with respect to

any claims made by or on behalf of other Persons for fees, in each case of the type contemplated by this Section 4.22 that may be due in connection with the transactions contemplated by this Agreement or the Transaction Documents.

4.23 **Manipulation of Price**. The Company has not, and, to the Company's knowledge, no Person acting on its behalf has taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale of any of the Shares.

4.24 **No Integrated Offering.** Neither the Company nor any of its subsidiaries, officers, directors, any person acting on its or their behalf, nor to the Company's knowledge, any of its affiliates, has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any Company security, under circumstances that would require registration of any of the Shares under the Securities Act or cause this offering of the Shares to be integrated with prior offerings by the Company for purposes of the Securities Act.

4.25 **ERISA.** To the knowledge of the Company, each material employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), that is maintained, administered or contributed to by the Company or any of its affiliates for employees or former employees of the Company and any of its subsidiaries has been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including ERISA and the Internal Revenue Code of 1986, as amended (the "Code"); no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred which would result in a material liability to the Company with respect to any such plan excluding transactions effected pursuant to a statutory or administrative exemption; and for each such plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no "accumulated funding deficiency" as defined in Section 412 of the Code has been incurred, whether or not waived, and the fair market value of the assets of each such plan (excluding for these purposes accrued but unpaid contributions) exceeds the present value of all benefits accrued under such plan determined using reasonable actuarial assumptions; neither the Company nor any of its affiliates sponsors, maintains, contributes to, participates in or has any obligations to, or any liability under, any multiemployer plan (as defined in Section 4001(a)(3) of ERISA).

4.26 **Money Laundering Laws.** The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial record keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, the money laundering laws of all jurisdictions to which the Company or its subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental authority (collectively, the "Money Laundering Laws"); and no action, suit or proceeding by or before any governmental authority involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

4.27 **No Improper Practices.** (i) Neither the Company nor its subsidiaries, nor, to the Company's knowledge, any current or former director, officer, employee, agent, affiliate or other person acting on behalf of the Company or any subsidiary has used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity, or made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government or regulatory official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or

candidate for political office; (ii) no relationship, direct or indirect, exists between or among the Company or any subsidiary or any affiliate of any of them, on the one hand, and the directors, officers and stockholders of the Company or any subsidiary, on the other hand, that is required to be described in the SEC Documents that is not so described, except as would not cause a Material Adverse Effect; (iii) except as described in the SEC Documents, there are no material outstanding loans or advances or material guarantees of indebtedness by the Company or any subsidiary to or for the benefit of any of their respective officers or directors or any of the members of the families of any of them; and (iv) the Company has not offered, or caused any placement agent to offer, securities to any person with the intent to influence unlawfully (A) a customer or supplier of the Company or any subsidiary to alter the customer's or supplier's level or type of business with the Company or any subsidiary or (B) a trade journalist or publication to write or publish favorable information about the Company or any subsidiary or any of their respective products or services, and, (v) neither the Company nor any subsidiary nor any director, officer or employee of the Company or any subsidiary nor, to the Company's knowledge, any agent, affiliate or other person acting on behalf of the Company or any subsidiary has (A) violated or is in violation of any applicable provision of the U.S. Foreign Corrupt Practices Act of 1977, or any other applicable anti-bribery or anti-corruption law (collectively, "Anti-Corruption Laws"), (B) promised, offered, provided, attempted to provide or authorized the provision of anything of value, directly or indirectly, to any person for the purpose of obtaining or retaining business, influencing any act or decision of the recipient or securing any improper advantage, or (C) made any payment of funds of the Company or any subsidiary or received or retained any funds in violation of any Anti-Corruption Laws.

4.28 **Sanctions.**

(a) The Company represents that neither the Company nor any of its subsidiaries (collectively, the "Entity") or, to its knowledge, any current or former director, officer, employee, agent, affiliate or representative of the Entity, is (or is owned or controlled by) a person that is: (i) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authorities, including designation on OFAC's Specially Designated Nationals and Blocked Persons List or OFAC's Foreign Sanctions Evaders List (as amended, collectively, "Sanctions"), nor (ii) located, organized or resident in a country or territory that is the subject of Sanctions that broadly prohibit dealings with that country or territory (including Cuba, Iran, North Korea, Syria and the Crimea Region of the Ukraine) (the "Sanctioned Countries"), nor directly or indirectly owned or controlled by a person subject to Sanctions or located, organized or resident in any Sanctioned Countries.

(b) The Entity represents and covenants that it will not, directly or indirectly, knowingly use the proceeds of the sale of the Shares hereunder (the "Offering"), or lend, contribute or otherwise make available such Offering proceeds to any subsidiary, joint venture partner or other Person: (i) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions or is a Sanctioned Country; or (ii) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the Offering, whether as underwriter, advisor, investor or otherwise).

(c) The Entity represents and covenants that, for the past 5 years, it has not engaged in, is not now engaging in, and will not engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions or is or was a Sanctioned Country, in each case in a manner that would violate applicable law; the Entity shall maintain policies and procedures designed to promote and achieve compliance with the Sanctions and Anti-Corruption Laws applicable to it and each of its affiliates and subsidiaries.

4.29 **Environmental Laws.** Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, neither the Company nor any of its subsidiaries is in violation of any statute, rule, regulation, decision or order of any governmental agency or body or any court, domestic or foreign, relating to the use, disposal or release of hazardous or toxic substances or relating to the protection or restoration of the environment or human exposure to hazardous or toxic substances (collectively, "Environmental Laws"), has released any hazardous substances regulated by Environmental Law on to any real property that it owns or operates, or has received any written notice or claim that it is liable for any off-site disposal or contamination pursuant to any Environmental Laws; and to the Company's knowledge, there is no pending or threatened investigation that would reasonably be expected to lead to such a claim.

4.30 **Compliance with Laws.** The Company has operated and currently is in compliance in all material respects with all applicable Health Care Laws (defined herein), including, without limitation, the rules and regulations of the FDA, the U.S. Department of Health and Human Services Office of Inspector General, the Centers for Medicare & Medicaid Services, the Office for Civil Rights, the Department of Justice or any other governmental agency or body having jurisdiction over the Company or any of its properties, and has not engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other state or federal health care program. For purposes of this Agreement, "Health Care Laws" shall mean the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Act (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.) ("HIPAA"), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the patient privacy, data security and breach notification provisions under HIPAA, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), the regulations promulgated pursuant to such laws, and any other similar local, state or federal law and regulations. The Company has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence, communication or notice from the FDA or any other governmental or regulatory authority alleging or asserting noncompliance with any Health Care Laws applicable to the Company. The Company is not a party to nor has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any governmental or regulatory authority. Neither the Company nor any of its employees, officers, directors or, to the Company's knowledge, consultants has been excluded, suspended or debarred from participation in any U.S. state or federal health care program or human clinical research or, to the Company's knowledge, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

4.31 **Regulatory.** The Company has conducted an assessment and determined that none of the Company, any subsidiary, or any of its affiliates (a) produce, design, test, manufacture, fabricate, or develop "critical technologies" as that term is defined in 31 C.F.R. § 800.215; (b) perform the functions as set forth in column 2 of Appendix A to 31 C.F.R. part 800 with respect to covered investment critical infrastructure; or (c) maintain or collect, directly or indirectly, "sensitive personal data" as that term is defined in 31 C.F.R. § 800.241.

SECTION 5. REPRESENTATIONS AND WARRANTIES OF PURCHASER.

5.1 The Purchaser hereby represents and warrants, as of the date hereof and the Closing Date, to the Company that:

(a) Purchaser is a duly organized, validly existing corporation, limited partnership or limited liability company and in good standing under the laws of the jurisdiction of its organization with the requisite corporate, partnership or limited liability company power and authority to enter into and consummate the transactions contemplated by the Transaction Documents and to carry out its obligations hereunder and thereunder, and to invest in the Shares pursuant to this Agreement.

(b) Purchaser acknowledges that it can bear the economic risk and complete loss of its investment in the Shares and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment contemplated hereby.

(c) Purchaser has had an opportunity to receive, review and understand all information related to the Company requested by it and to ask questions of and receive answers from the Company regarding the Company and its subsidiaries, its business and the terms and conditions of the offering of the Shares, and has conducted and completed its own independent due diligence. Purchaser acknowledges that the Company has made available the SEC Documents. Based on the information the Purchaser has deemed appropriate, and without reliance upon any placement agent, it has independently made its own analysis and decision to enter into the Transaction Documents. Purchaser is relying exclusively on its own sources of information, investment analysis and due diligence (including professional advice it deems appropriate) with respect to the execution, delivery and performance of the Transaction Documents, the Shares and the business, condition (financial and otherwise), management, operations, properties and prospects of the Company, including but not limited to all business, legal, regulatory, accounting, credit and tax matters. Purchaser is not relying and has not relied on any representations or warranties whatsoever regarding the subject matter of this Agreement, express or implied, except for the representations and warranties set forth in Section 4. Such representations and warranties by the Company constitute the sole and exclusive representations and warranties of the Company in connection with the transactions contemplated by this Agreement and Purchaser understands, acknowledges and agrees that all other representations and warranties of any kind or nature whether express, implied or statutory are specifically disclaimed by the Company.

(d) The Shares to be received by the Purchaser hereunder will be acquired for the Purchaser’s own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the Securities Act, and the Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the Securities Act without prejudice, however, to the Purchaser’s right at all times to sell or otherwise dispose of all or any part of such Shares in compliance with applicable federal and state securities laws. Purchaser understands that the Shares are characterized as “restricted securities” under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances.

Purchaser represents that it is familiar with Rule 144 under the Securities Act ("Rule 144"), as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act. Purchaser will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the securities purchased hereunder except in compliance with the Securities Act, applicable blue sky laws, and the rules and regulations promulgated thereunder.

(e) Purchaser has determined based on its own independent review and such professional advice as it deems appropriate that its purchase of the Shares and participation in the transactions contemplated by the Transaction Documents (i) are consistent with its financial needs, objectives and condition, (ii) comply and are consistent with all investment policies, guidelines and other restrictions applicable to the Purchaser, (iii) do not and will not violate or constitute a default under the Purchaser's charter, by-laws or other constituent document or under any law, rule, regulation, agreement or other obligation by which the Purchaser is bound and (iv) are a fit, proper and suitable investment for the Purchaser, notwithstanding the substantial risks inherent in investing in or holding the Shares.

(f) The execution, delivery and performance by the Purchaser of the Transaction Documents have been duly authorized and each has been duly executed and when delivered will constitute the valid and legally binding obligation of the Purchaser, enforceable against the Purchaser in accordance with their respective terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability, relating to or affecting creditors' rights generally.

(g) Purchaser is an "accredited investor" within the meaning of Rule 501(a) under the Securities Act. Purchaser is not a broker or dealer registered pursuant to Section 15 of the Exchange Act (a "registered broker-dealer") or an entity engaged in a business that would require it to be so registered and is not affiliated with a registered broker dealer or an entity engaged in a business that would require it to be so registered. Purchaser is not party to any agreement for distribution of any of the Shares.

(h) Purchaser shall have completed or caused to be completed and delivered to the Company at no later than the date hereof, the Selling Stockholder Questionnaire for use in preparation of the registration statement(s) meeting the requirements set forth in the Registration Rights Agreement and covering the resale by the Purchaser of the Registrable Securities (as defined in the Registration Rights Agreement) (each, a "Registration Statement"), and the answers to the Selling Stockholder Questionnaire are true and correct in all material respects as of the date of this Agreement and will be true and correct as of the Closing and the effective date of each Registration Statement; provided, that the Purchaser shall be entitled to update such information by providing notice thereof to the Company before the effective date of each such Registration Statement.

(i) Purchaser understands that no U.S. federal or state agency, or similar agency of any other country, has reviewed, approved, passed upon, or made any recommendation or endorsement of the Company or the purchase of the Shares.

(j) Purchaser has not taken any of the actions set forth in, and is not subject to, the disqualification provisions of Rule 506(d)(1) of the Securities Act (each a "Disqualification Event"). Purchaser hereby agrees that it shall notify the Company promptly in writing in the event a Disqualification Event becomes applicable to the Purchaser or any of its Rule 506(d) Related Parties, except, if applicable, for a Disqualification Event as to which Rule 506(d)(2)(ii) or (iii) or (d)(3) is applicable. For purposes of this Subsection 5.1(j), "Rule 506(d) Related Party" shall mean a person or entity that is a beneficial owner of the Purchaser's securities for purposes of Rule 506(d) of the Securities Act.

(k) Purchaser did not learn of the investment in the Shares as a result of any general solicitation or general advertising.

(l) Purchaser's offices in which its investment decision with respect to the Shares was made are located at the address immediately below the Purchaser's name on its signature page hereto.

5.2 Purchaser understands that nothing in this Agreement or any other materials presented to the Purchaser in connection with the purchase and sale of the Shares constitutes legal, tax or investment advice. Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Shares.

5.3 **Legends.**

(a) Purchaser understands that, until such time as the Shares have been sold pursuant to a Registration Statement or the Shares may be sold pursuant to Rule 144 without any restriction as to the number of securities as of a particular date that can then be immediately sold, the book entry notations evidencing the Shares may bear one or more legends in substantially the following form and substance:

"THESE SECURITIES, INCLUDING ANY SECURITIES INTO WHICH THESE SECURITIES IS EXERCISABLE, HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE REOFFERED, SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCUMBERED, HYPOTHECATED OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO A TRANSACTION WHICH IS EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION REQUIREMENTS, IN EACH CASE IN ACCORDANCE WITH ALL APPLICABLE SECURITIES LAWS, AND IN THE CASE OF A TRANSACTION EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO IT THAT SUCH

TRANSACTION DOES NOT REQUIRE REGISTRATION UNDER THE SECURITIES ACT AND SUCH OTHER APPLICABLE LAWS."

In addition, book entry notations representing the Shares may contain such other restrictive legends as may be reasonably required under applicable state blue sky laws.

(b) The Company agrees that at such time as any legend is no longer required under this Section 5.3, it will, no later than three (3) Business Days following the delivery by the Purchaser to the Company or the Company's transfer agent of a request to remove such legend, together with such representations and covenants of the Purchaser or the Purchaser's executing broker as the Company may reasonably require in connection therewith, deliver or cause to be delivered to the Purchaser a book entry position representing such shares that is free from any such legend. The Company shall not make any notation on its records or give instructions to any transfer agent of the Company that enlarge the restrictions on transfer set forth in this Section 5.3. Any certificates for Shares subject to legend removal shall be transmitted by the transfer agent of the Company to the Purchaser by crediting the account of the Purchaser's prime broker with the Depository Trust Company ("DTC"). All costs and expenses related to the removal of the legends and the reissuance of any Shares shall be borne by the Company.

(c) The restrictive legend set forth in this Section 5.3 above shall be removed and the Company shall issue a certificate or book entry position without such restrictive legend or any other restrictive legend to the holder of the applicable shares upon which it is stamped or issue to such holder by electronic delivery with the applicable balance account at DTC or in physical certificated shares, if appropriate, if (i) such Shares have been sold or transferred pursuant to an effective Registration Statement; (ii) such Shares are sold or transferred pursuant to Rule 144 (if the transferor is not an affiliate of the Company); or (iii) such Shares are eligible for sale without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such securities and without volume or manner-of-sale restrictions. Upon Rule 144 becoming available for the resale of the Shares, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to the Shares and without volume or manner-of-sale restrictions, the Company shall, at the request of the Purchaser, issue to the Company's transfer agent the instructions with respect to legend removal consistent with this Section 5.3. Any fees (with respect to the transfer agent, the Company's counsel or otherwise) associated with the issuance of such opinion or the removal of such legend shall be borne by the Company.

SECTION 6. CONDITIONS TO CLOSING.

6.1 The obligation of the Purchaser to purchase the Shares at the Closing is subject to the fulfillment to the Purchaser's satisfaction, on or prior to the Closing Date, of each of the following conditions, any of which may be waived by the Purchaser:

(a) The representations and warranties made by the Company in Section 4 hereof and in Section 12 of the License Agreement shall be true and correct in all material respects as of the date when made and as of the Closing Date, as though made on and as of such date, except to the extent that any such representation or warranty expressly speaks as of an earlier date, in which

case such representation or warranty shall be true and correct in all material respects as of such earlier date. The Company shall have performed in all material respects all obligations and covenants in the Transaction Documents and the License Agreement required to be performed by it on or prior to the Closing Date.

(b) With the exception of declarations of effectiveness by the Commission with respect to the registration statements contemplated in the Registration Rights Agreement, the Company shall have obtained any and all consents, permits, approvals, registrations and waivers necessary for consummation of the purchase and sale of the Shares and the consummation of the other transactions contemplated by the Transaction Documents, all of which shall be in full force and effect.

(c) The Company shall have filed with the Nasdaq Stock Market a Notification Form: Listing of Additional Shares for the listing of the Shares and cause such approval to be obtained.

(d) No judgment, writ, order, injunction, award or decree of or by any court, or judge, justice or magistrate, including any bankruptcy court or judge, or any order of or by any governmental authority, shall have been issued, and no action or proceeding shall have been instituted by any governmental authority, enjoining or preventing the consummation of the transactions contemplated at the Closing.

(e) Purchaser shall have received a certificate signed by the Chief Executive Officer or the Principal Financial Officer of the Company, dated as of the Closing Date, certifying to the fulfillment of the conditions specified in subsections (a), (b), (c), (d), (h), and (i) of this Section 6.1.

(f) Purchaser shall have received a certificate signed by the Company's Secretary, dated as of the Closing Date, certifying the resolutions adopted by the board of directors of the Company (the "Board") approving the transactions contemplated by the Transaction Documents and the License Agreement and the issuance of the Shares, certifying the current versions of the certificate of incorporation and by-laws of the Company and certifying as to the signatures and authority of persons signing the Transaction Documents, the License Agreement and related documents on behalf of the Company.

(g) Purchaser shall have received an opinion of Gibson, Dunn & Crutcher LLP, counsel to the Company, dated as of the Closing Date, covering the opinions listed on Exhibit B.

(h) No stop order or suspension of trading shall have been imposed by the Nasdaq Stock Market, the Commission or any other governmental regulatory body with respect to public trading in the Common Stock.

(i) There shall not have occurred any material adverse change in the Company's consolidated business or financial condition since the date of the Company's most recently filed SEC Document.

(j) The Company shall have executed and delivered to the Purchaser the Registration Rights Agreement.

(k) The Company shall have executed the License Agreement and the Effective Date (as defined in the License Agreement) shall have occurred.

6.2 The obligation of the Company to sell and issue the Shares and to deliver the Shares to the Purchaser at the Closing is subject to fulfillment to the satisfaction of the Company on or prior to the Closing Date of the following conditions, any of which may be waived by the Company:

(a) The representations and warranties made by the Purchaser in Section 5 hereof and in Section 12 of the License Agreement shall be true and correct in all material respects as of the date when made and as of the Closing Date, except to the extent that any such representation or warranty expressly speaks as of an earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date. Purchaser shall have performed in all material respects all obligations and covenants herein required to be performed by it on or prior to the Closing Date.

(b) Purchaser shall have executed and delivered to the Company the Registration Rights Agreement and the License Agreement.

(c) The Effective Date (as defined in the License Agreement) shall have occurred.

(d) The Company shall have received payment, by wire transfer of immediately available funds, in the full amount of the purchase price for the number of Shares being purchased at the Closing, as determined in accordance with Section 2 hereof.

(e) No judgment, writ, order, injunction, award or decree of or by any court, or judge, justice or magistrate, including any bankruptcy court or judge, or any order of or by any governmental authority, shall have been issued, and no action or proceeding shall have been instituted by any governmental authority, enjoining or preventing the consummation of the transactions contemplated hereby.

SECTION 7. TERMINATION OF OBLIGATIONS TO EFFECT CLOSING; EFFECTS.

7.1 The obligations of the Company, on the one hand, and the Purchaser, on the other hand, to effect the Closing shall terminate as follows:

(a) By the Purchaser if any of the conditions set forth in Section 6.1 shall have become incapable of fulfillment with respect to the Company and shall not have been waived by the Purchaser, prior to the Closing Date; provided, however, that if the failure of any such condition is a result of any curable breach by the Company of this Agreement, such breach has not been cured by the earlier of 10 days after the giving of written notice by the Purchaser to the Company of the breach.

(b) By the Company if any of the conditions set forth in Section 6.2 shall have become incapable of fulfillment with respect to the Purchaser, and shall not have been waived by the Company, prior to the Closing Date; provided, however, that if the failure of any such condition is a result of any curable breach by the Purchaser of this Agreement, such breach has not been cured by the earlier of 10 days after the giving of written notice by the Company to the Purchaser of the breach. provided, however, that the right to terminate this Agreement under this Section 7.1 shall not be available to any party whose failure to comply with its obligations under this Agreement has been the cause of or resulted in the failure of the Closing to occur.

7.2 Nothing in this Section 7 shall be deemed to release any party from any liability for any breach by such party of the terms and provisions of this Agreement or the other Transaction Documents or to impair the right of any party to compel specific performance by any other party of its obligations under this Agreement or the other Transaction Documents.

SECTION 8. ADDITIONAL COVENANTS AND AGREEMENTS.

8.1 **Nasdaq Listing.** The Company will use commercially reasonable efforts to continue the listing and trading of its Common Stock on the Nasdaq Stock Market and, in accordance, therewith, will use commercially reasonable efforts to comply in all material respects with the Company's reporting, filing and other obligations under the bylaws or rules of such market or exchange, as applicable. The provisions of this Section 8.1 shall terminate and be of no further force and effect on the date on which the Company's obligations under the Registration Rights Agreement to register or maintain the effectiveness of any registration covering the Registrable Securities (as such term is defined in the Registration Rights Agreement) shall terminate.

8.2 **Information Rights.**

(a) For so long as the Purchaser beneficially owns at least 4,062,292 shares of Common Stock (subject to appropriate adjustment in the event of a stock dividend, stock split, combination or other similar recapitalization affecting the Common Stock), the Purchaser shall be entitled to consult on a quarterly basis with the Company's officers with respect to the Company's business and financial matters, including management's proposed annual operating plans and to review progress in achieving said plans, as well as key operating data relevant to such plans. Consistent with, and subject to, the terms and conditions of Section 220 of the Delaware General Corporation Law, the Purchaser shall be entitled to inspect appropriate books and records of the Company.

(b) The Purchaser agrees that it will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company pursuant to this Agreement) any confidential information obtained from the Company pursuant to the terms of this Agreement, including Section 8.2(a), unless such confidential information is known or becomes known to the public in general (other than as a result of a breach of this Section 8.2(b) by the Purchaser).

(c) The Purchaser acknowledges that money damages would not be a sufficient remedy for any breach of Section 8.2(b) and consents to a court of competent jurisdiction entering

an order finding that the Company has been irreparably harmed as a result of any such breach and to the granting of injunctive relief without proof of actual damages as a remedy for any such breach. Such remedies shall not be deemed to be the exclusive remedies for such breach, but shall be in addition to all other remedies available at law or equity to the Company.

8.3 **Form D.** The Company agrees to timely file a Form D with respect to the Shares and to provide a copy thereof, promptly upon request of the Purchaser.

8.4 **Integration.** The Company shall not, and shall use its commercially reasonable efforts to ensure that no affiliate of the Company shall, sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that will be integrated with the offer or sale of the Shares in a manner that would require the registration under the Securities Act of the sale of the Shares to the Purchaser, or that will be integrated with the offer or sale of the Shares for purposes of the rules and regulations of any trading market such that it would require stockholder approval prior to the closing of such other transaction unless stockholder approval is obtained before the closing of such subsequent transaction.

8.5 **Short Sales and Confidentiality After the Date Hereof.** Purchaser covenants that neither it nor any Affiliates acting on its behalf or pursuant to any understanding with it will, directly or indirectly, engage in any transactions in the Company's securities (including, without limitation, any Short Sales involving the Company's securities) during the period from the date hereof until the earlier of such time as (i) after the transactions contemplated by this Agreement are first publicly announced by the Company or (ii) this Agreement is terminated in full. Purchaser understands and acknowledges that the Commission currently takes the position that coverage of short sales of shares of the Common Stock "against the box" prior to effectiveness of a resale registration statement with securities included in such registration statement would be a violation of Section 5 of the Securities Act, as set forth in Item 239.10 of the Securities Act Rules Compliance and Disclosure Interpretations compiled by the Office of Chief Counsel, Division of Corporation Finance.

8.6 **Use of Proceeds.** The Company shall use the net proceeds of the sale of the Shares to fund the costs and expenses of clinical trials and commercialization of its product candidates, as well as for general working capital. The Company shall not use the net proceeds of the sale of the Shares to effect any cash dividend or other form of distribution to any stockholders of the Company.

8.7 **Standstill.** During the period beginning from the date of this Agreement and continuing to and including the date 365 days after the date of this Agreement, neither the Purchaser nor any of its Affiliates shall, without the prior approval of the Company, directly or indirectly:

(a) purchase, offer to purchase, or agree to purchase or otherwise acquire "beneficial ownership" (as defined in Rule 13d-3 and Rule 13d-5 under the Exchange Act) of any Common Stock or Common Stock Equivalents.

(b) make, or in any way participate in, any solicitation of proxies to vote, or seek to advise or influence any person with respect to the voting of, any voting securities of the Company or any of its subsidiaries, or seek or propose to influence, advise, change or control the Board,

management, policies, affairs or strategy of the Company by way of any public communication or other communications to security holders intended for such purpose.

(c) form, join or in any participate in a "group" (within the meaning of Section 13(d) of the Exchange Act) with respect to any voting securities of the Company.

(d) make a proposal for, or offer of (with or without conditions) any acquisition of or extraordinary transaction involving the Company or any of the Company's subsidiaries or any of their respective securities or assets.

(e) effect or seek to effect (including, without limitation, by entering into discussions, negotiations, agreements or understandings with any third person), offer or propose (whether publicly or otherwise) to effect, or cause or participate in, or in any way assist or facilitate any other person to effect or seek, offer or propose (whether public or otherwise) to effect or participate (except as a holder of Common Stock) in a merger, consolidation, division, acquisition or exchange of substantially all assets or equity, Change of Control, recapitalization, restructuring, liquidation or similar transaction involving the Company or any of its subsidiaries.

(f) enter into any discussions, negotiations, arrangements or understandings with or form a group with, any third party in connection with such third party's taking, planning to take, or seeking to take any of the actions prohibited by clauses (a) through (d) of this Section or otherwise act, alone or in concert with others, to seek to control or influence the Board or the management or policies of the Company, including its subsidiaries.

Notwithstanding the foregoing: (A) nothing in this Agreement shall prohibit the Purchaser or any of its Affiliates from (i) submitting to the Board or to management of the Company a confidential proposal for a transaction involving a Change of Control or other proposed action, provided that neither the Company nor the Purchaser or any of its Affiliates is required to publicly disclose the fact that such proposal or request to consider such a proposal was made or (ii) exercising its rights under the Transaction Documents, including the Registration Rights Agreement; (B) if any executive officer or director of the Purchaser serves as a member of the Company's Board, any action he or she takes in the performance of his or her duties as a member of the Company's board of directors shall not be deemed to violate this Section; (C) nothing in this Agreement shall limit the ability of the Purchaser or any of its Affiliates to freely vote or transfer (subject to Section 8.8 below) its Common Stock; and (D) the provisions of this Section shall terminate and be of no further force or effect if (i) the Company publicly announces the entry into a definitive agreement for the acquisition of the Company or more than fifty percent (50%) of its consolidated assets by a Third Party, or (ii) any person commences a tender or exchange offer with respect to the securities representing fifty percent (50%) or more of the voting power of the Company, unless the Company files a recommendation statement under Rule 14d-9 of the Exchange Act (or such successor provision) with the SEC within then (10) Business Days following commencement of such offer advising the Company's stockholders to reject such offer (provided that if any transaction referred to in the foregoing clauses (i) and (ii) is terminated or abandoned, then the provisions of this Section shall again become effective).

8.8 **Transfer Restrictions.**

(a) During the period beginning from the date of this Agreement and continuing to and including the earliest of: (A) the date of the expiration or early termination of the License Agreement, or (B) the date 365 days after the date of this Agreement (the "Restricted Period"), the Purchaser shall not, and shall cause its Affiliates not to, without the prior consent of the Company, directly or indirectly, Transfer (i) any shares of Common Stock or Common Stock Equivalents beneficially owned by the Purchaser or any of its Affiliates as of the Closing Date, together with any Common Stock or Common Stock Equivalents issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization, or (ii) any shares of Common Stock or Common Stock Equivalents issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Common Stock or Common Stock Equivalents described in clause (i) of this sentence.

(b) Notwithstanding anything to the contrary in Section 8.8(a), each of the Purchaser and its Affiliates shall be permitted to Transfer any portion or all of its shares of Common Stock or Common Stock Equivalents during the Restricted Period (i) to a Permitted Transferee, provided that such Permitted Transferee shall sign and deliver a lock-up letter with terms substantially similar to the terms of this Section 8.8, (ii) to the Company or a subsidiary of the Company, (iii) in response to a merger, tender or exchange offer or other business combination, acquisition of assets or similar transaction entered into by the Company or any transaction resulting in a Change of Control of the Company or (iv) as otherwise provided in this Agreement.

8.9 **Purchaser Required Disclosures and Transaction Announcement.**

(a) Notwithstanding anything to the contrary in this Agreement but nevertheless subject to Section 8.2(b) of this Agreement, the Purchaser shall always be entitled to make disclosures as required by law, regulation or rules, including stock exchange rules, or by any order of court or other competent authority or tribunal. In the event that the Purchaser would be required to make any such disclosure, the Purchaser agrees to give the Company notice as soon as reasonably possible prior to any such disclosure (to the extent legally permitted and reasonably practicable), to enable the Company to seek an appropriate protective order or other remedy.

(b) As soon as possible after signing of the Transaction Documents and License Agreement, the Purchaser shall be entitled to make such announcements as are required by law, regulation and rules, including stock exchange rules.

(c) The parties hereto shall cooperate to ensure that announcement of the transactions contemplated by the Transaction Documents and License Agreement takes place as soon as possible after signing of such agreements and that the respective disclosures and announcements by such parties are aligned in respect of the timing and content of such announcement, in each case to the extent legally permissible. If either party seeks to redact from public disclosure certain confidential information within the Transaction Documents or the License Agreement, the other party will use commercially reasonable efforts to accommodate such redaction

requests, to the extent permitted under applicable law, regulation and rules, including stock exchange rules.

SECTION 9. INDEMNIFICATION.

9.1 **Indemnification by the Company.** The Company agrees to indemnify and hold harmless the Purchaser, the officers, directors, partners, members, and employees of the Purchaser, each Person who controls any such Purchaser (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) and the officers, directors, partners, members and employees of each such controlling Person (each, an "Indemnified Party"), against any losses, claims, damages, liabilities or expenses, joint or several, to which such Indemnified Party may become subject under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation (including in settlement of any litigation, if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) arise out of or are based in whole or in part on the inaccuracy in the representations and warranties of the Company contained in this Agreement or the failure of the Company to perform its obligations hereunder, and will reimburse each Indemnified Party for legal and other expenses reasonably incurred as such expenses are reasonably incurred by such Indemnified Party in connection with investigating, defending, settling, compromising or paying such loss, claim, damage, liability, expense or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage, liability or expense arises out of or is based upon (i) the failure of such Indemnified Party to comply with the covenants and agreements contained herein, or (ii) the inaccuracy of any representations made by such Indemnified Party herein.

9.2 **Indemnification Procedure.** Promptly after any Indemnified Party has received notice of any indemnifiable claim hereunder, or the commencement of any action, suit or proceeding by a third Person, which the Indemnified Party believes in good faith is an indemnifiable claim under this Agreement, the Indemnified Party shall give the indemnitor hereunder (the "Indemnifying Party") written notice of such claim or the commencement of such action, suit or proceeding, but failure to so notify the Indemnifying Party will not relieve the Indemnifying Party from any liability it may have to such Indemnified Party hereunder except to the extent that the Indemnifying Party is materially prejudiced by such failure. Such notice shall state the nature and the basis of such claim to the extent then known. The Indemnifying Party shall have the right to defend and settle, at its own expense and by its own counsel who shall be reasonably acceptable to the Indemnified Party, any such matter as long as the Indemnifying Party pursues the same diligently and in good faith. If the Indemnifying Party undertakes to defend or settle, it shall promptly notify the Indemnified Party of its intention to do so, and the Indemnified Party shall cooperate with the Indemnifying Party and its counsel in all commercially reasonable respects in the defense thereof and the settlement thereof. Such cooperation shall include, but shall not be limited to, furnishing the Indemnifying Party with any books, records and other information reasonably requested by the Indemnifying Party and in the Indemnified Party's possession or control. Such cooperation of the Indemnified Party shall be at the cost of the Indemnifying Party. After the Indemnifying Party has notified the Indemnified Party of its intention to undertake to defend or settle any such asserted liability, and for so long as the Indemnifying Party diligently pursues such defense, the Indemnifying

Party shall not be liable for any additional legal expenses incurred by the Indemnified Party in connection with any defense or settlement of such asserted liability; provided, however, that the Indemnified Party shall be entitled (a) at its expense, to participate in the defense of such asserted liability and the negotiations of the settlement thereof and (b) if (i) the Indemnifying Party has failed to assume the defense or employ counsel reasonably acceptable to the Indemnified Party or (ii) if the defendants in any such action include both the Indemnified Party and the Indemnifying Party and counsel to the Indemnified Party shall have concluded that there may be reasonable defenses available to the Indemnified Party that are different from or in addition to those available to the Indemnifying Party or if the interests of the Indemnified Party reasonably may be deemed to conflict with the interests of the Indemnifying Party, then the Indemnified Party shall have the right to select a separate counsel and to assume such legal defense and otherwise to participate in the defense of such action, with the expenses and fees of such separate counsel and other expenses related to such participation to be reimbursed by the Indemnifying Party as incurred. Notwithstanding any other provision of this Agreement, the Indemnifying Party shall not settle any indemnified claim without the consent of the Indemnified Party, unless the settlement thereof imposes no liability or obligation on, and includes a complete release from liability of, and does not include any admission of wrongdoing or malfeasance by, the Indemnified Party.

SECTION 10. NOTICES.

All notices, requests, consents and other communications hereunder shall be in writing, shall be sent by confirmed electronic mail, or mailed by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, and addressed as follows:

if to the Company, to:

Selecta Biosciences, Inc.
480 Arsenal Way
Watertown, MA 02472
Attention: Elona Kogan
Email: ekogan@selectabio.com

with a copy (which shall not constitute notice) to:

Gibson, Dunn & Crutcher LLP
555 Mission St.
San Francisco, CA 94105
Attention: Ryan A. Murr
Email: rmurr@gibsondunn.com

or to such other Person at such other place as the Company shall designate to the Purchaser in writing; and if to the Purchaser, at the address as set forth at the end of this Agreement, or at such other address or addresses as may have been furnished to the Company in writing.

SECTION 11. MISCELLANEOUS.

11.1 **Waivers and Amendments.** Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the Purchaser.

11.2 **Headings.** The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.

11.3 **No Third-Party Beneficiaries.** This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

11.4 **Severability.** Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof but shall be interpreted as if it were written so as to be enforceable to the maximum extent permitted by applicable law, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the parties hereby waive any provision of law which renders any provision hereof prohibited or unenforceable in any respect.

11.5 **Replacement of Certificates.** If the Shares are certificated and any certificate or instrument evidencing any Shares are mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof, or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company and the Company's transfer agent of such loss, theft or destruction and the execution by the holder thereof of a customary lost certificate affidavit of that fact and an agreement to indemnify and hold harmless the Company and the Company's transfer agent for any losses in connection therewith or, if required by the transfer agent, a bond in such form and amount as is required by the transfer agent. The applicants for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs associated with the issuance of such replacement Shares. If a replacement certificate or instrument evidencing any Shares is requested due to a mutilation thereof, the Company may require delivery of such mutilated certificate or instrument as a condition precedent to any issuance of a replacement.

11.6 **Governing Law; Consent to Jurisdiction; Waiver of Jury Trial.** This Agreement will be governed by and construed in accordance with the laws of the State of Delaware without regard to any choice of laws or conflict of laws provisions that would require the application of the laws of any other jurisdiction. The parties hereby irrevocably and unconditionally consent to submit to the exclusive jurisdiction of Delaware Court of Chancery and any state appellate court therefrom within the State of Delaware (or, if the Delaware Court of Chancery declines to accept jurisdiction over a particular matter, any state or federal court within the State of Delaware) for any actions, suits or proceedings arising out of or relating to this Agreement and the transactions contemplated hereby. Each party to this Agreement hereby irrevocably waives any defense in any such action, suit or proceeding that it is not personally subject to the jurisdiction of the above named courts and to the fullest extent permitted by applicable law, that the action, suit or proceeding in any such court

is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. **EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT AND THE OTHER TRANSACTION DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY AND THEREBY**.

11.7 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and, all of which taken together shall constitute one and the same Agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) the same with the same force and effect as if such facsimile of ".pdf" signature were the original thereof.

11.8 **Successors and Assigns.** Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto.

11.9 **Entire Agreement.** This Agreement and other documents delivered pursuant hereto, including the exhibit and the Schedule of Exceptions, the License Agreement and the other Transaction Documents constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and thereof.

11.10 **Payment of Fees and Expenses.** Each of the Company and the Purchaser shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

11.11 **Survival.** Subject to applicable statutes of limitations, the representations, warranties, covenants, and agreements contained in this Agreement shall survive the Closing for a period of two years after the date hereof and thereafter shall thereafter have no further force and effect.

[*signature page follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

SELECTA BIOSCIENCES, INC.

By: /s/ Carsten Brunn, Ph.D.
Name: Carsten Brunn, Ph. D.
Title: *President and Chief Executive Officer*

SWEDISH ORPHAN BIOVITRUM AB (PUBL)

By: /s/ Guido Oelkers
Name: Guido Oelkers
Title: *CEO*

By: /s/ Torbjörn Hallberg
Name: Torbjörn Hallberg
Title: *General Counsel*

[*Signature Page To Stock Purchase Agreement*]

EXHIBIT A

PURCHASE INFORMATION

Name	Swedish Orphan Biovitrum AB (publ)
Address	Tomtebodavägen 23A, SE-112 76 Stockholm, Sweden
Numbers of Shares to be Purchased*	5,416,390
Closing Purchase Amount	$25,000,000 USD

* Subject to appropriate adjustment in the event of a stock dividend, stock split, combination or other similar recapitalization affecting the Common Stock.

EXHIBIT B

SCOPE OF OPINION

1. The Company is a validly existing corporation in good standing under the laws of the State of Delaware and is qualified to do business as a foreign corporation in and is in good standing under the laws of the State of Massachusetts.

2. The Company has authorized 200,000,000 shares of Common Stock, par value $0.0001 per share. The Shares have been duly authorized and, when issued and delivered to and paid for by the Purchaser in accordance with the terms of the Purchase Agreement, will be validly issued, fully paid and non-assessable and free of preemptive or similar rights arising under the Company's Certificate of Incorporation or Bylaws.

3. The Company has all requisite corporate power and authority to (i) issue, sell and deliver the Shares pursuant to the Transaction Documents, (ii) execute and deliver the Transaction Documents and (iii) to carry out and perform its obligations under the Transaction Documents. The Transaction Documents have been duly and validly executed and delivered by the Company.

4. The execution and delivery by the Company of the Transaction Documents, the performance of its obligations thereunder, and the issuance by the Company of the Shares to the Purchaser:

(i) do not and will not violate the charter or bylaws of the Company;

(ii) based solely upon review of such agreements, do not and will not result in a breach of or default under any agreement to which the Company is a party that is identified to us in a certificate of the Company as being material to the Company and its subsidiaries taken as a whole, which agreements are listed on Annex A[1]; and

(iii) do not and will not (A) violate any law, rule or regulation of the State of New York or the United States of America applicable to the Company that, in our experience, is generally applicable to transactions in the nature of those contemplated by the Transaction Documents, (B) violate the Delaware General Corporation Law, or (C) require any filing with or approval of any governmental authority or regulatory body of (a) the State of New York or the United States of America under any law or regulation currently in effect of the State of New York or the United States of America applicable to the Company that, in our experience, is generally applicable to transactions in the nature of those contemplated by the Transaction Documents, or (b) the State of Delaware under the Delaware General Corporation Law, except for such filings or approvals as already have been made or obtained and except for the filing of a Notice of Exempt Offering of Securities on Form D, filed under Regulation D under the Securities Act.

5. Assuming the accuracy of the representations and the Purchaser's compliance with the covenants made by the Purchaser in the Transaction Documents, the offering, sale and issuance of the Shares to the Purchaser pursuant to the Transaction Documents is exempt from registration under the Securities Act.

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[1] To include indentures, loan agreements, mortgages, leases and other material agreements filed with the SEC.

6. The Company is not and, after giving effect to the sale of the Shares in accordance with the Transaction Documents, will not be an “investment company” that is required to be registered under the Investment Company Act of 1940, as amended.

APPENDIX I

SELLING STOCKHOLDER QUESTIONNAIRE

APPENDIX II

REGISTRATION RIGHTS AGREEMENT

Exhibit 31.1

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

August 6, 2020

/s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.

President and Chief Executive Officer, and Director

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Bradford D. Dahms, certify that:

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

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

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

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

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

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

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

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

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

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

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

August 6, 2020

/s/ Bradford D. Dahms

Bradford D. Dahms

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

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

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

1. The Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

August 6, 2020

/s/ Carsten Brunn, Ph.D.

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

Exhibit 32.2

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

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

1. The Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

August 6, 2020

/s/ Bradford D. Dahms

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