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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2023

OR

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

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

Commission File Number: 001-37798

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**Selecta Biosciences, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**26-1622110**  
(I.R.S. Employer  
Identification No.)

**65 Grove Street,  
Watertown, MA**  
(Address of principal executive offices)

**02472**  
(Zip Code)

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

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**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  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of August 4, 2023, the registrant had 153,427,571 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 ability to execute our strategic initiative plans and manage operating expenses;
- 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 maximize the value of our pipeline of product candidates;
- 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 and to seek new collaborations, licenses or partnerships;
- 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 U.S. Food and Drug Administration, or FDA, regulation of our product candidates;
- our ability to obtain and retain key executives and attract and retain qualified personnel; and
- developments relating to our competitors and our industry, including the impact of government regulation.

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)

	June 30, 2023	December 31, 2022
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 112,027	\$ 106,438
Marketable securities	—	28,164
Accounts receivable	5,385	6,596
Unbilled receivables	1,055	3,162
Prepaid expenses and other current assets	4,258	3,778
Total current assets	<u>122,725</u>	<u>148,138</u>
<b>Non-current assets:</b>		
Property and equipment, net	2,593	2,794
Right-of-use asset, net	10,775	11,617
Long-term restricted cash	1,377	1,311
Investments	2,000	2,000
Other assets	36	26
Total assets	<u>\$ 139,506</u>	<u>\$ 165,886</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 267	\$ 316
Accrued expenses	12,902	14,084
Loan payable	10,235	8,476
Lease liability	1,729	1,608
Deferred revenue	4,234	593
Total current liabilities	<u>29,367</u>	<u>25,077</u>
<b>Non-current liabilities:</b>		
Loan payable, net of current portion	13,787	17,786
Lease liability	9,163	10,055
Deferred revenue	4,863	—
Warrant liabilities	16,878	19,140
Total liabilities	<u>74,058</u>	<u>72,058</u>
Commitments and contingencies (Note 17)		
<b>Stockholders' equity:</b>		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized; 153,427,571 and 153,042,435 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	15	15
Additional paid-in capital	498,016	493,308
Accumulated deficit	(427,987)	(394,937)
Accumulated other comprehensive loss	(4,596)	(4,558)
Total stockholders' equity	<u>65,448</u>	<u>93,828</u>
Total liabilities and stockholders' equity	<u>\$ 139,506</u>	<u>\$ 165,886</u>

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

**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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration and license revenue	\$ 5,249	\$ 39,273	\$ 11,187	\$ 73,272
Operating expenses:				
Research and development	17,782	19,182	36,406	36,871
General and administrative	6,105	6,231	11,800	11,768
Total operating expenses	23,887	25,413	48,206	48,639
Operating (loss) income	(18,638)	13,860	(37,019)	24,633
Investment income	1,394	207	2,725	222
Foreign currency transaction, net	23	(104)	42	(76)
Interest expense	(752)	(715)	(1,560)	(1,422)
Change in fair value of warrant liabilities	6,341	(4,647)	2,262	13,868
Other income, net	245	—	500	154
Net (loss) income	\$ (11,387)	\$ 8,601	\$ (33,050)	\$ 37,379
Other comprehensive income (loss):				
Foreign currency translation adjustment	(27)	118	(49)	86
Unrealized gain on marketable securities	—	—	11	—
Total comprehensive income (loss)	\$ (11,414)	\$ 8,719	\$ (33,088)	\$ 37,465
Net (loss) income per share:				
Basic	\$ (0.07)	\$ 0.06	\$ (0.22)	\$ 0.27
Diluted	\$ (0.07)	\$ 0.06	\$ (0.22)	\$ 0.17
Weighted average common shares outstanding:				
Basic	153,442,413	148,505,729	153,396,380	136,436,316
Diluted	153,442,413	148,505,729	153,396,380	136,966,312

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

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

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Stockholders' equity
	Shares	Amount				
Balance at December 31, 2022	<u>153,042,435</u>	<u>\$ 15</u>	<u>\$493,308</u>	<u>\$ (394,937)</u>	<u>\$ (4,558)</u>	<u>\$ 93,828</u>
Issuance of common stock under Employee Stock Purchase Plan	108,068	—	149	—	—	149
Issuance of vested restricted stock units	276,480	—	—	—	—	—
Stock-based compensation expense	—	—	2,276	—	—	2,276
Currency translation adjustment	—	—	—	—	(22)	(22)
Unrealized gain on marketable securities	—	—	—	—	11	11
Net loss	—	—	—	(21,663)	—	(21,663)
Balance at March 31, 2023	<u>153,426,983</u>	<u>\$ 15</u>	<u>\$495,733</u>	<u>\$ (416,600)</u>	<u>\$ (4,569)</u>	<u>\$ 74,579</u>
Issuance of vested restricted stock units	588	—	—	—	—	—
Stock-based compensation expense	—	—	2,283	—	—	2,283
Currency translation adjustment	—	—	—	—	(27)	(27)
Net loss	—	—	—	(11,387)	—	(11,387)
Balance at June 30, 2023	<u>153,427,571</u>	<u>\$ 15</u>	<u>\$498,016</u>	<u>\$ (427,987)</u>	<u>\$ (4,596)</u>	<u>\$ 65,448</u>

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

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

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Stockholders' 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 income	—	—	—	28,778	—	28,778
Balance at March 31, 2022	<u>124,380,844</u>	<u>\$ 12</u>	<u>\$461,888</u>	<u>\$ (401,538)</u>	<u>\$ (4,598)</u>	<u>\$ 55,764</u>
Issuance of vested restricted stock units	10,938	—	—	—	—	—
Issuance of common stock and common warrants	27,428,572	3	21,477	—	—	21,480
Issuance of common stock, license agreement	892,857	—	1,000	—	—	1,000
Other financing fees	—	—	79	—	—	79
Stock-based compensation expense	—	—	2,564	—	—	2,564
Currency translation adjustment	—	—	—	—	118	118
Net income	—	—	—	8,601	—	8,601
Balance at June 30, 2022	<u>152,713,211</u>	<u>\$ 15</u>	<u>\$487,008</u>	<u>\$ (392,937)</u>	<u>\$ (4,480)</u>	<u>\$ 89,606</u>

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



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

	Six Months Ended June 30,	
	2023	2022
<b>Cash flows from operating activities</b>		
Net (loss) income	\$ (33,050)	\$ 37,379
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	382	696
Amortization of premiums and discounts on marketable securities	(79)	—
Non-cash lease expense	842	591
Gain on disposal of property and equipment	—	(147)
Stock-based compensation expense	6,059	6,317
Non-cash interest expense	533	579
Warrant liabilities revaluation	(2,262)	(13,868)
Changes in operating assets and liabilities:		
Accounts receivable	1,211	(14,080)
Unbilled receivable	2,107	—
Prepaid expenses, deposits and other assets	815	(374)
Accounts payable	(49)	300
Income taxes payable	—	(280)
Deferred revenue	8,504	(42,213)
Accrued expenses and other liabilities	(3,673)	965
Net cash used in operating activities	(18,660)	(24,135)
<b>Cash flows from investing activities</b>		
Proceeds from maturities of marketable securities	28,254	10,000
Purchases of property and equipment	(142)	(554)
Net cash provided by investing activities	28,112	9,446
<b>Cash flows from financing activities</b>		
Repayments of principal on outstanding debt	(2,586)	—
Debt amendment fee included in debt discount	—	(110)
Net proceeds from issuance of common stock- at-the-market offering	—	1,675
Net proceeds from issuance of common stock and common warrants	—	36,890
Proceeds from exercise of stock options	—	21
Proceeds from issuance of common stock under Employee Stock Purchase Plan	149	127
Net cash (used in) provided by financing activities	(2,437)	38,603
Effect of exchange rate changes on cash	(49)	86
Net change in cash, cash equivalents, and restricted cash	6,966	24,000
Cash, cash equivalents, and restricted cash at beginning of period	108,038	115,436
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 115,004</u>	<u>\$ 139,436</u>
<b>Supplemental cash flow information</b>		
Cash paid for interest	\$ 1,242	\$ 1,014
<b>Noncash investing and financing activities</b>		
Issuance of common stock, license agreement in stock-based compensation expense	\$ —	\$ 1,000
Stock-based compensation expense in accrued liabilities	\$ 1,500	\$ —
Purchase of property and equipment not yet paid	\$ 48	\$ 320
Equity offering costs in accrued liabilities	\$ —	\$ 31

*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 biotechnology company leveraging the Company's ImmTOR<sup>®</sup> platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses. With a proven ability to induce tolerance to highly immunogenic proteins, the Company believes ImmTOR has the potential to amplify the efficacy of biologic therapies, including redosing of life-saving gene therapies, as well as restore the body's natural self-tolerance in autoimmune diseases. The Company has several proprietary and partnered programs in its pipeline focused on enzyme therapies, gene therapies, and autoimmune diseases.

In April 2023, in light of current market conditions, the Company's Board of Directors, or the Board, took steps to extend cash runway by pausing further development of SEL-302 for the treatment of methylmalonic acidemia, or MMA, and conducting a targeted headcount reduction of approximately 25%. On August 17, 2023, the Company announced additional steps to extend cash runway and maximize value for stockholders by continuing to prioritize development of SEL-212 and support of its collaboration with Astellas Gene Therapies, or Astellas, for Xork, and pausing further development of all of the Company's other clinical and preclinical product candidates that it is no longer actively advancing. The Company intends to seek collaboration partners for the assets in the development programs that it is no longer actively advancing.

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

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

**Unaudited Interim Financial Information**

The accompanying unaudited consolidated financial statements for the three and six months ended June 30, 2023 and 2022 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, 2022 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 2, 2023. The unaudited interim financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments that are necessary for a fair statement of the Company's financial position as of June 30, 2023, the consolidated results of operations for the three and six months ended June 30, 2023, and cash flows for the six months ended June 30, 2023. Such adjustments are of a normal and recurring nature. The results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023.

## **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 public offerings and private placements of its securities, funding received from research grants, collaboration and license arrangements and its credit facility. 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 June 30, 2023, the Company's cash, cash equivalents and restricted cash were \$115.0 million, of which \$3.0 million was restricted cash related to lease commitments and \$0.2 million was held by its Russian subsidiary designated solely for use in its operations. In April 2023, in light of current market conditions, the Board took steps to extend cash runway by pausing further development of SEL-302 for the treatment of MMA and conducting a targeted headcount reduction of approximately 25%. On August 17, 2023, the Company announced additional steps to extend cash runway and maximize value for stockholders by continuing to prioritize development of SEL-212 and support of its collaboration with Astellas for Xork, and pausing further development of all of the Company's other clinical and preclinical product candidates that it is no longer actively advancing. The Company intends to seek collaboration partners for the assets in the development programs that it is no longer actively advancing. The Company believes the cash, cash equivalents and restricted cash as of June 30, 2023 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 or maintain its operations or otherwise capitalize on its commercialization of its product candidates. The Company anticipates continuing to generate operating losses for the foreseeable future due to, among other things, costs related to research and development of its product candidates and its administrative organization.

## **Guarantees and Indemnifications**

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at the Company. Through June 30, 2023, 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, 2022. There have been no material changes to the Company's significant accounting policies during the three or six months ended June 30, 2023, with the exception of the matters discussed in recent accounting pronouncements.

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### Recent Accounting Pronouncements

#### Recently Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*. Subsequently, in November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses*. ASU 2016-13 requires entities to measure all expected credit losses for most financial assets held at the reporting date based on an expected loss model which includes historical experience, current conditions, and reasonable and supportable forecasts. ASU 2016-13 also requires enhanced disclosures to help financial statement users better understand significant estimates and judgments used in estimating credit losses. This ASU is effective for smaller reporting companies for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company adopted the new standard effective January 1, 2023, using a modified retrospective transition method, and there was no impact on its consolidated financial statements or results of operations upon adoption.

### 3. Marketable Securities and Investments

No marketable securities were held as of June 30, 2023. The following table summarizes the marketable securities held as of December 31, 2022 (in thousands):

	Amortized cost	Unrealized losses	Fair value
<b>December 31, 2022</b>			
U.S. government agency securities and treasuries	\$ 13,566	\$ (9)	\$13,557
Corporate bonds	\$ 1,953	\$ (2)	\$ 1,951
Commercial paper	12,656	—	12,656
Total	<u>\$ 28,175</u>	<u>\$ (11)</u>	<u>\$28,164</u>

#### Investments

As of June 30, 2023 and December 31, 2022, 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 (Loss) Income Per Share

The following table sets forth the computation of basic and diluted net (loss) income per share for the three and six months ended June 30, 2023 and 2022 (in thousands, except share and per-share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<b>Numerator:</b>				
Net (loss) income	\$ (11,387)	\$ 8,601	\$ (33,050)	\$ 37,379
Less: Change in fair value of liability warrants	—	—	—	(13,868)
Adjusted net (loss) income	<u>\$ (11,387)</u>	<u>\$ 8,601</u>	<u>\$ (33,050)</u>	<u>\$ 23,511</u>
<b>Denominator:</b>				
Weighted-average common shares outstanding - basic	153,442,413	148,505,729	153,396,380	136,436,316
Dilutive effect of employee equity incentive plans and outstanding warrants	—	—	—	529,996
Weighted-average common shares used in per share calculations - diluted	<u>153,442,413</u>	<u>148,505,729</u>	<u>153,396,380</u>	<u>136,966,312</u>
<b>Net (loss) income per share:</b>				
Basic	<u>\$ (0.07)</u>	<u>\$ 0.06</u>	<u>\$ (0.22)</u>	<u>\$ 0.27</u>
Diluted	<u>\$ (0.07)</u>	<u>\$ 0.06</u>	<u>\$ (0.22)</u>	<u>\$ 0.17</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Options, RSUs and ESPP shares	22,607,689	16,422,488	22,607,689	16,660,700
Warrants to purchase common stock	31,228,279	31,307,409	31,228,279	20,863,898
Total	<u>53,835,968</u>	<u>47,729,897</u>	<u>53,835,968</u>	<u>37,524,598</u>

## 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 June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds (included in cash equivalents)	\$73,384	\$73,384	\$ —	\$ —
Total assets	<u>\$73,384</u>	<u>\$73,384</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrant liabilities	\$16,878	\$ —	\$ —	\$16,878
Total liabilities	<u>\$16,878</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$16,878</u>

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds (included in cash equivalents)	\$53,552	\$53,552	\$ —	\$ —
<b>Marketable securities:</b>				
U.S. government agency securities and treasuries	13,557	—	13,557	—
Corporate bonds	1,951	—	1,951	—
Commercial paper	12,656	—	12,656	—
Total assets	<u>\$81,716</u>	<u>\$53,552</u>	<u>\$28,164</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrant liabilities	\$19,140	\$ —	\$ —	\$19,140
Total liabilities	<u>\$19,140</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$19,140</u>

There were no transfers within the fair value hierarchy during the six months ended June 30, 2023 or year ended December 31, 2022.

### Cash, Cash Equivalents, and Restricted Cash

As of June 30, 2023 and December 31, 2022, 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 June 30, 2023, the Company had restricted cash balances relating to secured letters of credit in connection with its lease for the Company's headquarters. Short-term restricted cash is included within prepaid expenses and other current assets in the consolidated balance sheets. The Company's consolidated statements of cash flows include the following as of June 30, 2023 and 2022 (in thousands):

	June 30,	
	2023	2022
Cash and cash equivalents	\$112,027	\$138,057
Short-term restricted cash	1,600	—
Long-term restricted cash	1,377	1,379
Total cash, cash equivalents, and restricted cash	<u>\$115,004</u>	<u>\$139,436</u>

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### *Marketable Securities*

No marketable securities were held as of June 30, 2023. As of December 31, 2022, marketable securities classified as Level 2 within the valuation hierarchy consist of U.S. government agency securities and treasuries, 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 June 30, 2023, 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, a division of First-Citizens Bank & Trust Company (successor by purchase to the Federal Deposit Insurance Corporation as Receiver for Silicon Valley Bridge Bank, N.A. (as successor to 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 to purchase common stock 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 were required to be measured at fair value and reported as a liability on the balance sheet. On December 20, 2022, the Company amended the terms of the outstanding 2019 Warrants held by certain members of the Board, or the Amended 2019 Warrants, to remove the cash settlement provision. As a result, the Amended 2019 Warrants were remeasured at fair value on December 20, 2022 and reclassified from a liability to equity on the balance sheet. See Note 10 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022 for further discussion on the equity-classified Amended 2019 Warrants.

In April 2022, the Company issued warrants in connection with an underwritten offering of shares of common stock and warrants to purchase shares of common stock, or the 2022 Warrants. Pursuant to the terms of the 2022 Warrants, the Company could be required to settle the 2022 Warrants in cash in the event of an acquisition of the Company under certain circumstances and, as a result, the 2022 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 and the 2022 Warrants upon issuance using the Black-Scholes valuation model and is required to revalue the 2019 Warrants and the 2022 Warrants at each reporting date, with any changes in fair value recorded in the statement of operations and comprehensive income (loss). The valuations of the 2019 Warrants and the 2022 Warrants are classified as Level 3 of the fair value hierarchy due to the need to use assumptions in the valuations that are both significant to the fair value measurement and unobservable, including the stock price volatility and the expected life of the 2019 Warrants and the 2022 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 estimated fair values of the 2019 Warrants and the 2022 Warrants were 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 and the 2022 Warrants is assumed to be equivalent to their remaining contractual terms which expire on December 23, 2024 and April 11, 2027, respectively.

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

A summary of the Black-Scholes pricing model assumptions used to record the fair value of the 2019 Warrants liability is as follows:

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Risk-free interest rate	5.40%	4.74%
Dividend yield	—	—
Expected life (in years)	1.48	1.98
Expected volatility	82.80%	79.92%

A summary of the Black-Scholes pricing model assumptions used to record the fair value of the 2022 Warrants liability is as follows:

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Risk-free interest rate	4.49%	4.22%
Dividend yield	—	—
Expected life (in years)	3.78	4.28
Expected volatility	91.59%	98.05%

### *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 to these unaudited consolidated financial statements), for the six months ended June 30, 2023 (in thousands):

	<u>Warrant liabilities</u>
Fair value as of December 31, 2022	\$19,140
Change in fair value	(2,262)
Fair value as of June 30, 2023	<u>\$16,878</u>

## **6. Property and Equipment**

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

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Laboratory equipment	\$ 6,263	\$ 6,001
Computer equipment and software	702	697
Leasehold improvements	61	57
Furniture and fixtures	453	453
Office equipment	196	192
Construction in process	492	599
Total property and equipment	8,167	7,999
Less: Accumulated depreciation	(5,574)	(5,205)
Property and equipment, net	<u>\$ 2,593</u>	<u>\$ 2,794</u>

Depreciation expense was \$0.2 million for each of the three months ended June 30, 2023 and 2022 and \$0.4 million and \$0.3 million for the six months ended June 30, 2023 and 2022, respectively.

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### 7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Payroll and employee related expenses	\$ 2,978	\$ 4,242
Collaboration and licensing	2,523	—
Accrued patent fees	471	696
Accrued external research and development costs	5,094	7,274
Accrued professional and consulting services	1,257	985
Accrued interest	187	222
Other	392	665
Accrued expenses	<u>\$12,902</u>	<u>\$ 14,084</u>

### 8. Leases

#### *65 Grove Street Lease*

In July 2019, the Company entered into a lease with BRE-BMR Grove LLC for 25,078 square feet of laboratory and office space located at 65 Grove Street, Watertown, Massachusetts, or the Headquarters Lease. On September 1, 2022, the Company entered into an amendment, or the Lease Agreement Amendment, to the Headquarters Lease, to expand the Company's corporate headquarters located at 65 Grove Street, Watertown, Massachusetts by approximately 7,216 square feet. In connection with the Lease Agreement Amendment, the Company secured a letter of credit for the Headquarters Lease from SVB for \$1.6 million as of December 31, 2022.

In May 2023, the Company received notice from BRE-BMR Grove LLC that the requirements to reduce the amount of the letter of credit for the Headquarters Lease had been met. In connection therewith, in June 2023, the Company secured a letter of credit from JPMorgan Chase Bank, N.A. for \$1.4 million, which is recognized as long-term restricted cash as of June 30, 2023, and renews automatically each year. As of June 30, 2023, the existing letter of credit from SVB for \$1.6 million has been classified as current based on the anticipated release date of the restrictions of this cash.

For the three and six months ended June 30, 2023 and 2022, the components of lease costs were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating lease cost	\$ 696	\$ 505	\$1,392	\$1,011
Variable lease cost	270	205	412	425
Short-term lease cost	2	2	5	5
Less: Sublease income	(251)	—	(506)	—
Total lease cost	<u>\$ 717</u>	<u>\$ 712</u>	<u>\$1,303</u>	<u>\$1,441</u>

The maturity of the Company's operating lease liabilities as of June 30, 2023 were as follows (in thousands):

	June 30, 2023
2023 (remainder)	\$ 1,349
2024	2,740
2025	2,818
2026	2,902
2027	2,990
Thereafter	946
Total future minimum lease payments	<u>13,745</u>
Less: Imputed interest	2,853
Total operating lease liabilities	<u>\$10,892</u>



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

	Six Months Ended June 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:	\$ 1,319	\$ 924

The changes in the Company's right-of-use assets and lease liabilities for the six months ended June 30, 2023 and 2022 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:

	June 30,	
	2023	2022
Weighted-average remaining lease term	4.9 years	5.9 years
Weighted-average discount rate	9.7%	8.9%

## 9. Debt

### 2020 Term Loan

On August 31, 2020, the Company entered into the Loan and Security Agreement with Oxford and Silicon Valley Bank. On March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or the FDIC, was appointed as receiver. On March 13, 2023, the FDIC announced that all of Silicon Valley Bank's deposits and substantially all of its assets had been transferred to a newly created, full-service, FDIC-operated bridge bank, Silicon Valley Bridge Bank, N.A., or SVBB. SVBB assumed all loans that were previously held by Silicon Valley Bank. On March 27, 2023, First-Citizens Bank & Trust Company assumed all of SVBB's customer deposits and certain other liabilities and acquired substantially all of SVBB's loans and certain other assets from the FDIC, including the Loan and Security Agreement.

On March 31, 2023, the Company entered into a Fourth Amendment to Loan and Security Agreement or the Fourth Amendment, with Oxford as Collateral Agent and a Lender and SVB. The Fourth Amendment relieved the Company of the requirement to maintain all Collateral Accounts (as such term is defined in the Loan and Security Agreement) with SVB and instead requires the Company to hold an amount equal to the lesser of (i) 100% of our consolidated cash and (ii) 150% of the then-outstanding Obligations (as such term is defined in the Loan and Security Agreement) in Collateral Accounts with SVB that are subject to a Control Agreement (as such term is defined in the Loan and Security Agreement) in favor of SVB.

As of June 30, 2023 and December 31, 2022, the outstanding principal balance under the 2020 Term Loan was \$22.4 million and \$25.0 million, respectively.

Total 2020 Term Loan and unamortized debt discount balances as of June 30, 2023 are as follows (in thousands):

Outstanding principal	\$ 22,414
Venture debt termination fee	2,250
Less: Debt discount	(642)
Less: Current portion of loan payable	(10,235)
Loan payable, net of current portion	<u>\$ 13,787</u>

Future minimum principal payments on the 2020 Term Loan as of June 30, 2023 are as follows (in thousands):

<b>Year ended:</b>	
2023 (remainder)	\$ 5,173
2024	10,345
2025	6,896
Total minimum principal payments	<u>\$22,414</u>

## 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 Leerink Partners LLC), or Leerink Partners, 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 Leerink Partners 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), for aggregate gross sales proceeds of up to \$75.0 million.

During the year ended December 31, 2022, the Company sold 774,544 shares of its common stock pursuant to the 2021 Sales Agreement for aggregate net proceeds of \$2.1 million, after deducting commissions and other transaction costs.

During the six months ended June 30, 2023, the Company sold no shares of its common stock pursuant to the 2021 Sales Agreement.

### Warrants

During the three and six months ended June 30, 2023, there were no warrants issued, exercised, or canceled. See Note 10 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022 for further discussion of the terms related to the Company’s warrants.

	Number of Warrants			Weighted average exercise price
	Equity classified	Liability classified	Total	
Outstanding at June 30, 2023	2,236,326	28,991,953	31,228,279	\$ 1.53

### Reserved Shares

The Company has authorized shares of common stock for future issuance as of June 30, 2023 as follows:

Exercise of warrants	31,228,279
Shares available for future stock incentive awards	8,073,729
RSUs reserved for issuance	125
Unvested restricted stock units	2,411,792
Outstanding common stock options	20,114,139
Accrued Ginkgo Bioworks Holdings, Inc. milestone award	1,339,285
Total	63,167,349

## 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 2023, the number of shares of common stock that may be issued under the 2016 Plan was increased by 6,121,697 shares. As of June 30, 2023, 2,587,797 shares remain available for future issuance under the 2016 Plan.

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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 June 30, 2023, there are 425,858 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), including \$1.5 million recognized as stock-based compensation expense upon the achievement of a technical milestone by Ginkgo Bioworks Holdings, Inc., or Ginkgo, during the three and six months ended June 30, 2023 and \$1.0 million recognized as stock-based compensation expense upon the issuance of common stock to Ginkgo during the three and six months ended June 30, 2022 as described in Note 14, was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	\$ 2,677	\$ 2,021	\$3,869	\$3,039
General and administrative	1,106	1,543	2,190	3,278
Total stock-based compensation expense	<u>\$ 3,783</u>	<u>\$ 3,564</u>	<u>\$6,059</u>	<u>\$6,317</u>

### 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Risk-free interest rate	3.38%	3.26%	3.95%	1.63%
Dividend yield	—	—	—	—
Expected term	6.00	6.05	5.94	6.03
Expected volatility	94.40%	92.03%	94.64%	91.85%
Weighted-average fair value of common stock	\$ 1.31	\$ 1.29	\$ 1.15	\$ 3.10

The expected term of the Company's stock options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. Under the simplified method, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data and the plain nature of its stock-based awards.

The weighted average grant date fair value of stock options granted to employees was \$1.02 and \$0.99 during the three months ended June 30, 2023 and 2022, respectively, and \$0.90 and \$2.33 during the six months ended June 30, 2023 and 2022, respectively.

As of June 30, 2023, total unrecognized compensation expense related to unvested employee stock options was \$13.2 million, which is expected to be recognized over a weighted average period of 2.7 years.

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

	Number of options	Weighted-average exercise price (\$)	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
<b>Employees</b>				
Outstanding at December 31, 2022	15,578,412	\$ 3.44	7.57	\$ 4
Granted	5,477,200	\$ 1.15		
Forfeited	(1,207,712)	\$ 2.84		
Outstanding at June 30, 2023	<u>19,847,900</u>	\$ 2.85	7.93	\$ 1
Vested at June 30, 2023	8,956,975	\$ 3.92	6.68	\$ 1
Vested and expected to vest at June 30, 2023	18,564,837	\$ 2.93	7.84	\$ 1
<b>Non-employee consultants</b>				
Outstanding at December 31, 2022	266,239	\$ 8.05	5.08	\$ —
Outstanding at June 30, 2023	<u>266,239</u>	\$ 8.05	4.58	\$ —
Vested at June 30, 2023	266,239	\$ 8.05	4.58	\$ —
Vested and expected to vest at June 30, 2023	266,239	\$ 8.05	4.58	\$ —

### Restricted Stock Units

During the six months ended June 30, 2023, the Company granted 1,054,600 restricted stock awards with a weighted average fair value of \$1.13 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 experience.

Unrecognized compensation expense for all restricted stock units was \$3.1 million as of June 30, 2023, which is expected to be recognized over a weighted average period of 2.5 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, 2022	1,705,558	\$ 2.62
Granted	1,054,600	1.13
Vested	(277,193)	3.22
Forfeited	(71,173)	1.99
Unvested at June 30, 2023	<u>2,411,792</u>	<u>\$ 1.92</u>

### 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 2023, the number of shares of common stock authorized for issuance under the ESPP was increased by 1,530,424 shares. During the six months ended June 30, 2023, the Company issued 108,068 shares of common stock under the ESPP. As of June 30, 2023, 5,060,074 shares remain available for future issuance under the ESPP.

For each of the three and six months ended June 30, 2023 and 2022, the Company recognized less than \$0.1 million of stock-based compensation expense under the ESPP.

## 12. Revenue Arrangements

### Astellas Gene Therapies

In January 2023, the Company entered into a License and Development Agreement, or the Astellas Agreement, with Audentes Therapeutics, Inc., doing business as Astellas. Under the Astellas Agreement, the Company granted Astellas an exclusive license to the Company's IdeXork technology arising from Xork (defined below), to develop and commercialize Xork for use in Pompe disease in combination with an Astellas gene therapy investigational or authorized product. Xork, Genovis' IgG Protease, is licensed by the Genovis Agreement, as described in Note 14 to these consolidated financial statements, Astellas paid a \$10.0 million upfront payment to the Company upon signing of the Astellas Agreement, and the Company is entitled to receive up to \$340.0 million in future additional payments over the course of the partnership that are contingent on the achievement of various development and regulatory milestones and, if commercialized, sales thresholds for annual net sales where Xork is used as a pre-treatment for an Astellas investigational or authorized product, and tiered royalty payments ranging from low to high single digits.

Pursuant to the Astellas Agreement, the Company will have the exclusive right and responsibility to complete research and development of Xork products and to conduct all preclinical studies and clinical trials for Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product, or the Xork Development Services. Astellas will reimburse the Company for 25% of all budgeted costs incurred to complete the development of Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product. The Company will have control and responsibility over regulatory filings, including any investigational drug applications, biologics license applications, and marketing authorization applications relating to the licensed product. Astellas will have the exclusive right and responsibility to research, develop, and commercialize Astellas products used in combination with Xork and will have control and responsibility over all regulatory filings, including any investigational drug applications, biologics license applications, and marketing authorization applications, relating to Astellas products and Astellas products used in combination with Xork.

The Company determined the Astellas Agreement represents a service arrangement under the scope of ASC 606. The Company determined that the sublicense of Xork to Astellas, the licensed know-how, and the Xork Development Services represent a single promise and performance obligation to be transferred to Astellas over time due to the nature of the promises in the contract. As such, the Company will recognize the transaction price as revenue utilizing the input method to measure the progress of satisfying the single performance obligation to Astellas.

In determining the transaction price, the Company concluded the upfront payment of \$10.0 million and development cost reimbursements of \$5.5 million will be included in the initial transaction price. All other development milestones will be fully constrained and will only be included in the transaction price when the applicable 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 development 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. 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. The Company determined that a significant financing component does not exist in its arrangement with Astellas. The Company also determined the options to negotiate additional fields, enter into a clinical supply agreement, and enter into a commercial supply agreement do not represent material rights under the Astellas Agreement. Astellas has the right to terminate the Astellas Agreement in its entirety or on a field-by-field basis, upon 90 days' written notice to the Company.

As of June 30, 2023, the Company recorded \$4.2 million as a short-term contract liability and \$4.9 million as a long-term contract liability, representing deferred revenue associated with the Astellas Agreement. As of June 30, 2023, the Company recorded a receivable of \$0.3 million, representing billings for the Xork Development Services that are subject to reimbursement by Astellas. Revenue of \$0.8 million and \$1.4 million related to the Astellas Agreement was recognized during the three and six months ended June 30, 2023, respectively.

**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. A more detailed description of the Takeda Agreement and the Company's evaluation of this agreement under ASC 606 can be found in Note 12 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022.

On March 9, 2023, the Company was notified by Takeda of the achievement of the milestone event related to the completion of a non-clinical milestone for one of the specified disease indications within the field of lysosomal storage disorders under the Takeda Agreement. Accordingly, the Company received a milestone payment of \$0.5 million during the three months ended June 30, 2023.

In April 2023, the Company was notified by Takeda of its intention to terminate the Takeda Agreement effective July 25, 2023.

As of June 30, 2023 and December 31, 2022, the Company recorded no short-term contract liability and \$0.1 million as a short-term contract liability, respectively, representing deferred revenue associated with the Takeda Agreement. Revenue of \$0.1 million and \$0.6 million related to the Takeda Agreement was recognized during the three and six months ended June 30, 2023, respectively. No revenue was recognized during the three months ended June 30, 2022, and revenue of \$1.0 million related to the Takeda Agreement was recognized during the six months ended June 30, 2022.

**Swedish Orphan Biovitrum AB (publ.)**

*License and Development Agreement*

In June 2020, the Company and Sobi entered into a License and Development Agreement, or 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 pegadricase, 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. A more detailed description of the Sobi License and the Company's evaluation of this agreement under ASC 606 can be found in Note 12 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022.

As of June 30, 2023 and December 31, 2022, the Company recorded a total outstanding receivable of \$5.1 million and \$5.0 million, respectively, representing billings for the Phase 3 DISSOLVE program that are subject to reimbursement by Sobi. Additionally, as of June 30, 2023 and December 31, 2022, the Company recorded a total unbilled receivable of \$1.1 million and \$3.2 million, respectively, representing revenue earned but not yet billed for the Phase 3 DISSOLVE program. Revenue of \$4.3 million and \$8.7 million related to the Sobi License was recognized during the three and six months ended June 30, 2023, respectively. Revenue of \$29.2 million and \$52.9 million related to the Sobi License was recognized during the three and six months ended June 30, 2022, 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

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Muscular Dystrophy subtypes, or the Indications. Sarepta initially had an option term of 24 months during which it could 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 agreed to supply ImmTOR to Sarepta for clinical supply on a cost-plus basis under the Sarepta Agreement. A more detailed description of the Sarepta Agreement and the Company's evaluation of this agreement under ASC 606 can be found in Note 12 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022.

On March 13, 2023, the Company was notified by Sarepta that Sarepta would not be exercising its exclusive option under the Sarepta Agreement. Therefore, the remaining deferred revenue balance as of December 31, 2022 of \$0.5 million was recognized as revenue during the six months ended June 30, 2023. No revenue was recognized during the three months ended June 30, 2023. Revenue of \$10.1 million and \$10.2 million was recognized during the three and six months ended June 30, 2022, respectively.

### **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 six months ended June 30, 2022. No revenue was recognized during the three months ended June 30, 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 June 30, 2023, the aggregate amount of the transaction price allocated to remaining performance obligations was \$9.1 million.

### **Contract Balances from Contracts with Customers**

The following table presents changes in the Company's contract liabilities during the six months ended June 30, 2023 (in thousands):

	<u>Balance at beginning of period</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at end of period</u>
<b>Six Months Ended June 30, 2023</b>				
Contract liabilities:				
Deferred revenue	\$ 593	\$ 10,500	\$ (1,996)	\$ 9,097
Total contract liabilities	<u>\$ 593</u>	<u>\$ 10,500</u>	<u>\$ (1,996)</u>	<u>\$ 9,097</u>

## **13. Related-Party Transactions**

#### *April 2022 Offering*

During the three and six months ended June 30, 2022, the Company completed the underwritten offering as described in Note 10 to the consolidated financial statements within the Company's Annual Report on Form 10-K for the year ended December 31, 2022. The following table sets forth the number of shares of common stock and 2022 Warrants purchased in such offering by directors and executive officers, as of the time of such offering, and related parties thereto:

<u>Name</u>	<u>Shares of common stock purchased</u>	<u>2022 Warrants purchased</u>	<u>Total aggregate purchase price</u>
TAS Partners, LLC (affiliate of Timothy A. Springer, Ph.D.)	6,681,600	5,011,200	\$ 9,421,056

During the three and six months ended June 30, 2023, there were no related party transactions.

## 14. Collaboration and License Agreements

### Ginkgo Bioworks Holdings, Inc.

#### *Collaboration and License Agreements*

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 adeno-associated virus, or 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 research and development fees, clinical and commercial milestone payments of up to \$85.0 million in cash, as well as certain milestone payments for fixed fair values in the form of shares of the Company's common stock. 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.

On June 13, 2022, the Company was notified of the achievement of the midpoint of the technical development plan under the First Ginkgo Agreement by Ginkgo. This milestone resulted in the payment of \$0.5 million and issuance of 892,857 shares of the Company's common stock then-valued at \$1.0 million to Ginkgo during the year ended December 31, 2022.

On July 19, 2023, the Company and Ginkgo mutually agreed that the completion of the technical development plan's midpoint task under the Second Ginkgo Agreement had been achieved as of June 30, 2023. This milestone resulted in the accrual of \$2.5 million as of June 30, 2023 expected to be settled through a payment of \$1.0 million and future issuance of 1,339,285 shares of the Company's common stock then-valued at \$1.5 million to Ginkgo.

### 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 from the Company development and sales-based milestones and sublicensing fees. The Genovis Agreement was assessed for



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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.

In February 2023, the Company made a \$4.0 million payment to Genovis as a result of the sublicense of Xork to Astellas. See Note 12 to these unaudited consolidated financial statements for further discussion on the Astellas Agreement.

### **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 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 \$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 has recognized the \$2.0 million investment of Cyrus' Series B Preferred Stock at cost on the purchase date.

On June 13, 2022, the Company and Cyrus mutually agreed that the preclinical key in-vitro success milestone had been achieved.

As of June 30, 2023, 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, or the AskBio Collaboration Agreement, with Asklepios Biopharmaceutical, Inc., or AskBio. 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.

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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 AskBio intended to opt-out of development of the MMA indication. The AskBio Collaboration Agreement otherwise remains in effect. Consequently, the Company has assumed all rights to the MMA program. The Company filed an investigational new drug application, or IND, to conduct a Phase 1/2 clinical trial of its SEL-302 product candidate in pediatric patients with MMA in the third quarter of 2021. In December 2022, the Company initiated Reimagine, the Phase 1/2 clinical trial of SEL-302, however, the Company has since paused further development of SEL-302 for the treatment of MMA.

The SEL-399 program combined an empty AAV capsid (EMC-101), which is an AAV capsid containing no transgene, with ImmTOR and is being conducted in partnership with AskBio. Building on the preclinical data 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, development and commercialization 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 has 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 related 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 and comprehensive income (loss).

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.

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During the three and six months ended June 30, 2023, the Company recognized less than \$0.1 million and \$0.1 million, respectively, of collaboration expense under the AskBio Collaboration Agreement in which actual costs incurred by both parties approximate a 50% cost share. During the three and six months ended June 30, 2022, the Company recognized \$0.2 million and \$0.6 million, respectively, of collaboration expense under the AskBio Collaboration Agreement.

### **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 June 30, 2023, 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. In connection with the Spark Purchase Agreement and the calculated premium paid by Spark for the equity investments made as described in Note 12 to the consolidated financial statements within the Company's Annual Report on Form 10-K for the year ended December 31, 2022, the Company has made additional contractual payments pursuant to the MIT License which totaled \$0.4 million as of June 30, 2023. The Company made no additional payments during the three and six months ended June 30, 2023.

### **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 June 30, 2023. 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 June 30, 2023, the Company has performed a high-level analysis of the impact of this legislation enactment and determined the projected taxable loss position for 2023 does not result in income tax due. As of December 31, 2022, the Company has \$62.4 million of federal net operating losses available, subject to an 80% limitation. The Company also has \$2.3 million of federal tax credits, subject to a 75% limitation. The Company maintains its full valuation allowance.

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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 research and development tax credit study through December 31, 2020. The Company generated research credits for the years ended December 31, 2022 and 2021, but has not conducted a formal study to document its qualified activities.

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(k) Plan, under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The 401(k) Plan provides for matching contributions on a portion of participant contributions pursuant to the 401(k) Plan's matching formula. Commencing in January 2022, all matching contributions vest ratably over two years and participant contributions vest immediately. Contributions by the Company totaled \$0.1 million during each of the three months ended June 30, 2023 and 2022, and \$0.2 million during each of the six months ended June 30, 2023 and 2022.

### **17. Commitments and Contingencies**

As of June 30, 2023, 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.

### **Other**

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

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

### **18. Subsequent Events**

The Company has evaluated subsequent events through the date on which the consolidated financial statements were issued. The Company has concluded that no subsequent events have occurred that require disclosure, except as disclosed within these consolidated financial statements.

## 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, 2022, which we filed with the SEC on March 2, 2023. 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, 2022 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 biotechnology company leveraging our ImmTOR<sup>®</sup> platform to develop tolerogenic therapies designed to selectively mitigate unwanted immune responses. With a proven ability to induce tolerance to highly immunogenic proteins, ImmTOR has the potential to amplify the efficacy of biologic therapies, including redosing of life-saving gene therapies, as well as restore the body’s natural self-tolerance in autoimmune diseases. We have several proprietary and partnered programs in our pipeline focused on enzyme therapies, gene therapies, and autoimmune diseases.

In April 2023, in light of current market conditions, our Board of Directors, or the Board, took steps to extend cash runway by pausing further development of SEL-302 for the treatment of methylmalonic acidemia, or MMA, and conducting a targeted headcount reduction of approximately 25%. On August 17, 2023, we announced additional steps to extend cash runway and maximize value for stockholders by continuing to prioritize development of SEL-212 and support of our collaboration with Astellas Gene Therapies, or Astellas, for Xork, and pausing further development of all of our other clinical and preclinical product candidates that we are no longer actively advancing. We intend to seek collaboration partners for the assets in the development programs that we are no longer actively advancing.

### Our Product Candidates

Our ImmTOR platform has a broad range of potential applications. Our product development strategy has historically been 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 announced positive topline results from the Phase 3 DISSOLVE I and DISSOLVE II clinical trials in March 2023, 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 immunoglobulin G, or IgG, protease, called 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 capsid-specific 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 potentially 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 molecule 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 molecule 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.

### **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 serum urate to the more soluble metabolite, allantoin. There is a natural limit to the amount of serum urate that can be excreted by the kidneys, which decreases with age and can be reduced by some medications. By converting serum urate to allantoin, uricase provides an additional way for the body to reduce serum urate.

On March 21, 2023, we announced top-line data from the Phase 3 DISSOLVE I and II trials. Top-line results include:

- During month six, 56% and 48% of DISSOLVE I patients randomized to receive SEL-212 at the high dose of 0.15 mg/kg of ImmTOR ( $p < 0.0001$ ) and the low dose of 0.1 mg/kg of ImmTOR ( $p < 0.0001$ ), respectively, reached the primary endpoint of serum urate (SU) levels  $< 6$  mg/dL for 80% of the time in month six, compared to 4% of patients randomized to receive placebo. During month six, 47% and 41% of DISSOLVE II patients randomized to receive SEL-212 at the high dose ( $p = 0.0002$ ) and the low dose ( $p = 0.0015$ ) of ImmTOR, respectively, reached the primary endpoint, compared to 12% of patients randomized to receive placebo.

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- 65% and 47% of DISSOLVE I patients 50 years and older randomized to receive SEL-212 at the high dose ( $p < 0.0001$ ) and the low dose ( $p < 0.0001$ ) of ImmTOR, respectively, reached the primary endpoint, compared to 5% of patients randomized to receive placebo; 48% and 45% of DISSOLVE II patients 50 years and older randomized to receive SEL-212 the high dose ( $p = 0.0017$ ) and the low dose ( $p = 0.0044$ ) of ImmTOR, respectively, reached the primary endpoint, compared to 14% of patients randomized to receive placebo.
- In DISSOLVE I, a significant and clinically meaningful overall reduction of 69% in mean SU levels at month six was observed in patients randomized to receive SEL-212 at the high dose, as compared with placebo.
- Adverse events (AEs) identified in the trials were expected, including mild to moderate stomatitis which was observed in 3.4% of the low dose group and 9.2% of the high dose group compared to 0% in placebo across both trials, and a greater number of infusion reactions were observed at 24 hours and 1 hour after drug administration in both treatment groups compared to placebo. Treatment-related serious AEs were observed in six patients, including two cases of anaphylaxis and one gout flare in both the high and low dose treatment groups. Only 4.5% of patients receiving the low dose of SEL-212 and 3.4% at the high dose of SEL-212 had infusion reactions, across both trials, evaluated one hour post-dose. All infusion reactions occurred within the first three infusions, and each occurred during infusions and completely resolved with infusion halt and symptomatic treatment. There was one death in the six-month extension phase of the DISSOLVE I trial, which was caused by a motor vehicle accident unrelated to the study drug. There was no difference in gout flares when both treatment groups were compared to placebo.
- In the six-month extension period for the DISSOLVE I trial, 75% of patients who completed six months of SEL-212 treatment as responders were observed to continue to be successfully treated through 12 months with no infusion reactions or safety signals.

On July 10, 2023, as required under the Sobi License, we transferred control and ownership of the investigational new drug applications, or INDs, associated with SEL-212 to Sobi.

We estimate that peak sales of SEL-212, if approved, could reach over \$700 million.

### ***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 Asklepios Biopharmaceutical, Inc., or AskBio. In October and November 2020, we received rare pediatric disease designation and orphan drug designation, respectively, from the Food and Drug Administration, or the FDA, for SEL-302, for the treatment of MMA due to methylmalonyl-CoA mutase, or MMUT gene mutations. See “—Licenses and Collaborations — Asklepios Biopharmaceutical, Inc.” 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. 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 December 2022, we initiated ReIMMAgine, the Phase 1/2 clinical trial of SEL-302, however, we have since paused further development of SEL-302 for the treatment of MMA.

### ***Gene Therapies – IgG Protease (Xork)***

We have exclusively licensed Xork, an IgG-specific protease from Genovis AB (publ.), or 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.



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In January 2023, we entered into an exclusive licensing and development agreement for Xork to be developed for use with AT845, Astellas' investigational AAV-based treatment for Pompe disease in adults. We are responsible for the early development activities and manufacturing of Xork and will maintain the rights for the development of additional indications beyond Pompe disease. We intend to work to satisfy our remaining contractual obligations in connection with our partnership with Astellas.

### ***Tolerogenic Therapies for Autoimmune Disease – ImmTOR & ImmTOR-IL***

We believe our ImmTOR platform shows potential to treat autoimmune diseases. In preclinical studies, we have observed ImmTOR's ability to induce antigen-specific T regulatory cells. We believe that 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 molecules, expanding T-regulatory cells beyond IL-2 alone and we intend to pursue a combination of ImmTOR and IL-2, which we refer to as ImmTOR-IL, in diseases for which 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 molecule 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 have paused further development of ImmTOR-IL product candidates.

Cyrus Biotechnology, Inc., or Cyrus, 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 molecule we have observed a substantial synergistic activity in increasing the percentage and durability of Treg expansion in the spleen.

### ***Licenses and Collaborations***

#### ***In-licenses***

##### ***Ginkgo Bioworks Holdings, Inc.***

In October 2021, we entered into a Collaboration and License Agreement, or the First Ginkgo Agreement, with Ginkgo Bioworks Holdings, Inc., or 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.

In January 2022, we entered into a Collaboration and License Agreement, or the Second Ginkgo Agreement, with Ginkgo. Under the Second Ginkgo Agreement, we and Ginkgo collaborate 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 June 2022, we were notified of the achievement of the midpoint of the technical development plan under the First Ginkgo Agreement by Ginkgo. In July 2023, we mutually agreed with Ginkgo that the completion of the technical development plan's midpoint task under the Second Ginkgo Agreement had been achieved as of June 2023.



***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 and sub-licensing fees, as well as tiered royalties on worldwide sales in the low double digits. Outside of the remaining contractual obligations under our partnership with Astellas, we have paused further development of Xork product candidates.

***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.

In June 2022, we mutually agreed with Cyrus that the preclinical key in-vitro success milestone had been achieved. We intend to pause further development of product candidates involving Cyrus' engineered protein therapeutics.

***Out-licenses***

***Astellas Gene Therapies***

In January 2023, we entered into a License and Development Agreement with Astellas. Under this agreement, Astellas obtained the sole and exclusive right to commercialize Xork for use in Pompe disease in combination with an Astellas gene therapy investigational or authorized product, with a current focus on AT845. In connection with entry into this agreement, we received a \$10 million upfront payment and are eligible to receive \$340.0 million for certain additional development and commercial milestones plus royalties on any potential commercial sales where Xork is used as a pre-treatment for AT845. As a result of the sublicense of Xork to Astellas, we made a \$4.0 million payment to Genovis in February 2023.

***Takeda Pharmaceuticals USA, Inc.***

In October 2021, we entered into a strategic licensing agreement, or the Takeda Agreement, with Takeda Pharmaceuticals USA, Inc., or Takeda. 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. In June 2023, we received a payment of \$0.5 million for the achievement of a certain non-clinical milestone. In April 2023, we were notified by Takeda of its intention to terminate the Takeda Agreement effective July 25, 2023.

***Swedish Orphan Biovitrum AB (publ.)***

In June 2020, we announced that we had entered into a License and Development Agreement, or the Sobi License, with Sobi 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. In July 2022, we received \$10.0 million for the completion of the enrollment of the DISSOLVE II trial.

Additionally, in 2020, 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 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. In March 2023, we announced positive topline results from the Phase 3 DISSOLVE I and DISSOLVE II clinical trials.

***Sarepta Therapeutics, Inc.***

In June 2020, we entered into a research license and option agreement, or the Sarepta Agreement, with Sarepta Therapeutics, Inc., or Sarepta. Pursuant to the Sarepta 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 had an option term of 24 months during which it was permitted to 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 paid an additional fee to us. Sarepta made an upfront payment to us upon signing of the Sarepta Agreement, and we were eligible to receive additional payments under the option term. If Sarepta opted-in to an exclusive license agreement, we could have received option exercise payments per indication and we would have been 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 preclinical milestones. In August 2022, we received a payment of \$2.0 million in exchange for a nine-month extension to Sarepta's options to both Sarepta Indications and a payment of \$4.0 million for the achievement of certain non-clinical milestones. In March 2023, we were notified by Sarepta that Sarepta would not be exercising its exclusive option under the Sarepta Agreement.

***Asklepios Biopharmaceutical, Inc.***

*Feasibility Study and License Agreement*

In August 2019, we entered into the AskBio Collaboration Agreement. The initial product candidate being developed under this collaboration is gene therapy for MMA, which is a disease that 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, although we have paused further development of SEL-302 for the treatment of MMA.

***Impact of Global Events***

***COVID-19***

We continue to closely monitor how the COVID-19 pandemic is affecting our employees, business, preclinical studies and clinical trials. 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 commence and conduct 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 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.

***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.

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Except for the year ended December 31, 2022, we have incurred significant operating losses since our inception. We incurred a net loss of \$33.1 million and had net income of \$37.4 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of \$428.0 million.

In April 2023, in light of current market conditions, our Board took steps to extend cash runway by pausing further development of SEL-302 for the treatment of MMA and conducting a targeted headcount reduction of approximately 25%. On August 17, 2023, we announced additional steps to extend cash runway and maximize value for stockholders by continuing to prioritize development of SEL-212 and support of our collaboration with Astellas for Xork, and pausing further development of all of our other clinical and preclinical product candidates that we are no longer actively advancing. We intend to seek collaboration partners for the assets in the development programs that we are no longer actively advancing. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we:

- continue to support the development of SEL-212 and satisfy our contractual obligations under our collaboration with Astellas for Xork;
- assess ways to maximize value and support further development of our product candidates, other than SEL-212 and Xork, through potential partnerships;
- seek regulatory approvals for any product candidates that successfully complete clinical trials; and
- maintain, expand and protect our intellectual property portfolio, including through licensing arrangements.

We believe that following the capital efficiencies expected to be realized through our strategic reprioritization, our existing cash, cash equivalents, and restricted cash as of June 30, 2023, combined with the next anticipated milestone payment related to SEL-212 development activities, will enable us to fund our operating expenses and capital expenditure requirements into 2027. 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 further description of the agreements underlying our collaboration and license revenue, see Note 12 to our consolidated financial statements included elsewhere in this Quarterly Report.

### **Research and development expenses**

Our research and development expenses consist of external research and development costs, which we track on a program-by-program basis and primarily include contract manufacturing organization related costs and fees paid to contract research organizations, 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.

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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 SEL-212, including but not limited to costs incurred while conducting and completing the Phase 3 DISSOLVE trials, will be reimbursed by Sobi. These costs, when reimbursed, will be recognized as revenue consistent with the revenue recognition methodology disclosed in 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.

In January 2023, we and Astellas entered into the Astellas Agreement. Pursuant to the Astellas Agreement, Astellas will reimburse us for 25% of all budgeted costs incurred to complete the development of Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product. 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.

### **General and administrative expenses**

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, net**

Other income, net consists primarily of sublease income during the three and six months ended June 30, 2023 and was de minimis during the three and six months ended June 30, 2022.

### **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 each of June 30, 2023 and December 31, 2022, we maintained cash of \$0.2 million in Russian banks accounts in denominations of both Russian rubles and 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.

[Table of Contents](#)**Results of Operations****Comparison of the Three Months Ended June 30, 2023 and 2022****Collaboration and license revenue**

The following is a comparison of collaboration and license revenue for the three months ended June 30, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended June 30,		Increase (decrease)	
	2023	2022		
Collaboration and license revenue	\$5,249	\$39,273	\$(34,024)	(87)%

During the three months ended June 30, 2023, collaboration and license revenue was \$5.2 million, compared to \$39.3 million in 2022. During the three months ended June 30, 2023 and 2022, we recognized \$4.3 million and \$29.2 million, respectively, under the license agreement with Sobi resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program. Additionally, during the three months ended June 30, 2023, \$0.8 million was recognized under the Astellas Agreement and \$0.1 million was recognized under the Takeda Agreement. During the three months ended June 30, 2022, \$10.1 million was recognized under the Sarepta Agreement.

**Research and development expenses**

The following is a comparison of research and development expenses for the three months ended June 30, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended June 30,		Increase (decrease)	
	2023	2022		
Research and development	\$17,782	\$19,182	\$(1,400)	(7%)

During the three months ended June 30, 2023, our research and development expenses decreased by \$1.4 million, or 7%, as compared to the three months ended June 30, 2022. The decrease in cost was primarily the result of the strategic reprioritization in April 2023, partially offset by a one-time cash charge to salaries and benefits as a result of our headcount reduction in April 2023 and increased contract license and milestone payments.

**General and administrative expenses**

The following is a comparison of general and administrative expenses for the three months ended June 30, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended June 30,		Increase (decrease)	
	2023	2022		
General and administrative	\$ 6,105	\$ 6,231	\$(126)	(2%)

During the three months ended June 30, 2023, our general and administrative expenses decreased by \$0.1 million, or 2%, as compared to the three months ended June 30, 2022. The decrease in costs was primarily the result of a reduction in expenses incurred for stock compensation, partially offset by a one-time cash charge to salaries and benefits as a result of our headcount reduction in April 2023.

**Investment income**

Investment income was \$1.4 million and \$0.2 million for the three months ended June 30, 2023 and 2022, respectively. The increase in investment income was due to increased investment and higher interest rates.

**Foreign currency transaction gain (loss)**

We recognized de minimis foreign currency fluctuations during each of the three months ended June 30, 2023 and 2022.

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### **Interest expense**

Interest expense was \$0.8 million and \$0.7 million for the three months ended June 30, 2023 and 2022, respectively, representing interest expense and amortization of the carrying costs of our credit facilities.

### **Change in fair value of warrant liabilities**

For the three months ended June 30, 2023, we recognized \$6.3 million of income from the decrease 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 price of our common stock. For the three months ended June 30, 2022, we recognized a \$4.6 million charge from the increase in the fair value of warrant liabilities primarily driven by an increase in the price of our common stock.

### **Other income, net**

Other income, net consists primarily of sublease income for the three months ended June 30, 2023 and was de minimis for the three months ended June 30, 2022.

### **Net (loss) income**

Net loss for the three months ended June 30, 2023 was \$11.4 million compared to net income of \$8.6 million for the three months ended June 30, 2022.

### **Comparison of the Six Months Ended June 30, 2023 and 2022**

#### **Collaboration and license revenue**

The following is a comparison of collaboration and license revenue for the six months ended June 30, 2023 and 2022 (in thousands, except percentages):

	Six Months Ended June 30,		Increase (decrease)	
	2023	2022		
Collaboration and license revenue	\$11,187	\$73,272	\$(62,085)	(85)%

During the six months ended June 30, 2023 and 2022, we recognized \$8.7 million and \$52.9 million under the Sobi License resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program. Additionally, during the six months ended June 30, 2023, \$1.4 million was recognized under the Astellas Agreement and \$0.6 million was recognized under the Takeda Agreement, and \$0.5 million was recognized under the Sarepta Agreement. During the six months ended June 30, 2022, \$10.2 million was recognized under the Sarepta Agreement, \$9.2 million was recognized upon the mutual termination of the Spark License Agreement, and \$1.0 million was recognized under the Takeda Agreement.

#### **Research and development expenses**

The following is a comparison of research and development expenses for the six months ended June 30, 2023 and 2022 (in thousands, except percentages):

	Six Months Ended June 30,		Increase (decrease)	
	2023	2022		
Research and development	\$36,406	\$36,871	\$(465)	(1)%

During the six months ended June 30, 2023, our research and development expenses decreased by \$0.5 million, or 1%, as compared to the six months ended June 30, 2022. The decrease in cost was primarily the result of the strategic reprioritization in April 2023, partially offset by increased contract license and milestone payments and a one-time cash charge to salaries and benefits as a result of our headcount reduction in April 2023.

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### General and administrative expenses

The following is a comparison of general and administrative expenses for the six months ended June 30, 2023 and 2022 (in thousands, except percentages):

	Six Months Ended June 30,		Increase (decrease)	—%
	2023	2022		
General and administrative	\$11,800	\$11,768	\$32	—%

During the six months ended June 30, 2023, our general and administrative expenses increased by less than \$0.1 million as compared to the six months ended June 30, 2022. The increase in costs was primarily driven by a one-time cash charge to salaries and benefits as a result of our headcount reduction in April 2023 partially offset by a reduction in expenses incurred for stock compensation.

### Investment income

Investment income was \$2.7 million and \$0.2 million, for the six months ended June 30, 2023 and 2022, respectively. The increase in investment income was due to increased investments and higher interest rates.

### Foreign currency transaction gain (loss)

We recognized de minimis foreign currency fluctuations during the six months ended June 30, 2023 and 2022, respectively.

### Interest expense

Interest expense was \$1.6 million and \$1.4 million for the six months ended June 30, 2023 and 2022, respectively, representing interest expense and amortization of the carrying costs of our credit facilities.

### Change in fair value of warrant liabilities

For the six months ended June 30, 2023, we recognized \$2.3 million of income for the decrease in the fair value of warrant liabilities utilizing a Black-Scholes valuation methodology. The decrease in value was primarily driven by a decrease in the remaining expected life of the warrants. For the six months ended June 30, 2022, we recognized \$13.9 million of income for the decrease in the fair value of warrant liabilities primarily driven by a decrease in the price of our common stock.

### Other income (expense)

Other income was \$0.5 million and \$0.2 million for the six months ended June 30, 2023 and 2022, respectively. The increase was primarily driven by sublease income.

### Net income (loss)

Net loss for the six months ended June 30, 2023 was \$33.1 million compared to net income of \$37.4 million for the six months ended June 30, 2022.

### Liquidity and Capital Resources

Except for the year ended December 31, 2022, in which we had net income of \$35.4 million, we have incurred recurring net losses since our inception. We expect that we will continue to incur losses and that such cumulative losses will increase for the foreseeable future.

Since inception, we have financed our operations with a combination of issuance of preferred and common stock, government grant funding, borrowings under credit facilities and proceeds from our collaboration and license agreements.

As of June 30, 2023, our cash, cash equivalents, and restricted cash were \$115.0 million, of which \$3.0 million was restricted cash related to lease commitments and \$0.2 million was held by our Russian subsidiary designated solely for use in its operations.

In addition to our existing cash equivalents, we have from time to time, and may, in the future receive research and development funding pursuant to our collaboration and license 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 a loan and security agreement among us and Oxford Finance LLC, or Oxford, as collateral agent and a lender, and Silicon Valley Bank, as a lender. The Term A Loan was funded in full on August 31, 2020, or the Funding Date, and will mature on August 1, 2025. The second draw period expired on September 30, 2021 and the Term B Loan is no longer available to be drawn by the Company.

On March 21, 2022, we entered into a Second Amendment to Loan and Security Agreement, or the Second Amendment. The Second Amendment extends the date on which amortization payments in respect of the 2020 Term Loan will commence 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 was recorded as an addition to the debt discount on the effective date.

On September 20, 2022, we entered into a Third Amendment to the Loan and Security Agreement or the Third Amendment. The Third Amendment was entered into in connection with the expansion of our corporate headquarters to provide for an increase of \$0.2 million in the letter of credit for a total of \$1.6 million which renews automatically each year.

On March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or the FDIC, was appointed as receiver. On March 13, 2023, the FDIC announced that all of Silicon Valley Bank's deposits and substantially all of its assets had been transferred to a newly created, full-service FDIC-operated bridge bank, Silicon Valley Bridge Bank, N.A., or SVBB. SVBB assumed all loans that were previously held by Silicon Valley Bank. On March 27, 2023, First-Citizens Bank & Trust Company assumed all of SVBB's customer deposits and certain other liabilities and acquired substantially all of SVBB's loans and certain other assets from the FDIC.

On March 31, 2023, we entered into a Fourth Amendment to Loan and Security Agreement or the Fourth Amendment, with Oxford as collateral agent and a lender and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (successor by purchase to the Federal Deposit Insurance Corporation as Receiver for Silicon Valley Bridge Bank, N.A. (as successor to Silicon Valley Bank)), or SVB. The Fourth Amendment relieved us of the requirement to maintain all Collateral Accounts (as such term is defined in the Loan and Security Agreement) with SVB and instead requires us to hold an amount equal to the lesser of (i) 100% of our consolidated cash and (ii) 150% of the then-outstanding Obligations (as such term is defined in the Loan and Security Agreement) in Collateral Accounts with SVB that are subject to a Control Agreement (as such term is defined in the Loan and Security Agreement) in favor of SVB.

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. We expect that we will continue to generate losses for the foreseeable future.



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As of June 30, 2023, we had an accumulated deficit of \$428.0 million. In April 2023, in light of current market conditions, our Board took steps to extend cash runway by pausing further development of SEL-302 for the treatment of MMA and conducting a targeted headcount reduction of approximately 25%. On August 17, 2023, we announced additional steps to extend cash runway and maximize value for stockholders by continuing to prioritize development of SEL-212 and support of our collaboration with Astellas for Xork, and pausing further development of all of our other clinical and preclinical product candidates that we are no longer actively advancing. We intend to seek collaboration partners for the assets in the development programs that we are no longer actively advancing. We intend to continue evaluating our development programs and operating expenses on an ongoing basis. 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, debt issuance, potential royalty and/or milestone monetization transactions and the issuance of equity instruments 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 instruments, the ownership interest of our existing stockholders will be diluted, and other preferences may be necessary that adversely affect the rights of existing stockholders.

We believe that following the capital efficiencies expected to be realized through our strategic reprioritization, our existing cash, cash equivalents, and restricted cash as of June 30, 2023, combined with the next anticipated milestone payment related to SEL-212 development activities, will enable us to fund our current planned operations into 2027, though we may realize additional cash resources upon the achievement of certain contingent collaboration milestones and we may pursue additional cash resources through public or private equity or debt financings, by establishing collaborations with other companies or through the monetization of potential royalty and/or milestone payments pursuant to our existing collaboration and license arrangements. 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 further curtail, delay, or discontinue one or more of our 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.

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

- 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;
- the size of our headcount 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;

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- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the effect of competing technological and market developments..

### Summary of Cash Flows

(In thousands)	Six Months Ended June 30,	
	2023	2022
Cash (used in) and provided by:		
Operating activities	\$(18,660)	\$(24,135)
Investing activities	28,112	9,446
Financing activities	(2,437)	38,603
Effect of exchange rate changes on cash	(49)	86
Net change in cash, cash equivalents, and restricted cash	<u>\$ 6,966</u>	<u>\$ 24,000</u>

#### *Operating activities*

Net cash used in operating activities of \$18.7 million for the six months ended June 30, 2023 included approximately \$27.6 million of net loss, adjusted for non-cash items, and approximately \$8.9 million cash provided by changes in operating assets and liabilities.

Net cash used in operating activities of \$24.1 million for the six months ended June 30, 2022 included approximately \$31.6 million of net income, adjusted for non-cash items, and uses of cash of approximately \$55.7 million for changes in operating assets and liabilities.

#### *Investing activities*

Net cash provided by investing activities for the six months ended June 30, 2023 was \$28.1 million compared to net cash provided by investing activities of \$9.4 million in the same period in 2022. The net cash provided by investing activities for each of the six months ended June 30, 2023 and 2022 was primarily proceeds from the maturities of marketable securities offset by purchases of property and equipment.

#### *Financing activities*

Net cash used in financing activities for the six months ended June 30, 2023 was \$2.4 million compared to net cash provided by financing activities of \$38.6 million in the same period in 2022. The net cash used in financing activities in the six months ended June 30, 2023 was primarily the result of repayments of principal on outstanding debt offset by proceeds from issuance of common stock under the Employee Stock Purchase Plan and in the six months ended June 30, 2022 was primarily the result of net proceeds from underwritten and “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 June 30, 2023, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission.

## **Critical Accounting Policies and Use of Estimates**

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or 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 and six months ended June 30, 2023, 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, 2022.

## **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 June 30, 2023 and December 31, 2022, we had cash, cash equivalents, restricted cash and marketable securities of \$115.0 million and \$136.2 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 policy 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 June 30, 2023.

### **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 June 30, 2023 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**

None.

**Item 1A. Risk Factors**

See the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes from the risk factors previously disclosed in such filings.

**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.

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### Item 6. Exhibits

#### EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
<a href="#">3.1(a)</a>	<a href="#">Restated Certificate of Incorporation of Selecta Biosciences, Inc.</a>	8-K	001-37798	3.1	6/29/2016
<a href="#">3.1(b)</a>	<a href="#">Certificate of Amendment to the Restated Certificate of Incorporation of Selecta Biosciences, Inc., dated June 21, 2022</a>	8-K	001-37798	3.1	6/21/2022
<a href="#">3.2</a>	<a href="#">Amended and Restated By-laws of Selecta Biosciences, Inc.</a>	8-K	001-37798	3.2	8/22/2022
<a href="#">31.1</a>	<a href="#">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</a>	—	—	—	Filed herewith
<a href="#">31.2</a>	<a href="#">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</a>	—	—	—	Filed herewith
<a href="#">32.1</a>	<a href="#">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</a>	—	—	—	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.**

Date: August 17, 2023

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

Date: August 17, 2023

By:   /s/ Blaine Davis  
Blaine Davis  
*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.

August 17, 2023

/s/ Carsten Brunn, Ph.D.

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

## CERTIFICATIONS

I, Blaine Davis, certify that:

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

August 17, 2023

/s/ Blaine Davis  
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Blaine Davis  
Chief Financial Officer  
(Principal Financial Officer)



**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
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 June 30, 2023 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 June 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 17, 2023

/s/ Carsten Brunn, Ph.D.

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

August 17, 2023

/s/ Blaine Davis

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Blaine Davis  
*Chief Financial Officer*  
*(Principal Financial Officer)*