

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## FORM 10-K

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

For the fiscal year ended December 31, 2020

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-37798

## Selecta Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction  
of incorporation or organization)

65 Grove Street, Watertown, MA

(Address of principal executive offices)

26-1622110

(I.R.S. Employer Identification No.)

02472

(Zip Code)

(617) 923-1400

Registrant's telephone number, including area code

### 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 Stock Market LLC

### Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

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 and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant has filed a report on and attested to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The aggregate market value of common stock held by non-affiliates of the registrant based on the closing price of the registrant's common stock as reported on the Nasdaq Stock Market on June 30, 2020, the last business day of the registrant's most recently completed second quarter, was \$247,960,409.

As of March 5, 2021 the registrant had 112,373,199 shares of common stock, par value \$0.0001 per share, outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission are incorporated by reference into Part III of this Annual Report on Form 10-K.

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## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or the Annual 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual 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 coronavirus, COVID-19 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 Annual 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 Annual 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 Annual 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 such pipeline;
- 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 access 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 continuing 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 Annual Report and the documents that we reference in this Annual 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**

**Item 1. Business**

**Overview**

We are a clinical-stage biopharmaceutical company leveraging our ImmTOR™ immune tolerance platform with the goals of amplifying the efficacy of biologics, including enabling the re-dosing of life-saving gene therapies, and restoring self-tolerance in autoimmune diseases. Our ImmTOR platform encapsulates rapamycin, also known as sirolimus, an immunomodulator, in biodegradable nanoparticles and is designed to induce antigen-specific immune tolerance.

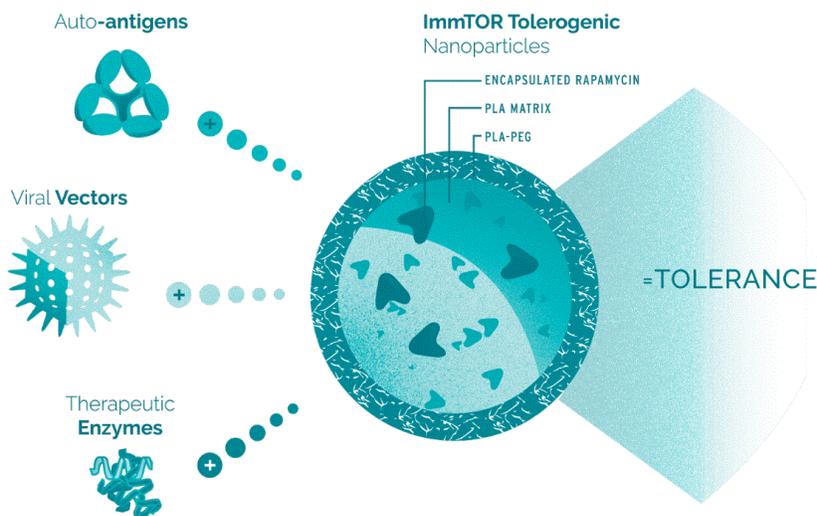
The ImmTOR platform has the potential to mitigate the formation of anti-drug antibodies, or ADAs, against biologic drugs and restore self-tolerance to auto-antigens in autoimmune diseases. ADAs can start developing in the body with the first dose of a biologic therapy and can render subsequent doses ineffective or unsafe, potentially depriving patients of life-saving therapeutic options and limiting the likelihood of success for many otherwise promising novel biologic drugs and technologies. Additionally, we believe, based on preclinical data, that ImmTOR combined with adeno-associated virus, or AAV, gene therapy has the potential to increase transgene expression and to prevent undesired immune responses to the AAV capsid and the transgene product that can occur with the first dose of gene therapy.

We believe ImmTOR has the potential to enhance the efficacy without compromising the safety of biologic therapies, improve product candidates under development, and enable novel therapeutic modalities. We have developed a portfolio of proprietary and collaboration-driven applications of ImmTOR, and we plan to continue to develop proprietary compounds and pursue collaboration-driven development in certain disease areas, which could include strategic collaborations, out-licensing, and in-licensing transactions.

**Our ImmTOR Platform**

ImmTOR consists of our biodegradable nanoparticles encapsulating the immunomodulator rapamycin. Rapamycin is the active ingredient of Rapamune, an immunosuppressant which has extensive prior use in humans and is currently FDA-approved as a prophylaxis of organ rejection in kidney transplant patients aged 13 or older. Poly(D,L-lactide), or PLA is part of the broader poly(lactic-co-glycolic acid), or PLGA, family of biodegradable polymers that have more than 30 years of commercial use and are formulation components in a number of approved products. Polyethylene glycol, or PEG, has been widely studied in clinical trials and is also a formulation component in many approved biologic products.

Our nanoparticles are designed to remain intact after injection into the body and accumulate predominantly in lymph nodes, the spleen, and the liver, where the immune response is coordinated. The nanoparticles are designed to be processed by specialized immune cells, such as dendritic cells and other antigen-presenting cells that initiate and regulate immune responses. ImmTOR is intended to induce a tolerogenic phenotype in these antigen-presenting cells, which then process and present co-administered antigen in a manner that results in the induction of antigen-specific regulatory T cells. To mitigate the formation of ADAs and induce immune tolerance in the body, we administer our ImmTOR with an antigen, such as a therapeutic enzyme, a viral vector in the case of our gene therapy program, or an auto-antigen, which is depicted in the figure below.

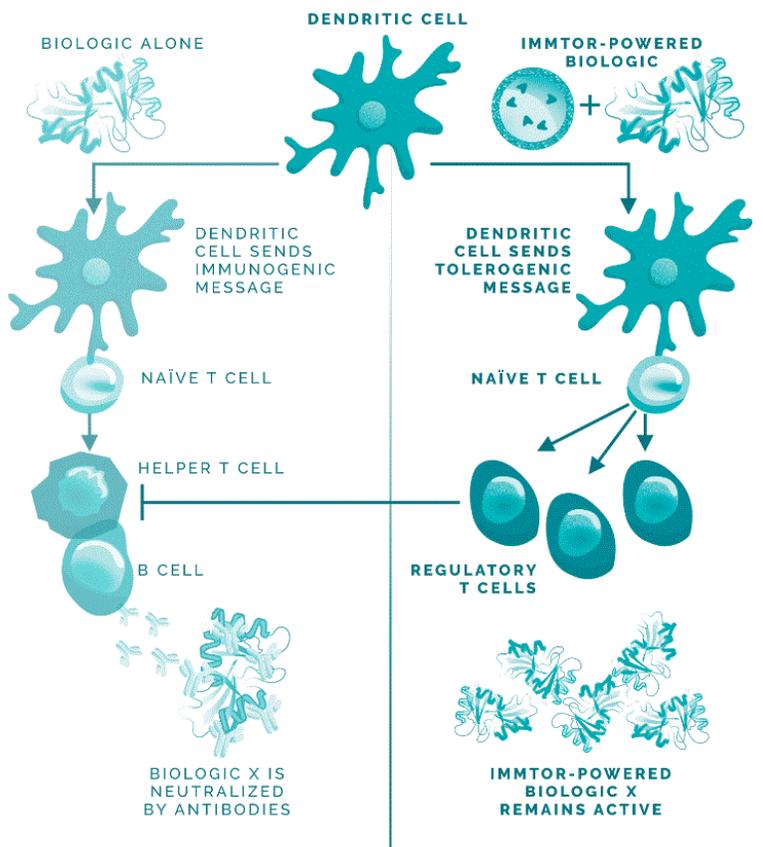


*Co-administration of ImmTOR with an auto-antigen, viral vector, or therapeutic enzyme.*

In the case of a biologic drug, ImmTOR is designed to be administered in conjunction with such biologic drug to mitigate the formation of ADAs without requiring the alteration of the drug or its dose regimen. As a result, we believe ImmTOR may provide us with significant opportunities in the areas of immune tolerance and ADA prevention because ImmTOR is designed

so that it can be co-administered at the beginning of therapy with many different biologic drugs, including enzymes and viral vectors. Importantly, we believe each pairing of ImmTOR with a biologic drug also offers us the opportunity to pursue a distinct proprietary product candidate, which we believe has the potential to be separately patented, approved and marketed. ImmTOR is manufactured in facilities subject to current good manufacturing practice, or cGMP, requirements using well-defined commercial operations, which, we believe, further enhances the scalability of our tolerance programs.

During preclinical studies, we observed that delivering an antigen together with ImmTOR provided the appropriate signals *in vivo* to induce regulatory T cells, which, in turn, inhibited effector immune responses, such as the formation of ADAs. In our preclinical studies, we observed that ImmTOR labeled with a fluorescent dye selectively accumulated in lymphoid organs where it was processed by antigen-presenting cells. The figure below depicts a model of how ImmTOR would be taken up by a dendritic cell in the spleen. We believe that both the biologic drug and ImmTOR are taken up and processed by dendritic cells and other antigen presenting cells in a manner that may induce regulatory T cells, which can potentially block the activation of helper T cells, mitigating the formation of ADAs.



*ImmTOR and Antigen/Biologic Drug Presentation and Related Immune Tolerance Induction*

ImmTOR leverages nanoparticle technology to target rapamycin, an approved immunomodulatory drug, to antigen presenting cells to generate antigen-specific immune tolerance when combined with the antigen of interest. We believe our ImmTOR platform has a broad range of potential applications.

- *Enzyme therapies.* Enzyme therapies are a frequently used class of biologic drugs to treat rare diseases. Through our analysis of biologic drugs, including our preclinical studies, we have observed that enzymes are especially prone to undesired immune responses. Our product candidate, SEL-212, which is currently in Phase 3 clinical development includes pegadricase, a pegylated uricase enzyme, which is an example of a highly immunogenic enzyme for which we are applying ImmTOR with the intention of improving the enzyme’s efficacy and safety. We are also combining ImmTOR with an IgA protease for the treatment of IgA nephropathy. We intend to seek, if appropriate, licenses to other enzymes that we would evaluate in combination with ImmTOR.
- *Gene therapies.* We believe gene therapies have the potential to address key unmet medical needs for many rare genetic diseases, but undesired immune responses to the viral vectors used for gene replacement, augmentation and editing may be restricting their broader use. Through our analysis of genetic diseases, we have identified applications and patient segments that we believe would benefit from our ImmTOR platform. We intend to develop ImmTOR-enabled non-immunogenic gene therapy candidates which are designed to be utilized with AAV, vectors (e.g., AAV8, AAV5). We believe our product candidates have the potential to increase transgene expression and to prevent undesired immune responses to the vector and transgene product that can occur with the first dose of gene therapy by

using our ImmTOR platform. Our initial area of focus is on genetic metabolic diseases but may also include lysosomal storage diseases and genetic muscular diseases. We believe we are the first company to systematically pursue the development of AAV gene therapy product candidates with the goal of enabling repeat administration. We have engaged third parties with experience in gene therapy and rare diseases to support the development of our proprietary products. We also have licensed our ImmTOR platform to Asklepios BioPharmaceutical, Inc., or AskBio, Sarepta Therapeutics, Inc., or Sarepta, and Spark Therapeutics, Inc., or Spark, for certain pre-specified targets.

- *Restoring self-tolerance to auto-antigens:* We believe that ImmTOR has the potential to restore self-tolerance to autoimmune diseases. Our first program in autoimmune diseases is in primary biliary cholangitis, or PBC. PBC has a significant unmet medical need and a well-defined target antigen, known as PDC-E2.
- *Other products and product candidates affected by undesired immune responses.* We have generated preclinical data which we believe suggests a broad potential benefit of ImmTOR for immune tolerance. For many biologic drugs, undesired immune responses limit efficacy and cause safety concerns. We intend to strategically out-license ImmTOR for use with other products that are outside our focus to larger biopharmaceutical companies. We believe our ImmTOR platform may also be of interest to biopharmaceutical companies with novel biologic development concepts or product candidates in clinical development that have demonstrated initial efficacy but are experiencing issues with safety or sustained efficacy due to inhibitory ADAs.

## Our Product Candidates

Below is a summary of our ongoing discovery, research and development programs:

<b><u>Program</u></b>	<b><u>Phase of Development</u></b>	<b><u>Next Steps</u></b>	<b><u>Commercial Rights</u></b>
<b>Amplifying the Efficacy of Biologic Therapies (Enzyme Therapies)</b>			
<i>SEL-212 (Chronic Refractory Gout)</i>	Phase 3 clinical trials (DISSOLVE I / DISSOLVE II)	Complete enrollment 2H 2021; top-line data 2H 2022	Sobi
<i>IgA Nephropathy</i>	Preclinical	IND filing 4Q 2021	Selecta
<b>Amplifying the Efficacy of Biologic Therapies (Gene Therapies)</b>			
<i>Methylmalonic Acidemia (MMA)</i>	Preclinical	Commence phase 1/2 2Q 2021; preliminary data 4Q 2021	Selecta and AskBio
<i>Ornithine Transcarbamylase (OTC) Deficiency</i>	IND-enabling	Clinical program expected to commence in 2022	Selecta
<i>SEL-399 (Empty AAV Capsid+ImmTOR)</i>	Phase 1	Data expected in 4Q 2021	Selecta and AskBio
<i>Pompe Disease</i>	Preclinical	Plans to be announced by our collaborator	AskBio
<i>Duchenne Muscular Dystrophy (DMD)</i>	Preclinical	Plans to be announced by our collaborator	Sarepta
<i>Limb-girdle Muscular Dystrophy</i>	Preclinical	Plans to be announced by our collaborator	Sarepta
<b>Restoring Self-Tolerance in Autoimmune Diseases</b>			
<i>Primary Biliary Cholangitis</i>	Preclinical	IND filing expected in 2022	Selecta

## ***Amplifying the Efficacy of Biologics: Enzyme Therapy – Chronic Refractory Gout***

SEL-212 is designed to be a monthly treatment for chronic refractory gout, a debilitating rare disease with an unmet medical need. SEL-212 consists of a combination of our ImmTOR platform co-administered with pegadricase. Pegadricase is an investigational recombinant pegylated uricase (urate oxidase), an enzyme not naturally found in humans, and is therefore highly immunogenic. This enzyme is designed to treat patients with symptomatic gout, refractory to standard uric acid lowering treatment, by breaking down the excess uric acid to the more soluble allantoin. In preclinical studies, we observed that ImmTOR, when co-administered with pegadricase, induced antigen-specific immune tolerance to pegadricase and substantially reduced the formation of associated ADAs. Based on our 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. Additionally, we believe that SEL-212 serves as proof of concept for the ImmTOR platform in ameliorating the unwanted immune response to an immunogenic biologic. SEL-212 is in two pivotal Phase 3 studies versus placebo, which we refer to as DISSOLVE I and DISSOLVE II, and with topline data expected in the second half of 2022. SEL-212 has been licensed (except as to Greater China) to Swedish Orphan Biovitrum AB, or Sobi, pursuant to our license and development agreement dated June 11, 2020 with Sobi, or the Sobi License.

### *The market for gout therapy*

Gout, a painful and potentially disabling form of arthritis resulting from excess accumulation of uric acid and deposition of uric acid crystals in joints and soft tissues, including those of the kidney and heart, causing harmful inflammation, is caused by an overproduction of uric acid and/or an inability of the kidneys to excrete adequate amounts of uric acid from the body. High concentrations of SUA lead to formation of uric acid crystals in joints and tissues, causing pain, inflammation and joint damage, and increase the risk for other conditions, including cardiovascular, cardiometabolic, joint and kidney disease.

Patients who are unable to reduce their SUA levels below 6.0 mg/dL with oral drugs are diagnosed with refractory gout. Chronic refractory gout constitutes a subset of gout patients exhibiting chronic high SUA levels and painful and damaging uric acid deposits. We estimate that there are approximately 160,000 chronic refractory gout patients in the U.S.

We believe SEL-212 may potentially address several key unmet needs in the treatment of chronic refractory gout: the durable control of SUA levels, the elimination of painful and damaging uric acid deposits, reduction in incidence and severity of flares, based on our preclinical studies, clinical studies, and market research. SEL-212 is designed to address these unmet medical needs while improving the dosing regimen to a once-monthly treatment.

We announced the top-line data of our Phase 2 head-to-head clinical trial, which we refer to as the COMPARE trial, against pegloticase, which is marketed as KRYSTEXXA®, in September 2020. SEL-212 showed a numerically higher response rate to pegloticase on the primary endpoint during months 3 and 6 combined, but did not meet the primary endpoint of statistical superiority. SEL-212 did demonstrate a statistically significant higher response rate of SEL-212 during the third month of treatment, as well as a statistically significant greater overall reduction in mean SUA levels in SEL-212 versus pegloticase. SEL-212 demonstrated a numerically higher response rate of SEL-212 during the sixth month of treatment. In patients with tophi at baseline, SEL-212 demonstrated substantially higher responder rates for SEL-212 compared to pegloticase on the primary endpoint, and a statistically significant reduction in mean SUA when compared to pegloticase. Approximately 41% of patients in the Phase 2 COMPARE trial had visible tophi at baseline. SEL-212 showed favorable safety results and was well-tolerated; there were no deaths during the study. There were no notable differences in serious Treatment Emergent Adverse Events, or TEAEs, treatment-related serious TEAEs, or infusion reactions between the two groups. A full analysis of safety signals, including gout flare incidence and severity, requires evaluation of the full data set and will be reported together with the full efficacy analysis in a manuscript in a medical journal.

We and Sobi commenced the Phase 3 DISSOLVE clinical program of SEL-212 in September 2020. The Phase 3 clinical program consists of two double blinded, placebo-controlled trials of SEL-212, DISSOLVE I and DISSOLVE II. Each trial is expected to enroll 105 patients, with 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. DISSOLVE I and DISSOLVE II both have a 6-month primary endpoint with a 6-month safety extension for DISSOLVE I. Topline data from the Phase 3 DISSOLVE clinical program is expected in the second half of 2022. The Phase 3 DISSOLVE clinical program is being conducted by Selecta and funded by Sobi.

### ***SEL-212 Components***

SEL-212 consists of ImmTOR co-administered with pegadricase. Our ImmTOR consists of nanoparticles composed of poly(D,L-lactide), or PLA, and poly(D,L-lactide)-block-poly(ethylene-glycol), or PLA-PEG, encapsulating rapamycin. Our pegadricase consists of a uricase modified with poly(ethylene-glycol), or PEG.

Pegadricase is a pegylated version of the therapeutic enzyme uricase, which we have licensed from Shenyang Sunshine Pharmaceutical Co., Ltd., or 3SBio, exclusively for all markets, except Japan and Greater China, and exclusively for Japan only in combination with our ImmTOR platform. Uricase is an enzyme endogenous to all mammals, except for humans and certain primates, which converts uric acid to the more soluble metabolite, allantoin. There is a natural limit to the amount of uric acid

that can be excreted by the kidneys, which decreases with age and can be reduced by some medications. By converting uric acid to allantoin, uricase provides an additional way for the body to reduce uric acid. In our Phase 1/2 program, out of 19 patients dosed with the pegadricase alone, three patients were responders at week 4.

### ***SEL-212 Clinical Development***

#### *Phase 1a and Phase 1b clinical trials*

We conducted Phase 1a and Phase 1b clinical trials for SEL-212 at multiple sites in the United States.

The Phase 1a trial consisted of a single ascending-dose trial of pegadricase alone in 22 patients with elevated SUA levels greater than 6.0 mg/dL. At the outset of the trial, each of five cohorts received a single intravenous infusion of pegadricase at ascending dose levels. We monitored the patients during a 30-day period post-infusion. We commenced enrollment of the clinical trial in the second quarter of 2015 and completed the treatment portion of the trial in November 2015. We observed that pegadricase showed no serious adverse events, or SAEs, and was well tolerated at the five dose levels tested. Additionally, we observed that pegadricase rapidly reduced and sustained average SUA levels below 6.0 mg/dL for each cohort for 14 to 30 days, depending on the dose level. Consistent with our preclinical studies in animals, pegadricase induced uricase-specific ADAs in all patients with varying levels in this Phase 1a trial.

The Phase 1b clinical trial enrolled 63 patients with SUA levels greater than 6.0 mg/dL. One group of five patients received a single 0.4 mg/kg dose of pegadricase alone. Four groups of patients, each containing two placebo-control patients and five test article patients, received a placebo or a single intravenous infusion of ImmTOR alone at the following ascending dose levels: 0.03 mg/kg, 0.1 mg/kg, 0.3 mg/kg and 0.5 mg/kg. Four groups of patients received a single intravenous infusion of ImmTOR at ascending dose levels of 0.03 mg/kg (5 patients), 0.1 mg/kg (10 patients), 0.15 mg/kg (5 patients) or 0.3 mg/kg (5 patients) with a fixed dose of pegadricase of 0.4 mg/kg, which we collectively call the SEL-212 cohorts. All patients were followed for at least 30 days after their initial dose.

At the completion of our Phase 1b program for SEL-212 we had dosed a total of 64 patients in the trial with either SEL-212 (ImmTOR and pegadricase), ImmTOR alone, pegadricase alone or placebo. The median serum acid level of patients enrolled was 7.3 mg/dL, with a mean of 7.4 mg/dL at baseline. Patients presented with an average of 5.3 co-morbidities, such as hypertension and diabetes.

We have generally observed that SEL-212 and its components, ImmTOR and pegadricase, have been well tolerated in this patient population. There were a total of six SAEs in the Phase 1b trial. Of the six SAEs, three were determined to not to be related to study drug by investigators. Of the remaining three SAEs that were determined to possibly or likely be related to study drug, two were cases of stomatitis that occurred at the highest dose of ImmTOR tested (0.5 mg/kg), leading us to define 0.3 mg/kg as the maximum tolerated dose of ImmTOR in this patient population. The remaining SAE was a case of drug hypersensitivity that occurred at a dose of 0.1 mg/kg of ImmTOR in combination with 0.4 mg/kg of pegadricase. In all cases, the patient fully recovered from the SAE without residual effects.

#### *Phase 2 dose-finding clinical trial*

We enrolled patients with symptomatic gout and elevated SUA levels in an open-label, multiple ascending-dose Phase 2 clinical trial of SEL-212 at 15 active U.S. clinical sites. The primary and secondary endpoints for this trial included safety, tolerability, pharmacokinetics, and reduction of SUA and ADA levels, in addition to data regarding flares and other patient-related observations.

The following are the results from the 152 patients dosed in the Phase 2 trial with the primary clinical endpoint of SUA levels below 6 mg/dL:

- *Control and 0.05 mg/kg ImmTOR Dose Cohorts* (cohorts receiving five monthly doses of pegadricase alone or three monthly doses of 0.2 mg/kg or 0.4 mg/kg of pegadricase + 0.05 mg/kg of ImmTOR followed by two monthly doses of pegadricase alone): Dosing of patients in the control cohorts receiving pegadricase alone was stopped early due to a loss of clinical activity caused by the immunogenicity of the enzyme. Clinical activity was lost by week 12 in the majority of patients receiving pegadricase in combination with the 0.05 mg/kg dose of ImmTOR.
- *0.08 and 0.1 mg/kg ImmTOR Dose Cohorts* (cohorts receiving three monthly doses of 0.2 mg/kg or 0.4 mg/kg of pegadricase + 0.08 or 0.10 mg/kg of ImmTOR followed by two monthly doses of pegadricase alone): A majority of patients in these cohorts maintained clinical activity while receiving the combination therapy through week 12. These results were consistent with the level of clinical activity observed through day 30 at a similar SEL-212 dose level in our Phase 1b trial. At the 0.1 mg/kg dose level, half of the patients that maintained clinical activity through week 12 also maintained clinical activity through week 20.
- *0.125 and 0.15 mg/kg ImmTOR Dose Cohorts* (cohorts receiving three monthly doses of pegadricase +0.125 or 0.15 mg/kg of ImmTOR followed by two monthly doses of pegadricase alone): A majority of patients in these cohorts maintained clinical activity while receiving the combination therapy through week 12. These results were consistent

with the level of clinical activity observed through day 30 at a similar SEL-212 dose level in our Phase 1b trial. Approximately 81% of evaluable patients (N=27) receiving up to 0.15 mg/kg ImmTOR in combination with 0.2 or 0.4 mg/kg of pegadricase followed by 2 monthly doses of pegadricase alone had SUA control below 6 mg/dL at week 12.

- *0.10 and 0.15 mg/kg ImmTOR 5 Combination Dose Cohorts* (cohorts receiving five monthly doses of pegadricase +0.10 or 0.15 mg/kg of ImmTOR): Five monthly doses of SEL-212 resulted in sustained SUA control and was well tolerated over the entire treatment period. 100% of the patients that had SUA levels below 6 mg/dL at 12 weeks maintained control through 20 weeks. Approximately 66% of evaluable patients (21/32) completed week 20 with SUA levels below 6 mg/dL.

SEL-212 was generally well-tolerated at clinically active doses following repeated administrations in the trial. Twenty patients reported a total of 23 SAEs in the Phase 2 clinical trial. Nine SAEs were reported in the five dose combination cohorts, seven of which were reported to be not related or unlikely related to study drug, and two of which were infusion reactions. All SAEs were successfully treated without further issues.

#### *Phase 2 head-to-head clinical trial (COMPARE)*

In March 2019, we initiated a non-registrational Phase 2 head-to-head clinical trial of SEL-212 (COMPARE), in which SEL-212 was compared against the current FDA-approved therapy for chronic refractory gout, pegloticase, in multiple clinical sites in the United States. The two-armed, open label trial enrolled 170 patients with 87 patients receiving pegloticase (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).

On September 30, 2020, we announced the topline results from the COMPARE trial. SEL-212 showed a numerically higher response rate to pegloticase on the primary endpoint during months 3 and 6 combined, but did not meet the primary endpoint of statistical superiority. SEL-212 did demonstrate a statistically significant higher response rate of SEL-212 during the third month of treatment, as well as a statistically significant greater overall reduction in mean SUA levels in SEL-212 versus pegloticase in months 3 and 6 combined. SEL-212 demonstrated a numerically higher response rate of SEL-212 during the sixth month of treatment. In patients with tophi at baseline, SEL-212 demonstrated substantially higher responder rates for SEL-212 compared to pegloticase on the primary endpoint, and a statistically significant reduction in mean SUA when compared to pegloticase. Approximately 41% of patients in the Phase 2 COMPARE trial had visible tophi at baseline, which is lower than expected for the general refractory gout population. SEL-212 showed a favorable safety profile and was well-tolerated. There were no deaths during the study. There were no notable differences in serious TEAEs, treatment-related serious TEAEs, or infusion reactions between the two groups. A full analysis of safety signals, including gout flare incidence and severity, requires evaluation of the full data set and will be reported together with the full efficacy analysis in a manuscript in a medical journal.

#### *Phase 3 DISSOLVE clinical program*

In September 2020, we commenced the Phase 3 clinical program of SEL-212, which we refer to as DISSOLVE. We are responsible for the execution of the DISSOLVE program and are being reimbursed by Sobi on a quarterly basis for expenses incurred in connection with these activities. The Phase 3 clinical program consists of two double-blinded, placebo-controlled trials of SEL-212. We refer to these trials as DISSOLVE I and DISSOLVE II. Each trial is expected to enroll 105 patients, with 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. We commenced enrollment of DISSOLVE I in September 2020 and DISSOLVE II in December 2020. DISSOLVE I is enrolling patients in the United States only and will have a 6-month primary endpoint followed by a 6-month safety extension. DISSOLVE II will have a 6-month primary endpoint with no extension. The primary endpoint of the DISSOLVE program is the maintenance of SUA levels below 6 mg/dL at 6 months. Topline data from the Phase 3 DISSOLVE clinical program is expected in the second half of 2022.

#### ***Amplifying the Efficacy of Biologics: Enzyme Therapy – IgA Nephropathy***

The second indication in our enzyme therapy program is IgA nephropathy, an autoimmune kidney disease that occurs when immune complexes of a subclass of antibodies called immunoglobulin A1 (IgA1) accumulates in the kidneys.

On October 8, 2020, we entered into an Option and License Agreement, or the IGAN Agreement, with IGAN Biosciences, Inc., or IGAN. Pursuant to the IGAN Agreement, IGAN has granted us an exclusive license to research, evaluate, and conduct pre-clinical development activities on IGAN's proprietary IgA proteases. Previous studies in animal models conducted at independent laboratories demonstrated that IgA protease removed injurious IgA immune complexes from kidneys and reduced inflammation, fibrosis, and hematuria. These results suggest that it is an excellent candidate to potentially decrease the rate of disease progression and possibly even reverse the disease. The barrier to IgA protease commercialization is the bacterial origin of the protease, which makes it immunogenic. Our ImmTOR platform has shown in clinical studies the ability to mitigate the formation of ADAs to immunogenic enzymes, which has been demonstrated with our Phase 3 lead product candidate, SEL-212. We intend to combine IgA protease with our ImmTOR platform to develop a novel combination product candidate for the treatment of IgA nephropathy and IgA-mediated diseases. We will have an option term of 24 months, during which we can

elect to obtain an exclusive license to further develop and commercialize the product candidate to treat all IgA-mediated diseases, including IgA nephropathy, Linear IgA bullous dermatitis, IgA pemphigus, and Henoch-Schonlein purpura (also known as IgA vasculitis).

We plan to file an Investigational New Drug, or IND, application, for this program by the fourth quarter of 2021.

### ***Amplifying the Efficacy of Biologics: Gene Therapies***

When used in combination with AAV gene therapy vectors, ImmTOR has been observed to inhibit the immune response to the vector and enable successful redosing in mice and nonhuman primates. Currently, the ability to re-administer systemic AAV gene therapy is limited by the development of neutralizing antibodies. The ability to safely re-dose AAV may help achieve therapeutic benefit in patients who are under-dosed; it may also help restore transgene expression in patients, particularly pediatric patients, who may lose expression over time as they grow. In addition, a study conducted in nonhuman primates showed that co-administration of AAV vector and ImmTOR in non-human primates, or NHPs, enabled higher and more durable transgene expression after the first dose of gene therapy as well as robust inhibition of anti-AAV8 immunoglobulin G, or IgG and neutralizing antibodies. The observation that co-administration of AAV vector and ImmTOR leads to higher transgene expression demonstrates the potential for dosing lower levels of AAV gene therapies when combined with ImmTOR. Thus integrating ImmTOR into a gene therapy protocol has the potential to provide a first dose benefit by enhancing liver-directed transgene expression and durability, as well as the potential for enabling re-dosing.

Our lead gene therapy program 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. We and AskBio plan to file an IND for this product candidate, MMA-101, in MMA and commence a Phase 1 clinical trial in the first half of 2021 under this collaboration. We expect to report initial data from this trial by the end of 2021. In October and November 2020, we and AskBio received rare pediatric disease designation and orphan drug designation, respectively, from the FDA for MMA-101, for the treatment of MMA due to methylmalonyl-CoA mutase, or MMUT gene mutations. See “——Licenses and Collaborations—— AskBio” for more information.

Our proprietary gene therapy product candidate, SEL-313, is being developed to treat ornithine transcarbamylase, or OTC deficiency, and is currently in preclinical development. OTC deficiency is a rare genetic disorder that causes ammonia to accumulate in the blood due to mutations in the OTC gene, which is critical for proper function of the urea cycle. The most severe form of the disorder presents within the first few days of life. Severe symptoms include inability to control body temperature and breathing rate, seizures, coma, developmental delays and intellectual disability. Less severe forms of the disorder are characterized by delirium, erratic behavior, aversion to high protein foods, vomiting and seizures.

The SEL-399 program combines an empty AAV capsid (EMC-101), which is an AAV capsid containing no transgene, with ImmTOR and is being conducted in partnership with AskBio. Building on the preclinical data we have generated showing ImmTOR’s effect on mitigating or reducing the formation of neutralizing antibodies to AAV gene therapies, we have commenced a clinical trial of SEL-399 in healthy adult volunteers in Belgium. The goal of the SEL-399 clinical trial is to demonstrate the appropriate dose of ImmTOR in humans to mitigate the formation of antibodies to AAV capsids used in gene therapies. An initial control cohort of healthy volunteers received a single dose of EMC-101 in December 2020 and dose escalating cohorts of EMC-101 plus ImmTOR were initiated in February 2021. Topline results from the clinical trial are expected in the fourth quarter of 2021.

We have several additional programs in development with our collaborators.

### ***Restoring Self-tolerance in Autoimmune Diseases***

Our lead autoimmune diseases indication is PBC, a T-cell driven autoimmune disease that causes progressive destruction of the bile ducts. Patients with PBC are in need of a highly-targeted, liver-directed approach to treating the root cause of the disorder. We believe PBC has a well-defined target antigen, significant unmet medical need, and is well suited to the application of our ImmTOR immune tolerance platform, as preclinical data suggest that ImmTOR has the potential to enhance the tolerogenic environment in the liver and provide a hepatoprotective benefit.

### **Licenses and Collaborations**

#### ***Swedish Orphan Biovitrum***

In June 2020, we announced that we had entered into the Sobi License, pursuant to which we agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize SEL-212, which is currently in development for the treatment of chronic refractory gout. In September 2020, pursuant to the Sobi License, Sobi paid us a one-time, up-front payment of \$75 million. 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.

Additionally, Sobi purchased 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.

Under the Sobi License, we will have operational oversight of the Phase 3 DISSOLVE clinical program of SEL-212 (DISSOLVE I and DISSOLVE II) that commenced in September 2020, at Sobi's expense.

### ***IGAN Biosciences***

In October 2020, we entered into the IGAN Agreement. Pursuant to the IGAN Agreement, IGAN granted us an exclusive license to research, evaluate, and conduct pre-clinical development activities on IGAN's proprietary IgA proteases. We have an option term of 24 months, or the Option Term, during which we can elect to obtain an exclusive license to further develop and commercialize the product to treat all IgA-mediated diseases, including IgA nephropathy, Linear IgA bullous dermatitis, IgA pemphigus, and Henoch-Schonlein purpura (also known as IgA vasculitis).

Upon execution of the IGAN Agreement, we paid IGAN a one-time up-front payment of \$500,000 and we would owe additional payments to IGAN if we were to opt-in to an exclusive license agreement, as well as upon the achievement of certain development and sales milestones.

During the Option Term, we may terminate the IGAN Agreement immediately for any reason upon written notice to IGAN. If we opt-in to an exclusive license agreement, we may terminate the IGAN Agreement upon 120 days' written notice.

### ***Sarepta Therapeutics***

In June 2020, we entered into a research license and option agreement with Sarepta, or the Sarepta Agreement. Pursuant to the agreement, we granted 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 Sarepta Product, to treat Duchenne Muscular Dystrophy and certain Limb-Girdle Muscular Dystrophy subtypes, or the Sarepta 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 Sarepta Product to treat at least one Sarepta Indication, with a potential to extend the option term if Sarepta pays an additional fee to us. Sarepta made an up-front payment to us upon signing of the agreement, and we are eligible to receive additional 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***

#### ***Feasibility Study and License Agreement***

In August 2019, we entered into a feasibility study and license agreement with AskBio, or the AskBio Collaboration Agreement. 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 and will leverage that previous work within the collaboration. We expect to commence a Phase 1 clinical trial in MMA-101 in the first half of 2021, with initial proof of concept data expected by the end of 2021. The initial proof-of-concept data will potentially validate the use of our ImmTOR platform to mitigate the formation of neutralizing anti-AAV capsid antibodies, which currently precludes re-dosing. 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, the SEL-399 program in collaboration with AskBio, combines an empty AAV capsid (EMC-101), which is an AAV capsid containing no transgene, with ImmTOR. We commenced the trial in healthy adult volunteers in December 2020, with the goal to demonstrate the appropriate dose of ImmTOR in humans to mitigate the formation of antibodies to AAV capsids used in gene therapies. Topline results are expected in the fourth quarter of 2021.

We 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 we are responsible for manufacturing ImmTOR.

#### ***License Agreement for Pompe Disease***

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. Pursuant to the AskBio License Agreement, AskBio paid us upfront fees of

an aggregate of \$7.0 million. Also pursuant to the AskBio License Agreement, AskBio agreed to make additional payments to us based on the achievement of certain development and commercial milestones of up to an aggregate of \$237.0 million. AskBio will also be obligated to make tiered royalty payments, at percentages in the mid-to-high single digits, to us based on achievement of certain sales milestones.

We will supply AskBio with our ImmTOR platform and AskBio will be responsible for all preclinical, clinical and commercial manufacture and supply of products licensed under the AskBio License Agreement (other than ImmTOR) and carry out all other activities related to the research, development, and commercialization of such products at its sole expense, including all regulatory activities related thereto. The AskBio License Agreement contains other customary terms and conditions, including representations and warranties, covenants, termination, and indemnification obligations in favor of each party.

### ***Spark Therapeutics***

In 2016, we entered into a license and option agreement with Spark, 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.

Pursuant to the Spark License Agreement, Spark paid us an upfront payment of \$15.0 million. We will be eligible to receive up to an aggregate of \$430.0 million in milestone payments, with up to \$65.0 million being based on Spark's achievement of specified development and regulatory milestones and up to \$365.0 million for commercial milestones, as well as tiered royalties on global net sales at percentages ranging from mid-single to low-double digits.

Each party is responsible for its own costs and expenses incurred in connection with its respective activities under the Spark License, except that Spark has agreed to reimburse us for the full-time equivalent and out-of-pocket costs incurred in performing certain tasks or assistance specifically requested by Spark. We retain the responsibility to manufacture Spark's preclinical, clinical and commercial requirements for the ImmTOR platform, subject to the terms of the Spark License Agreement.

The Spark License Agreement will continue on a country-by-country and product-by-product basis until the expiration of Spark's royalty payment obligations with respect to such product in such country unless earlier terminated by the parties. 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 the material breach of the other party with respect to such target.

In connection with the Spark License Agreement, we also entered into a stock purchase agreement with Spark, pursuant to which Spark purchased in the aggregate \$15.0 million of shares of our common stock.

### ***Massachusetts Institute of Technology***

In 2008, we entered into a license agreement with the Massachusetts Institute of Technology, or MIT, which we refer to in its amended form as the MIT License. We amended the MIT License in January 2010, August 2013, November 2016, December 2019 and June 2020. Under the MIT License, we acquired an exclusive worldwide license, with the right to grant sublicenses, to develop, make, sell, use and import certain licensed products that are therapeutic or prophylactic vaccines and use certain licensed processes in the exercise of rights to the licensed products, the manufacture, sale and practice of which are covered by patent rights owned or controlled by MIT, including patents jointly owned with Brigham and Women's Hospital, or Brigham, the President and Fellows of Harvard College, the Immune Disease Institute and the Children's Medical Center Corporation. Our exclusivity is subject to certain retained rights of these institutions and other third parties.

Upon our entry into the MIT License, we paid MIT a non-refundable license issue fee, reimbursed certain of MIT's costs and issued shares of our common stock to MIT and the other institutional patent owners which were subject to certain anti-dilution, registration and other protective rights. We are obligated to pay MIT creditable annual maintenance fees, low-single-digit running royalty on annual net sales, developmental milestones up to an aggregate of \$1.5 million, a mid-single digit percentage of certain payments we receive from corporate partners and a specified percentage of certain income received from sublicensees after 2009 between 10% and 30%. We may terminate the MIT License at any time upon six months' written notice. MIT has the right to terminate the MIT License immediately upon written notice to us if we cease to carry on our business related to the MIT License, fail to maintain insurance as required under the MIT License, file for bankruptcy, fail to pay amounts due under the MIT License, challenge or assist others in bringing a challenge to MIT's patents or fail to cure material breach within 60 days' written notice thereof. Absent early termination, the MIT License will continue until the expiration or abandonment of the last to expire patent right subject to the MIT License.

In June 2020, we entered into a Fifth Amendment to the MIT License, or the MIT Amendment, which was effective as of May 15, 2020. Pursuant to the MIT Amendment, certain of our diligence obligations were extended to the second quarter of 2021, 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 our development and regulatory milestones and payments upon achievement of such milestones were adjusted.

***Shenyang Sunshine Pharmaceutical Co., Ltd.***

In 2014, we entered into a license agreement with 3SBio, as amended in 2017, which we refer to as the 3SBio License. Pursuant to the 3SBio License, we were granted an exclusive license to certain pegadricase-related patents and related know-how owned or in-licensed by 3SBio for the worldwide (except for Greater China and Japan) development and commercialization of products based thereupon for human therapeutic, diagnostic and prophylactic use. We are also granted a worldwide (except for Greater China) exclusive license to develop, commercialize and manufacture or have manufactured products combining our proprietary ImmTOR platform with pegadricase or related compounds supplied by 3SBio (or otherwise supplied if our rights to manufacture are in effect) for human therapeutic, diagnostic and prophylactic use. We were also granted a co-exclusive license to manufacture and have manufactured pegadricase and related compounds for our preclinical and clinical use or, if the 3SBio License is terminated for 3SBio's material breach, for any use under the 3SBio License. In addition, the 3SBio License, as amended, permits us to utilize one or more third parties to provide up to 20% of our commercial supply of pegadricase. Otherwise, except in the case of a supply shortage on the part of 3SBio, we are obligated to obtain at least 80% of our supply of such compounds for Phase 3 clinical trials and commercial use from 3SBio under the terms of our separate Commercial Supply Agreement with 3SBio dated August 1, 2019.

Under the 3SBio License we have paid to 3SBio an aggregate of \$7.0 million in upfront and milestone-based payments. We are 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 \$15.0 million for products containing our ImmTOR platform. We are also required to pay 3SBio tiered royalties on annual worldwide net sales related to the pegadricase component of products at percentages ranging from the low-to-mid single digits for products containing our ImmTOR platform, subject to specified reductions. These royalties are payable, on a country-by-country and product-by-product basis until the later of (i) the date that all of the patent rights for that product have expired in that country or (ii) a specified number of years from the first commercial sale of such product in such country.

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

**Manufacturing**

We manufacture ImmTOR using a scalable, self-assembly nanoemulsion process with well-defined, pharmaceutical unit operations. This proprietary, highly specialized and precisely controlled manufacturing process enables us to reproducibly manufacture ImmTOR across many production scales, from milligram-scale at the laboratory bench to hundreds of grams to multi-kilogram scale for commercial production. We have also developed and executed the required detailed analytic characterization of our products.

For our most advanced product candidate, SEL-212, we are producing ImmTOR at an approximately 400-gram scale process, which, at the doses being tested in the Phase 3 DISSOLVE program, we believe will be suitable for commercialization. The process is designed such that this same equipment is capable of potentially producing up to a one kilogram batch size scale. As our nanoparticle manufacturing process is compact, and therefore also portable, our strategy is to transfer our custom designed process skids to a contract manufacturing organization, or CMO, and have the CMO produce the nanoparticles, under our direction. This is the strategy we use for production of clinical supplies for clinical trials and would be the expected strategy for commercial production.

The pegadricase enzyme for SEL-212 is produced by fermentation in *E. coli* and is sourced from 3SBio in China. Through a licensing arrangement, we own exclusive worldwide rights to pegadricase outside of China, with co-ownership of rights in Japan and with 3SBio owning all rights in China. Under this arrangement, 3SBio has agreed to supply us with pegadricase. We also have a second supplier for pegadricase in the United States.

**Intellectual Property**

Our ImmTOR platform is designed to deliver precise instructions to the immune system as a result of the natural predisposition of the immune system to interrogate nanoparticles such as viruses. In connection with our founding, we licensed multiple patent families, including a patent family based in part on the pioneering research performed by our co-founders at Harvard University, MIT and Brigham. We have also conducted extensive research in-house to further research this area, leading to key discoveries regarding and uses for our ImmTOR technology. We have aggressively sought to extend and protect the proprietary intellectual property underlying the composition and use of ImmTOR for antigen-specific immunotolerance.

We endeavor to protect our nanoparticle technology, which we consider fundamental to our business, by seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties, relating to our program, product candidates, their methods of use and the processes for their manufacture. Our practice is to strive to protect our intellectual property by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions

outside of the United States related to our proprietary technology, inventions, improvements, programs and product candidates that are commercially important to the operation and growth of our business. We also rely on trade secrets and know-how relating to our proprietary technology, programs and product candidates, continuing innovation and in-licensing opportunities to maintain, advance and fortify our proprietary position in our nanoparticle-based immunotherapy program and product candidates. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our program technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned or controlled by third parties; to defend and enforce our proprietary rights, including our patents; and to operate without infringing the patents and proprietary rights of third parties.

We have developed and in-licensed numerous patents and patent applications and possess substantial know-how and trade secrets relating to our nanoparticle-based immunotherapy technology, program and product candidates. Our patent portfolio contains a number of issued patents in the United States and certain foreign jurisdictions. We also own a number of pending patent applications in the United States and certain foreign jurisdictions. These patents and patent applications include claims related to:

- tolerance immunotherapy programs;
- methods and compositions related to our proprietary nanoparticles in a variety of applications, including tolerance applications, such as:
  - mitigating anti-drug antibodies and/or their effects associated with protein drugs, such as for chronic refractory gout, including coverage for ImmTOR co-administered with pegadricase, which related patents are expected to expire between 2032 and 2040, and
  - genetic therapies (such as viral vector gene therapy), including coverage for ImmTOR co-administered with a viral vector, which related patents are expected to expire between 2032 and 2040; and
- development and commercialization of SEL-212, including both composition of matter and method of treatment claims (there are multiple patent families with claims that cover the SEL-212 product, one of which is a licensed, issued U.S. patent that expires in August 2021).

In addition, we have exclusively or non-exclusively licensed intellectual property, including U.S. issued patents, foreign issued patents, and pending applications in both the U.S. and foreign jurisdictions. The licensed patents and patent applications cover various aspects of the technology being developed by us, including claims directed to compositions of matter and methods of use, and have been filed in various countries worldwide including in North America, Europe and Asia, with material expiration dates varying from 2021 to, if claims are issued, 2029. In addition to filing and prosecuting patent applications in the United States, we often file analogous patent applications in the European Union and in additional foreign countries where we believe such filing is likely to be beneficial, including but not limited to, Australia, Brazil, China, Europe, South Korea, Mexico, India, Israel and/or Japan.

Each patent's term depends upon the laws of the countries in which they are obtained. The patent term in most countries in which we file is 20 years from the earliest date of filing of a non-provisional patent application. Notably, the term of U.S. patents may be extended due to delays incurred due to compliance with FDA or by delays encountered during prosecution that are caused by the USPTO. For example, the Hatch-Waxman Act permits a patent term extension for FDA-approved drugs of up to five years beyond the expiration of the patent, depending upon the length of time the drug is under regulatory review. There is a limit to the amount of time a patent may be extended in the United States; no patent extension can extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar patent term extensions are available in Europe and other jurisdictions for patents that cover regulatory-approved drugs. Currently, we own or license patents and patent applications with expected material expiration dates ranging from 2021 to 2040. However, the actual patent protection period varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

## **Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of any other tolerance or immune stimulation product candidates that we develop, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

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. 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.

SEL-212 may compete with others in the gout market, including KRYSTEXXA, which contains a pegylated uricase similar to the pegadricase component of SEL-212 and is indicated for the treatment of refractory gout. Horizon Pharma plc, whose affiliates own KRYSTEXXA, may find other approaches to eliminate undesired immunogenicity to KRYSTEXXA. Long-term treatment with global immunosuppressive products may increase the susceptibility to contract infections, tumors and may lead to organ failure.

Large companies with active research to prevent the formation of ADAs and treat allergies or autoimmune diseases include Sanofi S.A., Pfizer Inc., and Merck & Co., Inc. Small, early-stage biopharmaceutical companies active in the research for new technologies to induce antigen-specific immune tolerance include Anokion SA, Apitope International NV, Caladrius Biosciences, Cour Pharmaceutical Development Company, Inc., Dendright International, Inc., Parvus Therapeutics, REGiMMUNE Corporation, Rubius Therapeutics, Inc., Tolerion, Inc., Topas Therapeutics GmbH, SQZ Biotechnologies and Txcell SA. Biopharmaceutical companies active in the research for ornithine transcarbamylase include Ultragenyx, Poseida, TranslateBio, Arcturus, and Kaleido. Biopharmaceutical companies active in the research for MMA include LogicBio, Poseida, and Moderna. Biopharmaceutical companies active in the research for IgA nephropathy include Calliditas, Omeros, Travere, EMD Serono, Novartis, Ionis, Visterra, Reata, and Alnylam. Biopharmaceutical companies active in the research for PBC include Intercept Pharmaceuticals, Genfit, GenKyoTex, GSK, Eli Lilly, and CymaBay.

## **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing.

SEL-212 is subject to regulation in the United States as a combination product. If marketed individually, each component would be subject to different regulatory pathways and would require approval of independent marketing applications by the FDA. A combination product, however, is assigned to a Center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of SEL-212, we believe that the primary mode of action is attributable to the biologic component of the product. In the case of SEL-212, which we believe will be regulated as a therapeutic biologic, the FDA's Center for Drug Evaluation and Research, or CDER, will have primary jurisdiction over premarket development. We expect to seek approval of SEL-212 through a single BLA reviewed by CDER, and we do not expect that the FDA will require a separate marketing authorization for each constituent of SEL-212.

Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. SEL-212 and any other product candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries.

### *U.S. biological products development process*

The process required by the FDA before a biologic, including a gene therapy, may be marketed in the United States is summarized below.

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND which must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND

sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. In addition to the submission of an IND to the FDA, supervision of certain human gene transfer trials may also require 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.

Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, patient selection and exclusion criteria, and the parameters to be used to monitor patient safety, including stopping rules that assure a clinical study will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical study must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical study will be conducted. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The biological product candidate is initially introduced into healthy human patients and tested for safety.
- *Phase 2.* The biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research patients or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients.

Sponsors of clinical trials of FDA-regulated products, including biologics, are also required to register and disclose certain clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Concurrent with clinical trials, companies must also finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements.

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal trials, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act, or FDASIA, requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days after a Type C meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA to determine, among other things, whether the proposed product is safe, pure and potent for its intended use and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and

under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product candidate. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured to determine that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the applicant interprets the same data. If the FDA decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of standard BLAs in 10 months from the filing date and 90% of priority BLAs in six months from the filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs.

### ***Orphan Designation***

The FDA may grant orphan designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and marketing the product for this type of disease or condition will be recovered from sales in the United States. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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 receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure sufficient quantities of the approved orphan designated product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

### ***Rare Pediatric Disease Designation***

The Rare Pediatric Disease designation program allows for a sponsor who receives an approval for a product to potentially qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.

### ***Expedited Development and Review Programs***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a Fast Track product at any time during the clinical development of the product. The FDA may consider for review sections of the marketing application for a Fast Track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is

eligible for priority review if it treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness compared to marketed products. Additionally, a product may be eligible for accelerated approval. Biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biological product subject to accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

In addition, under the provisions of FDASIA, the FDA established a Breakthrough Therapy Designation which is intended to expedite the development and review of products that treat serious or life-threatening diseases or conditions. 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, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of Fast Track designation, as well as more intensive FDA interaction and guidance.

### ***Post-approval Requirements***

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products include record-keeping requirements, reporting of adverse effects and reporting updated safety and efficacy information.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

### ***Biosimilars and Exclusivity***

The Patient Protection and Affordable Care Act, or ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for

certain biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

### ***Government Regulation outside of the United States***

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries.

The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

In the European Economic Area, or EEA, which is composed of the 27 member states of the European Union plus Norway, Iceland and Liechtenstein medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

There are two types of MAs.

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), and medicinal products that contain a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure the standard 210 days review period is reduced to 150 days.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a marketing authorization application, which is similar to the U.S. BLA. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator’s data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator’s data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union’s regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity, during which time no marketing authorization application shall be accepted and no marketing authorization shall be granted for a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an “orphan medicinal product” in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such

condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if the:

- second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- applicant consents to a second orphan medicinal product application; or
- applicant cannot supply enough orphan medicinal product.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

When conducting clinical trials in the EU, we must adhere to the provisions of the European Union Clinical Trials Directive (Directive 2001/20/EC) and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial. In 2014, the EU passed the Clinical Trials Regulation (Regulation 536/2014), which will replace the current Clinical Trials Directive. To ensure that the rules for clinical trials are identical throughout the European Union, the EU Clinical Trials Regulation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive until the Clinical Trials Regulation becomes applicable. According to the current plans of the EMA, the Clinical Trials Regulation is expected to become applicable in 2020.

We are also subject to data privacy and security laws in the jurisdictions outside of the U.S. in which we are established, run clinical trials or in which we sell or market our products once approved. For example, in Europe we are subject to Regulation (EU) 2016/679 (General Data Protection Regulation or GDPR) in relation to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data in relation to participants in our clinical trials in the EEA., including the health and medical information of these participants. The GDPR is directly applicable in each E.U. Member State, however, it provides that E.U. Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to E.U. rules with respect to cross-border transfers of personal data out of the E.U. and EEA. We are subject to the supervision of local data protection authorities in those E.U. jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of EUR 20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/ change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm. Moreover, 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. 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 EU.

### ***Other Healthcare Laws***

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The federal false claims and civil monetary penalties laws, including the civil False Claims Act, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation. A claim includes “any request or demand” for money or property presented to the U.S. government. Violation of the federal Anti-Kickback Statute may also constitute a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the civil False Claims Act may be brought by the Attorney General or as a *qui tam* action by a private individual in the name of the government. Violations of the civil False Claims Act can result in very significant monetary penalties and treble damages. In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Many states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers. The ACA imposed, among other things, new annual reporting requirements through the Physician Payments Sunshine Act for covered manufacturers for certain payments and “transfers of value” provided 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 physicians and their immediate family members.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA’s security standards directly applicable to, as well as imposed certain other privacy obligations on, “business associates,” defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA Security Rule.

### ***Coverage and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological products for which we obtain regulatory approval. In the United States and markets in other countries, patients who are prescribed

treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Moreover, for drugs and biologics administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. Sales of any products for which we receive regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations.

The process for determining whether a third-party payor will provide coverage for a pharmaceutical or biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a pharmaceutical or biological product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate.

### ***Healthcare Reform***

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, the ACA, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced 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; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; and created 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 of 2017, or the TCJA, was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Further, in 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. In December 2019, the U.S. Court of Appeals for the Fifth 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 law.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and imaging centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies.

### ***Human Capital Resources***

As of December 31, 2020, we had 43 full-time employees and one part-time employee, 30 of whom are primarily engaged in research and development activities and five of whom are officers of Selecta Biosciences, Inc. As of December 31, 2020, we also had one full-time consultant. Twenty-three of our employees have either one or both of an M.S. or Ph.D. degree. We consider the intellectual capital of our employees to be an essential driver of our business and key to future prospects. To attract and retain a high-quality, experienced workforce, we offer a competitive mix of compensation and insurance benefits for our employees, as well as participation in our equity programs. Employees working 30 hours or more a week are eligible to participate in our medical, prescription, dental, vision, Flexible Spending Account and life insurance and disability plans. To

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assist employees with costs associated with rising healthcare costs, we pay 100% of an employee's deductible and co-insurance payments. We also offer employees an annual bonus plan and a 401(k)-retirement plan with a company match. All employees are awarded new hire equity and annual equity as well as the opportunity to participate in our Employee Stock Purchase Plan. Our 2020 annualized voluntary turnover rate was 4.93%. None of our employees are represented by a labor union and we consider our employee relations to be good.

In response to the COVID-19 pandemic, we implemented changes in our business in March 2020 in an effort to protect our employees, and to support appropriate health and safety protocols. In particular, we closed our principal executive office with our administrative employees continuing their work remotely and limited the number of staff in any given research and development laboratory.

### ***Available Information***

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. We make available on our website at [www.selectabio.com](http://www.selectabio.com), free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC.

## RISK FACTORS SUMMARY

Investing in our common stock involves various risks. You should carefully read and consider the matters discussed in this Annual Report under the heading “Risk Factors,” which include the following risks:

- 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.
- We will need substantial additional funding in order to complete development of our product candidates and commercialize our products, if approved.
- The terms of our credit facility place restrictions on our operating and financial flexibility.
- Our product candidates are based on our ImmTOR platform, which is an unproven approach designed to induce antigen-specific immune tolerance to biologic drugs.
- Regulatory authorities in the United States and European Union have limited experience in reviewing and approving gene therapy products.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome.
- The outbreak of COVID-19 may continue to adversely impact our business, including sourcing raw materials and supplies to produce our product candidates, our preclinical studies and clinical trials.
- 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.
- 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.
- 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.
- We may not have the funds necessary to fulfill our obligation to repurchase certain warrants.
- We are involved in two securities class action lawsuits.

## 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 Annual Report on Form 10-K. 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 losses were \$68.9 million for the year ended December 31, 2020, and \$55.4 million and \$65.3 million for each of the years ended December 31, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of \$404.6 million. To date, we have financed our operations primarily through public offerings 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
- 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 product 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 and on terms favorable to us, 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 December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the second 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, preclinical development, and laboratory testing;
- 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;
- our headcount growth and associated costs;
- 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, 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.

***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 August 31, 2020, we entered into a term loan, or the 2020 Term Loan, of up to \$35.0 million, consisting of term loans in an aggregate amount of \$25.0 million, or the Term A Loan, and term loans in an aggregate amount of \$10.0 million, or the Term B Loan, governed by a loan and security agreement among us and Oxford Finance LLC, or Oxford, as collateral agent and a lender, and Silicon Valley Bank, or SVB, as a lender. The Term A Loan was funded in full on August 31, 2020, the proceeds of which were used to repay our previously existing 2017 term loan and for general corporate and working capital purposes. The Term B Loan will be available, subject to Oxford's discretion and customary terms and conditions, during the period commencing on the date we have delivered to Oxford and SVB evidence: (i) we or one of our collaboration partners has enrolled its first randomized patient for a Phase 1 clinical trial evaluating the treatment of MMA and (ii) we have enrolled the

first patient in each of two Phase 3 pivotal trials evaluating SEL-212, or the Second Draw Period Milestone, and ending on the earliest of (i) the date which is 30 days following the date the Second Draw Period Milestone is achieved, (ii) September 30, 2021 (iii) and the occurrence of an event of default, other than an event of default that has been waived in writing by Oxford and SVB in their sole discretion. Because we have enrolled the first patient in each of our two Phase 3 trials for SEL-212, the Second Draw Period Milestone has been achieved, and we expect the Term B Loan will be available to be drawn, once we or AskBio enroll the first randomized patient in our planned Phase 1 clinical trial evaluating the treatment of MMA.

The 2020 Term Loan is secured by a lien on substantially all of our assets, other than intellectual property, provided that such lien includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. We also granted Oxford a negative pledge with respect to our intellectual property.

Failure to satisfy our current and future debt obligations, including covenants to take or avoid specific actions, under the 2020 Term Loan could result in an event of default, our lenders could accelerate all of the amounts due. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

***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. Subsequently, in March 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, removed the 80% limitation rule for tax years 2018 through 2020, and as of taxable years beginning on or after January 1, 2021, the 80% limitation has been reinstated. 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 Development 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.

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 product, or arrange for a third party to do so on our behalf, or conduct other sales and marketing activities necessary for successful product commercialization. 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 and not infringing or violating patents or other intellectual property of third parties;

- 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;
- 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;
- 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.

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 our 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 clinical trial requirements of the FDA 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 European Medicines Agency, or 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.

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 EU. 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.

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. 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 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. 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.***

Aside from SEL-212, 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. 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 topline clinical trial results we reported from our Phase 2 head-to-head COMPARE study of SEL-212 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. 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 us 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 us to incur additional costs or experience delays in

completing, or causing us 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;
- 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 is being developed for the treatment of chronic refractory gout, which affects a small patient population in the United States. Accordingly, there is a limited number of patients who could enroll in our clinical studies for SEL-212. Additionally, the COVID-19 pandemic could affect our ability to enroll or sustain patients in our clinical trials. 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 COVID-19 may continue to adversely impact our business, including our preclinical studies and clinical trials.***

The ongoing COVID-19 pandemic has impacted our business and we expect it to continue to do so. In response to the spread of COVID-19, we 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. As COVID-19 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 or sustaining 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 extent to which the COVID-19 pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

***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.

Additional 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 qualify for or obtain various designations from regulators that would have the potential to expedite the review process of one or more of our product candidates and even if we do receive one or more such designations there is no guarantee that they will ultimately expedite the process, or aid in our obtaining marketing approval or provide market exclusivity.***

There exist several designations that we can apply for from the FDA and other regulators that would provide us with various combinations of the potential for expedited regulatory review, certain financial incentives as well as the potential for post-approval exclusivity for a period of time. These designations include but are not limited to orphan drug designation, breakthrough therapy designation, accelerated approval, fast track status and priority review for our product candidates. For example, we and AskBio received orphan drug designation for MMA-101 in November 2020. We expect to seek one or more of these designations for our current and future product candidates. There can be no assurance that any of our other product candidates will qualify for any of these designations. There can also be no assurance that any of our product candidates that do qualify for these designations will be granted such designations or that the FDA will not revoke a designation it grants at a later date. Further, there can be no assurance that any of our product candidates that are granted such designations will ever benefit from such designations or that the FDA would not withdraw such designations once granted. Were we to receive a designation that promised a period of market exclusivity, such as orphan drug exclusivity, such exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Further with respect to orphan drug status, 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.

***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. For example, we and Sobi announced top-line data from the Phase 2 COMPARE trial for SEL-212 in September 2020. 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.

***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 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. We terminated the license of LMB-100, a component of SEL-403, from NCI in April 9, 2019 and are no longer pursuing this product candidate.

Further, the clinical development of SEL-212 over many years has required multiple clinical trials and resulted in the use of different formulations of ImmTOR. While we do not believe that such 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 observed in our clinical trials 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 the 3SBio License, 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 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 COVID-19 continues to impact U.S. business operations, including those of our CMOs and suppliers, we could face additional disruptions to our supply chain that could affect the supply of drug product for our 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 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. These factors and increasing wage rates due to increased demand for skilled laborers and the declining availability of skilled labor in China could cause our labor costs to rise.

We rely, and expect to continue to rely, in addition to 3SBio, on other third parties for the manufacture of our product candidates for supply in preclinical studies and clinical trials, 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, and even if we do rely 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.

***If we are unable to maintain any of our existing 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 us, and certain collaborations, licenses and agreements may result in increased expenditures by us. Our existing collaborations, and any future collaborations, 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, 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 and we would potentially lose the right to pursue further development or commercialization of the applicable product candidates as well as have difficulty entering into a similar collaboration where the potential collaborator is aware of the prior termination;
- 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.

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 rely, and 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 ongoing Phase 3 DISSOLVE clinical program for SEL-212, consisting of the DISSOLVE I and DISSOLVE II trials, 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. 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. 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, [www.ClinicalTrials.gov](http://www.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 commercial 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 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.

### **Risks Related to Commercialization of our Product Candidates and Legal Compliance Matters**

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

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or REMS;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

***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. 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. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

***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 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 still being interpreted and implemented by the FDA, and as a result, its ultimate impact, implementation, and meaning are subject to uncertainty. However, 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 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 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. Third-party payors often require 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 is 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, 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;
- the inability to commercialize any products that we may develop;
- distraction of management's attention from our primary business; and

- 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 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.

***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;
- 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 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. 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 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. By way of example, the TCJA was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. In 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. In December 2019, the U.S. Court of Appeals for the Fifth 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.

***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. Separately, in response to the COVID-19 pandemic, the FDA has periodically modified its regular practices with respect to inspection of manufacturing facilities. 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.

***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. The Leahy-Smith Act America Invents Act, or the Leahy-Smith Act, included 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, including its first-to-file provisions. A third party that files a patent application in the USPTO 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, the date such provisions became effective, 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.

***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 corporate strategy may not be successful.***

On January 3, 2019, following a strategic business review, we announced a 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 depends on our ability to successfully develop our product candidates, hire and retain senior management or other highly qualified personnel, prioritize competing projects and efforts and obtain sufficient resources, including additional capital, as well as our ability to enter into collaborations with third parties. The early stage development of novel product candidates is highly unpredictable due to the lengthy and expensive process of clinical drug development, potential for safety, efficacy or tolerability problems with such product candidates, unexpected expenses or inaccurate financial assumptions or forecasts, potential delays or unfavorable decisions of regulatory agencies and competition for targeted indications or within targeted markets. Accordingly, there are no assurances our change in strategic focus will be successful, which may have an adverse effect on our results of operations or financial condition.

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

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

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

***We 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, we have incurred and expect to continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC 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 bring with them significant 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 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 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. 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 30.9% of our outstanding voting stock as of December 31, 2020. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

***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.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, 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. As of December 31, 2020, we had 108,071,249 shares of common stock outstanding. In addition, as of December 31, 2020, 7,775,249 and 87,500 shares of common stock that are subject to outstanding options or restricted stock unit awards, respectively, under our outstanding equity plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 under the Securities Act. If these additional shares of common stock are sold, or it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***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 December 31, 2021, 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 have, historically, relied on these exemptions, and we may continue to do so until they are no longer available to us. 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.

***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.

***We are involved in two securities class action lawsuits.***

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. Involvement in such litigation, could result in substantial costs and a diversion of management's attention and resources, which could harm our business. On August 4, 2020, a putative stockholder of Selecta filed a stockholder derivative action purportedly on behalf of Selecta and against certain current and former members of our 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 authorized the private placement transaction, announced on December 19, 2019, at a price allegedly below fair value. On September 25, 2020, the defendants filed a motion to dismiss. On November 6, 2020, the plaintiff filed an amended complaint, and the defendants filed a second motion to dismiss on January 8, 2021.

On December 31, 2020, we received a stockholder litigation demand from other shareholders, relating to the same private placement transaction. While we intend to vigorously defend against this demand, which we believe to be without merit, there can be no assurance as to the outcome of any stockholder litigation. Unfavorable outcomes in securities class action litigation could require us to pay extensive damages, which could delay or prevent our ability to develop our product candidates and harm our operations.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. Properties**

Our corporate headquarters are currently located at 65 Grove Street, Watertown, Massachusetts and consist of 25,078 total square feet of leased office and laboratory space under a lease that expires in May 2028.

We also lease approximately 2,500 square feet of office and laboratory space in Moscow, Russia on a month-to-month basis.

**Item 3. Legal Proceedings**

On August 4, 2020, a putative stockholder of Selecta filed a stockholder derivative action, purportedly on behalf of Selecta 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 authorized a private placement transaction, announced on December 19, 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. On September 25, 2020, the defendants filed a motion to dismiss the lawsuit. On November 6, 2020, the plaintiff filed an amended complaint, and the defendants filed a second motion to dismiss on January 8, 2021. On December 31, 2020, we received a litigation demand letter from two other putative stockholders relating to the same private placement transaction.

**Item 4. Mine Safety Disclosures**

Not applicable.

**PART II**

**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

**Market Information**

Our common stock is publicly traded on The Nasdaq Stock Market under the symbol “SELB.”

**Holders**

As of March 5, 2021, there were approximately 112,373,199 shares of our common stock outstanding held by approximately 33 holders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

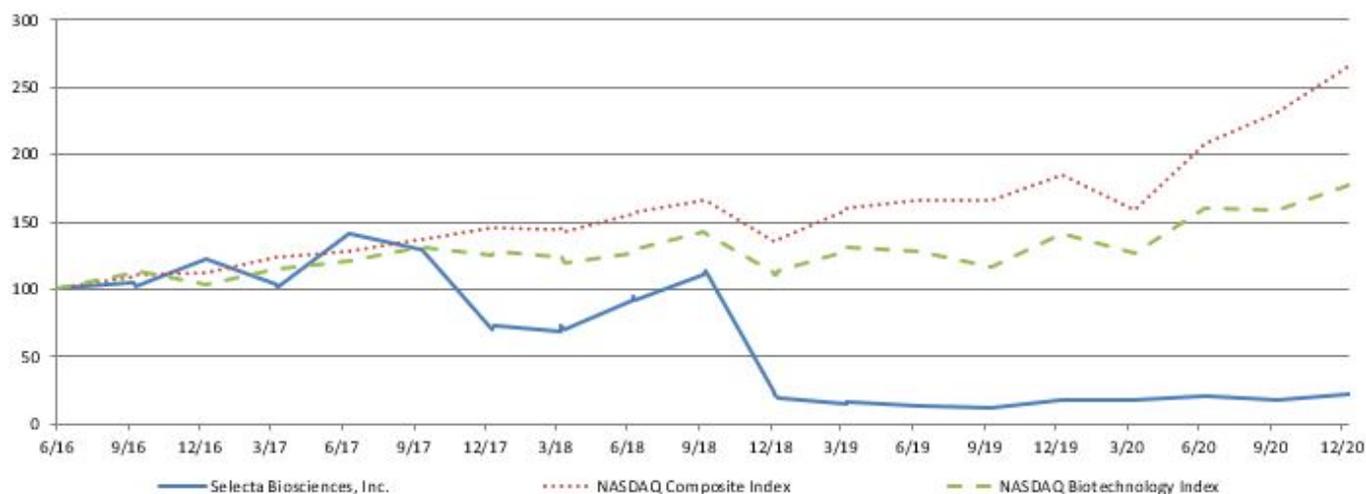
**Dividends**

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, our loan and security agreement with Oxford and SVB currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise preclude us from paying dividends. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

**Stock Performance Graph**

The graph set forth below compares the cumulative total stockholder return on our common stock between June 21, 2016 (the date of our initial public offering) and December 31, 2020, with the cumulative total return of (a) the Nasdaq Composite Index and (b) the Nasdaq Biotechnology Index, over the same period. This graph assumes the investment of \$100 at the market close on June 21, 2016 in our common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index and assumes the reinvestment of dividends, if any. The stock price performance of the following graph is not necessarily indicative of future stock price performance.

**Comparison Of Cumulative Total Return Selecta Biosciences, Inc.,  
NASDAQ COMPOSITE INDEX AND NASDAQ BIOTECHNOLOGY INDEX**



*This performance graph shall not be deemed “soliciting material” or to be “filed” with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities or the Exchange Act.*

**Purchases of Equity Securities by the Issuer or Affiliated Purchasers**

We did not repurchase any of our equity securities during the quarter ended December 31, 2020.

**Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities**

On June 11, 2020, we entered into a stock purchase agreement, or the Sobi Purchase Agreement, with Swedish Orphan Biovitrum AB (Publ) pursuant to which we sold an aggregate of 5,416,390 shares of our common stock at a purchase price

equal to \$4.6156 per share, which represented 120% of the 10-day volume-weighted average price of our common stock prior to signing, for aggregate gross proceeds of \$25 million, or the Sobi Private Placement. The closing of the Sobi Private Placement occurred on July 31, 2020. 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.

On December 18, 2019, we entered into a Securities Purchase Agreement, or the 2019 Purchase Agreement, with purchasers including certain members of our board of directors. Pursuant to the 2019 Purchase Agreement, we sold (i) an aggregate of 37,634,883 shares of our common stock at a purchase price of \$1.46 per share, which was equal to the most recent consolidated closing bid price on the Nasdaq Stock Market on December 18, 2019, (ii) warrants to purchase an aggregate of 22,988,501 shares of common stock at a purchase price equal to \$0.125 per share underlying each warrant, and (iii) pre-funded warrants to purchase an aggregate of 8,342,128 shares of common stock at a purchase price equal to \$1.46 per share underlying each pre-funded warrant, for aggregate net proceeds of approximately \$65.6 million, after deducting approximately \$4.4 million in placement agent commissions and other transaction costs. Each warrant has an exercise price per share of common stock equal to \$1.46 per share. Each pre-funded warrant has an exercise price per share of common stock equal to \$0.0001 per share. The closing of the offering occurred on December 23, 2019.

On August 19, 2019, we sold 3,178,174 shares of our common stock pursuant to a stock purchase agreement, or the 2019 Private Placement, to individual investors, including certain executive officers and members of the board of directors of Selecta for aggregate net proceeds of approximately \$5.7 million, after deducting transaction costs, at a purchase price equal to \$1.81 per share, which was equal to the most recent consolidated closing bid price on the Nasdaq Stock Market on August 19, 2019. The shares in the 2019 Private Placement were issued as “restricted securities” (as defined in Rule 144 of the Securities Act) and carry no registration rights that require or permit the filing of any registration statement.

## **Item 6. Selected Financial Data**

Not required.

## **Item 7. 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 Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K 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 Item 1A. “Risk Factors.” A discussion of the year ended December 31, 2019 compared to the year ended December 31, 2018 has been reported previously in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 12, 2020, under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”*

### **Overview**

We are a clinical-stage biopharmaceutical company leveraging our ImmTOR™ immune tolerance platform with the goals of amplifying the efficacy of biologics, including enabling the re-dosing of life-saving gene therapies, and restoring self-tolerance in autoimmune diseases. Our ImmTOR platform encapsulates rapamycin, also known as sirolimus, an immunomodulator, in biodegradable nanoparticles and is designed to induce antigen-specific immune tolerance.

We believe ImmTOR has the potential to enhance the efficacy without compromising the safety of biologic therapies, improve product candidates under development, and enable novel therapeutic modalities. We have developed a portfolio of proprietary and collaboration-driven applications of ImmTOR, and we plan to continue to develop proprietary compounds and pursue collaboration-driven development in certain disease areas, which could include strategic collaborations, out-licensing, and in-licensing transactions.

### **Impact of COVID-19**

We are closely monitoring how COVID-19 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 Annual Report on Form 10-K, it could have an impact on our ability to complete the Phase 3 DISSOLVE clinical program of SEL-212, and our

ability to commence preclinical and clinical studies of our IgA nephropathy, 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 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 Annual Report on Form 10-K, we believe we will have adequate supply of all material necessary to conduct our Phase 3 DISSOLVE 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 COVID-19 pandemic and the impact of related responses. Any impact of COVID-19 on our business, revenues, results of operations and financial condition will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. See “Risk Factors —The outbreak of COVID-19 may continue to adversely impact our business, including our preclinical studies and clinical trials.” in Part I, Item 1A of this Annual Report on Form 10-K.

## Financial Operations

To date, we have financed our operations primarily through public offerings 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 \$68.9 million and \$55.4 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of \$404.6 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, short term investments, and restricted cash as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the second 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.

## Collaboration and grant revenue

To date, we have not generated any product sales. Our revenue consists of collaboration and grant 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 Annual Report on Form 10-K.

## 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 \$295.3 million in research and development expenses from inception through December 31, 2020, with a majority of the expenses being spent on the development of SEL-212 and a prior nicotine vaccine candidate, and the remainder being spent on our various discovery and preclinical stage product candidate programs and the general expansion of our technology.

In connection with our intention to focus on advancing our ImmTOR platform, 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):

	Year ended December 31,		
	2020	2019	2018
Research and development expenses (key projects and initiatives):			
SEL-212	\$ 32,288	\$ 25,489	\$ 22,770
AskBio collaboration	2,807	—	—
SELA-070	—	46	1,602
Discovery and preclinical stage product candidate programs, collectively	1,717	1,614	2,623
Other internal research and development expenses	17,693	15,594	20,692
<b>Total research and development expenses</b>	<b>\$ 54,505</b>	<b>\$ 42,743</b>	<b>\$ 47,687</b>

On June 11, 2020, we and Sobi entered into the Sobi License. Pursuant to the Sobi License, clinical trial costs incurred to complete development of SEL-212, including but not limited to costs incurred while conducting and completing the Phase 3 DISSOLVE trials, will be reimbursed by Sobi. These costs, when reimbursed, will be recognized as revenue consistent with the revenue recognition methodology disclosed in Footnote 12. The reimbursable costs exclude any costs of additional development activities required that are related to ImmTOR and that are unrelated to SEL-212.

## 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 the years ended December 31, 2020, and 2018, and for the year ended December 31, 2019 it consists primarily of issuance fees associated with warrant liabilities.

**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 December 31, 2020 and 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 Years Ended December 31, 2020 and 2019*

**Revenue**

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

	Year Ended December 31,		Increase	
	2020	2019	(decrease)	
Collaboration revenue	\$ 16,597	\$ 6,677	\$ 9,920	149 %

During the year ended December 31, 2020, collaboration revenue increased by \$9.9 million, or 149%, from collaboration revenue generated in 2019. During the year ended December 31, 2020 we recognized \$16.6 million under the license agreement with Sobi resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program and a de minimis amount recognized for shipments under the collaboration agreement with Sarepta. During the year ended December 31, 2019, we recognized \$6.7 million in revenue upon expiration of the term for Spark to exercise additional target options that represented material rights and less than \$0.1 million of revenue for two shipments to Spark under our collaboration agreement.

**Research and development**

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

	Year Ended December 31,		Increase	
	2020	2019	(decrease)	
Research and development	\$ 54,505	\$ 42,743	\$ 11,762	28 %

During the year ended December 31, 2020, our research and development expenses increased by \$11.8 million, or 28%, as compared to 2019. The increase in cost was primarily the result of expenses incurred for the Phase 3 DISSOLVE clinical program for SEL-212, the Phase 2 COMPARE trial for SEL-212 and for the AskBio Collaboration.

**General and administrative**

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

	<u>Year Ended December 31,</u>		<u>Increase</u>	
	<u>2020</u>	<u>2019</u>	<u>(decrease)</u>	
General and administrative	\$ 18,913	\$ 16,389	\$ 2,524	15 %

During the year ended December 31, 2020, our general and administrative expenses increased by \$2.5 million, or 15%, as compared to 2019. The increase in costs was the result of expenses for patent and professional fees offset by reduced consulting fees and travel expenses.

**Investment income**

Investment income was \$0.3 million and \$0.8 million for the years ended December 31, 2020 and 2019, respectively. The decrease reflects reduced interest rates.

**Loss on extinguishment of debt**

For the year ended December 31, 2020, we recognized a \$0.5 million loss on extinguishment of the 2017 Term Loan (see Note 9).

**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 the years ended December 31, 2020 and 2019, respectively.

**Interest expense**

Interest expense was \$1.6 million and \$1.5 million for the years ended December 31, 2020 and 2019, respectively, representing interest expense and amortization of the carrying costs of our credit facilities.

**Change in fair value of warrant liabilities**

For the year ended December 31, 2020, we recognized a \$10.4 million charge for the increase in the fair value of warrant liabilities utilizing the Black-Scholes valuation methodology. The increase in value was primarily driven by an increase in the share price and volatility (see Note 5). For the year ended December 31, 2019, we recognized \$0.9 million as a change in the fair value of warrant liabilities primarily driven by an increase in the share price from issuance.

**Other income (expense)**

Other income (expense) was \$0.1 million and (\$1.3 million) for the years ended December 31, 2020 and 2019, respectively. The other expense during 2019 was the result of fees incurred as a result of the issuance of liability classified common warrants in our December 2019 private placement.

**Net Loss**

Net loss for the year ended December 31, 2020 was \$68.9 million compared to \$55.4 million for the year ended December 31, 2019.

**Liquidity and Capital Resources**

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

From our inception through December 31, 2020, we have raised an aggregate of \$549.1 million to fund our operations, which includes \$118.5 million from the sale of preferred stock, \$11.1 million in government grant funding, \$36.7 million from borrowings under our credit facility, \$165.9 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 \$3.1 million in aggregate net proceeds from “at-the-market” offerings of our common stock.

### *Collaborations*

On October 8, 2020, we entered into the IGAN Agreement, and paid IGAN a \$0.5 million one-time up-front payment.

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. Sobi paid us a one-time, up-front payment of \$75 million, and upon the closing of the Sobi Private Placement, we received an additional \$25 million from Sobi in consideration for Sobi's purchase of our common stock at \$4.6156 per share. 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 Phase 3 clinical program of SEL-212, which commenced in September 2020. We expect this to substantially reduce our 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 2017 Sales Agreement, with Jefferies LLC, as sales agent, to sell shares of our common stock with an aggregate value of up to \$50 million in an "at-the-market" offering. In August 2020, concurrent with the filing of a new shelf registration statement, we entered into a new sales agreement, or the 2020 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. The 2017 Sales Agreement terminated pursuant to its terms in August 2020.

Sales of common stock, if any, pursuant to the 2020 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 Stock 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 2020 Sales Agreement at any time.

From August 11, 2017, the date we entered into the 2017 Sales Agreement, to December 31, 2019, we sold 615,453 shares of our common stock pursuant to the 2017 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 year ended December 31, 2020, we sold 1,069,486 shares of our common stock pursuant to the 2017 Sales Agreement and 2020 Sales Agreement, as applicable, 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 December 31, 2020, our cash, cash equivalents, and restricted cash were \$140.1 million, of which \$1.4 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 August 31, 2020, we entered into a term loan of up to \$35.0 million, consisting of term loans in an aggregate amount of \$25.0 million, or the Term A Loan, and term loans in an aggregate amount of \$10.0 million, or the Term B Loan, governed by a loan and security agreement among us and Oxford, as collateral agent and a lender, and SVB, as a lender. The Term A Loan was funded in full on August 31, 2020, the proceeds of which were used to repay our previously existing 2017 Term Loan and for general corporate and working capital purposes. The Term B Loan will be available, subject to the collateral agent's discretion and customary terms and conditions, during the period commencing on the date we have delivered to Oxford and SVB evidence: (i) we or one of the our collaboration partners has enrolled its first randomized patient for a Phase 1 clinical trial evaluating the treatment of MMA, and (ii) we have enrolled the first patient in each of two Phase 3 pivotal trials evaluating SEL-212, or the Second Draw Period Milestone, and ending on the earliest of (i) the date which is thirty (30) days following the date the Second Draw Period Milestone is achieved, (ii) September 30, 2021 (iii) and the occurrence of an event of default, other than an event of default that has been waived in writing by Oxford and SVB in their sole discretion. Because we have enrolled the first patient in each of our two Phase 3 trials for SEL-212, the Second Draw Period Milestone has been achieved, and we expect the Term B Loan will be available to be drawn, once we or AskBio enroll the first randomized patient in our planned Phase 1 clinical trial evaluating the treatment of MMA.

The 2020 Term Loan 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 Oxford a negative pledge with respect to our intellectual property.

The 2020 Term Loan 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 2020 Term Loan also contains other customary provisions, such as expense reimbursement, non-disclosure obligations as well as indemnification rights.

The events of default under the 2020 Term Loan include, but are not limited to, our failure to make any payments of principal or interest under the 2020 Term Loan or other transaction documents, our breach or default in the performance of any covenant under the 2020 Term Loan or other transaction documents, the occurrence of a material adverse event, making a false or misleading representation or warranty in any material respect under the 2020 Term Loan, our insolvency or bankruptcy, any attachment or judgment on our assets of at least approximately \$0.5 million, or the occurrence of any default under any of our agreements or obligations involving indebtedness in excess of approximately \$0.5 million. If an event of default occurs, Oxford and SVB are entitled to take enforcement action, including acceleration of amounts due under the 2020 Term Loan. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

For a further description of the 2020 Term Loan, see Note 9 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

### **Plan of operations and future funding requirements**

As of the date of this Annual Report on Form 10-K, 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 December 31, 2020, we had an accumulated deficit of \$404.6 million. 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.

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

We believe that our existing cash, cash equivalents, and restricted cash as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. 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;

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- 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 Annual Report on Form 10-K as this continues to evolve globally.

### Summary of Cash Flows

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Cash provided by (used in):			
Operating activities	\$ 34,881	\$ (51,435)	\$ (59,161)
Investing activities	(741)	229	25,272
Financing activities	14,431	105,041	697
Effect of exchange rate changes on cash	(58)	34	(153)
Net change in cash, cash equivalents, and restricted cash	\$ 48,513	\$ 53,869	\$ (33,345)

#### *Operating activities*

Net cash provided by operating activities for the year ended December 31, 2020 was \$34.9 million compared to \$51.4 million used in the same period in 2019. The increase in net cash provided by operating activities was primarily due to the recognition of \$94.1 million in deferred revenue, and a \$2.8 million change in accounts receivable, offset by a \$0.4 million change in accrued expenses and other liabilities, and \$7.1 million changes in prepaid expenses, deposits and other assets and accounts payable when compared to the prior year and a \$3.2 million increase in recorded net loss after adjusting for non-cash items.

#### *Investing activities*

Net cash used in investing activities for the year ended December 31, 2020 was \$0.7 million compared to net cash provided by investing activities of \$0.2 million in the same period in 2019. The net cash used in investing activities in 2020 was to purchase property and equipment.

The net cash provided by investing activities in 2019 was the result of purchases of short-term investments of \$18.2 million, offset by \$16.4 million of maturities and \$2.0 million of sales of short term investments.

#### *Financing activities*

Net cash provided by financing activities for the year ended December 31, 2020 was \$14.4 million compared to net cash provided by financing activities of \$105.0 million in the same period in 2019. The net cash provided by financing activities in 2020 was the result of \$10.3 million from the Sobi Private Placement, \$24.7 million from the Term A Loan, \$2.1 million net proceeds from “at-the-market” offerings, and \$1.0 million proceeds from warrant exercises, offset by \$4.4 million of issuance costs paid for December 2019 financing and \$19.3 million principal payment on outstanding debt.

The net cash provided by financing activities in 2019 was the result of \$30.9 million net proceeds from an underwritten follow-on offering of our common stock in January, \$75.7 million net proceeds from private placement offerings in August and December and \$1.0 million net proceeds from “at-the-market” offerings, offset by \$2.8 million principal payment on outstanding debt.

## **Research and development contract obligations**

Under our license agreement with MIT, milestone payments are due upon the occurrence of certain events and royalty payments commence upon our commercialization of a product. As of December 31, 2020, contractual obligations were \$0.4 million. We have assumed license payments are fully offset by royalty payments in 2028.

## **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 Annual Report on Form 10-K.

## **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 cancellable, 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 research and development 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 us. The historical clinical accrual estimates made by us 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 Sobi, AskBio, and Sarepta (see Note 12 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K) 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 we fulfill 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 research and development 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 estimate 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, adjust 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 a securities purchase agreement between us and a group of institutional investors and certain members of our board of directors. 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 us 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 December 31, 2020, the fair value of the common warrants of \$28.7 million was recorded as a long-term liability on our balance sheet, which resulted in a change in fair value of \$10.4 million for the year ended December 31, 2020.

### **Stock-Based Compensation**

We account for all stock-based compensation granted to employees and non-employees using a fair value method. Stock-based compensation is measured at the grant date fair value using the Black-Scholes option pricing model and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. 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 ultimately vest.

### **Emerging Growth Company Status**

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. We will remain an emerging growth company until December 31, 2021, 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.

### **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 7A. 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 December 31, 2020 and 2019, we had cash, cash equivalents, restricted cash and investments of \$140.1 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 December 31, 2020, we held cash and cash equivalents totaling \$0.3 million in Russian banks to support our Russian subsidiary, all of which were denominated in U.S. dollars. We do not hedge against foreign currency risks. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

## **Item 8. Financial Statements and Supplementary Data**

The consolidated financial statements together with the report of our independent registered public company accounting firm, required to be filed pursuant to this Item 7 are appended to this Annual Report on Form 10-K. An index of those consolidated financial statements is found in Item 15 of this Annual Report on Form 10-K.

## **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

None.

## **Item 9A. 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 Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under 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 December 31, 2020.

### **Management's annual report on internal control over financial reporting**

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

### **Attestation Report of the Registered Public Accounting Firm**

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

### **Changes in internal control over financial reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Item 9B. Other Information**

None.

## PART III

### **Item 10. Directors, Executive Officers and Corporate Governance**

Our board of directors has adopted a written Code of Business Conduct and Ethics applicable to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of our Code of Business Conduct and Ethics on our website at [www.selectabio.com](http://www.selectabio.com) in the “Investors & Media” section under “Corporate Governance.” We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics, as well as the Nasdaq Stock Market LLC’s requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified above. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K.

The information required by this Item is contained in part under the caption “Information about our Executive Officers” at the end of Part I of this Annual Report on Form 10-K. The remainder of the response to this item will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders under the headings “Proposal 1—Election of Directors,” “Delinquent Section 16(a) Reports,” and “Committees of the Board” and is incorporated herein by reference.

### **Item 11. Executive Compensation**

The information required by this Item regarding executive compensation will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders under the headings “Executive and Director Compensation” and “Compensation Committee Interlocks and Insider Participation” and is incorporated herein by reference.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this Item will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Executive and Director Compensation—Equity Compensation Plan Information” and is incorporated herein by reference.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this Item will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders under the headings “Corporate Governance,” “Committees of the Board” and “Certain Relationships” and is incorporated herein by reference.

### **Item 14. Principal Accountant Fees and Services**

The information required by this Item regarding principal accountant fees and services will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders under the heading “Independent Registered Public Accounting Firm Fees and Other Matters” and is incorporated herein by reference.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

**(a)(1) Financial Statements**

The financial statements listed below are filed as part of this Annual Report on Form 10-K.

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a>	<a href="#"><u>F-1</u></a>
<a href="#"><u>Consolidated Balance Sheets at December 31, 2020 and 2019</u></a>	<a href="#"><u>F-2</u></a>
<a href="#"><u>Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020, 2019 and 2018</u></a>	<a href="#"><u>F-3</u></a>
<a href="#"><u>Consolidated Statements of Changes in Stockholders' (Deficit) Equity for the years ended December 31, 2020, 2019 and 2018</u></a>	<a href="#"><u>F-4</u></a>
<a href="#"><u>Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018</u></a>	<a href="#"><u>F-5</u></a>
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	<a href="#"><u>F-6</u></a>

**(a)(2) Financial Statement Schedules**

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements filed as part of this Annual Report on Form 10-K or the notes thereto or is not applicable or required.

**(a)(3) Exhibits**

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
<a href="#"><u>3.1</u></a>	<a href="#"><u>Restated Certificate of Incorporation of Selecta Biosciences, Inc.</u></a>	8-K	001-37798	3.1	6/29/2016	
<a href="#"><u>3.2</u></a>	<a href="#"><u>Amended and Restated By-laws of Selecta Biosciences, Inc.</u></a>	8-K	001-37798	3.2	6/29/2016	
<a href="#"><u>4.1</u></a>	<a href="#"><u>Specimen Stock Certificate evidencing the shares of common stock</u></a>	S-1	333-211555	4.2	5/24/2016	
<a href="#"><u>4.2</u></a>	<a href="#"><u>Form of Warrant to Purchase Shares of Series D Preferred Stock, dated August 9, 2013 or July 25, 2014, issued by the Registrant to Oxford Finance LLC and Square One Bank, together with a schedule of warrant holders</u></a>	S-1	333-211555	4.5	5/24/2016	
<a href="#"><u>4.3</u></a>	<a href="#"><u>Form of Warrant to Purchase Shares of Series E Preferred Stock, dated December 31, 2015, issued by the Registrant to Oxford Finance LLC and Square One Bank, together with a schedule of warrant holders</u></a>	S-1	333-211555	4.6	5/24/2016	
<a href="#"><u>4.4</u></a>	<a href="#"><u>Common Stock Purchase Warrant, dated June 27, 2017, by and between the Registrant and Timothy Springer, Ph.D.</u></a>	8-K	001-37798	4.1	6/28/2017	

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<a href="#"><u>4.5</u></a>	<a href="#"><u>Registration Rights Agreement, dated December 23, 2019, by and among the Registrant and the Investors named therein</u></a>	8-K	001-37798	10.2	12/26/2019
<a href="#"><u>4.6</u></a>	<a href="#"><u>Registration Rights Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)</u></a>	10-Q	001-37798	4.1	8/6/2020
<a href="#"><u>4.7</u></a>	<a href="#"><u>Registration Rights Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ), as amended on November 4, 2020</u></a>	10-Q	001-37798	4.2	11/5/2020
<a href="#"><u>4.8</u></a>	<a href="#"><u>Form of Common Stock Purchase Warrant, dated December 23, 2019</u></a>	8-K	001-37798	4.1	12/26/2019
<a href="#"><u>4.9</u></a>	<a href="#"><u>Form of Pre-Funded Common Stock Purchase Warrant, dated December 23, 2019</u></a>	8-K	001-37798	4.2	12/26/2019
<a href="#"><u>4.10</u></a>	<a href="#"><u>Form of Warrant to Purchase Stock, dated August 31, 2020, issued by Selecta Biosciences, Inc. to Oxford Finance LLC and Silicon Valley Bank, together with a schedule of warrants.</u></a>	8-K	001-37798	4.1	9/3/2020
<a href="#"><u>4.11</u></a>	<a href="#"><u>Description of Securities</u></a>				*
<a href="#"><u>10.1#</u></a>	<a href="#"><u>2016 Incentive Award Plan and form of award agreements thereunder</u></a>	S-1/A	333-211555	10.2	6/8/2016
<a href="#"><u>10.2#</u></a>	<a href="#"><u>2016 Employee Stock Purchase Plan</u></a>	S-1/A	333-211555	10.3	6/8/2016
<a href="#"><u>10.3#</u></a>	<a href="#"><u>2018 Employment Inducement Incentive Award Plan, amended and restated, and forms agreement thereunder</u></a>	S-8	333-230501	10.1	3/25/2019
<a href="#"><u>10.4#</u></a>	<a href="#"><u>2008 Stock Incentive Plan and form of award agreements thereunder</u></a>	S-1/A	333-211555	10.1	6/20/2016
<a href="#"><u>10.5#</u></a>	<a href="#"><u>Non-Employee Director Compensation Program</u></a>	10-Q	001-37798	10.1	5/7/2020
<a href="#"><u>10.6#</u></a>	<a href="#"><u>Form of Indemnification Agreement for Directors and Officers</u></a>	S-1	333-211555	10.5	5/24/2016
<a href="#"><u>10.7(a)†</u></a>	<a href="#"><u>Exclusive Patent License Agreement, dated as of November 25, 2008, by and between the Registrant and the Massachusetts Institute of Technology</u></a>	S-1	333-211555	10.7(a)	5/24/2016
<a href="#"><u>10.7(b)†</u></a>	<a href="#"><u>First Amendment to Exclusive Patent License Agreement, dated as of January 12, 2010, by and between the Registrant and the Massachusetts Institute of Technology</u></a>	S-1	333-211555	10.7(b)	5/24/2016
<a href="#"><u>10.7(c)†</u></a>	<a href="#"><u>Letter Agreement, dated as of November 27, 2012, by and among the Registrant, Massachusetts Institute of Technology and Sanofi</u></a>	S-1	333-211555	10.7(c)	5/24/2016
<a href="#"><u>10.7(d)†</u></a>	<a href="#"><u>Letter Amendment, dated as of November 27, 2012, by and between the Registrant and the Massachusetts Institute of Technology</u></a>	S-1	333-211555	10.7(d)	5/24/2016
<a href="#"><u>10.7(e)†</u></a>	<a href="#"><u>Second Amendment to Exclusive Patent License Agreement, dated as of August 29, 2013, by and between the Registrant and the Massachusetts Institute of Technology</u></a>	S-1	333-211555	10.7(e)	5/24/2016

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<a href="#"><u>10.7(f)†</u></a>	<a href="#"><u>Third Amendment to Exclusive Patent License Agreement, entered into on November 21, 2016 and effective as of November 18, 2016, by and between the Massachusetts Institute of Technology and the Registrant</u></a>	8-K/A	001-37798	10.3(a)	12/14/2016
<a href="#"><u>10.7(g)†</u></a>	<a href="#"><u>Letter Agreement, dated as of December 2, 2016, by and between the Massachusetts Institute of Technology and the Registrant</u></a>	8-K/A	001-37798	10.3(b)	12/14/2016
<a href="#"><u>10.7(h)†</u></a>	<a href="#"><u>Letter Agreement, dated as of December 2, 2016, by and among Spark Therapeutics, Inc., the Massachusetts Institute of Technology and the Registrant</u></a>	8-K/A	001-37798	10.3(c)	12/14/2016
<a href="#"><u>10.7(i)†</u></a>	<a href="#"><u>Fourth Amendment to Exclusive Patent License Agreement, entered into on December 13, 2019, by and between the Massachusetts Institute of Technology and the Registrant</u></a>	10-K	001-37798	10.7(i)	3/12/2020
<a href="#"><u>10.7(j)†</u></a>	<a href="#"><u>Fifth Amendment to Exclusive Patent License Agreement, dated as of May 15, 2020, by and between the Registrant and the Massachusetts Institute of Technology</u></a>	10-Q	001-37798	10.1	8/6/2020
<a href="#"><u>10.8†</u></a>	<a href="#"><u>Amended and Restated License Agreement, dated as of May 31, 2017, by and between the Registrant and Shenyang Sunshine Pharmaceutical Co., Ltd.</u></a>	10-Q	001-37798	10.6	8/11/2017
<a href="#"><u>10.9†</u></a>	<a href="#"><u>Manufacturing Services Agreement, dated as of August 1, 2014, by and between the Registrant and Shenyang Sunshine Pharmaceutical Co., Ltd.</u></a>	S-1	333-211555	10.10	5/24/2016
<a href="#"><u>10.10†</u></a>	<a href="#"><u>Lease, dated as of September 30, 2008, as amended by the First Amendment, dated as of July 12, 2011, the Second Amendment, dated as of October 11, 2011 and the Third Amendment, dated as of April 6, 2015, by and between the Registrant and ARE-480 Arsenal Street, LLC</u></a>	S-1	333-211555	10.13	5/24/2016
<a href="#"><u>10.11†</u></a>	<a href="#"><u>Fourth Amendment to Lease, dated August 21, 2016, by and between ARE-480 Arsenal Street LLC and Selecta Biosciences, Inc.</u></a>	8-K	001-37798	10.1	9/14/2016
<a href="#"><u>10.12</u></a>	<a href="#"><u>Lease Agreement by and between BRE-BMR Grove LLC and Selecta Biosciences, Inc. dated July 23, 2019</u></a>	10-Q	001-37798	10.3	11/8/2019
<a href="#"><u>10.13#</u></a>	<a href="#"><u>Employment Agreement, dated as of September 25, 2018, by and between the Registrant and Carsten Brunn, Ph.D.</u></a>	8-K	001-37798	10.2	9/27/2018
<a href="#"><u>10.14#</u></a>	<a href="#"><u>Employment Agreement, dated as of June 6, 2016, by and between the Registrant and Takashi Kei Kishimoto</u></a>	S-1/A	333-211555	10.18	6/8/2016
<a href="#"><u>10.15#</u></a>	<a href="#"><u>Employment Agreement, dated as of June 6, 2016, by and between the Registrant and Lloyd P. M. Johnston, Ph.D.</u></a>	S-1/A	333-211555	10.21	6/8/2016
<a href="#"><u>10.16#</u></a>	<a href="#"><u>Employment Agreement, dated as of August 12, 2019, by and between the Registrant and Bradford D. Dahms</u></a>	10-Q	001-37798	10.1	11/8/2019

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<a href="#"><u>10.17#</u></a>	<a href="#"><u>Employment Agreement, dated as of July 31, 2020, by and between the Registrant and Peter G. Traber, M.D</u></a>	10-Q	001-37798	10.1	11/5/2020	
<a href="#"><u>10.18†</u></a>	<a href="#"><u>Stock Purchase Agreement, dated as of December 2, 2016, by and between Spark Therapeutics, Inc. and the Registrant</u></a>	8-K/A	001-37798	10.2	12/14/2016	
<a href="#"><u>10.19†</u></a>	<a href="#"><u>Feasibility Study and License Agreement by and between Asklepios BioPharmaceutical, Inc. and Selecta Biosciences, Inc. dated August 6, 2019</u></a>	10-Q	001-37798	10.2	11/8/2019	
<a href="#"><u>10.20†</u></a>	<a href="#"><u>License and Development Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)</u></a>	10-Q	001-37798	10.2	8/6/2020	
<a href="#"><u>10.21</u></a>	<a href="#"><u>Securities Purchase Agreement, dated June 26, 2017, by and between the Registrant and Timothy Springer, Ph.D.</u></a>	8-K	001-37798	10.2	6/28/2017	
<a href="#"><u>10.22</u></a>	<a href="#"><u>Stock Purchase Agreement, dated August 19, 2019, by and among the Registrant and the Investors named therein</u></a>	8-K	001-37798	10.1	8/20/2019	
<a href="#"><u>10.23</u></a>	<a href="#"><u>Securities Purchase Agreement, dated December 18, 2019, by and among the Registrant and the Investors named therein</u></a>	8-K	001-37798	10.1	12/26/2019	
<a href="#"><u>10.24</u></a>	<a href="#"><u>Stock Purchase Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)</u></a>	10-Q	001-37798	10.3	8/6/2020	
<a href="#"><u>10.25</u></a>	<a href="#"><u>Loan and Security Agreement, dated August 31, 2020, between Selecta Biosciences, Inc., Oxford Finance LLC, as Collateral Agent and as a lender, and Silicon Valley Bank, as a lender.</u></a>	8-K	001-37798	10.1.1	9/3/2020	
<a href="#"><u>21.1</u></a>	<a href="#"><u>Subsidiaries of Selecta Biosciences, Inc.</u></a>	S-1	333-211555	21.1	5/24/2016	
<a href="#"><u>23.1</u></a>	<a href="#"><u>Consent of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm</u></a>					*
<a href="#"><u>31.1</u></a>	<a href="#"><u>Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer</u></a>					*
<a href="#"><u>31.2</u></a>	<a href="#"><u>Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer</u></a>					*
<a href="#"><u>32.1</u></a>	<a href="#"><u>Section 1350 Certification of Chief Executive Officer</u></a>					**
<a href="#"><u>32.2</u></a>	<a href="#"><u>Section 1350 Certification of Chief Financial Officer</u></a>					**
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					***

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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.

# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24h-2 under the Securities Exchange Act of 1934.

### **Item 16. Form 10-K Summary**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**SELECTA BIOSCIENCES, INC.**

Date: March 12, 2021

By:           /s/ Carsten Brunn, Ph.D.            
          Carsten Brunn, Ph.D.  
          *President and Chief Executive Officer*

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.

<b><u>Signature</u></b>	<b><u>Title</u></b>	<b><u>Date</u></b>
<u>          /s/ Carsten Brunn, Ph.D.          </u> Carsten Brunn, Ph.D.	President and Chief Executive Officer, and Director (Principal Executive Officer)	March 12, 2021
<u>          /s/ Bradford D. Dahms          </u> Bradford D. Dahms	Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2021
<u>          /s/ Carrie S. Cox          </u> Carrie S. Cox	Director	March 12, 2021
<u>          /s/ Goran A. Ando, M.D.          </u> Goran A. Ando, M.D.	Director	March 12, 2021
<u>          /s/ Timothy C. Barabe          </u> Timothy C. Barabe	Director	March 12, 2021
<u>          /s/ Scott D. Myers          </u> Scott D. Myers	Director	March 12, 2021
<u>          /s/ Aymeric Sallin          </u> Aymeric Sallin	Director	March 12, 2021
<u>          /s/ Timothy Springer, Ph.D.          </u> Timothy Springer, Ph.D.	Director	March 12, 2021
<u>          /s/ Patrick Zenner          </u> Patrick Zenner	Director	March 12, 2021

## **Report of Independent Registered Public Accounting Firm**

**To the Stockholders and Board of Directors of Selecta Biosciences, Inc.**

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Selecta Biosciences, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in stockholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2009.

Boston, Massachusetts

March 12, 2021

**Selecta Biosciences, Inc. and Subsidiaries**  
**Consolidated Balance Sheets**  
(Amounts in thousands, except share data and par value)

	December 31, 2020	December 31, 2019
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 138,685	\$ 89,893
Restricted cash	—	279
Accounts receivable	7,224	5,000
Prepaid expenses and other current assets	5,434	1,495
Total current assets	<u>151,343</u>	<u>96,667</u>
Property and equipment, net	1,395	1,222
Right-of-use asset, net	10,948	301
Long-term restricted cash	1,379	1,379
Other assets	370	—
Total assets	<u>\$ 165,435</u>	<u>\$ 99,569</u>
<b>Liabilities and stockholders' (deficit) equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 443	\$ 500
Accrued expenses	8,146	13,492
Loan payable	—	18,905
Lease liability	908	372
Deferred revenue	72,050	1,674
Total current liabilities	<u>81,547</u>	<u>34,943</u>
<b>Non-current liabilities:</b>		
Loan payable, net of current portion	24,793	—
Lease liability	9,647	—
Deferred revenue	38,746	14,680
Warrant liabilities	28,708	41,549
Total liabilities	<u>183,441</u>	<u>91,172</u>
Commitments and contingencies (Note 17)		
<b>Stockholders' (deficit) equity:</b>		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 108,071,249 and 86,325,547 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	11	9
Additional paid-in capital	391,175	348,664
Accumulated deficit	(404,629)	(335,753)
Accumulated other comprehensive loss	(4,563)	(4,523)
Total stockholders' (deficit) equity	<u>(18,006)</u>	<u>8,397</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 165,435</u>	<u>\$ 99,569</u>

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

**Selecta Biosciences, Inc. and Subsidiaries**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(Amounts in thousands, except share and per share data)

	Year Ended December 31,		
	2020	2019	2018
Grant and collaboration revenue	\$ 16,597	\$ 6,677	\$ 903
Operating expenses:			
Research and development	54,505	42,743	47,687
General and administrative	18,913	16,389	18,238
Total operating expenses	73,418	59,132	65,925
Loss from operations	(56,821)	(52,455)	(65,022)
Investment income	260	834	1,050
Loss on extinguishment of debt	(461)	—	—
Foreign currency transaction gain (loss), net	56	(47)	120
Interest expense	(1,556)	(1,519)	(1,494)
Change in fair value of warrant liabilities	(10,443)	(857)	—
Other income (expense), net	89	(1,306)	10
Net loss	(68,876)	(55,350)	(65,336)
Other comprehensive loss:			
Foreign currency translation adjustment	(40)	34	(153)
Unrealized gain on securities	—	—	16
Total comprehensive loss	\$ (68,916)	\$ (55,316)	\$ (65,473)
Net loss per share:			
Basic and diluted	\$ (0.68)	\$ (1.22)	\$ (2.92)
Weighted average common shares outstanding:			
Basic and diluted	101,202,176	45,548,511	22,389,286

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

**Selecta Biosciences, Inc. and Subsidiaries**  
**Consolidated Statements of Changes in Stockholders' (Deficit) Equity**  
(Amounts in thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Stockholders' (Deficit) Equity
	Shares	Amount				
Balance at December 31, 2017	22,343,254	\$ 3	\$ 273,128	\$ (216,897)	\$ (4,420)	\$ 51,814
Adoption of new accounting principle	—	—	—	1,830	—	1,830
Issuance of common stock under Employee Stock Purchase Plan	24,738	—	196	—	—	196
Issuance of common stock upon exercise of options	103,784	—	501	—	—	501
Stock-based compensation expense	—	—	5,714	—	—	5,714
Currency translation adjustment	—	—	—	—	(153)	(153)
Unrealized gains on securities	—	—	—	—	16	16
Net loss	—	—	—	(65,336)	—	(65,336)
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	17,205	—	28	—	—	28
Issuance of common stock upon exercise of options	125,600	—	150	—	—	150
Issuance of vested restricted stock units	93,750	—	—	—	—	—
Issuance of common stock, net	22,188,706	2	30,940	—	—	30,942
Issuance of common stock through at-the-market offering, net	615,453	—	1,006	—	—	1,006
Issuance of common stock through private placement	3,178,174	—	5,715	—	—	5,715
Issuance of common stock, pre-funded warrants and warrants through private placement	37,634,883	4	26,125	—	—	26,129
Stock-based compensation expense	—	—	5,161	—	—	5,161
Currency translation adjustment	—	—	—	—	34	34
Net loss	—	—	—	(55,350)	—	(55,350)
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	110,212	—	184	—	—	184
Issuance of common stock upon exercise of options	76,128	—	193	—	—	193
Issuance of vested restricted stock units	93,750	—	—	—	—	—
Issuance of common stock through at-the-market offering, net	1,069,486	—	2,108	—	—	2,108
Issuance of common stock through private placement	5,416,390	—	10,268	—	—	10,268
Issuance of common stock upon exercise of pre-funded warrants	8,342,128	1	—	—	—	1
Issuance of common stock upon exercise of common warrants	6,637,608	1	24,262	—	—	24,263
Other financing fees	—	—	(370)	—	—	(370)
Issuance of common warrants with long-term debt, net	—	—	444	—	—	444
Stock-based compensation expense	—	—	5,422	—	—	5,422
Currency translation adjustment	—	—	—	—	(40)	(40)
Net loss	—	—	—	(68,876)	—	(68,876)
Balance at December 31, 2020	108,071,249	\$ 11	\$ 391,175	\$ (404,629)	\$ (4,563)	\$ (18,006)

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

**Selecta Biosciences, Inc. and Subsidiaries**  
**Consolidated Statements of Cash Flows**  
**(Amounts in thousands)**

	Year Ended December 31,		
	2020	2019	2018
<b>Cash flows from operating activities</b>			
Net loss	\$ (68,876)	\$ (55,350)	\$ (65,336)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	734	726	975
Accretion of discounts on investments	—	(154)	(101)
Non-cash lease expense	1,127	1,301	—
(Gain) loss on disposal of property and equipment	(52)	104	(81)
Stock-based compensation expense	5,422	5,161	5,714
Non-cash interest expense	620	402	449
Warrant liabilities revaluation	10,443	857	—
Loss on extinguishment of debt	461	—	—
Net realized losses on investments	—	(1)	—
Changes in operating assets and liabilities:			
Accounts receivable	(2,224)	(5,000)	—
Prepaid expenses, deposits and other assets	(4,418)	3,179	(2,631)
Accounts payable	(57)	(600)	(516)
Deferred revenue	94,462	337	(101)
Accrued expenses and other liabilities	(2,761)	(2,397)	2,467
Net cash provided by (used in) operating activities	<u>34,881</u>	<u>(51,435)</u>	<u>(59,161)</u>
<b>Cash flows from investing activities</b>			
Receipts from the maturity of short-term investments	—	16,350	41,655
Purchases of short-term investments	—	(18,188)	(15,598)
Sale of short term investments	—	1,992	—
Purchases of property and equipment	(815)	(47)	(884)
Proceeds from the sale of property and equipment	74	122	99
Net cash (used in) provided by investing activities	<u>(741)</u>	<u>229</u>	<u>25,272</u>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of long-term debt, net of expenses	24,736	—	—
Repayments of principal on outstanding debt	(19,313)	(2,800)	—
Net proceeds from issuance of common stock	—	30,942	—
Net proceeds from issuance of common stock- at-the-market offering	2,108	1,006	—
Net proceeds from issuance of common stock- private placement	10,268	5,715	—
Issuance costs paid for December 2019 financing	(4,381)	—	—
Other financing fees	(343)	—	—
Net proceeds from exercise of pre-funded and common warrants	979	70,000	—
Proceeds from exercise of stock options	193	150	501
Proceeds from issuance of common stock under Employee Stock Purchase Plan	184	28	196
Net cash provided by financing activities	<u>14,431</u>	<u>105,041</u>	<u>697</u>
Effect of exchange rate changes on cash	(58)	34	(153)
Net change in cash, cash equivalents, and restricted cash	48,513	53,869	(33,345)
Cash, cash equivalents, and restricted cash at beginning of period	91,551	37,682	71,027
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 140,064</u>	<u>\$ 91,551</u>	<u>\$ 37,682</u>
<b>Supplement cash flow information</b>			
Cash paid for interest	\$ 1,018	\$ 1,223	\$ 1,134
<b>Noncash investing and financing activities</b>			
Cashless warrant exercise	\$ 21,790	\$ —	\$ —
Reclassification of warrant liability to equity upon exercise of warrants	\$ 1,494	\$ —	\$ —
Fair value of warrants issued in connection with issuance of long-term debt	\$ 444	\$ —	\$ —
Purchase of property and equipment not yet paid	\$ 4	\$ —	\$ 145
Equity offering costs in accrued liabilities	\$ 27	\$ 4,381	\$ —
Unrealized gain on marketable securities	\$ —	\$ —	\$ 16
Debt issuance costs in accrued liabilities	\$ 2	\$ —	\$ —

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

**Selecta Biosciences, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements**

**1. Nature of the Business and Basis of Presentation**

Selecta Biosciences, Inc. (the “Company”) was incorporated in Delaware on December 10, 2007, and is based in Watertown, Massachusetts. The Company is a clinical-stage biopharmaceutical company leveraging its ImmTOR™ immune tolerance platform with the goals of amplifying the efficacy of biologics, including enabling the re-dosing of life-saving gene therapies, and restoring self-tolerance in autoimmune diseases. The Company's ImmTOR platform encapsulates rapamycin, also known as sirolimus, an immunomodulator, in biodegradable nanoparticles and is designed to induce antigen-specific immune tolerance. The Company believes ImmTOR has the potential to enhance the efficacy without compromising the safety of biologic therapies, improve product candidates under development, and enable novel therapeutic modalities. 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.

**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, private placements 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 December 31, 2020, the Company's cash, cash equivalents and restricted cash were \$140.1 million, of which \$1.4 million was restricted cash related to lease commitments and \$0.3 million was held by its Russian subsidiary designated solely for use in its operations. The Company believes the cash, cash equivalents, and restricted cash as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. The Company has incurred losses and negative cash flows from operating activities since inception. As of December 31, 2020, the Company had an accumulated deficit of \$404.6 million. 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 COVID-19 pandemic and the impact of related responses. Any impact of COVID-19 on our business, revenues, results of operations and financial condition will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and

other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

### **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 December 31, 2020, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

## **2. Summary of Significant Accounting Policies**

### **Principles of Consolidation**

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

### **Foreign Currency**

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

### **Use of Estimates**

The preparation of consolidated financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's management considers many factors in selecting appropriate financial accounting policies and controls, and bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. In preparing these consolidated financial statements, management used significant estimates in the following areas, among others: revenue recognition, the 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, 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 year ended December 31, 2020, there were no realized losses on sales of investments, and no investments were adjusted for other than temporary declines in fair value.

As of December 31, 2020, the Company had restricted cash balances relating to a secured letter of credit in connection with its 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:

	Year Ended December 31,		
	2020	2019	2018
Cash and cash equivalents	\$ 138,685	\$ 89,893	\$ 37,403
Short-term restricted cash	—	279	—
Long-term restricted cash	1,379	1,379	279
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	<u>\$ 140,064</u>	<u>\$ 91,551</u>	<u>\$ 37,682</u>

### 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 December 31, 2020, the Company maintained approximately \$0.3 million in Russian bank accounts, all of which was held in U.S. dollars.

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

### Fair Value of Financial Instruments

The Company’s financial instruments consist mainly of cash equivalents, restricted cash, accounts payable, loans payable, and common warrants. The carrying amounts of cash equivalents, restricted cash, accounts receivable, and accounts payable approximate their estimated fair value due to their short-term maturities. At December 31, 2020, given the recent issuance of the Term A Loan under the 2020 Term Loan (each, as defined below), the Company believes the carrying value approximates the fair value of the loan.

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 years ended December 31, 2020 or 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 years ended December 31, 2020 and 2019.

## **Debt Issuance Costs**

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

## **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.

## **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 Swedish Orphan Biovitrum (“Sobi”), Asklepios Biopharmaceutical, Inc. (“AskBio”), Sarepta Therapeutics, Inc. (“Sarepta”), and Spark Therapeutics, Inc. (“Spark”) (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, stock-based compensation expenses, 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 cancellable, 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.

On June 11, 2020, we and Sobi entered into a license and development agreement (the “Sobi License”). Pursuant to the Sobi License, clinical trial costs incurred to complete development of SEL-212, including but not limited to costs incurred while conducting and completing the Phase 3 DISSOLVE trials, will be reimbursed by Sobi. These costs, when reimbursed, will be recognized as revenue consistent with the revenue recognition methodology disclosed in Footnote 12. The reimbursable costs exclude any costs of additional development activities required that are related to ImmTOR and that are unrelated to SEL-212.

## **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. 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 ultimately 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 antidilutive 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.

### **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, the FASB issued ASU 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 October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. 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 August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)*. ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. This ASU is effective for smaller reporting companies for fiscal years beginning after December 15, 2023, with early adoption permitted no earlier than January 1, 2021. The Company is assessing the impact this standard will have on its consolidated financial statements and disclosures.

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

### 4. Net Loss Per Share

The Company has reported a net loss for the years ended December 31, 2020, 2019 and 2018. 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 were 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):

	Year Ended December 31,		
	2020	2019	2018
<b>Numerator:</b>			
Net loss attributable to common stockholders	\$ (68,876)	\$ (55,350)	\$ (65,336)
<b>Denominator:</b>			
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	101,202,176	45,548,511	22,389,286
Net loss per share attributable to common stockholders —basic and diluted	\$ (0.68)	\$ (1.22)	\$ (2.92)

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:

	Year Ended December 31,		
	2020	2019	2018
Stock options to purchase common stock	7,775,249	6,796,669	4,093,979
Unvested restricted stock units	87,500	181,250	175,000
Stock warrants to purchase common stock	12,378,016	23,084,120	95,619
Total	20,240,765	30,062,039	4,364,598

### 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 December 31, 2020 and December 31, 2019, and indicate the level within the fair value hierarchy where each measurement is classified. Below is a summary of assets and liabilities measured at fair value on a recurring basis (in thousands):

	December 31, 2020			
	Total	(Level 1)	(Level 2)	(Level 3)
<b>Assets:</b>				
Money market funds	\$ 80,576	\$ 80,576	\$ —	\$ —
<b>Total</b>	<b>\$ 80,576</b>	<b>\$ 80,576</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Liabilities:</b>				
Warrant liabilities	\$ 28,708	\$ —	\$ —	\$ 28,708
<b>Total</b>	<b>\$ 28,708</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 28,708</b>
	December 31, 2019			
	Total	(Level 1)	(Level 2)	(Level 3)
<b>Assets:</b>				
Money market funds	\$ 50,401	\$ 50,401	\$ —	\$ —
<b>Total</b>	<b>\$ 50,401</b>	<b>\$ 50,401</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Liabilities:</b>				
Warrant liabilities	\$ 41,549	\$ —	\$ —	\$ 41,549
<b>Total</b>	<b>\$ 41,549</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 41,549</b>

As of December 31, 2020 and December 31, 2019, the money market funds were classified as cash and cash equivalents on the accompanying consolidated balance sheets 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 is required to revalue the common warrants at each reporting date with any changes in fair value recorded in the statement of operations. The valuation of the common warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The change in the fair value of the Level 3 warrant liability is reflected in the statement of operations for the year ended December 31, 2020.

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

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

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

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

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

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

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

	<b>December 31, 2020</b>
Risk-free interest rate	0.36%
Dividend yield	—
Expected life (in years)	3.98
Expected volatility	98.63%

*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 year ended December 31, 2020 (in thousands):

	<b>Warrant liabilities</b>
Fair value as of December 31, 2019	\$ 41,549
Exercises	(23,284)
Change in fair value	10,443
Fair value as of December 31, 2020	<u>\$ 28,708</u>

## 6. Property and Equipment

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

	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Laboratory equipment	\$ 4,427	\$ 4,836
Computer equipment and software	532	515
Leasehold improvements	38	278
Furniture and fixtures	327	237
Office equipment	163	135
Construction in process	163	2
Total property and equipment	<u>5,650</u>	<u>6,003</u>
Less accumulated depreciation	(4,255)	(4,781)
Property and equipment, net	<u>\$ 1,395</u>	<u>\$ 1,222</u>

Depreciation expense was \$0.6 million, \$0.7 million and \$1.0 million for the years ended December 31, 2020, 2019 and 2018, respectively. During the fourth quarter of 2020, capitalized website development costs of \$0.1 million were recorded within construction in process. The Company recorded accelerated depreciation costs of less than \$0.1 million in the reported property and equipment for the year ended December 31, 2020 relating to the new corporate headquarters move in 2020.

## 7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Payroll and employee related expenses	\$ 3,049	\$ 2,235
Collaboration and licensing	1,350	1,050
Accrued patent fees	534	487
Accrued external research and development costs	2,029	4,379
Accrued professional and consulting services	798	468
Accrued interest	170	82
Issuance costs, December 2019 financing	—	4,381
Other	216	410
Accrued expenses	<u>\$ 8,146</u>	<u>\$ 13,492</u>

## 8. Leases

On January 1, 2019, the Company adopted ASC 842 using the modified retrospective approach. The Company recorded operating lease assets (right-of-use assets) of \$1.6 million and operating lease liabilities of \$1.8 million and reversed a lease liability of \$0.2 million related to straight-line rent and incentives. There was no impact to accumulated deficit upon adoption of ASC 842. The underlying assets of the Company's leases are primarily office space. The Company determines if an arrangement qualifies as a lease at its inception.

As a practical expedient permitted under ASC 842, the Company elected to account for the lease and non-lease components as a single lease component for all leases of which it is the lessee. Lease payments, which may include lease and non-lease components, were included in the measurement of the Company's lease liabilities to the extent that such payments were either fixed amounts or variable amounts dependent upon on a rate or index as stipulated in the lease contract.

When the Company cannot readily determine the rate implicit in the lease, the Company determines its incremental borrowing rate by using the rate of interest that it would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. On January 1, 2019, the discount rate used on existing operating leases at adoption, which had remaining lease terms of 15 months, was 10.0%.

The Company enters into lease agreements with terms generally ranging from 2-8 years. Some of the Company's lease agreements include Company options to either extend and/or early terminate the lease, the costs of which are included in its operating lease liabilities to the extent that such options are reasonably certain of being exercised. Leases with renewal options allow the Company to extend the lease term typically between 1 and 5 years. When determining the lease term, renewal options reasonably certain of being exercised are included in the lease term. When determining if a renewal option is reasonably certain of being exercised, the Company considers several economic factors, including but not limited to, the significance of leasehold improvements incurred on the property, whether the asset is difficult to replace, underlying contractual obligations, or specific characteristics unique to that particular lease that would make it reasonably certain that the Company would exercise such option. Renewal and termination options were generally not included in the lease term for the Company's existing operating leases. Leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

### *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, or the 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 had 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, or 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, or the Headquarters Lease. As part of the Headquarters Lease, the Company incurred \$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.

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Rent expense for the years ended December 31, 2020, 2019 and 2018 was \$2.7 million, \$2.1 million and \$2.0 million, respectively.

As of December 31, 2020 and 2019, the components of the operating leases were as follows (in thousands):

	December 31,	
	2020	2019
<b>Assets:</b>		
Right-of-use asset, net	\$ 10,948	\$ 301
<b>Liabilities:</b>		
Current operating lease liabilities	\$ 908	\$ 372
Non-current operating lease liabilities	9,647	—
Total operating lease liabilities	\$ 10,555	\$ 372

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

	Year Ended December 31,	
	2020	2019
Operating lease cost	\$ 2,096	\$ 1,365
Variable lease cost	624	828
Short-term lease cost	10	16
Total lease cost	\$ 2,730	\$ 2,209

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

	December 31, 2020
2021	\$ 1,812
2022	1,866
2023	1,922
2024	1,980
2025	2,039
Thereafter	4,945
Total future minimum lease payments	\$ 14,564
Less imputed interest	4,009
Total operating lease liabilities	\$ 10,555

The supplemental disclosure for the statement of cash flows related to operating leases were as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:	\$ 2,523	\$ 1,482

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 years ended December 31, 2020 and 2019 are reflected in the non-cash lease expense and accrued expenses and other liabilities, respectively, in the consolidated statements of cash flows.

The following summarizes additional information related to operating leases:

	December 31,	
	2020	2019
Weighted-average remaining lease term	7.4 years	0.3 years
Weighted-average discount rate	8.9%	10%

## 9. Debt

### 2020 Term Loan

On August 31, 2020, the Company entered into a term loan of up to \$35.0 million (the “2020 Term Loan”), consisting of term loans in an aggregate amount of \$25.0 million (the “Term A Loan”) and term loans in an aggregate amount of \$10.0 million (the “Term B Loan”), governed by a loan and security agreement between the Company and Oxford Finance LLC, a Delaware limited liability company (“Oxford”) as Collateral Agent and a Lender, and Silicon Valley Bank, a California corporation (“SVB”), as a Lender (the “Loan Agreement”). The Term A Loan was funded in full on August 31, 2020 (the “Funding Date”).

The Term B Loan will be available, subject to Collateral Agent’s discretion and customary terms and conditions, during the period commencing on the date the Company has delivered to the Collateral Agent and the Lenders evidence: (i) the Company or one of the Company’s collaboration partners has enrolled its first randomized patient for a Phase 1 clinical trial evaluating the treatment of methylmalonic acidemia (“MMA”), and (ii) the Company has enrolled the first patient in each of two Phase 3 pivotal trials evaluating SEL-212 (the “Second Draw Period Milestone”) and ending on the earliest of (i) the date which is thirty (30) days following the date the Second Draw Period Milestone is achieved, (ii) September 30, 2021 (iii) and the occurrence of an event of default, other than an event of default that has been waived in writing by Collateral Agent and the Lenders in their sole discretion (such period, the “Second Draw Period”).

The 2020 Term Loan will mature on August 1, 2025. Each advance under the Term Loan accrues interest at a floating per annum rate equal to the greater of (a) 7.90%, and (b) the lesser of (x) the sum of (i) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, and (ii) 4.65% and (y) 10.00%. The Term Loan provides for interest-only payments on a monthly basis until April 1, 2022; provided however, if the Company has delivered to the Collateral Agent and the Lenders prior to September 30, 2021 evidence that Borrower has achieved the Second Draw Period Milestone, the Term Loan provides for interest-only payments on a monthly basis until October 1, 2022. Thereafter, amortization payments will be payable monthly in equal installments of principal and interest to fully amortize the outstanding principal over the remaining term of the loan, subject to recalculation upon a change in the prime rate. The Company may prepay the Term Loan in full but not in part provided that the Company (i) provides ten days’ prior written notice to Collateral Agent, (ii) pays on the date of such prepayment (A) all outstanding principal plus accrued and unpaid interest, and (B) a prepayment fee of between 3.0% and 1.0% of the aggregate original principal amount advanced by the lender depending on the timing of the prepayment. Amounts outstanding during an event of default are payable upon SVB’s demand and shall accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding. At the end of the loan term (whether at maturity, by prepayment in full or otherwise), the Company shall make a final payment to the lender in the amount of 9.0% of the aggregate original principal amount advanced by the lender. The final payment fee totaling \$2.3 million is recorded as a loan discount.

The 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 the Collateral Agent a negative pledge with respect to its intellectual property.

The Loan Agreement 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 Loan Agreement also contains other customary provisions, such as expense reimbursement, non-disclosure obligations as well as indemnification rights for the benefit of the Collateral Agent.

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 change, 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 of at least \$0.5 million, or the occurrence of any default under any agreement or obligation of the Company involving indebtedness in excess of \$0.5 million. If an event of default occurs, the Collateral Agent is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Company incurred \$0.4 million in debt issuance costs in connection with the closing of the 2020 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 Company assessed all terms and features of the 2020 Term Loan 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 2020 Term Loan, including any put, call, and contingent features. The Company determined that the interest rate collar and

prepayment call option did not require bifurcation; whereas the contingent put option and default (contingent) interest rate feature met bifurcation criteria resulting in immaterial amounts.

*Warrants*

On August 31, 2020, in connection with the 2020 Term A Loan, the Company issued warrants to the Lenders to purchase an aggregate of 196,850 shares of its common stock at an exercise price equal to \$2.54 per share. In accordance with ASC 815-40, these warrants are classified as permanent equity in the accompanying consolidated balance sheets and will expire ten years from the date of issuance. The initial grant date fair value of the warrants was \$0.4 million as determined by the Black-Scholes valuation model and recorded to shareholders' equity, with the SVB portion allocated to the reacquisition price of the 2017 Term Loan and the Oxford fair value portion as a loan discount to the Term A Loan.

Additionally, on August 31, 2020, pursuant to the terms of a Warrant Side Letter agreement among the Company and the Lenders, the Company agreed to issue to the Lenders, on the date the Company draws the Term B Loan and in accordance with each party's respective pro rata share with respect to the Term B Loan, one or more warrants to purchase an aggregate number of shares of its common stock that is equal to \$200,000 divided by the average closing price of the Company's common stock on The Nasdaq Stock Market LLC for the ten consecutive trading days ending the day before such issuance, rounded down to the nearest whole number of shares, and having an exercise price equal to the Term B Warrant Price.

*Payoff*

On the Funding Date, the Company entered into a payoff letter with SVB, pursuant to which the Company utilized \$13.7 million of the 2020 Term Loan to pay off all outstanding obligations under the 2017 Term Loan (as defined below), consisting of the principal payment, final prepayment and accrued interest. During the three months ended September 30, 2020, the Company recognized a loss on extinguishment of debt in the amount of \$0.5 million determined as the difference between the reacquisition price and carrying value at August 31, 2020.

**2017 Term Loan**

On September 12, 2017, the Company entered into a term loan of up to \$21.0 million (the "2017 Term Loan" and, together with the 2020 Term Loan, the "Term Loans") with Silicon Valley Bank. The 2017 Term Loan was governed by a loan and security agreement, dated September 12, 2017, between the Company and SVB. The 2017 Term Loan was funded in full on September 13, 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 were 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.

Prior to the extinguishment of the 2017 Term Loan in August 2020 discussed in greater detail above, the 2017 Term Loan was 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 included any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. The Company had also granted SVB a negative pledge with respect to its intellectual property. Each advance under the 2017 Term Loan accrued 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 through August 31, 2019. The monthly interest was subject to recalculation upon a change in the prime rate.

As of December 31, 2020, the outstanding principal balance was \$25.0 million under the 2020 Term Loan and as of December 31, 2019, the outstanding principal balance was \$18.2 million under the 2017 Term Loan.

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

2021	2,002
2022	7,343
2023	8,611
2024	8,027
2025	7,274
Total minimum debt payments	\$ 33,257
Less: Amount representing interest	(6,008)
Less: Debt discount and deferred charges	(2,456)
Less: Current portion of loan payable	—
Loan payable, net of current portion	\$ 24,793

During the years ended December 31, 2020, 2019 and 2018, the Company recognized \$1.6 million, \$1.5 million and \$1.5 million respectively of interest expense related to the 2020 and 2017 Term Loans.

## 10. Equity

### Equity Financings

#### *August 2020 Shelf Registration Statement*

On August 6, 2020, the Company filed an updated universal shelf registration statement on Form S-3 (Reg. No. 333-241692) 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 14, 2020.

#### *“At-the-Market” Offerings*

In August 2017, the Company entered into a sales agreement (the “2017 Sales Agreement”), with Jefferies LLC, as sales agent, to sell shares of its common stock with an aggregate value of up to \$50 million in an “at the market offering.” On August 6, 2020, concurrent with the filing of the updated shelf registration statement, the Company entered into a new sales agreement (the “2020 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.” The 2017 Sales Agreement terminated pursuant to its terms in August 2020.

Sales of common stock, if any, pursuant to the 2020 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 Stock 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 2020 Sales Agreement at any time.

During the year ended December 31, 2019, the Company sold 615,453 shares of its common stock pursuant to the 2017 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, pursuant to its shelf registration statement filed in August 2017.

During the year ended December 31, 2020, the Company sold 1,069,486 shares of its common stock pursuant to the 2017 Sales Agreement and the 2020 Sales Agreement, as applicable, 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.

#### *June 2020 Sobi Stock Purchase*

On June 11, 2020, the Company entered into a stock purchase agreement with Swedish Orphan Biovitrum AB (Publ), pursuant to which the Company sold 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. 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.

In accordance with ASC 815, this forward sale treatment qualified as equity classification as the shares are not within the scope of ASC 480. The gross proceeds of \$25 million were determined to include a premium to the fair value of the Company’s shares as of July 28, 2020 of approximately \$14.5 million. As a result, such amount was included in the transaction price for revenue recognition of the Sobi License. See Note 12 for details.

Also on June 11, 2020, the Company entered into a registration rights agreement (as amended by that certain letter agreement, dated as of November 4, 2020, the “Sobi Registration Rights Agreement”) with Sobi, pursuant to which the Company 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 30 days following receipt by the Company of a written request from Sobi to file such resale registration statement, and to have the registration statement declared effective within ten (10) Business Days after the SEC informs the Company that no review of such resale registration statement will be made or that the SEC has no further comments on such resale registration statement.

#### *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. 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.

The common warrants were revalued as of December 31, 2020 at \$28.7 million. During the years ended December 31, 2020 and 2019, the Company recorded losses on the increases in the fair value of the warrants of \$(10.4) million and \$(0.9) million, respectively, in the consolidated statements of operations.

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 Stock 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 Stock 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 year ended December 31, 2020, warrant holders exercised 10,233,154 common warrants on a cashless basis and received 5,967,808 shares of common stock. In addition, warrant holders exercised 669,800 common warrants and 8,342,128 pre-funded warrants, and paid the exercise price in cash. On August 31, 2020, in connection with the 2020 Term A Loan, 196,850 equity classified warrants were issued to the Lenders.

	Number of Warrants			Weighted average exercise price
	Equity classified	Liability classified	Total	
Outstanding at December 31, 2019	8,437,747	22,988,501	31,426,248	\$ 1.12
Exercises	(8,342,128)	(10,902,954)	(19,245,082)	0.83
Issuance	196,850	—	196,850	2.54
Outstanding at December 31, 2020	292,469	12,085,547	12,378,016	\$ 1.60

## Common Stock

As of December 31, 2020, the Company had 200,000,000 shares of common stock authorized for issuance, \$0.0001 par value per share, with 108,071,249 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 December 31, 2020, no dividends have been declared or paid on common stock.

### *Liquidation*

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

## Reserved Shares

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

	Period ended	
	December 31, 2020	December 31, 2019
Exercise of common warrants	12,378,016	31,426,248
Shares available for future stock incentive awards	4,916,374	1,765,018
Unvested restricted stock units	87,500	181,250
Outstanding common stock options	7,775,249	6,796,669
Total	25,157,139	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. Pursuant to the terms of the 2016 Plan, the Board is authorized to grant awards with respect to common stock, and may delegate to a committee of one or more members of the Board or executive officers of the Company the authority to grant options and restricted stock units. On December 9, 2020, the Board established a Stock Option Committee authorized to grant awards to certain employees and consultants subject to conditions and limitations within the 2016 Plan.

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 year ended December 31, 2020 and 2019, the number of shares of common stock that may be issued under the 2016 Plan was increased by 3,453,022 shares and 898,871 shares, respectively. As of December 31, 2020, 2,057,593 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 “2018 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 2018 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 2018 Inducement Incentive Award Plan. On March 25, 2019, the Board approved the amendment and restatement of the 2018 Inducement Incentive Award Plan to reserve an additional 2,000,000 shares of the Company’s common stock for issuance thereunder. As of December 31, 2020, there are 1,358,333 shares available for future grant under the 2018 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:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	1.11%	1.86%	2.85%
Dividend yield	—	—	—
Expected term	6.04	5.94	6.06
Expected volatility	91.00%	87.66%	85.17%
Weighted-average fair value of common stock	\$ 2.49	\$ 2.01	\$ 8.45

The weighted average grant date fair value of stock options granted to employees during the years ended December 31, 2020, 2019 and 2018 was \$1.86, \$1.47, and \$6.17 respectively.

As of December 31, 2020 and December 31, 2019, total unrecognized compensation expense related to unvested employee stock options was \$8.0 million and \$9.8 million, respectively, which is expected to be recognized over a weighted average period of 2.3 years and 2.5 years, respectively.

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### Non-employee consultants

No stock option awards were granted to non-employee consultants during the year ended December 31, 2020.

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

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	—%	1.92%	2.77%
Dividend yield	—	—	—
Expected term	0.00	5.33	5.81
Expected volatility	—%	88.60%	85.86%

The weighted average grant date fair value of stock options granted to non-employee consultants during the years ended December 31, 2019 and 2018 was \$1.32 and \$6.78, respectively. As of December 31, 2020, no unrecognized compensation expense related to unvested non-employee consultants 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)
<b>Employee awards</b>				
Outstanding at December 31, 2019	6,323,596	\$ 4.91	8.71	\$ 1,716
Granted	3,087,709	\$ 2.49		
Exercised	(76,128)	\$ 2.57		
Forfeited	(2,033,001)	\$ 4.67		
Outstanding at December 31, 2020	<u>7,302,176</u>	\$ 3.98	8.43	\$ 4,456
Vested at December 31, 2020	2,684,785	\$ 5.72	7.60	\$ 1,544
Vested and expected to vest at December 31, 2020	6,830,530	\$ 4.08	8.37	\$ 4,148
<b>Non-employee awards</b>				
Outstanding at December 31, 2019	473,073	\$ 5.89	6.23	\$ 38
Granted	—	\$ —		
Exercised	—	\$ —		
Forfeited	—	\$ —		
Outstanding at December 31, 2020	<u>473,073</u>	\$ 5.89	5.23	\$ 86
Vested at December 31, 2020	445,855	\$ 5.70	5.08	\$ 86
Vested and expected to vest at December 31, 2020	473,073	\$ 5.89	5.23	\$ 86

### 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 \$0.5 million as of December 31, 2020, which is expected to be recognized over a weighted average period of 1.9 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	93,750	4.07
Forfeited	—	—
Unvested at December 31, 2020	87,500	\$ 6.03

### 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 1<sup>st</sup> and the other beginning September 1<sup>st</sup> 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 years ended December 31, 2020 and 2019, the number of shares of common stock that may be issued under the ESPP was increased by 863,254 shares and 224,717 shares, respectively. During the year ended December 31, 2020, the Company issued 110,212 shares of common stock under the ESPP. As of December 31, 2020, 1,500,448 shares remain available for future issuance under the ESPP.

For each of the years ended December 31, 2020 and 2019, the Company recognized \$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):

	Year Ended December 31,		
	2020	2019	2018
Research and development	\$ 2,271	\$ 2,079	\$ 2,453
General and administrative	3,151	3,082	3,261
Total stock-based compensation expense	\$ 5,422	\$ 5,161	\$ 5,714

## 12. Revenue Arrangements

### Swedish Orphan Biovitrum

#### *License and Development Agreement*

On June 11, 2020, the Company and Sobi, entered into 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. The SEL-212 drug candidate is a pharmaceutical composition containing a combination of SEL-037 (the “Compound”) and ImmTOR. 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, if commercialized, 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 the Compound and ImmTOR as necessary for completion of the two Phase 3 clinical trials of SEL-212 (DISSOLVE I and DISSOLVE II) and a 6-month placebo extension. The Company is required to supply quantities of the Compound until all rights to the Compound and any materials needed to manufacture the Compound are transferred to Sobi. 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 DISSOLVE trials, 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 investigational drug applications (IND), biologics license applications (BLA), and marketing authorization applications (MAA) relating to the licensed product.

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 all rights granted under the Sobi License would revert back to the Company. In addition, if Sobi were to terminate the Sobi License, the Company has the option to obtain a license to all patents and know-how necessary to exploit SEL-212 in existence as of the termination date from Sobi in return for making an equitable royalty payment to Sobi.

Additionally, on June 11, 2020, the Company entered into the Sobi Purchase Agreement in connection with the Sobi License. The closing of the Sobi Private Placement occurred on July 31, 2020, following the closing of the transactions contemplated under the Sobi License. See Note 10 for details.

The Company determined that the Sobi License represents a service arrangement under the scope of ASC 606. In addition, given the Sobi License and Sobi Purchase Agreement were executed contemporaneously and negotiated as a package with a single commercial objective, the Company will account for the two agreements as a single contract. The term of the Sobi License commenced upon the effective date of July 28, 2020 and will continue on a product-by-product basis until the royalty terms for each country have expired. The royalty term for a given product begins upon the first commercial sale of the product in a country and ends at the later of ten years from the first commercial sale, expiration of the last valid patent claim covering the product and expiration of all regulatory exclusivity periods for the product in a country. Given the reversion of the rights under the Sobi License represents a penalty in substance for a termination by Sobi, the contract term would remain the stated term of the Sobi License.

The Company determined that the Sobi License contains three distinct performance obligations due to the nature of the promises in the contract, which includes conducting the Phase 3 DISSOLVE trials, Sobi's option to set-up a second source supplier, and a combined obligation comprised of the delivery of the license to SEL-212, transfer of the know-how and the manufacturing and delivery of SEL-212 supply for development (the "Combined License Obligation"). As the set-up of a second source supplier is optional for Sobi and the Company will be reimbursed at cost for its efforts in the subsequent set-up and technology transfer, the option for this future service was determined to be at a significant and incremental discount to its standalone selling price and treated as a material right in the arrangement, namely a distinct performance obligation.

In determining the transaction price, the Company concluded the upfront payment of \$75 million and the \$5 million development milestone associated with the dosing of the first patient in the Phase 3 DISSOLVE trials will be included in the transaction price. All other development 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 the evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company and probability of success criteria is estimated. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved. In accordance with ASC 606, the Company will only recognize revenue associated with sales-based milestones and royalties when the subsequent sales thresholds are reached and underlying sales occur, respectively. In connection with the Sobi Purchase Agreement, the Company determined that the gross proceeds of \$25 million from the Sobi Private Placement included a premium to the fair value of the Company's shares as of July 28, 2020 equal to approximately \$14.5 million. The premium amount will be included in the transaction price for revenue recognition. The Company will estimate and include in the transaction price the total reimbursements to be received from Sobi for both the manufacturing and delivery of the Compound and ImmTOR as well as conducting the Phase 3 DISSOLVE trials. The Company determined that a significant financing component does not exist in its arrangement with Sobi.

The Company allocated the transaction price based on the relative standalone selling prices of the three distinct performance obligations. The Company estimated the standalone selling price of conducting the Phase 3 DISSOLVE trials by forecasting its anticipated costs and applying a margin reflective of the industry. The Company must determine the standalone selling price of the second source supplier option by determining the discount given to Sobi multiplied by the likelihood that Sobi will exercise the option in the future. Similar to the Phase 3 program estimate, the Company estimated the discount of the option by forecasting the set-up costs and applying a margin that is reflective of the industry. As the Company will be providing the set-up and technology transfer services and the future supply at cost, the discount of the option is equal to the margin

amount. The Company considered discussions with Sobi as well as probability of regulatory success of SEL-212 in determining the likelihood of exercise. The Company estimated the standalone selling price of the Combined License Obligation by utilizing a discounted cash flow model.

The Company determined that the delivery of the supply to Sobi best represents the pattern of delivery of the Combined License Obligation as the supply is essential to the utility of the license and know-how. The Company will recognize the revenue allocated to the Combined License Obligation by utilizing the output method. The Company estimated the total supply of the Compound and ImmTOR to be required during the clinical trial period and will recognize revenue as this supply is shipped for use in the clinical trials. The Company will recognize the revenue allocated to the conducting of the Phase 3 DISSOLVE trials obligation by utilizing the input method. The Company estimated the total budgeted costs to be incurred over the Phase 3 DISSOLVE trials and will recognize revenue as these costs are incurred. The Company's costs best represent the pattern of transfer as these will capture all performance of the trials completed to date and can be readily measured. The Company will recognize the revenue allocated to the second source supplier option when the future services and goods are transferred.

As of December 31, 2020, the Company recorded \$68.3 million as a short-term contract liability and \$24.2 million as a long-term contract liability representing deferred revenue associated with this agreement. In addition, the Company has recorded \$1.4 million of contract assets related to incremental costs that would not have been incurred if the Sobi License had not been obtained, of which \$1.0 million is presented in prepaid expenses and other current assets and \$0.4 million is in other assets in the accompanying Consolidated Balance Sheets. Amortization of contract assets was \$0.1 million for the year ended December 31, 2020.

As of December 31, 2020, the Company recorded a total outstanding receivable of \$6.9 million, representing billings for the Phase 3 DISSOLVE program that are subject to reimbursement by Sobi. Revenue of \$16.6 million related to the Sobi License was recognized during the year ended December 31, 2020.

## **Sarepta Therapeutics, Inc.**

### *Research License and Option Agreement*

On June 13, 2020, the Company and 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 December 31, 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. During the year ended December 31, 2020, the Company and Sarepta entered into two amendments relating to an additional feasibility study. Neither of the amendments had a material impact on deferred revenue or revenue recognition.

As of December 31, 2020, the Company recorded \$2.0 million as a short-term contract liability representing deferred revenue associated with this agreement. Revenue of \$0.3 million related to the Sarepta Agreement was recognized during the third quarter and subsequently adjusted during the fourth quarter due to a change in the supply estimate, resulting in de minimis revenue recognition during the year ended December 31, 2020.

### **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 December 31, 2020 and December 31, 2019, all milestones were constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

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

As of December 31, 2020 and December 31, 2019, the Company recorded \$1.7 million as a short-term contract liability and \$5.3 million as a long-term contract liability representing deferred revenue associated with this agreement. 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 year ended December 31, 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 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 Option Obligation, 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 December 31, 2020, all future milestones are constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

The Company determined that the up-front payment of \$12.3 million (\$15.0 million, less fair value of the equity totaling \$2.7 million as discussed above) was included in the transaction price and was allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company allocated \$7.1 million to the Combined License and Supply Obligation and \$5.2 million to the discount on the target options (\$1.3 million for each option) using the relative standalone selling price method to each obligation. The standalone selling price for the Combined License and Supply Obligation was determined using a discounted cash flow model. The standalone selling prices for the target options were determined based on the fair values of the licenses minus the strike prices 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 year ended December 31, 2020 as no deliveries were made during the period.

As of December 31, 2020 and December 31, 2019, there was a contract liability of \$9.2 million representing deferred revenue presented as long-term 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 represented 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’ (deficit) equity.

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 December 31, 2020, the Company received \$2.0 million from Skolkovo.

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

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

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

#### **Transaction Price Allocated to Future Performance Obligations**

Remaining performance obligations represent the transaction price of contracts for which work has not been performed (or has been partially performed). As of December 31, 2020, the aggregate amount of the transaction price allocated to remaining performance obligations was \$110.8 million.

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

The following table presents changes in the Company’s contract liabilities during the year ended December 31, 2020 (in thousands):

	Balance at beginning of period	Additions	Deductions	Balance at end of period
<b>Twelve Months Ended December 31, 2020</b>				
<b>Contract liabilities:</b>				
Deferred revenue	\$ 16,354	\$ 104,158	\$ (9,716)	\$ 110,796
<b>Total contract liabilities</b>	<b>\$ 16,354</b>	<b>\$ 104,158</b>	<b>\$ (9,716)</b>	<b>\$ 110,796</b>

**13. Related-Party Transactions**

*Consulting Services*

The Company incurred expenses for consulting services provided by its founders totaling \$0.1 million, \$0.5 million and \$0.2 million during the years ended December 31, 2020, 2019 and 2018, 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 AskBio's AAV gene therapy, or MMA-101, for the treatment of MMA, 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 SEL-399 program combines an empty AAV capsid (EMC-101), which is an AAV capsid containing no transgene, with ImmTOR and is being conducted in partnership with AskBio. Building on the preclinical data we have generated showing ImmTOR’s effect on mitigating or reducing the formation of neutralizing antibodies to AAV gene therapies, we have commenced a clinical trial of SEL-399 in healthy adult volunteers in Belgium. The goal of the SEL-399 clinical trial is to demonstrate the appropriate dose of ImmTOR in humans to mitigate the formation of antibodies to AAV capsids used in gene therapies.

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 year ended December 31, 2020, the Company recognized \$3.8 million, of collaboration expense under the AskBio Collaboration Agreement in which actual costs incurred by both parties approximate a 50% cost share.

Under certain collaborative arrangements, the Company is entitled to reimbursement of certain R&D expense. Activities under collaborative arrangements for which the Company is entitled to reimbursement are considered to be collaborative activities under the scope of ASC 808. For these units of account, the Company does not analogize to ASC 606 or recognize revenue. Rather, the Company analogizes to the guidance in ASC 730, which requires that reimbursements from counterparties be recognized as an offset to the related costs. In accordance with ASC 730, the Company records reimbursement payments received from 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 December 31, 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 year ended December 31, 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 \$7.0 million in upfront and milestone-based payments under the 3SBio License as of December 31, 2020. The Company is required to make future payments to 3SBio contingent upon the occurrence of events related to the achievement of clinical and regulatory approval milestones of up to an aggregate of \$15.0 million for products containing the Company’s 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.

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For the years ended December 31, 2020, 2019 and 2018, the Company did not record a current or deferred income tax expense or benefit. The following table reconciles the federal statutory income rate to the Company's effective income tax rate:

	Year Ended December 31,		
	2020	2019	2018
Statutory U.S. federal rate	21.0%	21.0%	21.0%
State income taxes - net of federal benefit	5.8%	6.3%	7.0%
Permanent items	(2.9%)	(2.1%)	(0.5%)
Research tax credits/other	1.0%	1.1%	1.6%
Valuation allowance, net	(23.6%)	(26.3%)	(29.1%)
Stock Compensation	(1.3%)	—%	—%
Effective income tax rate	—%	—%	—%

The tax effects of temporary differences that give rise to the Company's net deferred tax assets are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
<b>Deferred Tax Assets</b>		
Net operating loss carryforwards	\$ 63,678	\$ 71,270
Research and development credits	7,632	6,586
Stock-based compensations expense	2,919	2,516
Other expenses	788	812
Deferred revenue	26,699	4,468
Operating lease liability	2,884	102
Patent costs/amortization	5,379	5,111
Gross deferred tax assets	109,979	90,865
<b>Deferred Tax Liabilities</b>		
Depreciation	\$ (11)	\$ (57)
Operating lease right-of-use asset	(2,991)	(82)
Gross deferred tax liabilities	(3,002)	(139)
Net deferred tax assets before valuation allowance	106,977	90,726
Valuation allowance	(106,977)	(90,726)
Net deferred tax assets	\$ —	\$ —

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.

Realization of future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and concluded that it is more likely than not that the Company will not realize the benefit of its deferred tax assets. The valuation allowance increased by \$16.3 million for the year ended December 31, 2020, primarily as a result of an increase in deferred revenue. The valuation allowance increased by \$14.6 million for the year ended December 31, 2019, primarily as a result of an increase in net operating loss. In 2014, the Company's Russian subsidiary was granted a 10 year tax holiday in Russia. The Company's foreign operations continue to benefit from the tax holiday, which is set to expire on December 31, 2023, however the Company is in the process of closing down operations in Russia and does not expect any tax liability.

At December 31, 2020, the Company has federal and state net operating loss carryforwards of \$234.5 million and \$228.5 million, respectively, which will expire at various times beginning 2028. Of the federal net operating losses, \$99.6 million can be carried forward indefinitely. The Company has \$4.9 million and \$3.5 million, respectively, of federal and state research and development tax credit carryforwards, which will expire at various times through 2040.

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, 2020, the Company completed a Section 382 study, noting that an ownership change occurred

during 2017. The Company has determined that all of the \$234.5 million of net operating losses are available in the future, with approximately \$36.5 million of that total limited under Section 382 and therefore available for future use through 2028.

The Company applies ASC 740, *Income Taxes* to uncertain tax positions. As of December 31, 2020 and 2019, 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.

Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as income tax expense in the accompanying statement of operations. As of December 31, 2020, the Company had no accrued interest related to uncertain tax positions.

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.

## **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 \$0.1 million, \$0.1 million and \$0.2 million during each of the years ended December 31, 2020, 2019 and 2018, respectively.

## **17. Commitments and Contingencies**

As of December 31, 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.

As of December 31, 2020 and December 31, 2019, the Company was not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

On August 4, 2020, a putative stockholder of Selecta filed a stockholder derivative action, purportedly on behalf of Selecta 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 authorized a private placement transaction, announced on December 19, 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. On September 25, 2020, the defendants filed a motion to dismiss the lawsuit. On November 6, 2020, the plaintiff filed an amended complaint, and the defendants filed a second motion to dismiss on January 8, 2021. On December 31, 2020, we received a litigation demand letter from two other putative stockholders relating to the same private placement transaction. At this time, the Company has not accrued a liability for this matter, as any liability has been determined to be either not estimable or probable.

## **Other**

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

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

## **18. Subsequent Events**

### *“At-the-Market” Offerings*

Subsequent to December 31, 2020 through March 5, 2021, the Company sold 4,119,613 shares of its common stock pursuant to the 2020 Sales Agreement, at an average price of approximately \$4.59 per share for aggregate net proceeds of \$18.3 million, after deducting commissions and other transaction costs of \$0.6 million which was paid in the three months ended December 31, 2020.