# UNITED STATES <br> SECURITIES AND EXCHANGE COMMISSION <br> WASHINGTON, D.C. 20549 <br> FORM 10-Q <br> 区 QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 <br> For the quarterly period ended March 31, 2022 <br> OR 

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

For the transition period from $\qquad$ to $\qquad$
Commission File Number: 001-37798

## Selecta Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware<br>(State or other jurisdiction of incorporation or organization)<br>65 Grove Street, Watertown, MA<br>(Address of principal executive offices)<br>26-1622110<br>(I.R.S. Employer Identification No.)<br>$$
02472
$$<br>(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 |

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 $\mathbb{\text { No }} \square$

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

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

Large accelerated filer $\square$
Non-accelerated filer $\boxtimes$

Accelerated filer
Smaller reporting company $\boxtimes$
Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes $\square$ No $\boxtimes$
As of April 29, 2022, the registrant had $151,809,416$ shares of common stock, par value $\$ 0.0001$ per share, outstanding.

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## FORWARD-LOOKING STATEMENTS

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

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

- our status as a development-stage company and our expectation to incur losses in the future;
- our future capital needs and our need to raise additional funds;
- our ability to build a pipeline of product candidates and develop and commercialize 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 risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risk and uncertainties.

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

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements (unaudited)

## Selecta Biosciences, Inc. and Subsidiaries

## Consolidated Balance Sheets

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

|  | $\begin{gathered} \text { March 31, } \\ 2022 \end{gathered}$ |  | $\begin{gathered} \text { December 31, } \\ 2021 \end{gathered}$ |  |
| :---: | :---: | :---: | :---: | :---: |
| Assets |  |  |  |  |
| Current assets: |  |  |  |  |
| Cash and cash equivalents | \$ | 113,437 | \$ | 114,057 |
| Marketable securities |  | 3,997 |  | 13,998 |
| Accounts receivable |  | 7,153 |  | 9,914 |
| Prepaid expenses and other current assets |  | 5,420 |  | 6,474 |
| Total current assets |  | 130,007 |  | 144,443 |
| Non-current assets: |  |  |  |  |
| Property and equipment, net |  | 2,689 |  | 2,142 |
| Right-of-use asset, net |  | 9,536 |  | 9,829 |
| Long-term restricted cash |  | 1,379 |  | 1,379 |
| Investments |  | 2,000 |  | 2,000 |
| Other assets |  | 85 |  | 90 |
| Total assets | \$ | 145,696 | \$ | 159,883 |
| Liabilities and stockholders' equity |  |  |  |  |
| Current liabilities: |  |  |  |  |
| Accounts payable | \$ | 264 | \$ | 224 |
| Accrued expenses |  | 8,889 |  | 10,533 |
| Loan payable |  | 696 |  | 5,961 |
| Lease liability |  | 1,087 |  | 1,049 |
| Income taxes payable |  | 320 |  | 601 |
| Deferred revenue |  | 27,990 |  | 53,883 |
| Total current liabilities |  | 39,246 |  | 72,251 |
| Non-current liabilities: |  |  |  |  |
| Loan payable, net of current portion |  | 25,042 |  | 19,673 |
| Lease liability |  | 8,316 |  | 8,598 |
| Deferred revenue |  | 10,420 |  | 11,417 |
| Warrant liabilities |  | 6,908 |  | 25,423 |
| Total liabilities |  | 89,932 |  | 137,362 |
| Commitments and contingencies (Note 17) |  |  |  |  |
| Stockholders' equity: |  |  |  |  |
| Preferred stock, $\$ 0.0001$ par value; $10,000,000$ shares authorized; no shares issued and outstanding at March 31, 2022 and December 31, 2021 |  | - |  | - |
| Common stock, $\$ 0.0001$ par value; $200,000,000$ shares authorized; $124,380,844$ and $123,622,965$ shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively |  | 12 |  | 12 |
| Additional paid-in capital |  | 461,888 |  | 457,391 |
| Accumulated deficit |  | $(401,538)$ |  | $(430,316)$ |
| Accumulated other comprehensive loss |  | $(4,598)$ |  | $(4,566)$ |
| Total stockholders' equity |  | 55,764 |  | 22,521 |
| Total liabilities and stockholders' equity | \$ | 145,696 | \$ | 159,883 |

[^0]Selecta Biosciences, Inc. and Subsidiaries

## Consolidated Statements of Operations and Comprehensive Income (Loss)

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

|  | Three Months Ended March 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  | 2021 |  |
| Collaboration and license revenue | \$ | 33,999 | \$ | 11,050 |
| Operating expenses: |  |  |  |  |
| Research and development |  | 17,689 |  | 13,004 |
| General and administrative |  | 5,537 |  | 5,204 |
| Total operating expenses |  | 23,226 |  | 18,208 |
| Operating income (loss) |  | 10,773 |  | $(7,158)$ |
| Investment income |  | 15 |  | 12 |
| Foreign currency transaction, net |  | 28 |  | 7 |
| Interest expense |  | (707) |  | (711) |
| Change in fair value of warrant liabilities |  | 18,515 |  | $(16,747)$ |
| Other income, net |  | 154 |  | - |
| Net income (loss) | \$ | 28,778 | \$ | $(24,597)$ |
|  |  |  |  |  |
| Other comprehensive income (loss): |  |  |  |  |
| Foreign currency translation adjustment |  | (32) |  | (6) |
| Unrealized loss on marketable securities |  | - |  | (1) |
| Total comprehensive income (loss) | \$ | 28,746 | \$ | $(24,604)$ |
|  |  |  |  |  |
| Net income (loss) per share: |  |  |  |  |
| Basic | \$ | 0.23 | \$ | (0.22) |
| Diluted | \$ | 0.08 | \$ | (0.22) |
| Weighted average common shares outstanding: |  |  |  |  |
| Basic |  | 232,799 |  | 110,742,150 |
| Diluted |  | 7,53,485 |  | 110,742,150 |

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

Selecta Biosciences, Inc. and Subsidiaries

## Consolidated Statements of Changes in Stockholders' Equity

(Amounts in thousands, except share data)

|  | Common stock |  |  | Additional paid-in capital |  | Accumulated deficit |  | Accumulated other comprehensive loss |  | Stockholders' <br> Equity |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Shares | Amount |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2021 | 123,622,965 | \$ | 12 | \$ | 457,391 | \$ | $(430,316)$ | \$ | $(4,566)$ | \$ | 22,521 |
| Issuance of common stock under Employee Stock Purchase Plan | 81,057 |  | - |  | 127 |  | - |  | - |  | 127 |
| Issuance of common stock upon exercise of options | 11,262 |  | - |  | 21 |  | - |  | - |  | 21 |
| Issuance of vested restricted stock units | 89,142 |  | - |  | - |  | - |  | - |  | - |
| Issuance of common stock through at-the-market offering, net | 576,418 |  | - |  | 1,675 |  | - |  | - |  | 1,675 |
| Other financing fees | - |  | - |  | (79) |  | - |  | - |  | (79) |
| Stock-based compensation expense | - |  | - |  | 2,753 |  | - |  | - |  | 2,753 |
| Currency translation adjustment | - |  | - |  | - |  | - |  | (32) |  | (32) |
| Net loss | - |  | - |  | - |  | 28,778 |  | - |  | 28,778 |
| Balance at March 31, 2022 | 124,380,844 | \$ | 12 | \$ | 461,888 | \$ | $(401,538)$ | \$ | (4,598) | \$ | 55,764 |

The accompanying notes are an integral part of these unaudited 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 <br> deficit |  | Accumulated other comprehensive loss |  | $\begin{gathered} \text { Stockholders' } \\ \text { (Deficit) } \\ \text { Equity } \\ \hline \end{gathered}$ |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Shares | Amount |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2020 | 108,071,249 | \$ | 11 | \$ | 391,175 | \$ | $(404,629)$ | \$ | $(4,563)$ |  | $(18,006)$ |
| Issuance of common stock under Employee Stock Purchase Plan | 34,696 |  | - |  | 72 |  | - |  | - |  | 72 |
| Issuance of common stock upon exercise of options | 153,278 |  | - |  | 244 |  | - |  | - |  | 244 |
| Issuance of vested restricted stock units | 10,937 |  | - |  | - |  | - |  | - |  | - |
| Issuance of common stock through at-the-market offering, net | 4,706,844 |  | - |  | 20,943 |  | - |  | - |  | 20,943 |
| Stock-based compensation expense | - |  | - |  | 1,780 |  | - |  | - |  | 1,780 |
| Currency translation adjustment | - |  | - |  | - |  | - |  | (6) |  | (6) |
| Unrealized (losses) on marketable securities | - |  | - |  | - |  | - |  | (1) |  | (1) |
| Net loss | - |  | - |  | - |  | $(24,597)$ |  | - |  | $(24,597)$ |
| Balance at March 31, 2021 | 112,977,004 | \$ | 11 | \$ | 414,214 | \$ | $(429,226)$ | \$ | $(4,570)$ | \$ | $(19,571)$ |

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

## Selecta Biosciences, Inc. and Subsidiaries

## Consolidated Statements of Cash Flows

 (Amounts in thousands)|  | Three Months Ended March 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  | 2021 |  |
| Cash flows from operating activities |  |  |  |  |
| Net income (loss) | \$ | 28,778 | \$ | $(24,597)$ |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |  |  |  |
| Depreciation and amortization |  | 351 |  | 207 |
| Amortization of premiums and discounts on marketable securities |  | 1 |  | 14 |
| Non-cash lease expense |  | 293 |  | 272 |
| (Gain) on disposal of property and equipment |  | (147) |  | - |
| Stock-based compensation expense |  | 2,753 |  | 1,780 |
| Non-cash interest expense |  | 383 |  | 387 |
| Warrant liabilities revaluation |  | $(18,515)$ |  | 16,747 |
| Changes in operating assets and liabilities: |  |  |  |  |
| Accounts receivable |  | 2,761 |  | $(1,118)$ |
| Prepaid expenses, deposits and other assets |  | 853 |  | $(1,512)$ |
| Accounts payable |  | 18 |  | 151 |
| Income taxes payable |  | (281) |  | - |
| Deferred revenue |  | $(26,890)$ |  | $(2,728)$ |
| Accrued expenses and other liabilities |  | $(2,222)$ |  | $(1,736)$ |
| Net cash (used in) operating activities |  | $(11,864)$ |  | $(12,133)$ |
| Cash flows from investing activities |  |  |  |  |
| Proceeds from maturities of marketable securities |  | 10,000 |  | - |
| Purchases of marketable securities |  | - |  | $(22,420)$ |
| Purchases of property and equipment |  | (455) |  | (25) |
| Net cash provided by (used in) investing activities |  | 9,545 |  | $(22,445)$ |
| Cash flows from financing activities |  |  |  |  |
| Debt amendment fee included in Debt Discount |  | (110) |  | - |
| Net proceeds from issuance of common stock- at-the-market offering |  | 1,690 |  | 20,991 |
| Proceeds from exercise of stock options |  | 21 |  | 244 |
| Proceeds from issuance of common stock under Employee Stock Purchase Plan |  | 127 |  | 72 |
| Net cash provided by financing activities |  | 1,728 |  | 21,307 |
| Effect of exchange rate changes on cash |  | (29) |  | (7) |
| Net change in cash, cash equivalents, and restricted cash |  | (620) |  | $(13,278)$ |
| Cash, cash equivalents, and restricted cash at beginning of period |  | 115,436 |  | 140,064 |
| Cash, cash equivalents, and restricted cash at end of period | \$ | 114,816 | \$ | 126,786 |
| Supplemental cash flow information |  |  |  |  |
| Cash paid for interest | \$ | 494 | \$ | 494 |
| Noncash investing and financing activities |  |  |  |  |
| Purchase of property and equipment not yet paid | \$ | 91 | \$ | 10 |
| Equity offering costs in accrued liabilities | \$ | 94 | \$ | 48 |

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

## Selecta Biosciences, Inc. and Subsidiaries

## Notes to Consolidated Financial Statements

## 1. Description of the Business

Selecta Biosciences, Inc., or the Company, was incorporated in Delaware on December 10, 2007, and is based in Watertown, Massachusetts. The Company is a clinical-stage biopharmaceutical company. The Company's ImmTOR ${ }^{\circledR}$ platform encapsulates rapamycin, also known as sirolimus, an FDA approved immunomodulator, in biodegradable nanoparticles. ImmTOR is designed to induce antigen-specific immune tolerance. The Company believes, by combining ImmTOR with antigens of interest, the Company's precision immune tolerance platform has the potential to restore self-tolerance to autoantigens in autoimmune diseases, amplify the efficacy of biologics (including gene therapies) and mitigate the formation of anti-drug antibodies, or ADAs, against biologic drugs.

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

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

## Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements for the three months ended March 31, 2022 and 2021 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 10, 2022. The unaudited interim financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments that are necessary for a fair statement of the Company's financial position as of March 31, 2022, the consolidated results of operations for the three months ended March 31, 2022, and cash flows for the three months ended March 31, 2022. Such adjustments are of a normal and recurring nature. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

## 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 and sustain 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, research collaborations and licenses. The Company currently has no source of product revenue, and it does not expect to generate product revenue for the foreseeable future. To date, the Company's revenue has primarily been from collaboration and license agreements. 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 clinical trials. The Company is in the early stages of development of its product candidates, and it has not completed development of any ImmTOR-enabled therapies.

As of March 31, 2022, the Company's cash, cash equivalents, restricted cash and marketable securities were $\$ 118.8$ 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, restricted cash and marketable securities as of March 31, 2022 will enable it to fund its current planned operations for at least the next twelve months from the date of issuance of these financial statements, though it may realize additional cash resources upon the achievement of certain contingent collaboration milestones or it may pursue additional cash resources through public or private equity or debt financings or by establishing collaborations with other companies. Management's expectations with respect to its ability to fund current and long term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any collaboration milestones will be achieved or that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If the Company is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand its operations or otherwise capitalize on its commercialization of its product candidates. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research and development of its product candidates and its administrative organization.

At this time, any impact of COVID-19 on the Company's business, revenues, results of operations and financial condition will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the emergence of new virus variants, travel restrictions and social distancing in the United States and other countries, business closures or disruptions, supply chain 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 March 31, 2022, 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

The Company disclosed its significant accounting policies in Note 2 - Summary of Significant Accounting Policies included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes during the three months ended March 31, 2022, with the exception of the matters discussed in recent accounting pronouncements.

## Recent Accounting Pronouncements

## Recently Adopted

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt - Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. ASU 2021-04 provides guidance as to how entities should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains equity-classified after modification or exchange as an exchange of the original instrument for a new instrument. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. This new standard was effective for all entities for fiscal years beginning after December 15, 2021. The adoption of ASU 2021-04 did not have an impact on the Company's financial position or results of operations upon adoption.

## Not Yet Adopted

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 new standard will be effective for smaller reporting companies for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. 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 will be effective for smaller reporting companies for fiscal years beginning after December 15,2022 , with early adoption permitted. The adoption of ASU 2016-13 is not expected to have an impact on the Company's financial position or results of operations upon adoption.

## 3. Marketable Securities and Investments

The following table summarizes the marketable securities held as of March 31, 2022 and December 31, 2021 (in thousands):

|  | Amortizedcost |  | Unrealized gains |  | Unrealized losses |  | Fair value |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| March 31, 2022 |  |  |  |  |  |  |  |  |
| Commercial paper |  | 3,997 |  | - |  | - |  | 3,997 |
| Total | \$ | 3,997 | \$ | - | \$ | - | \$ | 3,997 |
|  |  |  |  |  |  |  |  |  |
| December 31, 2021 |  |  |  |  |  |  |  |  |
| Corporate bonds | \$ | 2,007 | \$ | - | \$ | (1) | \$ | 2,006 |
| Commercial paper |  | 11,992 |  | - |  | - |  | 11,992 |
| Total | \$ | 13,999 | \$ | - | \$ | (1) | \$ | 13,998 |

All marketable securities held at March 31, 2022 and December 31, 2021 had maturities of less than 12 months when purchased and are classified as short-term marketable securities on the accompanying consolidated balance sheet. During the three months ended March 31, 2022, there were no marketable securities adjusted for other than temporary declines in fair value. The Company does not intend to sell its investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

## Investments

As of March 31, 2022 and December 31, 2021, the Company has a $\$ 2.0$ million investment in Cyrus Biotechnology, Inc., or Cyrus, pursuant to an investment agreement entered into in connection with the Collaboration and License Agreement with Cyrus. The Company's maximum exposure to loss related to this variable interest entity is limited to the carrying value of the investment.

## 4. Net Income (Loss) Per Share

The Company has reported a net income for the three months ended March 31, 2022 and a net loss for the three months ended March 31, 2021. The following table sets forth the computation of basic and diluted net income (loss) per share (in thousands, except share and per-share data):

|  | Three Months Ended March 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  | 2021 |  |
| Numerator: |  |  |  |  |
| Net income (loss) | \$ | 28,778 | \$ | $(24,597)$ |
| Less: Change in fair value of 2019 Warrants |  | $(18,515)$ |  | - |
| Adjusted net income (loss) | \$ | 10,263 | \$ | $(24,597)$ |
| Denominator: |  |  |  |  |
| Weighted-average common shares outstanding - basic |  | 124,232,799 |  | 110,742,150 |
| Dilutive effect of employee equity incentive plans and outstanding 2019 warrants |  | 3,340,686 |  | - |
| Weighted-average common shares used in per share calculations - diluted |  | 127,573,485 |  | 110,742,150 |
| Net income (loss) per share: |  |  |  |  |
| Basic | \$ | 0.23 | \$ | (0.22) |
| Diluted | \$ | 0.08 | \$ | (0.22) |

The following table represents the potential dilutive shares of common stock excluded from the computation of the diluted net loss per share for all periods presented, as the effect would have been anti-dilutive:

|  | Three Months Ended March 31, |  |
| :---: | :---: | :---: |
|  | 2022 | 2021 |
| Options, RSUs and ESPP shares | 15,292,967 | 10,864,811 |
| Warrants to purchase common stock | 292,469 | 12,378,016 |
| Total | 15,585,436 | 23,242,827 |

## 5. Fair Value Measurements

The following tables present the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2022 and December 31, 2021 (in thousands):


|  | Decemb |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Total |  | Level 1 |  | Level 2 |  | Level 3 |  |
| Assets: |  |  |  |  |  |  |  |  |
| Money market funds (included in cash equivalents) | \$ | 66,563 | \$ | 66,563 | \$ | - | \$ | - |
| Marketable securities: |  |  |  |  |  |  |  |  |
| Corporate bonds |  | 2,006 |  | - |  | 2,006 |  | - |
| Commercial paper |  | 11,992 |  | - |  | 11,992 |  | - |
| Total assets | \$ | 80,561 | \$ | 66,563 | \$ | 13,998 | \$ | - |
|  |  |  |  |  |  |  |  |  |
| Liabilities: |  |  |  |  |  |  |  |  |
| Warrant liabilities | \$ | 25,423 | \$ | - | \$ | - | \$ | 25,423 |
| Total liabilities | \$ | 25,423 | \$ | - | \$ | - | \$ | 25,423 |

There were no transfers within the fair value hierarchy during the three months ended March 31, 2022 or year ended December 31, 2021.

## Cash, Cash Equivalents, and Restricted Cash

As of March 31, 2022 and December 31, 2021, 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.

As of March 31, 2022, the Company had restricted cash balances relating to a secured letter of credit in connection with its lease for the Company's headquarters. The Company's consolidated statements of cash flows include the following as of March 31, 2022 and 2021 (in thousands):

|  | March 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  | 2021 |  |
| Cash and cash equivalents | \$ | 113,437 | \$ | 125,407 |
| Long-term restricted cash |  | 1,379 |  | 1,379 |
| Total cash, cash equivalents, and restricted cash | \$ | 114,816 | \$ | 126,786 |

## Marketable Securities

As of March 31, 2022, marketable securities classified as Level 2 within the valuation hierarchy consist of corporate bonds and commercial paper which are available-for-sale securities in accordance with the Company's investment policy. The Company estimates the fair value of these marketable securities by taking into consideration valuations that include market pricing based on real-time trade data for the same or similar securities, and other observable inputs. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to the earliest call date for premiums or to maturity for discounts.

## Loans Payable

At March 31, 2022, in light of the issuance of the first tranche under the Company's term loan pursuant the Loan and Security Agreement, dated August 31, 2020, as amended, among the Company, Oxford Finance LLC, or Oxford, as Collateral Agent and a Lender, and Silicon Valley Bank, or SVB, as a Lender, or the Loan and Security Agreement, the Company believes the carrying value approximates the fair value of the loan.

## Warrants

In December 2019, the Company issued warrants in connection with a private placement of shares of common stock, or the 2019 Warrants. Pursuant to the terms of the 2019 Warrants, the Company could be required to settle the 2019 Warrants in cash in the event of certain acquisitions of the Company and, as a result, the 2019 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 2019 Warrants upon issuance using the Black-Scholes valuation model and is required to revalue the 2019 Warrants at each reporting date with any changes in fair value recorded in the statement of operations and comprehensive income (loss). The valuation of the 2019 Warrants is considered 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 including the volatility rate and the estimated term of the 2019 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 changes in the fair values of the Level 3 warrant liability are reflected in the statement of operations and comprehensive income (loss) for the three months ended March 31, 2022 and 2021.

The estimated fair value of 2019 Warrants is determined using the following inputs to 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 2019 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 2019 Warrants.

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

|  | $\begin{gathered} \text { March 31, } \\ 2022 \end{gathered}$ | $\begin{gathered} \text { December 31, } \\ 2021 \end{gathered}$ |
| :---: | :---: | :---: |
| Risk-free interest rate | 2.45 \% | 0.97 \% |
| Dividend yield | - | - |
| Expected life (in years) | 2.73 | 2.98 |
| Expected volatility | 93.60 \% | 96.10 \% |

## 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 three months ended March 31, 2022 (in thousands):

|  | Warrant liabilities |  |
| :---: | :---: | :---: |
| Fair value as of December 31, 2021 | \$ | 25,423 |
| Change in fair value |  | $(18,515)$ |
| Fair value as of March 31, 2022 | \$ | 6,908 |

## 6. Property and Equipment

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

|  | $\begin{gathered} \text { March 31, } \\ 2022 \end{gathered}$ |  | $\begin{gathered} \text { December 31, } \\ 2021 \end{gathered}$ |  |
| :---: | :---: | :---: | :---: | :---: |
| Laboratory equipment | \$ | 5,771 | \$ | 5,134 |
| Computer equipment and software |  | 683 |  | 731 |
| Leasehold improvements |  | 48 |  | 45 |
| Furniture and fixtures |  | 331 |  | 332 |
| Office equipment |  | 163 |  | 163 |
| Construction in process |  | 354 |  | 534 |
| Total property and equipment |  | 7,350 |  | 6,939 |
| Less accumulated depreciation |  | $(4,661)$ |  | $(4,797)$ |
| Property and equipment, net | \$ | 2,689 | \$ | 2,142 |

Depreciation expense was $\$ 0.1$ million for each of the three months ended March 31, 2022 and 2021, respectively.

## 7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

|  | $\begin{gathered} \text { March 31, } \\ 2022 \end{gathered}$ |  | $\begin{gathered} \text { December 31, } \\ 2021 \end{gathered}$ |  |
| :---: | :---: | :---: | :---: | :---: |
| Payroll and employee related expenses | \$ | 1,116 | \$ | 3,179 |
| Accrued patent fees |  | 711 |  | 309 |
| Accrued external research and development costs |  | 4,973 |  | 4,339 |
| Accrued professional and consulting services |  | 1,560 |  | 815 |
| Accrued interest |  | 179 |  | 170 |
| Other |  | 350 |  | 1,721 |
| Accrued expenses | \$ | 8,889 | \$ | 10,533 |

Other accrued expenses as of March 31, 2022 and December 31, 2021 include a $\$ 0.9$ million estimated liability for the settlement of litigation relating to the two lawsuits described further within Note 17.

## 8. Leases

For the three months ended March 31, 2022 and 2021 the components of lease costs were as follows (in thousands):

|  | Three Months Ended March 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  | 2021 |  |
| Operating lease cost | \$ | 506 | \$ | 444 |
| Variable lease cost |  | 220 |  | 288 |
| Short-term lease cost |  | 3 |  | 3 |
| Total lease cost | \$ | 729 | \$ | 735 |

The maturity of the Company's operating lease liabilities as of March 31, 2022 were as follows (in thousands):

|  | March 31, <br>  <br> 2022 (remainder) <br> 2023 |
| :--- | ---: |
| 2024 | 1,409 |
| 2025 | 1,922 |
| 2026 | 1,980 |
| Thereafter | 2,039 |
| $\quad 2,101$ |  |
| Total future minimum lease payments | 2,844 |
| Less imputed interest | 12,295 |
| Total operating lease liabilities | 2,892 |

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

| March 31, |  |
| :--- | :--- |
| Cash paid for amounts included in the measurement of lease liabilities: | $\mathbf{2 0 2 2}$ |

Other than the initial recording of the right-of-use asset and lease liability for the Headquarters Lease in 2020, which was non-cash, the changes in the Company's right-of-use asset and lease liability for the three months ended March 31, 2022 and 2021 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:

|  | March 31, |
| :--- | :---: |
| Weighted-average remaining lease term | $\mathbf{2 0 2 2}$ |
| Weighted-average discount rate | 6.1 years |

## 9. Debt

## 2020 Term Loan

On March 21, 2022, the Company entered into a Second Amendment to its 2020 Term Loan. The Second Amendment extends the date on which amortization payments in respect of the 2020 Term Loan will commence by twelve months to April 1, 2023. Thereafter, amortization payments will be paid monthly in equal installments of principal and interest to fully amortize the outstanding principal over the remaining term of the 2020 Term Loan, subject to recalculation upon a change in the prime rate. The Second Amendment was determined to be a loan modification, and the $\$ 0.1$ million fee is recorded as an addition to the debt discount on the effective date.

As of March 31, 2022 and December 31, 2021, the outstanding principal balance under the 2020 Term Loan was $\$ 25.0$ million.
Total 2020 Term Loan and unamortized debt discount balances as of March 31, 2022 are as follows (in thousands):

| Face value | 25,000 <br> Venture debt termination fee <br> Less: Debt discount <br> $(1,512)$ <br> Less: Current portion of loan payable <br> Loan payable, net of current portion$(696)$ |
| :--- | ---: | ---: |
| 25,042 |  |

Future minimum principal payments on the 2020 Term Loan as of March 31, 2022 are as follows (in thousands):

| Year ended: |  |  |
| :---: | :---: | :---: |
| 2023 |  | 7,759 |
| 2024 |  | 10,345 |
| 2025 |  | 6,896 |
| Total minimum principal payments | \$ | 25,000 |

## 10. Equity

## Equity Financings

## "At-the-Market" Offerings

On October 25, 2021, the Company entered into a Sales Agreement, or the 2021 Sales Agreement, with SVB Leerink LLC (now known as SVB Securities LLC), or SVB Leerink, pursuant to which the Company may sell shares of the Company's common stock, from time to time, through an "at the market" equity offering program under which SVB Leerink will act as sales agent. The shares of common stock sold pursuant to the 2021 Sales Agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-241692), aggregate gross sales proceeds of up to $\$ 75.0$ million.

During the three months ended March 31, 2022, the Company sold 576,418 shares of its common stock pursuant to the 2021 Sales Agreement for aggregate net proceeds of $\$ 1.7$ million, after deducting commissions and other transaction costs.

## Warrants

During the three months ended March 31, 2022, there were no warrants issued, exercised, or canceled. Refer to Note 10 to the consolidated financial statements within our 2021 Annual Report on Form 10-K for further discussion of the terms related to the Company's warrants.

|  | Number of Warrants |  |  | Weighted average exercise price |  |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\begin{gathered} \text { Equity } \\ \text { classified } \end{gathered}$ | Liability classified | Total |  |  |
| Outstanding at March 31, 2022 | 292,469 | 10,443,511 | 10,735,980 | \$ | 1.62 |

## Reserved Shares

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

|  | As of |  |
| :---: | :---: | :---: |
|  | March 31, 2022 | December 31, 2021 |
| Exercise of warrants | 10,735,980 | 10,735,980 |
| Shares available for future stock incentive awards | 7,006,788 | 6,039,564 |
| Unvested restricted stock units | 1,118,508 | 394,450 |
| Outstanding common stock options | 15,349,539 | 11,039,873 |
| Total | 34,210,815 | 28,209,867 |

## 11. Stock Incentive Plans

The Company maintains the 2008 Stock Incentive Plan, or 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.

In June 2016, the Company's stockholders approved the 2016 Incentive Award Plan, or the 2016 Plan, which authorized 1,210,256 shares of common stock for future issuance under the 2016 Plan and the Company ceased granting awards under the 2008 Plan. Upon the effective date of the 2016 Plan, awards issued under the 2008 Plan remain subject to the terms of the 2008 Plan. Awards granted under the 2008 Plan that expire, lapse or terminate become available under the 2016 Plan as shares available for future grants.

Additionally, 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. In January 2022 and 2021, the number of shares of common stock that may be issued under the 2016 Plan was increased by $4,944,919$ and 4,322,850 shares, respectively. As of March 31, 2022, 1,737,589 shares remain available for future issuance under the 2016 Plan.

In September 2018, the Company's 2018 Employment Inducement Incentive Award Plan, or the 2018 Inducement Incentive Award Plan was adopted by the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules, which authorized 1,175,000 shares of its common stock for issuance. In March 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 March 31, 2022, there are 1,591,661 shares available for future grant under the 2018 Inducement Incentive Award Plan.

## Stock-based Compensation Expense

Stock-based compensation expense by classification included within the consolidated statements of operations and comprehensive income (loss) was as follows (in thousands):

|  | Three Months Ended March 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  | 2021 |  |
| Research and development | \$ | 1,018 | \$ | 754 |
| General and administrative |  | 1,735 |  | 1,026 |
| Total stock-based compensation expense | \$ | 2,753 | \$ | 1,780 |

## Stock Options

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

|  | Three Months Ended March 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  |  | 2021 |
| Risk-free interest rate |  | 1.48 \% |  | 0.44 \% |
| Dividend yield |  | - |  | - |
| Expected term |  | 6.03 |  | 5.28 |
| Expected volatility |  | 91.84 \% |  | 83.26 \% |
| Weighted-average fair value of common stock | \$ | 3.26 | \$ | 3.13 |

The weighted average grant date fair value of stock options granted to employees during the three months ended March 31, 2022 and 2021 was $\$ 2.45$ and $\$ 1.99$, respectively.

As of March 31, 2022, total unrecognized compensation expense related to unvested employee stock options was $\$ 18.5$ million, which is expected to be recognized over a weighted average period of 3.0 years.

The following table summarizes the stock option 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) |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Employees |  |  |  |  |  |  |
| Outstanding at December 31, 2021 | 10,616,800 | \$ | 3.99 | 8.19 | \$ | 4,982 |
| Granted | 4,476,500 | \$ | 3.26 |  |  |  |
| Exercised | $(10,000)$ | \$ | 2.10 |  |  |  |
| Outstanding at March 31, 2022 | 15,083,300 | \$ | 3.78 | 8.49 | \$ | - |
| Vested at March 31, 2022 | 5,602,046 | \$ | 4.46 | 7.30 | \$ | - |
| Vested and expected to vest at March 31, 2022 | 13,738,523 | \$ | 3.82 | 8.40 | \$ | - |
|  |  |  |  |  |  |  |
| Non-employee consultants |  |  |  |  |  |  |
| Outstanding at December 31, 2021 | 423,073 | \$ | 6.34 | 3.85 | \$ | 42 |
| Forfeited | $(156,834)$ | \$ | 3.44 |  |  |  |
| Outstanding at March 31, 2022 | 266,239 | \$ | 8.05 | 5.83 | \$ | - |
| Vested at March 31, 2022 | 266,239 | \$ | 8.05 | 5.83 | \$ | - |
| Vested and expected to vest at March 31, 2022 | 266,239 | \$ | 8.05 | 5.83 | \$ | - |

## Restricted Stock Units

During the three months ended March 31, 2022, the Company granted 813,200 restricted stock awards with a weighted average fair value of $\$ 3.31$ per share based on the closing price of the Company's common stock on the date of grant to employees under the 2016 Plan, which will vest over a four-year term. 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 $10 \%$ for restricted stock awards to employees based on historical attrition trends.

Unrecognized compensation expense for all restricted stock units was $\$ 2.8$ million as of March 31, 2022, which is expected to be recognized over a weighted average period of 3.4 years.

The following table summarizes the Company's restricted stock units under the 2016 Plan and 2018 Inducement Incentive Award Plan:

|  | Number of shares | Weighted average grant date fair value (\$) |  |
| :---: | :---: | :---: | :---: |
| Unvested at December 31, 2021 | 394,450 | \$ | 3.45 |
| Granted | 813,200 |  | 3.31 |
| Vested | $(89,142)$ |  | 3.36 |
| Unvested at March 31, 2022 | 1,118,508 | \$ | 3.36 |

## Employee Stock Purchase Plan

In June 2016, the Company approved the 2016 Employee Stock Purchase Plan, or the ESPP, which authorized 173,076 shares of common stock for future issuance under the ESPP to participating employees. In January 2022 and 2021, the number of shares of common stock authorized for issuance under the ESPP was increased by $1,236,229$ shares and $1,080,711$ shares, respectively. During the three months ended March 31, 2022, the Company issued 81,057 shares of common stock under the ESPP. As of March 31, 2022, 3,677,538 shares remain available for future issuance under the ESPP.

For each of the three months ended March 31, 2022 and 2021, the Company recognized less than $\$ 0.1$ million of stock-based compensation expense under the ESPP, respectively.

## 12. Revenue Arrangements

## Takeda Pharmaceuticals USA, Inc.

## License and Development Agreement

In October 2021, the Company entered into a License Agreement, or the Takeda Agreement, with Takeda Pharmaceuticals USA, Inc., or Takeda. Under the Takeda Agreement, the Company granted Takeda an exclusive license to the Company's ImmTOR technology initially for two specified disease indications within the field of lysosomal storage disorders. Takeda paid a $\$ 3.0$ million upfront payment to the Company upon signing of the Takeda Agreement, and the Company is entitled to receive up to $\$ 1.124$ billion in future additional payments over the course of the partnership that are contingent on the achievement of development or commercial milestones or Takeda's election to continue its activities at specified development stages. The Company is also eligible for tiered royalties on future commercial sales of any licensed products.

The Company determined the Takeda Agreement represents a service arrangement under the scope of ASC 606, and given the reversion of the rights under the Takeda Agreement represents a penalty in substance for a termination by Takeda, the contract term would remain the stated term of the Takeda Agreement. The Company determined that the research license, the licensed know-how, and the manufactured supply and delivery of materials represent a single promise and performance obligation to be transferred to Takeda 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. The material to be supplied by the Company to Takeda is unique to the Company and cannot be obtained by other vendors. As such, consideration in the initial transaction price will be allocated to the single performance obligation and the recognition period would not extend beyond the initial contractual period. The Company will recognize the revenue associated with the upfront payment and combined single performance obligation utilizing the output method over the term that manufactured supply is delivered to Takeda.

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 were 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 and timing of such study 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, or as other changes in circumstances occur. Takeda has the right to exercise covenant release rights on a field-by-field basis. If Takeda exercises its covenant release rights, we could receive exercise payments per indication and would be entitled to significant development and commercial milestone payments and tiered royalties on commercial sales. The Company determined that a significant financing component does not exist in its arrangement with Takeda. The Company also determined the options to negotiate additional fields, pursue other products, enter into a supply agreement explore additional fields, and pursue additional development under the initial fields do not represent material rights under the agreement. Takeda has the right to terminate the Takeda Agreement in its entirety or on a field-by-field basis, upon 90 days' written notice to the Company.

As of March 31, 2022, the Company recorded $\$ 1.0$ million, as a long-term contract liability, representing deferred revenue associated with this agreement. Revenue of $\$ 1.0$ million related to the Takeda Agreement was recognized during the three months ended March 31, 2022. As of December 31, 2021, the Company recorded $\$ 1.0$ million as a short term contract liability and $\$ 1.0$ million, as a long-term contract liability, respectively, representing deferred revenue associated with this agreement.

## Swedish Orphan Biovitrum

## License and Development Agreement

In June 2020, the Company and Sobi entered into the Sobi License. Pursuant to the Sobi License, the Company 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 SEL037, or the Compound, and ImmTOR. Pursuant to the Sobi License, in consideration of the license, Sobi agreed to pay the Company a one-time, upfront payment of $\$ 75.0$ million. Sobi has also agreed to make milestone payments totaling up to $\$ 630.0$ 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, biologics license applications, and marketing authorization applications relating to the licensed product.

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 for the sale of 5,416,390 shares of common stock for aggregate gross proceeds of $\$ 25.0$ million 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.

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, or 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 $\$ 75.0$ million and the $\$ 5.0$ 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 $\$ 25.0$ 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 March 31, 2022 and December 31, 2021, the Company recorded $\$ 21.7$ million and $\$ 37.5$ million, respectively, as a short-term contract liability and $\$ 4.1$ million and $\$ 5.1$ million, respectively, as a long-term contract liability, representing deferred revenue associated with this agreement. In addition, as of March 31, 2022, the Company has recorded an immaterial amount of contract assets related to incremental costs that would not have been incurred if the Sobi License had not been obtained.

As of March 31, 2022 and December 31, 2021, the Company recorded a total outstanding receivable of $\$ 7.1$ million and $\$ 9.9$ million, respectively, representing billings for the Phase 3 DISSOLVE program that are subject to reimbursement by Sobi. Revenue of $\$ 23.8$ million and $\$ 11.1$ million related to the Sobi License was recognized during the three months ended March 31, 2022 and 2021, respectively.

## Sarepta Therapeutics, Inc.

## Research License and Option Agreement

In June 2020, the Company and Sarepta Therapeutics, Inc., or Sarepta, entered into a Research License and Option Agreement, or 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, or the Indications. Sarepta will have an option term of 24 months during which it can opt-in to obtain an exclusive license to further develop and commercialize the Product to treat at least one Indication, with a potential to extend the option term 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 upfront 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.

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. During the year ended December 31, 2021, the Company and Sarepta entered into a third amendment relating to the additional feasibility study.

On April 13, 2021, the Company was notified by Sarepta of the achievement of the milestone event related to the completion of a non-clinical study for Duchenne muscular dystrophy and certain limb-girdle muscular dystrophies under the Sarepta Agreement. Accordingly, the Company received a milestone payment of $\$ 3.0$ million during the three months ended June 30, 2021.

As of March 31, 2022 and December 31, 2021, two milestones remained 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.

At each of March 31, 2022 and December 31, 2021, the Company recorded $\$ 4.6$ million as a short-term contract liability representing deferred revenue associated with this agreement. Revenue of less than $\$ 0.1$ million related to the Sarepta Agreement was recognized during the three months ended March 31, 2022. No revenue related to the Sarepta Agreement was recognized during the three months ended March 31, 2021.

## Asklepios Biopharmaceutical, Inc.

## License Agreement for Pompe Disease

In December 2019, the Company and Asklepios Biopharmaceutical, Inc., or AskBio, entered into a license agreement, or 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 adeno-associated viral, or AAV, gene therapy products utilizing ImmTOR, and targeting the lysosomal alpha-glucosidase, or 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, or the 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.

In determining the transaction price, the Company concluded that the future development milestones, regulatory milestones, sales milestones, and sales royalties all represent variable consideration. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company. Consideration related to sales-based milestones as well as royalties on net sales upon commercialization by AskBio, will be recognized when the related sales occur, as they were determined to relate predominantly to the intellectual property granted to AskBio and, therefore, have also been excluded from the transaction price in accordance with the royalty recognition constraint. As of March 31, 2022 and December 31, 2021, 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 upfront payment upon agreement of terms, and a $\$ 5.0$ million initial upfront execution fee.

At each of March 31, 2022 and December 31, 2021, the Company recorded $\$ 1.7$ million as 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 three months ended March 31, 2022 and 2021 as no deliveries were made during these periods.

## Spark Therapeutics, Inc.

## Spark License Agreement

In December 2016, the Company entered into a License and Option Agreement, or the Spark License Agreement, with Spark Therapeutics, Inc., or 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 Factor VIII, an essential blood clotting protein relevant to the treatment of hemophilia A, the initial target.

On January 18,2022 , both parties agreed to mutually terminate the Spark License Agreement. Therefore, the short-term contract liability of $\$ 9.2$ million as of December 31, 2021 was recognized as revenue during the three months ended March 31, 2022.

## Transaction Price Allocated to Future Performance Obligations

Remaining performance obligations represent the transaction price of contracts for which work has not been performed, or has been partially performed. As of March 31, 2022, the aggregate amount of the transaction price allocated to remaining performance obligations was $\$ 38.4$ million.

## Contract Balances from Contracts with Customers (Takeda, Sobi, Sarepta, and AskBio)

The following table presents changes in the Company's contract liabilities during the three months ended March 31, 2022 (in thousands):

| Three Months Ended March 31, 2022 | Balance at beginning of period |  | Additions |  |  | Deductions |  | Balance at end of period |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  |  |  |
| Contract liabilities: |  |  |  |  |  |  |  |  |  |
| Deferred revenue | \$ | 65,300 | \$ |  | - | \$ | $(26,890)$ | \$ | 38,410 |
| Total contract liabilities | \$ | 65,300 | \$ |  | - | \$ | $(26,890)$ | \$ | 38,410 |

## 13. Related-party Transactions

## Consulting Services

During the three months ended March 31, 2022, there were no related party transactions. The Company incurred expenses for consulting services provided by its founders to serve on its Scientific Advisory Board, totaling less than $\$ 0.1$ million during the three months ended March 31, 2021.

## 14. Collaboration and License Agreements

## Ginkgo Bioworks Holdings, Inc.

## Collaboration and License Agreement

On January 3, 2022, the Company entered into a Collaboration and License Agreement, or the Second Ginkgo Agreement, with Ginkgo Bioworks Holdings, Inc., or Ginkgo. Under this agreement, the Company will engage with Ginkgo to develop AAV capsids designed to enhance transduction efficiency and transgene expression. In return, Ginkgo is eligible to earn both upfront research and development fees and milestone payments, including certain milestone payments in the form of shares of the Company's common stock, clinical and commercial milestone payments of up to $\$ 207$ million in cash. The Second Ginkgo Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company will expense costs related to the Second Ginkgo Agreement as incurred until regulatory approval is received in accordance with ASC 730. The Company is accounting for the contingently issuable shares of common stock to be issued in exchange for the license obtained from Ginkgo as a liability-classified, stock-based compensation arrangement with a non-employee which will be recognized when achievement of the milestones is probable. The Company will assess the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, will amortize these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company is also obligated to pay Ginkgo tiered royalties ranging from low-single digit to high-single digit percentages of annual net sales of collaboration products which will be expensed as the commercial sales occur.

In October 2021, the Company entered into a Collaboration and License Agreement, or the First Ginkgo Agreement, with Ginkgo. Under the First Ginkgo Agreement, Ginkgo will design next generation IgA proteases with potentially transformative therapeutic potential. In return, Ginkgo is eligible to earn both upfront research and development fees and milestone payments,
including certain milestone payments for fixed fair values in the form of shares of the Company's common stock, clinical and commercial milestone payments of up to $\$ 85.0$ million in cash. The First Ginkgo Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company will expense costs related to the First Ginkgo Agreement as incurred until regulatory approval is received in accordance with ASC 730. The Company is accounting for the contingently issuable shares of common stock to be issued in exchange for the license obtained from Ginkgo as a liability-classified, stock-based compensation arrangement with a non-employee which will be recognized when achievement of the milestones is probable. The Company will assess the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, will amortize these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company is also obligated to pay Ginkgo tiered royalties ranging from low-single digit to high-single digit percentages of annual net sales of collaboration products which will be expensed as the commercial sales occur.

## Genovis AB (publ.)

## License Agreement

In October 2021, the Company entered into an Exclusive License Agreement, or the Genovis Agreement, with Genovis AB (publ.), or Genovis. Under the Genovis Agreement, the Company paid to Genovis an upfront payment in exchange for an exclusive license to Genovis' IgG protease, or Xork, enzyme technology across all therapeutic uses in humans, excluding research, preclinical, diagnostic and other potential non-therapeutic applications of the enzyme. Genovis is eligible to earn development and sales-based milestones. The Genovis Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company will expense costs related to the Genovis Agreement as incurred until regulatory approval is received in accordance with ASC 730. The Company will assess the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, will amortize these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company is also obligated to pay Genovis tiered royalties of low double-digit percentages of worldwide annual net sales of collaboration products which will be expensed as the commercial sales occur.

## Cyrus Biotechnology, Inc.

## Collaboration and License Agreement

In September 2021, the Company and Cyrus entered into a collaboration and license agreement, or the Cyrus Agreement. Pursuant to the Cyrus Agreement, Cyrus agreed to grant the Company an exclusive, worldwide license to certain intellectual property to form a protein engineering collaboration combining the Company's ImmTOR platform with Cyrus' ability to redesign protein therapeutics. The lead program is a proprietary interleukin-2, or IL-2, protein agonist designed to selectively promote expansion of regulatory T cells for treatment of patients with autoimmune diseases and other deleterious immune conditions. In return for the licensed intellectual property, the Company made an upfront payment and is obligated to pay certain discovery, development, and sales-based milestones which could potentially total up to approximately $\$ 1.5$ billion across multiple programs. The Cyrus Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company will expense costs related to the Cyrus Agreement as incurred until regulatory approval is received in accordance with ASC 730. The Company will assess the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, will amortize these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company is also obligated to pay Cyrus tiered royalties ranging from mid-single digit to low-double digit percentages of annual net sales of collaboration products which will be expensed as the commercial sales occur.

Additionally, on September 7, 2021, the Company entered into a stock purchase agreement, or the Series B Preferred Stock Purchase Agreement, in connection with the Cyrus Agreement. Pursuant to the Series B Preferred Stock Purchase Agreement, the Company purchased 2,326,934 shares of Cyrus' Series B Preferred Stock, par value $\$ 0.0001$ per share, at a purchase price of $\$ 0.8595$ per share for an aggregate purchase price of $\$ 2.0$ million.

In accordance with ASC 810, the Company has a variable interest in Cyrus resulting from its equity investment. The Company will share in Cyrus' expected losses or receive a portion of its expected returns and absorb the variability associated with changes in the entity's net assets. However, the Company is not the primary beneficiary as it does not have the power to direct the activities most significant to Cyrus, and therefore it is not required to consolidate Cyrus. The Company determined its equity interest to be within the scope of ASC 321 and elected to record the $\$ 2.0$ million investment of Cyrus' Series B Preferred Stock at cost on the purchase date.

As of March 31, 2022, no impairment indicators are present and therefore the carrying value of the investment in Cyrus is $\$ 2.0$ million on the accompanying consolidated balance sheet. The Company's maximum exposure to loss related to this variable interest entity is limited to the carrying value of the investment. The Company has not provided financing to Cyrus other than the amount contractually required by the Series B Preferred Stock Purchase Agreement.

## Asklepios Biopharmaceutical, Inc.

## Feasibility Study and License Agreement

In August 2019, the Company entered into a Feasibility Study and License Agreement with AskBio, or 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 SEL-302 (previously disclosed as MMA-101, in combination with ImmTOR), for the treatment of MMA, to mitigate the formation of neutralizing anti-AAV capsid antibodies, or the POC Studies. On April 29, 2021, the Company was notified by AskBio that it intended to opt-out of development of the MMA indication. The feasibility study and license agreement with AskBio, or AskBio Collaboration Agreement, otherwise remains in effect. Consequently, the Company has assumed all rights to the MMA program and intends to continue to progress the SEL-302 program through clinical development. The Company filed an IND to conduct a Phase $1 / 2$ clinical trial of its SEL-302 product candidate in pediatric patients with methylmalonic acidemia in the third quarter of 2021. On November 23, 2021, this trial was placed on clinical hold by the FDA, with questions specifically relating to chemistry, manufacturing and controls, or CMC, of the AAV vector. On March 9, 2022, the Company received a letter from the FDA indicating the clinical hold was removed and the trial may proceed.

The SEL-399 program combined an empty AAV capsid (EMC-101), which is an AAV capsid containing no transgene, with ImmTOR and was conducted in partnership with AskBio. Building on the preclinical data the Company has generated showing ImmTOR's effect on mitigating or reducing the formation of neutralizing antibodies to AAV gene therapies, the Company completed a clinical trial of SEL-399 in healthy adult volunteers in Belgium. The goal of the SEL-399 clinical trial was to demonstrate the appropriate dose of ImmTOR in humans to mitigate the formation of antibodies to AAV capsids used in gene therapies. The Company believes this promising study in healthy volunteers provides support for the potential use of ImmTOR for the inhibition of neutralizing antibodies to AAV8 in gene therapy clinical trials.

The Company and AskBio will share responsibility for the research and development of products developed under the SEL-399 program 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 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, or 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, or the IP Rights, for the purpose of performing the POC Studies, or the Research License, (3) granting an exclusive, nontransferable, worldwide license to the IP Rights for use in certain indications, or the Collaboration License, (4) providing manufactured supply of preclinical and clinical ImmTOR, or the Manufactured Supply, (5) participation on identified steering committees responsible for the oversight of the collaboration, or 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. 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 research and development expense and selling, general and administrative expense on the Company's condensed consolidated statements of operations.

Under certain collaborative arrangements, the Company is entitled to reimbursement of certain research and development 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 research and development expense.

For the three months ended March 31, 2022 and 2021, the Company recognized $\$ 0.4$ million and $\$ 1.2$ million, respectively, of collaboration expense under the AskBio Collaboration Agreement in which actual costs incurred by both parties approximate a $50 \%$ cost share.

## Massachusetts Institute of Technology

In November 2008, the Company entered into an Exclusive Patent License Agreement, or the MIT License, with the Massachusetts Institute of Technology, or MIT, under which the Company received an exclusive royalty-bearing license to utilize patents held by MIT in exchange for upfront consideration and annual license maintenance fees. Such fees are expensed as incurred and have not been material to any period presented.

In June 2020, the Company entered into a Fifth Amendment, or 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. The extension included the obligation to commence a Phase 3 trial for a licensed product by the second quarter of 2021 or to file an IND (or equivalent) with the FDA or comparable European regulatory agency for a licensed product by the second quarter of 2023. Additionally, certain of the Company's development and regulatory milestones and payments upon achievement of such milestones were adjusted.

As of March 31, 2022, 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, and $\$ 0.4$ million relative to the calculated premium paid by Spark for the equity investments made under the Spark Purchase Agreement. The Company made no additional payments during the three months ended March 31, 2022.

## Shenyang Sunshine Pharmaceutical Co., Ltd

In May 2014, the Company entered into a license agreement, or the 3SBio License, with Shenyang Sunshine Pharmaceutical Co., Ltd., or 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 March 31, 2022. 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.

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.

Effective for tax years beginning on or after January 1, 2022, research and experimental expenditures under IRC Section 174 must be capitalized over five years when performed in the U.S. and 15 years for research and experimental expenditures performed outside of the U.S. As of March 31, 2022, the Company has performed a high-level analysis of the impact of this legislation enactment and determined the projected taxable loss position for 2022 does not result in income tax due. As of December 31, 2021, the Company has $\$ 51.1$ million of federal net operating losses available, subject to an $80 \%$ limitation. The Company also has $\$ 1.2$ million of federal tax credits, subject to a $75 \%$ limitation. The Company maintains its full valuation allowance.

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, 2021, the Company completed both a Section 382 and R\&D tax credit study.

The statute of limitations for assessment by the Internal Revenue Service and Massachusetts tax authorities is open for tax years since inception as the Company claimed research tax credits on its 2020 tax return which remains open for examination for the 2020 year as well as for any year in which a credit has been claimed. 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, or the $401(\mathrm{k})$ Plan, under Section $401(\mathrm{k})$ of the Internal Revenue Code. The $401(\mathrm{k})$ 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 $401(\mathrm{k})$ Plan provides for matching contributions on a portion of participant contributions pursuant to the $401(\mathrm{k})$ Plan's matching formula. As of January 2022, all matching contributions vest ratably over 2 years and participant contributions vest immediately. Contributions by the Company totaled less than $\$ 0.1$ million during each of the three months ended March 31, 2022 and 2021, respectively.

## 17. Commitments and Contingencies

As of March 31, 2022, 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 3, 2020, a 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, the Company received a litigation demand letter from two other putative stockholders relating to the same private placement transaction. On April 12, 2021, the Court of Chancery in the State of Delaware granted a motion to stay the litigation pending a review by a Special Committee appointed by the Company's Board of Directors. While the litigation was stayed, the parties reached an agreement in principle to settle the matter, and on March 18, 2022, they submitted a Stipulation and Agreement of Settlement and other documentation to the Court for its approval of the settlement. As of March 31, 2022, the Company accrued an estimated liability of $\$ 0.9$ million for the litigation, as the liability has been determined to be 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 nonperformance 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

## Underwritten Offering

On April 6, 2022, the Company entered into an underwriting agreement, or the Underwriting Agreement, with SVB Leerink, as representative of the several underwriters named therein, relating to an underwritten offering, or the Offering, of 27,428,572 shares, or the Shares, of the Company's common stock and warrants, or the 2022 Warrants, and together with the Shares, the Securities, to purchase up to 20,571,429 shares of common stock. Each Share and accompanying Warrant to purchase 0.75 shares of common stock was sold at a combined offering price of $\$ 1.41$. The exercise price for the 2022 Warrants is $\$ 1.55$ per share. The Company received gross proceeds from the Offering of approximately $\$ 38.7$ million.

The 2022 Warrants are subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company's common stock and also upon any distributions for no consideration of assets to the Company's stockholders. Each 2022 Warrant is exercisable at any time and from time to time after issuance. In the event of certain corporate transactions, the holders of the 2022 Warrants will be entitled to receive, upon exercise of the 2022 Warrants, the kind and amount of securities, cash or other property that the holders would have received
had they exercised the Warrants immediately prior to such transaction. The 2022 Warrants do not entitle the holders thereof to any voting rights or any of the other rights or privileges to which holders of Common Stock are entitled.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes appearing elsewhere in this Quarterly Report and with our audited financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2021, which we filed with the SEC on March 10, 2022. In addition, you should read the "Risk Factors" and "Information Regarding Forward-Looking Statements" sections of this Quarterly Report and our Annual Report on Form 10-K for the year ended December 31, 2021 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

## Overview

We are a clinical-stage biopharmaceutical company. Our ImmTOR ${ }^{\circledR}$ platform encapsulates rapamycin, also known as sirolimus, an FDA approved immunomodulator, in biodegradable nanoparticles. ImmTOR is designed to induce antigen-specific immune tolerance.

We continually seek to enhance ImmTOR. In recent preclinical studies we have conducted, we have observed that ImmTOR may have synergistic activity with interleukin- 2 , or IL-2, molecules that have been engineered to be selective for regulatory T cells, or Tregs. Treg-selective IL-2 mutant molecules, or IL-2 muteins, have been shown to transiently expand all pre-existing Tregs in preclinical studies conducted by others. We have observed in preclinical studies that the combination of ImmTOR, a Treg-selective IL-2 mutein and an antigen, exhibited substantial synergistic activity in inducing and expanding antigen-specific Tregs beyond ImmTOR alone with evidence of enhanced durability of immune tolerance and the potential for ImmTOR dose sparing. This combination of ImmTOR with a Treg selective IL-2 molecule represents an evolution of the ImmTOR platform, which we call ImmTOR$\mathrm{IL}^{\mathrm{TM}}$. We believe this combination has the potential to be a best-in-class therapy in diseases where expansion of total Tregs may prove beneficial. We believe ImmTOR and ImmTOR-IL have the potential to enhance both the efficacy and safety of biologic therapies (including gene therapies), improve product candidates under development, and enable novel therapeutic modalities in autoimmune disease.

## Our Product Candidates

Our ImmTOR platform has a broad range of potential applications. Our product development strategy is built on the following three distinct pillars.
Biologic therapies. Biologic therapies are a class of biologic drugs frequently used to treat rare diseases. Through our analysis of biologic drugs, including in our preclinical studies, we have observed that enzymes foreign to the human body, such as enzymes derived from microbes or replacement enzymes in the case of patients that are deficient in the specific enzyme, are especially prone to causing undesired immune responses. Our partnered product candidate, SEL-212, which is currently in Phase 3 clinical development, consists of ImmTOR co-administered with pegadricase, a pegylated uricase enzyme of fungal origin. This is an example of an immunogenic enzyme that we are combining with ImmTOR with the intention of improving the enzyme's efficacy and safety. We believe that ImmTOR has the potential to enable and expand the use of enzymes derived from microbial sources, such as bacterial immunoglobulin A, or IgA, protease for the treatment of IgA nephropathy and bacterial IgG protease, or Xork, for the treatment of IgG-mediated autoimmune disease flares.

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. AAV immunogenicity and AAV toxicity represent two major challenges for the gene therapy field; in many cases these two issues are inextricably linked. Immunogenicity of AAV vectors is thought to cause or exacerbate many of the adverse events associated with AAV gene therapy. Induction of acute inflammation and capsidspecific CD8 T cells by AAV gene therapy is thought to contribute to observations of hepatotoxicity, which has been associated with loss of transgene expression. The formation of neutralizing antibodies against AAV after initial treatment with AAV mediated gene therapies effectively prevents the possibility of re-dosing in patients who may benefit from additional doses due to either the failure to achieve therapeutic benefit or loss of transgene expression over time. Additionally, a significant number of patients who would benefit from treatment by gene therapies are ineligible due to pre-existing immunity to the AAV vectors from a natural infection. This preexisting immunity could be addressed through an IgG protease pre-treatment to open a dosing window for AAV gene therapies. We believe that the combination of ImmTOR and Xork could simultaneously address the two key issues facing the AAV gene therapy modality and make them more accessible while also making them safer and more durable.

Tolerogenic Therapies for Autoimmune Disease: Autoimmune diseases are caused by a breakdown in natural tolerance to our own self-antigens. With over 24 million Americans afflicted with autoimmune diseases, there is a large unmet medical
need. As the ImmTOR platform is designed to induce or expand antigen specific T regulatory cells, we believe the ImmTOR platform has the potential to treat autoimmune diseases by restoring self-tolerance to auto-antigens.

In our preclinical studies, we observed that ImmTOR combined with a Treg-selective IL-2 mutant protein, or IL-2 mutein, exhibited substantial synergistic activity in increasing the percentage and durability of total Treg expansion in the spleen. We believe that this combination has the potential to be a best-in-class therapy in diseases where expansion of total Treg may prove beneficial. This antigen specificity differentiates ImmTOR-IL from other IL-2 mutein approaches which do not show an antigen specific T-cell expansion. Thus, we believe that not only is ImmTOR-IL a potentially best in class IL-2 where generalized T cell expansion can be beneficial, but also a "first in class" antigen specific IL-2 therapy.

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

| Program | Phase of Development | Anticipated Next Steps | Commercial Rights |
| :---: | :---: | :---: | :---: |
| Biologic Therapies |  |  |  |
| SEL-212 <br> (Chronic Refractory Gout) | Phase 3 clinical trials <br> (DISSOLVE I / DISSOLVE II) | Top-line data Q1 2023 | Sobi |
| IgA nephropathy | Preclinical | IND enabling studies, 2022 | Selecta |
| Gene Therapies |  |  |  |
| SEL-302 (Methylmalonic acidemia (MMA)) | IND filed / Phase 1 | Study commencement, 2H 2022 | Selecta |
| SEL-313 (Ornithine <br> Transcarbamylase (OTC) Deficiency) | IND-enabling | Currently paused | Selecta |
| SEL-018 (IgG protease (Xork)) | Preclinical | IND enabling studies, 2022 | Selecta |
| Pompe disease | Preclinical | Plans to be announced by our collaborator | AskBio |
| Duchenne muscular dystrophy (DMD) | Preclinical | Plans to be announced by our collaborator | Sarepta |
| Limb-girdle muscular dystrophy (LGMD) | Preclinical | Plans to be announced by our collaborator | Sarepta |
| Two indications for lysosomal storage disorders | Preclinical | Plans to be announced by our collaborator | Takeda |
| Tolerogenic Therapies for Autoimmune Disease |  |  |  |
| Proprietary IL-2 receptor agonist | Preclinical |  | Selecta |
| Primary biliary cholangitis (PBC) | Preclinical |  | Selecta |

## Biologic Therapies - Chronic Refractory Gout

SEL-212 consists of ImmTOR co-administered with pegadricase. Our pegadricase consists of a yeast-derived uricase modified with polyethylene glycol moieties. 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.

## Biologic Therapies - IgA Nephropathy

The second indication in our biologic therapies program is IgA nephropathy, an autoimmune kidney disease that occurs when immune complexes of a subclass of antibodies called immunoglobulin A1, or IgA1, accumulates in the kidneys. Previous studies in animal models conducted at independent laboratories demonstrated that bacterial IgA protease has the potential to remove injurious IgA immune complexes from kidneys and reduce inflammation, fibrosis, and hematuria. We believe these results suggest that $\operatorname{IgA}$ protease can potentially decrease the rate of disease progression and possibly even reverse the disease. The barrier to IgA protease commercialization has been the bacterial origin of the protease, which makes it highly
immunogenic. Based on the learnings of SEL-212, we believe the combination of ImmTOR with an IgA protease will enable repeated dosing to treat IgA Nephropathy.

## Gene Therapies - Methylmalonic Acidemia

Our lead therapeutic gene therapy program, SEL-302, is intended to use ImmTOR to enhance the treatment of methylmalonic acidemia, or MMA, an inherited disorder in which the body is unable to process certain proteins and fats (lipids) properly. This program was previously being conducted under our collaboration with AskBio. In October and November 2020, we 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. In April 2021, we were notified by AskBio that it intended to opt-out of development of the MMA indication. The feasibility study and license agreement with AskBio, or AskBio Collaboration Agreement, otherwise remains in effect. We filed an IND to conduct a Phase $1 / 2$ clinical trial of our SEL-302 product candidate in pediatric patients with methylmalonic acidemia in the third quarter of 2021. On November 23, 2021, this trial was placed on clinical hold by the FDA, with questions specifically relating to CMC of the AAV vector. On February 9, 2022, we submitted a written response to the FDA to answer its questions. On March 9, 2022, we received a letter from the FDA indicating the clinical hold was removed and the trial may proceed. ImmTOR manufacturing, controlled by us, continues to proceed in accordance with our expectations and we have not observed any impact to any of our ImmTOR programs.

## Gene Therapies - OTC Deficiency

Our second 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 development of this program is currently paused.

## Gene Therapies - IgG Protease (Xork)

We have exclusively licensed Xork, an IgG-specific protease from Genovis, an enzyme technology company. We plan to develop Xork, either alone or in combination with our ImmTOR platform, with the goal of enabling the dosing of transformative gene therapies in patients with pre-existing AAV immunity due to natural exposures to AAV viruses. Currently, significant proportions of the potential patient populations for many gene therapy trials are ineligible for treatment by AAV mediated gene therapies due to pre-existing antibodies which limits transduction efficiency of the therapy and could trigger potentially dangerous immune responses. IgG proteases are derived from bacteria. Xork exhibits low cross-reactivity to antibodies in normal human serum and is differentiated from IgG proteases derived from Streptococcus pyogenes, a common human pathogen.

## Tolerogenic Therapies for Autoimmune Disease - ImmTOR \& ImmTOR-IL

We intend to apply our ImmTOR platform to treat autoimmune diseases. In preclinical studies, we have observed ImmTOR's ability to induce antigenspecific $T$ regulatory cells. We believe that $\operatorname{ImmTOR}$, in combination with an autoantigen of interest, could create self-tolerance to auto-antigens and thus be a novel approach to the treatment of autoimmune diseases.

Additionally, in preclinical studies we have observed ImmTOR, in combination with IL-2 muteins, expanding T-regulatory cells beyond IL-2 alone and we intend to pursue a combination of ImmTOR and IL-2 (ImmTOR-IL) in diseases where general T cell expansion has shown a therapeutic benefit. Additionally, we have observed in preclinical studies that the combination of ImmTOR, a Treg-selective IL-2 mutein and an antigen, exhibited substantial synergistic activity in inducing and expanding antigen specific regulatory T cells when ImmTOR and IL-2 is combined with an antigen of interest. We intend to pursue and develop treatments for autoimmune diseases with well-defined antigens using either ImmTOR or ImmTOR-IL.

Cyrus Biotechnology, Inc., a collaboration partner, is engineering a proprietary IL-2 protein to combine with the ImmTOR platform to potentially mitigate unwanted immune responses by reducing the inherent immunogenicity of the protein while also promoting immune tolerance. The IL-2 pathway influences critical aspects of both immune stimulation and immune regulation, through the development and expansion of Treg cells. These Treg cells are a specialized subpopulation of T cells involved in suppressing certain immune responses and maintaining the body's self-tolerance. In preclinical studies investigating the effects of ImmTOR in combination with a Treg-selective IL-2 mutant protein, or IL-2 mutein, we have observed a substantial synergistic activity in increasing the percentage and durability of Treg expansion in the spleen.

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

## In-licenses

## Ginkgo Bioworks Holdings, Inc.

In January 2022, we entered into a Collaboration and License Agreement, or the Second Ginkgo Agreement, with Ginkgo. Under the Second Ginkgo Agreement, we will engage with Ginkgo to design novel AAV capsids with potentially improved transduction, enhanced tissue tropism and reduced immunogenicity. In return, Ginkgo is eligible to earn both upfront research and development fees and milestone payments, including certain milestone payments in the form of our common stock, clinical and commercial milestone payments of up to $\$ 207$ million in cash for each of a specified number of products which have the potential to total, in the aggregate, up to $\$ 1.1$ billion. Ginkgo is also entitled to potential further downstream value in the form of royalties on sales.

In October 2021, we entered into the First Ginkgo Agreement with Ginkgo. Under the First Ginkgo Agreement, Ginkgo will design next generation IgA proteases with potentially transformative therapeutic potential. In return, Ginkgo is eligible to earn both upfront research and development fees and milestone payments, including certain milestone payments in the form of our common stock, clinical and commercial milestone payments of up to $\$ 85$ million in cash, as well as downstream value in the form of royalties on sales.

## Genovis AB (publ.)

In October 2021, we entered into a strategic licensing agreement with Genovis, or the Genovis Agreement. Under the Genovis Agreement, we paid to Genovis an upfront payment in exchange for an exclusive license to Genovis' Xork enzyme technology for all therapeutic uses in humans, excluding research, preclinical, diagnostic, and other potential non-therapeutic applications of the enzyme. Genovis is eligible to earn development and sales-based milestones, as well as tiered royalties on worldwide sales in the low double digits.

## Cyrus Biotechnology, Inc.

In September 2021, we entered into a Collaboration and License Agreement with Cyrus, or the Cyrus Agreement, pursuant to which Cyrus agreed to grant us an exclusive, worldwide license to certain intellectual property in order to form a protein engineering collaboration combining the ImmTOR platform with Cyrus' engineered protein therapeutics. We expect that novel engineered protein therapeutic candidates from the partnership will be used to expand our proprietary pipeline and further bolster the ImmTOR platform. In return for the licensed intellectual property, we made an upfront payment and will pay certain discovery, development, and sales-based milestones which could potentially total up to approximately $\$ 1.5$ billion across multiple programs.

## IGAN Biosciences, Inc.

In October 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 granted us an exclusive license to research, evaluate, and conduct preclinical 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 $\operatorname{IgA}$-mediated diseases, including IgA nephropathy, Linear IgA bullous dermatitis, IgA pemphigus, and HenochSchonlein purpura.

Upon execution of the IGAN Agreement, we paid IGAN a one-time upfront payment of $\$ 0.5$ million 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.

## Out-licenses

## Takeda Pharmaceuticals USA, Inc.

In October 2021, we entered into a strategic licensing agreement with Takeda, or the Takeda Agreement. Under the Takeda Agreement, we granted Takeda an exclusive license to our ImmTOR technology initially for two specified disease indications within the field of lysosomal storage disorders. Under the terms of the Takeda Agreement, we received an upfront payment and are entitled to receive up to $\$ 1.124$ billion in future additional payments over the course of the partnership that are contingent on the achievement of development or commercial milestones or Takeda's election to continue its activities at specified development stages. We are also eligible for tiered royalties on future commercial sales of any licensed products.

## Swedish Orphan Biovitrum AB (publ.)

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, upfront 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 a purchase price of $\$ 4.6156$ per share for aggregate gross proceeds of $\$ 25$ million, which we refer to as the Sobi Private Placement.

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.

## Sarepta Therapeutics, Inc.

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 upfront 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 and 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. In June 2021, we received a payment of $\$ 3.0$ million for the achievement of certain pre-clinical milestones.

## Asklepios Biopharmaceutical, Inc.

## 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. In April 2021, we were notified by AskBio that it intended to opt-out of development of the MMA indication. The AskBio Collaboration Agreement otherwise remains in effect. We filed an IND to conduct a Phase $1 / 2$ clinical trial of our SEL-302 product candidate in pediatric patients with methylmalonic acidemia in the third quarter of 2021. On November 23, 2021, this trial was placed on clinical hold by the FDA, with questions specifically relating to CMC of the AAV vector. On February 9, 2022, we submitted a written response to the FDA to answer its questions. On March 9, 2022, we received a letter from the FDA indicating the clinical hold was removed and the trial may proceed. ImmTOR manufacturing, controlled by us, continues to proceed in accordance with our expectations and we have not observed any impact to any of our ImmTOR programs. In October and November 2020, we 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.

## 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 to us at percentages in the mid-to-high single digits 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

## Impact of Global Events

## COVID-19

We are closely monitoring how the COVID-19 pandemic is affecting our employees, business, supply chain, preclinical studies and clinical trials. In response to the spread of COVID-19, we have continued to have our administrative employees work outside of our offices to limit the total number of staff in our offices. We began encouraging more onsite employee presence in April 2022. 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 supply chain, preclinical study or clinical trial delays.

While the COVID-19 pandemic has not had a material impact on our clinical programs as of the date of this Quarterly Report, it could have an impact on our ability to complete the Phase 3 DISSOLVE clinical program of SEL-212, as the pandemic presents the potential to experience delays in enrollment as well as the inability of certain patients to complete the trial due to suffering from COVID-19, our ability to commence preclinical studies and clinical trials 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.

At this time, 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, for COVID-19, the duration of the pandemic, the emergence of new virus variants, travel restrictions and social distancing in the United States and other countries, business closures, disruptions, mandated stay at home orders or lockdowns, supply chain 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.

## Ukraine

We are also closely monitoring the ongoing and rapidly evolving geopolitical situation in Ukraine and Russia, and we have proactively undertaken mitigation steps to prioritize the safety of our patients and investigators, as well as address any potential disruptions. We have temporarily closed screening and randomization for new DISSOLVE II patients in both Russia and Ukraine and have reserved existing clinical trial supplies in these countries for those already enrolled in the study. In addition, to address the risk that this geopolitical situation presents to expected DISSOLVE II enrollment and completion timelines, we have proactively added 11 additional sites in the United States. As of the filing of this Quarterly Report, we now have 55 sites active and expect to complete the DISSOLVE II study in the fourth quarter of 2022, with topline results available in the first quarter of 2023. Finally, in agreement with our study partner, Sobi, we have increased enrollment in DISSOLVE II to approximately 140 subjects to replace subjects enrolled in Russia and Ukraine who may be lost due to operational or other issues arising from instability in the region. We anticipate that the steps we have outlined above will allow us to complete both DISSOLVE studies in the fourth quarter of 2022 with the combined study readout expected in the first quarter of 2023.

## Financial Operations

To date, we have financed our operations primarily through public offerings and private placements of our securities, funding received from research grants, collaboration and license arrangements and our credit facility. We do not have any products approved for sale and have not generated any product sales.

Since inception, we have incurred significant operating losses. We incurred a net income and net loss of $\$ 28.8$ million and $\$(24.6)$ million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $\$ 401.5$ million. We expect to continue to incur significant expenses and operating losses for at least the next several years as we:

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

Until we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, and license and collaboration agreements. 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, restricted cash, and marketable securities as of March 31, 2022, combined with the proceeds from the April 2022 underwritten offering, will enable us to fund our operating expenses and capital expenditure requirements into mid-2024. 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 license revenue

To date, we have not generated any revenue from product sales. Our revenue consists primarily of collaboration and license revenue, which includes amounts recognized related to upfront and milestone payments for research and development funding under collaboration and license agreements. We expect that any revenue we generate will fluctuate from quarter to quarter because of the timing and amounts 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 license revenue, see Notes 12 and 14 to our consolidated financial statements included elsewhere in this Quarterly Report.

## 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 $\$ 381.7$ million in research and development expenses from inception through March 31, 2022, with a majority of the expenses being spent on the development of SEL-212 and the remainder being spent on our various discovery and preclinical stage product candidate programs and the general expansion of our technology platform.

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.

In June 2020, we and Sobi entered into the Sobi License. Pursuant to the Sobi License, clinical trial costs incurred to complete development of SEL212, 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 Note 12 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report. The reimbursable costs exclude any costs of additional development activities required that are related to ImmTOR and that are unrelated to SEL-212.

We believe that our existing cash, cash equivalents, restricted cash, and marketable securities as of March 31, 2022 will enable us to fund our current planned operations into mid-2024, though we may realize additional cash resources upon the achievement of certain contingent collaboration milestones or it may pursue additional cash resources through public or private equity or debt financings or by establishing collaborations with other companies. Management's expectations with respect to our ability to fund current and long-term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, we may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any collaboration milestones will be achieved or
that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand our operations, meet long-term obligations or otherwise capitalize on our commercialization of our product candidates. 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.

## 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, cash equivalents and marketable securities.

## Interest expense

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

## Other income (expense)

Other income (expense) was de minimis during the three months ended March 31, 2022 and 2021.

## Change in fair value of warrant liabilities

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

## Foreign currency transaction gain (loss)

The functional currency of our Russian subsidiary is the Russian ruble. In addition to holding cash denominated in Russian rubles, our Russian bank accounts also hold cash balances denominated in U.S. dollars to facilitate payments to be settled in U.S. dollars or other currencies. As of March 31, 2022 and December 31, 2021, we maintained cash of $\$ 0.3$ million in Russian banks, all of which was denominated in U.S. dollars. The amounts denominated in U.S. dollars and used in transacting the day-to-day operations of our Russian subsidiary are subject to transaction gains and losses, which are reported as incurred.

## Results of Operations

## Comparison of the Three Months Ended March 31, 2022 and 2021

## Collaboration and license revenue

The following is a comparison of collaboration and license revenue for the three months ended March 31, 2022 and 2021 (in thousands, except percentages):
Increase
(decrease)

During the three months ended March 31,2022 , collaboration revenue was $\$ 34.0$ million, compared to $\$ 11.1$ million in 2021. During the three months ended March 31, 2022 and 2021, we recognized $\$ 23.8$ million and $\$ 11.1$ million, respectively, under the license agreement with Sobi resulting from both the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program. Additionally, during the three months ended March 31, 2022, $\$ 9.2$ million was recognized upon the mutual termination of the Spark License Agreement and $\$ 1.0$ million was recognized under the license agreement with Takeda.

## Research and development

The following is a comparison of research and development expenses for the three months ended March 31, 2022 and 2021 (in thousands, except percentages):

|  | Three Months Ended March 31, |  |  |  | Increase <br> (decrease) |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  | 2021 |  |  |  |  |
| SEL-212 | \$ | 7,057 | \$ | 6,724 | \$ | 333 | 5 \% |
| AskBio collaboration |  | 1,162 |  | 813 |  | 349 | 43 \% |
| Preclinical stage product candidate programs |  | 3,108 |  | 571 |  | 2,537 | 444 \% |
| Other internal research and development expenses |  | 6,362 |  | 4,896 |  | 1,466 | $30 \%$ |
| Total research and development expenses | \$ | 17,689 | \$ | 13,004 | \$ | 4,685 | 36 \% |

During the three months ended March 31, 2022, our research and development expenses increased by $\$ 4.7$ million, or $36 \%$, as compared to 2021 . The increase in cost was primarily the result of expenses incurred for the preclinical programs, salaries and contract license and milestone payments.

## General and administrative

The following is a comparison of general and administrative expenses for the three months ended March 31, 2022 and 2021 (in thousands, except percentages):


During the three months ended March 31, 2022, our general and administrative expenses increased by $\$ 0.3$ million, or $6 \%$, as compared to 2021 . The increase in costs was primarily the result of stock compensation expenses offset by decreases in salaries and wages associated with non-recurring severance expense recognized during the three months ended March 31, 2021.

## Investment income

Investment income was de minimis for each of the three months ended March 31, 2022 and 2021.

## Foreign currency transaction gain (loss)

We recognized de minimis foreign currency losses during each of the three months ended March 31, 2022 and 2021.

## Interest expense

Interest expense was $\$ 0.7$ million for each of the three months ended March 31, 2022 and 2021, representing interest expense and amortization of the carrying costs of our credit facilities.

## Change in fair value of warrant liabilities

For the three months ended March 31, 2022, we recognized $\$ 18.5$ million of income from the change in the fair value of warrant liabilities utilizing the Black-Scholes valuation methodology. The decrease in value was primarily driven by a decrease in the Company's share price. For the three months ended March 31, 2021, we recognized $\$(16.7)$ million change in the fair value of warrant liabilities primarily driven by an increase in the Company's share price and volatility, offset by a decreased discount rate.

## Other income (expense)

Other income (expense) was de minimis for each of the three months ended March 31, 2022 and 2021.

## Net income (loss)

Net income for the three months ended March 31, 2022 was $\$ 28.8$ million compared to a net loss of $\$(24.6)$ million for the three months ended March 31, 2021.

## Liquidity and Capital Resources

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

From our inception through March 31, 2022, we have raised an aggregate of $\$ 649.1$ 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 facilities past and present, $\$ 212.3$ million from our collaborations and license agreements, $\$ 64.5$ million in combined net proceeds from our initial public offering, $\$ 149.3$ million in combined net proceeds from private placements and follow-on offerings of our common stock, and, through March 31, 2022, $\$ 56.7$ million in aggregate net proceeds from "at-the-market" offerings of our common stock.

As of March 31, 2022, our cash, cash equivalents, restricted cash, and marketable securities were $\$ 118.8$ 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, or the 2020 Term Loan, 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 the Loan and Security Agreement. The Term A Loan was funded in full on August 31, 2020, or the Funding Date. The second draw period expired on September 30, 2021 and the Term B Loan is no longer available to be drawn by the Company in the future.

On March 21, 2022, we entered into a Second Amendment to Loan and Security Agreement, or the Second Amendment, which amended the Loan and Security Agreement. The Second Amendment extends the date on which amortization payments in respect of the 2020 Term Loan will commence by twelve months to April 1, 2023. Thereafter, amortization payments will be paid monthly in equal installments of principal and interest to fully amortize the outstanding principal over the remaining term of the 2020 Term Loan, subject to recalculation upon a change in the prime rate. The Second Amendment was determined to be a loan modification, and the $\$ 0.1$ million fee is recorded as an addition to the debt discount on the effective date.

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 is 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.

## Future funding requirements

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

As of March 31, 2022, we had an accumulated deficit of $\$ 401.5$ 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 continually evaluating various potential sources of additional funding such as strategic collaborations, license agreements 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, restricted cash, and marketable securities as of March 31, 2022 will enable us to fund our current planned operations into mid-2024, though we may realize additional cash resources upon the achievement of certain contingent collaboration milestones or it may pursue additional cash resources through public or private equity or debt financings or by establishing collaborations with other companies. Management's expectations with respect to our ability to fund current and long-term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, we may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any collaboration milestones will be achieved or that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand our operations, meet long-term obligations or otherwise capitalize on our commercialization of our product candidates. Additionally, while the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital as and when needed. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

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


## Summary of Cash Flows

| (In thousands) | Three Months Ended March 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2022 |  | 2021 |  |
| Cash (used in) and provided by: |  |  |  |  |
| Operating activities | \$ | $(11,864)$ | \$ | $(12,133)$ |
| Investing activities |  | 9,545 |  | $(22,445)$ |
| Financing activities |  | 1,728 |  | 21,307 |
| Effect of exchange rate changes on cash |  | (29) |  | (7) |
| Net change in cash, cash equivalents, and restricted cash | \$ | (620) | \$ | $(13,278)$ |

## Operating activities

Cash used in operating activities of $\$ 11.9$ million for the three months ended March 31, 2022 included approximately $\$ 13.9$ million of net income, adjusted for non-cash items, and uses of cash of approximately $\$ 25.8$ million for changes in operating assets and liabilities.

Cash used in operating activities of $\$ 12.1$ million for the three months ended March 31, 2021 included approximately $\$ 5.2$ million of net losses, adjusted for non-cash items, and uses of cash of approximately $\$ 6.9$ million for changes in operating assets and liabilities.

## Investing activities

Net cash provided by investing activities for the three months ended March 31, 2022 was $\$ 9.5$ million compared to net cash used in investing activities of $\$ 22.4$ million in the same period in 2021. The net cash provided by investing activities in 2022 was primarily proceeds from the maturities of marketable securities offset by purchases or property and equipment.

The net cash used in investing activities in 2021 was to purchase marketable securities.

## Financing activities

Net cash provided by financing activities for the three months ended March 31, 2022 was $\$ 1.7$ million compared to net cash provided by financing activities of $\$ 21.3$ million in the same period in 2021. The net cash provided by financing activities in the three months ended March 31, 2022 and 2021 was primarily the result of net proceeds from "at-the-market" offerings.

## Recent Accounting Pronouncements

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

## Off-Balance Sheet Arrangements

As of March 31, 2022, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

## Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgements that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities in our consolidated financial statements. Actual results may differ from these estimates under different assumptions or conditions. During the three months ended March 31, 2022, there were no material changes to our critical accounting policies from those described in our Annual Report on Form 10-K for the year ended December 31, 2021.

## Smaller Reporting Company

We qualify as a "smaller reporting company" under the rules of the Securities Act and the Exchange Act. As a result, we may choose to take advantage of certain scaled disclosure requirements available specifically to smaller reporting 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, is more than $\$ 700$ million as of the last business day of our most recently completed second fiscal quarter, or until the fiscal year following the year in which we have at least $\$ 100$ million in revenue and at least $\$ 250$ million in public float as of the last business day of our most recently completed second fiscal quarter.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of March 31, 2022 and December 31, 2021, we had cash, cash equivalents, restricted cash and marketable securities of $\$ 118.8$ million and $\$ 129.4$ 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 marketable securities, and our current plan to hold marketable securities 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 marketable securities.

## Item 4. Controls and Procedures

## Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report, 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 March 31, 2022.

## Inherent Limitations on Effectiveness of Controls

There are inherent limitations to the effectiveness of any system of internal control over financial reporting. Accordingly, even an effective system of internal control over financial reporting can only provide reasonable assurance with respect to financial statement preparation and presentation in accordance with U.S. GAAP. Our internal controls over financial reporting are subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, the possibility of human error, and the risk of fraud. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may be inadequate because of changes in conditions and the risk that the degree of compliance with policies or procedures may deteriorate over time.

## Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

## Item 1. Legal Proceedings

On August 3, 2020, a 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. On April 12, 2021, the Court of Chancery in the State of Delaware granted a motion to stay the litigation pending a review by a Special Committee appointed by the Company's Board of Directors. While the litigation was stayed, the parties reached an agreement in principle to settle the matter, and on March 18, 2022, they submitted a Stipulation and Agreement of Settlement and other documentation to the Court for its approval of the settlement.

## Item 1A. Risk Factors

Our risk factors are disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes from the risk factors previously disclosed in such filing.

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

None.

## Item 3. Defaults Upon Senior Securities

None.

## Item 4. Mine Safety Disclosures

None.

## Item 5. Other Information

None.

Item 6. Exhibits

## EXHIBIT INDEX

| Exhibit Number | Exhibit Description | Incorporated by Reference |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | Form | File No. | Exhibit | Filing Date |
| 3.1 | Restated Certificate of Incorporation of Selecta Biosciences, Inc. | 8-K | 001-37798 | 3.1 | 6/29/2016 |
| 3.2 | Amended and Restated By-laws of Selecta Biosciences, Inc. | 8-K | 001-37798 | 3.2 | 9/30/2021 |
| 10.1 | Second Amendment to Loan and Security Agreement, dated March 21, 2022, between Selecta Biosciences, Inc., Oxford Finance LLC, as Collateral Agent and as a lender, and Silicon Valley Bank, as a lender. | 8-K | 001-37798 | 10.1 | 3/22/2022 |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14 (a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | - | - | - | Filed herewith |
| 31.2 | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14 (a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | - | - | - | Filed herewith |
| 32.1 | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | - | - | - | Furnished herewith |
| 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) | - | - | - | Filed herewith |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | - | - | - | Filed herewith |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | - | - | - | Filed herewith |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | - | - | - | Filed herewith |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document | - | - | - | Filed herewith |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | - | - | - | Filed herewith |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | - | - | - | Filed herewith |

## SIGNATURES

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

## SELECTA BIOSCIENCES, INC.

By: $\qquad$ Carsten Brunn, Ph.D. President and Chief Executive Officer, and Director (Principal Executive Officer)

By:

| /s/Kevin Tan |
| :---: |
| Kevin Tan |
| Chief Financial Officer |
| (Principal Financial Officer) |

## CERTIFICATIONS

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

1. I have reviewed this Quarterly Report on Form 10-Q of Selecta Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 5, 2022
/s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President and Chief Executive Officer, and Director
(Principal Executive Officer)

## CERTIFICATIONS

I, Kevin Tan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Selecta Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 5, 2022

| /s/ Kevin Tan |
| :---: |
| Kevin Tan |
| Chief Financial Officer |
| (Principal Financial Officer) |

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

In connection with the Quarterly Report on Form 10-Q of Selecta Biosciences, Inc. (the "Company") for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

1. The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 5, 2022

| /s/ Carsten Brunn, Ph.D. |
| :---: |
| Carsten Brunn, Ph.D. |
| President and Chief Executive Officer, and Director |
| (Principal Executive Officer) |

May 5, 2022

| /s/ Kevin Tan |
| :---: |
| Kevin Tan |
| Chief Financial Officer |
| (Principal Financial Officer) |


[^0]:    The accompanying notes are an integral part of these unaudited consolidated financial statements.

