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

# **FORM 10-Q**

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

For the quarterly period ended June 30, 2021

OR

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

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

> > Commission File Number: 001-37798

# Selecta Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction

26-1622110

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

of incorporation or organization)

65 Grove Street, Watertown, MA

(Address of principal executive offices)

02472

(Zip Code)

(617) 923-1400

(Registrant's telephone number, including area code)

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

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

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  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes 🗵 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 $\Box$	Accelerated filer $\Box$
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 6, 2021, the registrant had 115,079,292 shares of common stock, par value \$0.0001 per share, outstanding.

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### FORWARD-LOOKING STATEMENTS

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

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

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

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

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

### PART I. FINANCIAL INFORMATION

### Item 1. Financial Statements

### Selecta Biosciences, Inc. and Subsidiaries **Consolidated Balance Sheets**

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

		June 30, 2021		December 31, 2020
		(Unaudited)		
Assets				
Current assets:	<i>*</i>		<i>•</i>	100.005
Cash and cash equivalents	\$	125,749	\$	138,685
Marketable securities		24,389		
Accounts receivable		8,464		7,224
Prepaid expenses and other current assets		8,210		5,434
Total current assets		166,812		151,343
Non-current assets:				
Property and equipment, net		1,778		1,395
Right-of-use asset, net		10,399		10,948
Long-term restricted cash		1,379		1,379
Other assets		154		370
Total assets	\$	180,522	\$	165,435
Liabilities and stockholders' (deficit) equity				
Current liabilities:				
Accounts payable	\$	154	\$	443
Accrued expenses		8,861		8,146
Loan payable		2,291		_
Lease liability		977		908
Deferred revenue		75,013		72,050
Total current liabilities		87,296		81,547
Non-current liabilities:				
Loan payable, net of current portion		22,931		24,793
Lease liability		9,143		9,647
Deferred revenue		24,739		38,746
Warrant liabilities		40,635		28,708
Total liabilities		184,744		183,441
Commitments and contingencies (Note 17)				
Stockholders' (deficit) equity:				
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2021 and December 31, 2020		_		_
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 115,079,292 and 108,071,249 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively		12		11
Additional paid-in capital		424,984		391,175
Accumulated deficit		(424,661)		(404,629)
Accumulated other comprehensive loss		(4,557)		(4,563)
Total stockholders' (deficit) equity		(4,222)		(18,006)
Total liabilities and stockholders' (deficit) equity	\$	180,522	\$	165,435
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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 E	Ended June 30,		
		2021		2020		2021		2020	
				(Unat	ıdited	)			
Grant and collaboration revenue	\$	19,663	\$	—	\$	30,713	\$	_	
Operating expenses:									
Research and development		14,463		10,730		27,467		25,454	
General and administrative		4,748		5,637		9,952		9,735	
Total operating expenses		19,211		16,367		37,419		35,189	
Operating income (loss)		452		(16,367)		(6,706)		(35,189)	
Investment income		12		13		24		253	
Foreign currency transaction, net		(14)		(42)		(7)		40	
Interest expense		(711)		(205)		(1,422)		(478)	
Change in fair value of warrant liabilities		4,820		(7,539)		(11,927)		(8,385)	
Other income, net		6		59		6		58	
Net income (loss)		4,565		(24,081)		(20,032)		(43,701)	
Other comprehensive income (loss):									
Foreign currency translation adjustment		12		31		6		(29)	
Unrealized gains on marketable securities		1		_		—		_	
Total comprehensive income (loss)	\$	4,578	\$	(24,050)	\$	(20,026)	\$	(43,730)	
Net income (loss) per share:									
Basic	\$	0.04	\$	(0.25)	\$	(0.18)	\$	(0.46)	
Diluted	\$	0.00	\$	(0.25)	\$	(0.18)	\$	(0.46)	
Weighted average common shares outstanding:	· · · · · · · · · · · · · · · · · · ·		-						
Basic		113,524,110		96,785,915		112,140,815		95,754,714	
Diluted		121,177,998		96,785,915		112,140,815		95,754,714	
			-		-				

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

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

(Unaudited)

			Additional			Accumulated other	Stockholders'
	Common stock		paid-in	Accum	ulated	(Deficit)	
	Shares	Amount	capital	def	icit	loss	Equity
Balance at December 31, 2020	108,071,249	5 11	\$ 391,175	\$ (4	04,629)	\$ (4,563)	\$ (18,006)
Issuance of common stock under Employee Stock Purchase Plan	34,696		72		_	—	72
Issuance of common stock upon exercise of options	153,278	—	244		—	—	244
Issuance of vested restricted stock units	10,937	—	—		_	—	—
Issuance of common stock through at-the-market offering, net	4,706,844	—	20,943		—	_	20,943
Stock-based compensation expense	—	—	1,780			—	1,780
Currency translation adjustment	—		—		—	(6)	(6)
Unrealized (losses) on marketable securities	—	—	—		—	(1)	(1)
Net loss	—	—	—	(	24,597)	—	(24,597)
Balance at March 31, 2021	112,977,004	5 11	\$ 414,214	\$ (4	29,226)	\$ (4,570)	\$ (19,571)
Issuance of common stock upon exercise of options	242,278		425		_		425
Issuance of vested restricted stock units	10,938	—	—		_	—	_
Issuance of common stock through at-the-market offering, net	1,849,072	1	8,562		—	—	8,563
Stock-based compensation expense	—	—	1,783		—	—	1,783
Currency translation adjustment	—	—	—		—	12	12
Unrealized gain on marketable securities	—	_	—		_	1	1
Net income		_			4,565		4,565
Balance at June 30, 2021	115,079,292	5 12	\$ 424,984	\$ (4	24,661)	\$ (4,557)	\$ (4,222)

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

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

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

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

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

Cash flows from operating activities         Net loss         Adjustments to reconcile net loss to net cash used in operating activities:         Depreciation and amortization         Amortization of premiums and discounts on marketable securities         Non-cash lease expense         Loss on disposal of property and equipment         Stock-based compensation expense         Non-cash interest expense         Warrant liabilities revaluation         Changes in operating assets and liabilities:         Accounts receivable         Prepaid expenses, deposits and other assets         Accounte revenue         Accounte spayable         Deferred revenue         Accound expenses and other liabilities         Net cash used in operating activities	\$ (20,032) 512 28 549 — 3,563 594	2020 udited) \$	(43,701) 356  602
Net loss       \$         Adjustments to reconcile net loss to net cash used in operating activities:       \$         Depreciation and amortization       \$         Amortization of premiums and discounts on marketable securities       \$         Non-cash lease expense       \$         Loss on disposal of property and equipment       \$         Stock-based compensation expense       \$         Non-cash interest expense       \$         Warrant liabilities revaluation       \$         Changes in operating assets and liabilities:       \$         Accounts receivable       \$         Prepaid expenses, deposits and other assets       \$         Accounts payable       \$         Deferred revenue       \$         Accrued expenses and other liabilities       \$         Net cash used in operating activities       \$	\$ (20,032) 512 28 549 — 3,563 594		356  602
Net loss       \$         Adjustments to reconcile net loss to net cash used in operating activities:       \$         Depreciation and amortization       \$         Amortization of premiums and discounts on marketable securities       \$         Non-cash lease expense       \$         Loss on disposal of property and equipment       \$         Stock-based compensation expense       \$         Non-cash interest expense       \$         Warrant liabilities revaluation       \$         Changes in operating assets and liabilities:       \$         Accounts receivable       \$         Prepaid expenses, deposits and other assets       \$         Accounts payable       \$         Deferred revenue       \$         Accrued expenses and other liabilities       \$         Net cash used in operating activities       \$	512 28 549  3,563 594	\$	356  602
Adjustments to reconcile net loss to net cash used in operating activities:         Depreciation and amortization         Amortization of premiums and discounts on marketable securities         Non-cash lease expense         Loss on disposal of property and equipment         Stock-based compensation expense         Non-cash interest expense         Warrant liabilities revaluation         Changes in operating assets and liabilities:         Accounts receivable         Prepaid expenses, deposits and other assets         Accounts payable         Deferred revenue         Accrued expenses and other liabilities         Net cash used in operating activities	512 28 549  3,563 594	\$	356  602
Depreciation and amortization Amortization of premiums and discounts on marketable securities Non-cash lease expense Loss on disposal of property and equipment Stock-based compensation expense Non-cash interest expense Non-cash interest expense Warrant liabilities revaluation Changes in operating assets and liabilities: Accounts receivable Prepaid expenses, deposits and other assets Accounts payable Deferred revenue Accrued expenses and other liabilities Net cash used in operating activities	28 549  3,563 594		602
Amortization of premiums and discounts on marketable securities         Non-cash lease expense         Loss on disposal of property and equipment         Stock-based compensation expense         Non-cash interest expense         Warrant liabilities revaluation         Changes in operating assets and liabilities:         Accounts receivable         Prepaid expenses, deposits and other assets         Accounts payable         Deferred revenue         Accrued expenses and other liabilities         Net cash used in operating activities	28 549  3,563 594		602
Non-cash lease expense         Loss on disposal of property and equipment         Stock-based compensation expense         Non-cash interest expense         Warrant liabilities revaluation         Changes in operating assets and liabilities:         Accounts receivable         Prepaid expenses, deposits and other assets         Accounts payable         Deferred revenue         Accrued expenses and other liabilities         Net cash used in operating activities	549 — 3,563 594		
Loss on disposal of property and equipment         Stock-based compensation expense         Non-cash interest expense         Warrant liabilities revaluation         Changes in operating assets and liabilities:         Accounts receivable         Prepaid expenses, deposits and other assets         Accounts payable         Deferred revenue         Accrued expenses and other liabilities         Net cash used in operating activities	 3,563 594		
Stock-based compensation expense         Non-cash interest expense         Warrant liabilities revaluation         Changes in operating assets and liabilities:         Accounts receivable         Prepaid expenses, deposits and other assets         Accounts payable         Deferred revenue         Accrued expenses and other liabilities         Net cash used in operating activities	594		(25)
Non-cash interest expense         Warrant liabilities revaluation         Changes in operating assets and liabilities:         Accounts receivable         Prepaid expenses, deposits and other assets         Accounts payable         Deferred revenue         Accrued expenses and other liabilities         Net cash used in operating activities	594		(35)
Warrant liabilities revaluation         Changes in operating assets and liabilities:         Accounts receivable         Prepaid expenses, deposits and other assets         Accounts payable         Deferred revenue         Accrued expenses and other liabilities         Net cash used in operating activities			2,890
Changes in operating assets and liabilities: Accounts receivable Prepaid expenses, deposits and other assets Accounts payable Deferred revenue Accrued expenses and other liabilities Net cash used in operating activities			173
Accounts receivable Prepaid expenses, deposits and other assets Accounts payable Deferred revenue Accrued expenses and other liabilities Net cash used in operating activities	11,927		8,385
Prepaid expenses, deposits and other assets Accounts payable Deferred revenue Accrued expenses and other liabilities Net cash used in operating activities			
Accounts payable Deferred revenue Accrued expenses and other liabilities Net cash used in operating activities	(1,241)		5,000
Deferred revenue Accrued expenses and other liabilities Net cash used in operating activities	(2,811)		451
Accrued expenses and other liabilities	(289)		735
Net cash used in operating activities	(11,046)		2,000
· ·	70		(362)
Cash flows from investing activities	(18,176)		(23,506)
Purchases of marketable securities	(24,417)		—
Purchases of property and equipment	(643)		(334)
Proceeds from the sale of property and equipment	—		45
Net cash used in investing activities	(25,060)		(289)
Cash flows from financing activities			
Repayments of principal on outstanding debt	—		(4,200)
Net proceeds from issuance of common stock- at-the-market offering	29,547		2,137
Issuance costs paid for December 2019 financing	_		(4,381)
Other financing fees	_		(147)
Proceeds from exercise of pre-funded and common warrants	—		49
Proceeds from exercise of stock options	672		101
Proceeds from issuance of common stock under Employee Stock Purchase Plan	72		114
Net cash provided by (used in) financing activities	30,291		(6,327)
Effect of exchange rate changes on cash	9		(42)
Net change in cash, cash equivalents, and restricted cash	(12,936)		(30,164)
Cash, cash equivalents, and restricted cash at beginning of period	140,064		91,551
Cash, cash equivalents, and restricted cash at end of period	\$ 127,128	\$	61,387
Supplement cash flow information	• , -	:	- ,
Cash paid for interest \$	\$ 998	\$	387
Noncash investing and financing activities	¢ 550	Ψ	507
Cashless warrant exercise \$	s —	\$	17,089
Reclassification of warrant liability to equity upon exercise of warrants		\$	77
Purchase of property and equipment not yet paid	•	\$	
Equity offering costs in accrued liabilities	۲ ۲ ۲		111

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

### Selecta Biosciences, Inc. and Subsidiaries

### Notes to Consolidated Financial Statements (Unaudited)

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

Selecta Biosciences, Inc., or the Company, was incorporated in Delaware on December 10, 2007, and is based in Watertown, Massachusetts. The Company is a clinical-stage biopharmaceutical company leveraging its ImmTOR<sup>™</sup> immune tolerance platform with the goals of amplifying the efficacy of biologics, including enabling the re-dosing of life-saving gene therapies, and restoring self-tolerance in autoimmune diseases. The Company's ImmTOR platform encapsulates rapamycin, also known as sirolimus, an immunomodulator, in biodegradable nanoparticles and is designed to induce antigen-specific immune tolerance. The Company believes ImmTOR has the potential to enhance the efficacy without compromising the safety of biologic therapies, improve product candidates under development, and enable novel therapeutic modalities. Since inception, the Company has devoted its efforts principally to research and development of its technology and product candidates, recruiting management and technical staff, acquiring operating assets, and raising capital.

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

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

### **Unaudited Interim Financial Information**

The accompanying unaudited consolidated financial statements for the three and six months ended June 30, 2021 and 2020 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, 2020 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 12, 2021. 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 for a fair statement of the Company's financial position as of June 30, 2021, consolidated results of operations for the three and six months ended June 30, 2021, and cash flows for the six months ended June 30, 2021. Such adjustments are of a normal and recurring nature. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

### Liquidity and Management's Plan

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

To date, the Company has financed its operations primarily through the initial public offering of its common stock, private placements of its common stock, issuances of common and preferred stock, debt, research grants and research collaborations. The Company currently has no source of product revenue, and it does not expect to generate product revenue for the foreseeable future. To date, all of the Company's revenue has been collaboration and grant revenue. The Company has devoted substantially all of its financial resources and efforts to developing its ImmTOR platform, identifying potential product candidates and conducting preclinical studies and its clinical trials. The Company is in the early stages of development of its product candidates, and it has not completed development of any ImmTOR-enabled therapies.



As of June 30, 2021, the Company's cash, cash equivalents, restricted cash and marketable securities were \$151.5 million, of which \$1.4 million was restricted cash related to lease commitments and \$0.3 million was held by its Russian subsidiary designated solely for use in its operations. The Company believes the cash, cash equivalents, restricted cash and marketable securities as of June 30, 2021 will enable it to fund its operating expenses and capital expenditure requirements for at least twelve months from the issuance of these financial statements. As of June 30, 2021, the Company had an accumulated deficit of \$424.7 million. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates, conducting preclinical studies and clinical trials, and its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy, and the Company will pursue a range of options to secure additional capital.

At this time, any impact of COVID-19 on the Company's business, revenues, results of operations and financial condition will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, supply chain disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

#### **Guarantees and Indemnifications**

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through June 30, 2021, 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

There have been no material changes to the Company's significant accounting policies during the three months ended June 30, 2021, as compared to the significant accounting policies disclosed 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, 2020.

### **Recent Accounting Pronouncements**

#### Recently Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740) - Simplifying the Accounting for Income Taxes*. ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The Company adopted the new standard effective January 1, 2021, and there was no impact on its consolidated financial statements.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company adopted the new standard effective January 1, 2021, and there was no impact on its consolidated financial statements.

### Not Yet Adopted

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)*. ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. This new standard will be effective for us for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than the fiscal year beginning after December 15, 2020. The Company is assessing the impact this standard will have on its consolidated financial statements and disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments.* Subsequently, in November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses.* ASU 2016-13 requires entities to measure all expected credit losses for most financial assets held at the reporting date based on an expected loss model which includes historical experience, current conditions, and reasonable and supportable forecasts. ASU 2016-13 also requires enhanced disclosures to help financial statement users better understand significant estimates and judgments used in estimating credit losses. This new standard will be effective for us for fiscal years beginning after December 15, 2021. The Company is assessing the impact this standard will have on its consolidated financial statements and disclosures.



### 3. Marketable Securities

The following table summarizes the marketable securities held as of June 30, 2021 (in thousands):

	1	Amortized cost		Unrealized gains		<b>Unrealized losses</b>		Fair value
June 30, 2021								
Corporate bonds	\$	2,007	\$	—	\$	—	\$	2,007
Commercial paper		22,382		—		—		22,382
Total	\$	24,389	\$		\$		\$	24,389

All marketable securities held at June 30, 2021 had maturities of less than 12 months when purchased and are classified as short-term marketable securities on the accompanying consolidated balance sheet. During the six months ended June 30, 2021, there were no marketable securities adjusted for other than temporary declines in fair value.

As of December 31, 2020, the Company held no marketable securities.

### 4. Net Income (Loss) Per Share

The Company has reported a net income for the three months ended June 30, 2021. The 2019 warrants have been included in the calculation of diluted net income per share for the three months ended June 30, 2021 as the warrants are both liability-classified and in-the-money. The Company used the treasury stock method to determine the number of dilutive shares. The following table sets forth the computation of basic and diluted net income per share (in thousands, except share and per-share data) for the three months ended June 30, 2021:

		hree Months nded June 30,
		2021
Numerator:		
Net income (loss)	\$	4,565
Less: Change in fair value of 2019 warrants		(4,820)
Adjusted net loss	\$	(255)
Denominator:	_	
Weighted-average common shares used in per share calculations - basic		113,524,110
Dilutive effect of employee equity incentive plans and outstanding warrants		7,653,888
Weighted-average common shares used in per share calculations - diluted		121,177,998
Net income (loss) per share:		
Basic	\$	0.04
Diluted	\$	0.00

For the three months ended June 30, 2020 and the six months ended June 30, 2021 and 2020, all potentially dilutive securities are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore basic and diluted net loss per share were the same for all periods presented.

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

	Three Months <b>E</b>	Ended June 30,	Six Months E	nded June 30,
	2021	2020	2021	2020
Options, RSUs and ESPP shares	10,574,133	7,671,099	10,574,133	7,671,099
Warrants to purchase common stock	292,469	14,841,100	12,378,016	14,841,100
Total	10,866,602	22,512,199	22,952,149	22,512,199

### 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, 2021 and December 31, 2020 (in thousands):

	June 30, 2021							
		Total		(Level 1)		(Level 2)		(Level 3)
Assets:		<u>.</u>						
Money market funds (included in cash equivalents)	\$	56,160	\$	56,160	\$	—	\$	—
Marketable securities:								
Corporate bonds		2,007		—		2,007		—
Commercial paper		22,382		—		22,382		
Total assets	\$	80,549	\$	56,160	\$	24,389	\$	_
Liabilities:								
Warrant liabilities	\$	40,635	\$	—	\$	—	\$	40,635
Total liabilities	\$	40,635	\$		\$	_	\$	40,635

	December 31, 2020																
	 Total		(Level 1)		(Level 1)		(Level 1) (Level 2)		(Level 3)								
Assets:																	
Money market funds (included in cash equivalents)	\$ 80,576	\$	80,576	\$	_	\$	_										
Total assets	\$ 80,576	\$	80,576	\$	_	\$	—										
Liabilities:																	
Warrant liabilities	\$ 28,708	\$	—	\$	—	\$	28,708										
Total liabilities	\$ 28,708	\$	_	\$	—	\$	28,708										
		_		_		_											

There were no transfers within the fair value hierarchy during the six months ended June 30, 2021 or the year ended December 31, 2020.

### Cash, Cash Equivalents, and Restricted Cash

As of June 30, 2021 and December 31, 2020, the money market funds were classified as cash and cash equivalents on the accompanying consolidated balance sheets as they mature within 90 days from the date of purchase.

As of June 30, 2021, the Company had restricted cash balances relating to a secured letter of credit in connection with its lease for the Company's headquarters (see Note 8 included elsewhere in this Quarterly Report). The Company's consolidated statement of cash flows includes the following as of June 30, 2021 and 2020 (in thousands):

	June 30,			
		2021		2020
Cash and cash equivalents	\$	125,749	\$	59,730
Short-term restricted cash		—		278
Long-term restricted cash		1,379		1,379
Total cash, cash equivalents, and restricted cash	\$	127,128	\$	61,387

### Marketable Securities

As of June 30, 2021, marketable securities classified as Level 2 within the valuation hierarchy consist of corporate bonds and commercial paper. Marketable securities represent holdings of available-for-sale marketable debt securities in accordance with the Company's investment policy. The Company estimates the fair values 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, 2021, given the recent issuance of the Term A Loan under the 2020 Term Loan, the Company believes the carrying value approximates the fair value of the loan.

### Common Warrants

In December 2019, the Company issued common warrants in connection with a private placement of common shares. Pursuant to the terms of the common warrants, the Company could be required to settle the common warrants in cash in the event of certain acquisitions of the Company and, as a result, the common warrants are required to be measured at fair value and reported as a liability on the balance sheet. The Company recorded the fair value of the common warrants upon issuance using the Black-Scholes valuation model and is required to revalue the common warrants at each reporting date with any changes in fair value recorded in the statement of operations and comprehensive income (loss). The valuation of the common warrants is considered Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The change in the fair value of the Level 3 warrant liability is reflected in the statement of operations and comprehensive income (loss) for the three and six months ended June 30, 2021 and 2020.

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

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

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

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

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

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

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

	June 30,
	2021
Risk-free interest rate	0.46 %
Dividend yield	—
Expected life (in years)	3.48
Expected volatility	97.48 %

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

The following table reflects a roll-forward of fair value for the Company's Level 3 warrant liabilities (see Note 10), for the six months ended June 30, 2021 (in thousands):

	Warra	nt liabilities
Fair value as of December 31, 2020	\$	28,708
Change in fair value		11,927
Fair value as of June 30, 2021	\$	40,635



### 6. Property and Equipment

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

	J	June 30,		ember 31,
		2021		2020
Laboratory equipment	\$	5,003	\$	4,427
Computer equipment and software		710		532
Leasehold improvements		41		38
Furniture and fixtures		327		327
Office equipment		163		163
Construction in process		44		163
Total property and equipment		6,288		5,650
Less accumulated depreciation		(4,510)		(4,255)
Property and equipment, net	\$	1,778	\$	1,395

Depreciation expense was \$0.2 million and \$0.3 million for the three and six months ended June 30, 2021, respectively. Depreciation expense was \$0.2 million and \$0.4 million for the three and six months ended June 30, 2020, respectively.

### 7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30,		ember 31,
	2021		2020
Payroll and employee related expenses	\$ 2,205	\$	3,049
Collaboration and licensing	1,350		1,350
Accrued patent fees	495		534
Accrued external research and development costs	3,634		2,029
Accrued professional and consulting services	661		798
Accrued interest	165		170
Other	351		216
Accrued expenses	\$ 8,861	\$	8,146

### 8. Leases

### 65 Grove Street Lease

In July 2019, the Company entered into a lease for 25,078 square feet of laboratory and office space located at 65 Grove Street, Watertown, Massachusetts, or the Headquarters Lease. As part of the Headquarters Lease, the Company incurred \$0.8 million in non-reimbursable construction costs. The lease began in March 2020, when the Company took control of the office space, and the lease term is 8 years. The discount rate of 8.9% was determined based on the Company's incremental borrowing rate adjusted for the lease term, including any reasonably certain renewal periods. In connection with the Headquarters Lease, the Company secured a letter of credit from Silicon Valley Bank, or SVB, for \$1.4 million, recognized as longterm restricted cash, as of June 30, 2021 and December 31, 2020, respectively, which automatically renews each year.

### Moscow, Russia Lease

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



As of June 30, 2021 and December 31, 2020, the components of the operating leases were as follows (in thousands):

	June 30, 2021	D	ecember 31, 2020
Assets:			
Right-of-use asset, net	\$ 10,399	\$	10,948
Liabilities:			
Current operating lease liabilities	\$ 977	\$	908
Non-current operating lease liabilities	9,143		9,647
Total operating lease liabilities	\$ 10,120	\$	10,555
	 	-	

For the three and six months ended June 30, 2021 and 2020 the components of lease costs were as follows (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
		2021		2020	2021		2020	
Operating lease cost	\$	454	\$	613	\$ 898	\$	1,085	
Variable lease cost		182		174	470		373	
Short-term lease cost		2		3	5		5	
Total lease cost	\$	638	\$	790	\$ 1,373	\$	1,463	

The maturity of the Company's operating lease liabilities as of June 30, 2021 were as follows (in thousands):

	June 30,
	2021
2021 (remainder)	\$ 914
2022	1,866
2023	1,922
2024	1,980
2025	2,039
Thereafter	4,945
Total future minimum lease payments	13,666
Less imputed interest	3,546
Total operating lease liabilities	\$ 10,120

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

	June 30,			
	2021	2020		
Cash paid for amounts included in the measurement of lease liabilities:	\$ 898	\$	825	

Other than the initial recording of the right-of-use asset and lease liability for the Headquarters Lease, which is non-cash, the changes in the Company's right-of-use asset and lease liability for the six months ended June 30, 2021 and 2020 are reflected in the non-cash lease expense and accrued expenses and other liabilities, respectively, in the consolidated statements of cash flows.

The following summarizes additional information related to operating leases:

	June 3	0,
	2021	2020
Weighted-average remaining lease term	6.9 years	7.9 years
Weighted-average discount rate	8.9 %	8.9 %

### 9. Debt

### 2020 Term Loan

On August 31, 2020, the Company 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, or the Loan Agreement, between the Company and Oxford Finance LLC, or Oxford, as Collateral Agent and a Lender, and SVB, as a Lender. The Term A Loan was funded in full on August 31, 2020, or the Funding Date.

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

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

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

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

The events of default under the Loan Agreement include, but are not limited to, the Company's failure to make any payments of principal or interest under the Loan Agreement or other transaction documents, the Company's breach or default in the performance of any covenant under the Loan Agreement or other transaction documents, the occurrence of a material adverse change, the Company making a false or misleading representation or warranty in any material respect under the Loan Agreement, the Company's insolvency or bankruptcy, any attachment or judgment on the Company's assets of at least \$0.5 million, or the occurrence of any default under any agreement or obligation of the Company involving indebtedness in excess of \$0.5 million. If an event of default occurs, the Collateral Agent is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Company incurred \$0.4 million in debt issuance costs in connection with the closing of the 2020 Term Loan. Debt issuance costs are presented in the consolidated balance sheet as a direct deduction from the associated liability and amortized to interest expense over the term of the related debt.

The Company assessed all terms and features of the 2020 Term Loan to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the 2020 Term Loan, including any put, call, and contingent features. The Company determined that the interest rate collar and prepayment call option did not require bifurcation; whereas the contingent put option and default (contingent) interest rate feature met bifurcation criteria resulting in immaterial amounts.

### Warrants

On August 31, 2020, in connection with the 2020 Term A Loan, the Company issued warrants to the Lenders to purchase an aggregate of 196,850 shares of its common stock at an exercise price equal to \$2.54 per share. In accordance with ASC



815-40, these warrants are classified as permanent equity in the accompanying consolidated balance sheets and will expire ten years from the date of issuance. The initial grant date fair value of the warrants was \$0.4 million as determined by the Black-Scholes valuation model and recorded to stockholders' equity, with the SVB portion allocated to the reacquisition price of the 2017 Term Loan and the Oxford fair value portion as a loan discount to the Term A Loan.

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

### Payoff

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

As of June 30, 2021 and December 31, 2020, the outstanding principal balance under the 2020 Term Loan was \$25.0 million.

Future minimum principal and interest payments on the 2020 Term Loan as of June 30, 2021 are as follows (in thousands):

2021 (remainder)	\$ 1,004
2022	7,343
2023	8,611
2024	8,027
2025	7,274
Total minimum debt payments	32,259
Less: Amount representing interest	(5,010)
Less: Debt discount and deferred charges	(2,027)
Less: Current portion of loan payable	(2,291)
Loan payable, net of current portion	\$ 22,931

### 10. Equity

### **Equity Financings**

### August 2020 Shelf Registration Statement

On August 6, 2020, the Company filed an updated universal shelf registration statement on Form S-3 (Reg. No. 333-241692) with the SEC to sell an aggregate amount of up to \$200.0 million of certain of its securities. The shelf registration statement was declared effective by the SEC on August 14, 2020.

### "At-the-Market" Offerings

In August 2017, the Company entered into a sales agreement, or the 2017 Sales Agreement, with Jefferies LLC, as sales agent, to sell shares of its common stock with an aggregate value of up to \$50.0 million in an "at the market offering." On August 6, 2020, concurrent with the filing of the updated shelf registration statement, the Company entered into a sales agreement, or the 2020 Sales Agreement with Jefferies LLC, as sales agent, pursuant to which the Company may, from time to time, issue and sell common stock with an aggregate value of up to \$50.0 million in an "at the market offering." The 2017 Sales Agreement terminated pursuant to its terms in August 2020.

Sales of common stock, if any, pursuant to the 2020 Sales Agreement, may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a) of the Securities Act, including sales made directly through the Nasdaq Stock Market or on any other existing trading market for the Company's common stock. The Company intends to use the proceeds from the offering for working capital and other general corporate purposes. The Company may suspend or terminate the 2020 Sales Agreement at any time.

During the six months ended June 30, 2021, the Company sold 6,555,916 shares of its common stock pursuant to the 2020 Sales Agreement at an average price of approximately \$4.65 per share for aggregate net proceeds of \$29.5 million, after deducting commissions and other transaction costs. During the year ended December 31, 2020, the Company sold 1,069,486



shares of its common stock pursuant to the 2020 and 2017 Sales Agreements at an average price of approximately \$2.16 per share for aggregate net proceeds of \$2.1 million, after deducting commissions and other transaction costs.

### June 2020 Sobi Stock Purchase

On June 11, 2020, the Company entered into a stock purchase agreement with Sobi, pursuant to which the Company sold an aggregate of 5,416,390 shares of its common stock at a purchase price equal to \$4.6156 per share, which represented 120% of the 10-day volume-weighted average price of the Company's common stock prior to signing, for aggregate gross proceeds of \$25.0 million, or the Sobi Private Placement. The closing of the Sobi Private Placement occurred on July 31, 2020. The shares of common stock acquired in the Sobi Private Placement are subject to a one-year lock-up from closing, during which time Sobi is prohibited from selling or otherwise disposing of such shares.

In accordance with ASC 815, this forward sale treatment qualified as equity classification as the shares are not within the scope of ASC 480. The gross proceeds of \$25.0 million were determined to include a premium to the fair value of the Company's shares as of July 28, 2020 of approximately \$14.5 million. As a result, such amount was included in the transaction price for revenue recognition of the Sobi License. See Note 12 for details.

Also on June 11, 2020, the Company entered into a registration rights agreement (as amended by that certain letter agreement, dated as of November 4, 2020) with Sobi, pursuant to which the Company agreed to prepare and file a registration statement with respect to the resale of the shares of common stock acquired in the Sobi Private Placement. The Company will be required to file this resale registration statement within 30 days following receipt by the Company of a written request from Sobi to file such resale registration statement, and to have the registration statement declared effective within 10 business days after the SEC informs the Company that no review of such resale registration statement will be made or that the SEC has no further comments on such resale registration statement.

#### December 2019 Financing

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

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

The common warrants were revalued as of June 30, 2021 at \$40.6 million. During the three months ended June 30, 2021 and 2020, the Company recorded a change in the fair value of the warrants of \$4.8 million and \$7.5 million, respectively, in the unaudited consolidated statements of operations and comprehensive income (loss). During the six months ended June 30, 2021 and 2020, the Company recorded a change in the fair value of the warrants of \$1.9 million and \$8.4 million, respectively, in the unaudited consolidated statements of \$1.9 million and \$8.4 million, respectively, in the unaudited consolidated statements of operations and comprehensive income (loss).

### Warrants

During the six months ended June 30, 2021, there were no warrants issued, exercised, or canceled.

	Equity classified	Liability classified	Total	Weighted exercise	
Outstanding at June 30, 2021	292,469	12,085,547	12,378,016	\$	1.60

### **Reserved Shares**

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

	Period ended		
	June 30, 2021	December 31, 2020	
Exercise of common warrants	12,378,016	12,378,016	
Shares available for future stock incentive awards	7,190,779	4,916,374	
RSUs reserved for issuance	78,750	—	
Unvested restricted stock units	458,675	87,500	
Outstanding common stock options	10,002,354	7,775,249	
Total	30,108,574	25,157,139	

### 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 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 2021 and 2020, the number of shares of common stock that may be issued under the 2016 Plan was increased by 4,322,850 and 3,453,022 shares, respectively. As of June 30, 2021, 3,052,654 shares remain available for future issuance under the 2016 Plan.

In September 2018, the Company's 2018 Employment Inducement Incentive Award Plan, or the 2018 Inducement Incentive Award Plan was adopted by the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules, which authorized 1,175,000 shares of its common stock for issuance. In March 2019, the Board approved the amendment and restatement of the 2018 Inducement Incentive Award Plan to reserve an additional 2,000,000 shares of the Company's common stock for issuance thereunder. As of June 30, 2021, there are 1,591,661 shares available for future grant under the 2018 Inducement Incentive Award Plan.

### Stock-based Compensation Expense

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

	Three Months Ended June 30,					Six Months Ended June 30,			
	2021		2020		2021		2020		
Research and development	\$	786	\$	618	\$	1,540	\$	1,241	
General and administrative		997		863		2,023		1,649	
Total stock-based compensation expense	\$	1,783	\$	1,481	\$	3,563	\$	2,890	

### **Stock Options**

### Employees

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	d June 30,	Six Months Ended June 30,				
	 2021 2020			202	2021		2020
Risk-free interest rate	 1.12 %		0.39 %		0.72 %		1.61 %
Dividend yield	—		—		_		_
Expected term	6.05		5.56		6.02		6.03
Expected volatility	94.96 %		89.70 %		95.52 %		88.12 %
Weighted-average fair value of common stock	\$ 4.16	\$	2.92	\$	3.39	\$	2.36

The weighted average grant date fair value of stock options granted to employees during the three and six months ended June 30, 2021 and 2020 was \$3.19 and \$2.08, \$2.59 and \$1.73 respectively.

As of June 30, 2021 total unrecognized compensation expense related to unvested employee stock options was \$11.4 million, which is expected to be recognized over a weighted average period of 2.7 years.

Non-employee consultants

As of June 30, 2021, there was no unrecognized compensation expense related to non-employee consultants stock options.

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

	Number of options		Weighted-average exercise price (\$)	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Employees		_			
Outstanding at December 31, 2020	7,302,176	\$	3.98	8.43	\$ 4,456
Granted	3,518,000	\$	3.39		
Exercised	(395,556)	\$	1.72		
Forfeited	(895,339)	\$	2.81		
Outstanding at June 30, 2021	9,529,281	\$	3.97	8.52	\$ 11,215
Vested at June 30, 2021	3,168,694	\$	5.53	7.45	\$ 3,579
Vested and expected to vest at June 30, 2021	8,773,300	\$	4.04	8.45	\$ 10,361
Non-employee consultants					
Outstanding at December 31, 2020	473,073	\$	5.89	5.23	\$ 86
Granted	_	\$	—		
Exercised	—	\$	_		
Forfeited		\$	—		
Outstanding at June 30, 2021	473,073	\$	5.89	4.73	\$ 286
Vested at June 30, 2021	473,073	\$	5.89	4.73	\$ 286
Vested and expected to vest at June 30, 2021	473,073	\$	5.89	4.73	\$ 286

### **Restricted Stock Units**

In January 2021, the Company granted 369,800 restricted stock awards to employees under the 2016 Plan which will vest over a four year term.

In addition, during the first quarter of 2021, the Company awarded 197,500 restricted stock units to executives under the 2016 Plan, of which 98,750 were determined to be granted as of the award date consistent with ASC 718. The remaining 98,750 restricted stock units do not have a defined performance metric as of the award date, resulting in the restricted stock units being reserved for future issuance as of June 30, 2021. These restricted stock units will vest in two equal installments on the dates an applicable performance condition is achieved, on or prior to December 31, 2021. If the performance conditions are not satisfied on or prior to December 31, 2021, the restricted stock units will be forfeited for no consideration.

The restricted stock units granted during the first quarter of 2021 had a weighted average fair value of \$2.99 per share based on the closing price of the Company's common stock on the date of grant. The restricted stock units were valued at

approximately \$1.4 million on their grant date. Forfeitures are estimated at the time of grant and are adjusted, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has estimated a forfeiture rate of 10% for restricted stock awards to employees based on historical attrition trends.

Unrecognized compensation expense for all restricted stock units was \$1.2 million as of June 30, 2021, which is expected to be recognized over a weighted average period of 2.9 years.

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

	Number of shares	V	Weighted average grant date fair value (\$)
Unvested at December 31, 2020	87,500	\$	6.03
Granted	468,550		2.99
Vested	(21,875)		6.03
Reserved for issuance	98,750		2.99
Forfeited	(95,500)		2.99
Unvested at June 30, 2021	537,425	\$	3.36

#### **Employee Stock Purchase Plan**

In June 2016, the Company approved the 2016 Employee Stock Purchase Plan, or the ESPP, which authorized 173,076 shares of common stock for future issuance under the ESPP to participating employees. In January 2021 and 2020, the number of shares of common stock authorized for issuance under the ESPP was increased by 1,080,711 shares and 863,254 shares, respectively. During the six months ended June 30, 2021, the Company issued 34,696 shares of common stock under the ESPP. As of June 30, 2021, 2,546,464 shares remain available for future issuance under the ESPP.

For each of the three and six months ended June 30, 2021 and 2020, the Company recognized less than \$0.1 million of stock-based compensation expense under the ESPP.

### 12. Revenue Arrangements

#### Swedish Orphan Biovitrum

#### License and Development Agreement

On June 11, 2020, the Company and Sobi entered into the Sobi License. Pursuant to the Sobi License, the Company has agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize the Company's SEL-212 drug candidate, which is currently in development for the treatment of chronic refractory gout. The SEL-212 drug candidate is a pharmaceutical composition containing a combination of SEL-037, or the Compound, and ImmTOR. Pursuant to the Sobi License, in consideration of the license, Sobi agreed to pay the Company a one-time, up-front payment of \$75.0 million. Sobi has also agreed to make milestone payments totaling up to \$630.0 million to the Company upon the achievement of various development and regulatory milestones and, if commercialized, sales thresholds for annual net sales of SEL-212, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier.

Pursuant to the Sobi License, the Company has agreed to supply (at cost) quantities of the Compound and ImmTOR as necessary for completion of the two Phase 3 clinical trials of SEL-212 (DISSOLVE I and DISSOLVE II) and a 6-month placebo extension. The Company is required to supply quantities of the Compound until all rights to the Compound and any materials needed to manufacture the Compound are transferred to Sobi. Sobi has agreed to reimburse the Company for all budgeted costs incurred to complete development of SEL-212, including but not limited to costs incurred while conducting and completing the Phase 3 DISSOLVE trials, except for any costs of additional development activities required that are related to ImmTOR and that are unrelated to SEL-212. Sobi will have control and responsibility over all regulatory filings, including any investigational drug applications (IND), biologics license applications (BLA), and marketing authorization applications (MAA) relating to the licensed product.

The transactions contemplated by the Sobi License were consummated on July 28, 2020 following the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Sobi may terminate the Sobi License for any reason upon 180 days' written notice to the Company, whereby all rights granted under the Sobi License would revert back to the Company. In addition, if Sobi were to terminate the Sobi License, the Company has the

option to obtain a license to all patents and know-how necessary to exploit SEL-212 in existence as of the termination date from Sobi in return for making an equitable royalty payment to Sobi.

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

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

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

In determining the transaction price, the Company concluded the upfront payment of \$75.0 million and the \$5.0 million development milestone associated with the dosing of the first patient in the Phase 3 DISSOLVE trials will be included in the transaction price. All other development milestones will be fully constrained and only be included in the transaction price when the respective milestone is deemed probable of achievement. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of the evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company and probability of success criteria is estimated. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved. In accordance with ASC 606, the Company will only recognize revenue associated with sales-based milestones and royalties when the subsequent sales thresholds are reached and underlying sales occur, respectively. In connection with the Sobi Purchase Agreement, the Company determined that the gross proceeds of \$25.0 million from the Sobi Private Placement included a premium to the fair value of the Company will estimate and include in the transaction price the total reimbursements to be received from Sobi for both the manufacturing and delivery of the Compound and ImmTOR as well as conducting the Phase 3 DISSOLVE trials. The Company determined that a significant financing component does not exist in its arrangement with Sobi.

The Company allocated the transaction price based on the relative standalone selling prices of the three distinct performance obligations. The Company estimated the standalone selling price of conducting the Phase 3 DISSOLVE trials by forecasting its anticipated costs and applying a margin reflective of the industry. The Company must determine the standalone selling price of the second source supplier option by determining the discount given to Sobi multiplied by the likelihood that Sobi will exercise the option in the future. Similar to the Phase 3 program estimate, the Company estimated the discount of the option by forecasting the set-up costs and applying a margin that is reflective of the industry. As the Company will be providing the set-up and technology transfer services and the future supply at cost, the discount of the option is equal to the margin amount. The Company considered discussions with Sobi as well as probability of regulatory success of SEL-212 in determining the likelihood of exercise. The Company estimated the standalone selling price of the Combined License Obligation by utilizing a discounted cash flow model.

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



As of June 30, 2021 and December 31, 2020, the Company recorded \$68.4 million and \$68.3 million, respectively, as a short-term contract liability and \$10.2 million and \$24.2 million, respectively, as a long-term contract liability, representing deferred revenue associated with this agreement. In addition, as of June 30, 2021 the Company has recorded \$1.1 million of contract assets related to incremental costs that would not have been incurred if the Sobi License had not been obtained, of which \$1.0 million is presented in prepaid expenses and other current assets and \$0.1 million is presented in other assets in the accompanying unaudited consolidated balance sheets. Amortization of contract assets was \$0.3 million for the six months ended June 30, 2021.

As of June 30, 2021 and December 31, 2020, the Company recorded a total outstanding receivable of \$8.3 million and \$6.9 million, respectively, representing billings for the Phase 3 DISSOLVE program that are subject to reimbursement by Sobi. Revenue of \$19.5 million and \$30.6 million related to the Sobi License was recognized during the three and six months ended June 30, 2021, respectively.

### Sarepta Therapeutics, Inc.

### Research License and Option Agreement

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

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

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

The Company determined that the Sarepta Agreement and supply obligation including the delivery of the research license, the licensed know-how, the manufactured supply and delivery of materials represent a single promise and performance obligation to be transferred to Sarepta over time due to the nature of the promises in the contract. The delivery of the manufactured supply is the predominant promise within the arrangement, as it is essential to the utility of the licensed intellectual property. As such, consideration in the initial transaction price will be allocated to the single performance obligation based on the contractual price.

In determining the transaction price, the Company concluded the payment associated with all the performance milestones will be fully constrained and only be included in the transaction price when the respective milestone is deemed probable of achievement. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such study milestones is outside the control of the Company and probability of success criteria is estimated.

The Company also determined the option to enter into a future commercial license agreement and extend the term of the option does not represent a material right since it was not priced at an incremental discount. Sarepta may terminate the Sarepta Agreement for any reason upon 30 days' written notice to the Company. The Sarepta Agreement contains other customary terms and conditions, including representations and warranties, covenants, termination, and indemnification obligations in favor of each party. During the year ended December 31, 2020, the Company and Sarepta entered into two amendments relating to an additional feasibility study.

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

As of June 30, 2021, two milestones remained constrained, and as of December 31, 2020, all milestones were constrained. The Company will reevaluate the transaction price in each reporting period, as uncertain events are resolved. The Company will recognize the revenue associated with the upfront payment and combined single performance obligation utilizing the output method, over the 24 month term as the manufactured supply is delivered to Sarepta.

As of June 30, 2021 and December 31, 2020, the Company recorded \$4.9 million and \$2.0 million, respectively, as a short-term contract liability representing deferred revenue associated with this agreement. Revenue of less than \$0.1 million related to the Sarepta Agreement was recognized during each of the three and six months ended June 30, 2021. No revenue related to the Sarepta License Agreement was recognized during the three and six months ended June 30, 2020 as no deliveries were made during these periods.

### Asklepios Biopharmaceutical, Inc.

### License Agreement for Pompe Disease

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

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

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

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

In determining the transaction price, the Company concluded that the future development milestones, regulatory milestones, sales milestones, and sales royalties all represent variable consideration. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company. Consideration related to sales-based milestones as well as royalties on net sales upon commercialization by AskBio, will be recognized when the related sales occur, as they were determined to relate predominantly to the intellectual property granted to AskBio and, therefore, have also been excluded from the transaction price in accordance with the royalty recognition constraint. As of June 30, 2021 and December 31, 2020, all milestones were constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

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

At each of June 30, 2021 and December 31, 2020, the Company recorded \$1.7 million as short-term contract liability and \$5.3 million as a long-term contract liability, representing deferred revenue associated with this agreement. Revenue will be recognized over the period in which the particles are delivered. No revenue related to the AskBio License Agreement was recognized during the three and six months ended June 30, 2021 and 2020 as no deliveries were made during these periods.

### Spark Therapeutics, Inc.

#### Spark License Agreement

The disclosures relating to the Company's license and option agreement, or the Spark License Agreement, with Spark pursuant to which the Company and Spark agreed to collaborate on the development of gene therapies for certain targets utilizing the ImmTOR platform reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 which was filed with the SEC on March 12, 2021 have not materially changed since the Company filed such report.



### **Skolkovo Foundation**

During the three and six months ended June 30, 2021, revenue of \$0.1 million related to the remaining contract liability of the Russia-based Development Fund of New Technologies Development and Commercialization Center, or Skolkovo, grant funding was recognized at the expiration of the three-year audit period.

### **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, 2021, the aggregate amount of the transaction price allocated to remaining performance obligations was \$99.8 million.

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

The following table presents changes in the Company's contract liabilities during the six months ended June 30, 2021 (in thousands):

	Balance at beginning of period		Additions	Deductions	Balance at end of period
Six Months Ended June 30, 2021					
Contract liabilities:					
Deferred revenue	\$ 110,7	'96 \$	3,000	\$ (14,044)	\$ 99,752
Total contract liabilities	\$ 110,7	'96 \$	3,000	\$ (14,044)	\$ 99,752

### 13. Related-Party Transactions

### **Consulting Services**

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

### 14. Collaboration Agreements

### Asklepios Biopharmaceutical, Inc.

#### Feasibility Study and License Agreement

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

Pursuant to the AskBio Collaboration Agreement, the Company and AskBio agreed to conduct proof of concept studies to potentially validate the use of ImmTOR in conjunction with AskBio's AAV gene therapy, or SEL-302, (previously disclosed as MMA-101, in combination with ImmTOR) for the treatment of MMA, to mitigate the formation of neutralizing anti-AAV capsid antibodies, or the POC Studies. On April 29, 2021, the Company was notified by AskBio that it intended to opt-out of development of the MMA indication. Consequently, the Company will assume all rights to the MMA program and intends to continue to progress the SEL-302 program through clinical development.

The SEL-399 program combines an empty AAV capsid (EMC-101), which is an AAV capsid containing no transgene, with ImmTOR and is being conducted in partnership with AskBio. Building on the preclinical data the Company has generated showing ImmTOR's effect on mitigating or reducing the formation of neutralizing antibodies to AAV gene therapies, the Company has commenced a clinical trial of SEL-399 in healthy adult volunteers in Belgium. The goal of the SEL-399 clinical trial is to demonstrate the appropriate dose of ImmTOR in humans to mitigate the formation of antibodies to AAV capsids used in gene therapies.

The Company and AskBio will share responsibility for the research, development and commercialization of products developed under the SEL-399 program collaboration. The parties will also share research, development, and commercialization costs equally for all collaboration products, but with a right of either party to opt out of certain products, and thereby no longer be required to share costs for such products. Each party will receive a percentage of net profits under the collaboration equal to the percentage of shared costs borne by such party in the development of such product. Pursuant to the AskBio Collaboration

Agreement, AskBio is responsible for manufacturing the AAV capsids and AAV vectors and the Company is responsible for manufacturing ImmTOR.

The AskBio Collaboration Agreement is considered to be within the scope of ASC 808, as both parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the AskBio Collaboration Agreement and have identified the following promises in the arrangement (1) conducting research and development activities to develop and commercialize products under the collaboration, or the R&D Services, (2) granting a non-exclusive, non-transferable, royalty-free, fully paid up, worldwide license to certain intellectual property of the Company, or the IP Rights, for the purpose of performing the POC Studies, or the Research License, (3) granting an exclusive, nontransferable, worldwide license to the IP Rights for use in certain indications, or the Collaboration License, (4) providing manufactured supply of preclinical and clinical ImmTOR, or the Manufactured Supply, (5) participation on identified steering committees responsible for the oversight of the collaboration, or the JSC Participation, and (6) granting an exclusive option to obtain a license under the IP Rights to research, develop and commercialize Licensed Products. The Company determined that the R&D Services, Research License, Collaboration License, Manufactured Supply, and JSC Participation were not capable of being distinct, and therefore must be combined into a single performance obligation. Therefore, promises (1) through (5) identified above were combined into a single performance obligation. Furthermore, the Company evaluated the Option Agreement and determined that it does not provide AskBio with a material right under ASC 606 as the option was not priced at a discount (see discussion of the option exercise in Note 12). The Company noted that AskBio did not meet the definition of a customer within the scope of ASC 606 for any distinct performance obligations as the Company concluded that such items were not an output of the Company's ordinary activities. As such, the Company determined that the entire arrangement would be accounted for within the scope of ASC 808. In accordance with ASC 808, collaboration expenses are recognized within R&D expense and selling, general and administrative expense on the Company's condensed consolidated statements of operations.

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

For the three and six months ended June 30, 2021, the Company recognized \$0.5 million and \$1.7 million, respectively, of collaboration expense under the AskBio Collaboration Agreement in which actual costs incurred by both parties approximate a 50% cost share. For the three and six months ended June 30, 2020, the Company recognized \$0.8 million and \$2.0 million, respectively, of collaboration expense under the AskBio Collaboration Agreement.

#### **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, 2021, and in connection with the execution of the Spark License Agreement, the Company has made contractual payments pursuant to the MIT License totaling \$2.2 million for the sublicense granted to Spark, and \$0.4 million relative to the calculated premium paid by Spark for the equity investments made under the Spark Purchase Agreement. The Company made no additional payments during the six months ended June 30, 2021.

#### 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, 2021. 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.

For the three and six months ended June 30, 2021 and 2020, the Company did not record a current or deferred income tax expense or benefit.

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

Utilization of the net operating loss and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code due to ownership change limitations that have occurred previously, or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. As of December 31, 2020, the Company completed a Section 382 study. The Company has determined that all of the \$234.5 million of net operating losses are available in the future, with approximately \$36.5 million of that total limited under Section 382 and therefore available for future use through 2028.

The Company applies ASC 740, *Income Taxes* to uncertain tax positions. As of June 30, 2021 and December 31, 2020, the Company had no unrecognized tax benefits or related interest and penalties accrued.

The Company has not, as of yet, conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position.

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

### 16. Defined Contribution Plan

The Company maintains a defined contribution plan, 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. All matching contributions vest ratably over 4 years and participant contributions vest immediately. Contributions by the Company totaled less than \$0.1 million during each of the three months ended June 30, 2021 and 2020, respectively, and \$0.1 million during each of the six months ended June 30, 2021 and 2020.

### 17. Commitments and Contingencies

As of June 30, 2021, the Company was not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

On August 4, 2020, a putative stockholder of Selecta filed a stockholder derivative action, purportedly on behalf of Selecta and against certain current and former members of the Company's Board of Directors, as well as one affiliated company owned by a current board member, in the Court of Chancery of the State of Delaware, namely Franchi v. Barabe, et al. The complaint alleges that the individual defendants breached their fiduciary duties and committed corporate waste when they authorized a private placement transaction, announced on December 19, 2019, at a price allegedly below fair value. The complaint further alleges that the four defendant directors who participated in the private placement were unjustly enriched in connection with the transaction. On September 25, 2020, the defendants filed a motion to dismiss the lawsuit. On November 6, 2020, the plaintiff filed an amended complaint, and the defendants filed a second motion to dismiss on January 8, 2021. On December 31, 2020, the Company received a litigation demand letter from two other putative stockholders relating to the same private placement transaction. On April 12, 2021, the Court of Chancery in the State of Delaware granted a motion to stay the litigation pending a review by a Special Committee appointed by the Company's Board of Directors. At this time, the Company has not accrued a liability for this matter, as any liability has been determined to be either not estimable or not probable.

### Other

As permitted under Delaware law, the Company indemnifies its directors for certain events or occurrences while the director is, or was, serving at the Company's request in such capacity. The term of the indemnification is for the director's



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

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

### 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, 2020, which we filed with the SEC on March 12, 2021. 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, 2020, which we filed with the SEC on March 12, 2021. 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, 2020 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

#### Overview

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

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

We believe our ImmTOR platform has a broad range of potential applications.

*Enzyme therapies*. Enzyme 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 are especially prone to causing undesired immune responses. Our product candidate, SEL-212, which is currently in Phase 3 clinical development, includes pegadricase, a pegylated uricase enzyme, which is an example of an immunogenic enzyme for which we are applying ImmTOR with the intention of improving the enzyme's efficacy and safety. We are also combining ImmTOR with an immunoglobulin A, or IgA, protease for the treatment of IgA nephropathy. We intend to seek, if appropriate, licenses to other enzymes that we would evaluate in combination with ImmTOR.

*Gene therapies*. We believe gene therapies have the potential to address key unmet medical needs for many rare genetic diseases, but undesired immune responses to the viral vectors used for gene replacement, augmentation and editing may be restricting their broader use. Through our analysis of genetic diseases, we have identified applications and patient segments that we believe would benefit from our ImmTOR platform. We intend to develop ImmTOR-enabled non-immunogenic gene therapy candidates which are designed to be utilized with adeno-associated virus, or AAV, vectors. We believe our product candidates have the potential to increase transgene expression and to prevent undesired immune responses to the vector and transgene product that can occur with the first dose of gene therapy by using our ImmTOR platform. Our initial area of focus is on genetic metabolic diseases but may also include lysosomal storage diseases and genetic muscular diseases. We believe we are the first company to systematically pursue the development of AAV gene therapy product candidates with the goal of enabling repeat administration. We have engaged third parties with experience in gene therapy and rare diseases to support the development of our products. We also have licensed our ImmTOR platform to AskBio, Sarepta, and Spark for certain pre-specified targets.

*Restoring self-tolerance to auto-antigens.* We believe that ImmTOR has the potential to restore self-tolerance in autoimmune diseases. Our first program in autoimmune diseases is in primary biliary cholangitis, or PBC. PBC has a significant unmet medical need and a well-defined target antigen, known as PDC-E2.

Other products and product candidates affected by undesired immune responses. We have generated preclinical data which we believe suggests a broad potential benefit of ImmTOR for immune tolerance. For many biologic drugs, undesired immune responses limit efficacy and cause safety concerns. We intend to strategically out-license ImmTOR for use with other products that are outside our focus to larger biopharmaceutical companies. We believe our ImmTOR platform may also be of interest to biopharmaceutical companies with novel biologic development concepts or product candidates in clinical development that have demonstrated initial efficacy but are experiencing issues with safety or sustained efficacy due to inhibitory ADAs.

#### **Our Current Programs**

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

SEL-212 is designed to be a monthly treatment for chronic refractory gout, a debilitating rare disease with an unmet medical need. SEL-212 consists of a combination of our ImmTOR platform co-administered with pegadricase. Pegadricase is an investigational recombinant pegylated uricase (urate oxidase), an enzyme not naturally found in humans, and is therefore highly immunogenic. This enzyme is designed to treat patients with symptomatic gout, refractory to standard uric acid lowering treatment, by breaking down the excess uric acid to the more soluble allantoin. In preclinical studies, we observed that ImmTOR, when co-administered with pegadricase, induced antigen-specific immune tolerance to pegadricase and substantially reduced the formation of associated ADAs. Based on our clinical data, we believe that SEL-212 has the potential to control serum uric acid, or SUA levels and mitigate the formation of ADAs in response to the therapeutic enzyme. Additionally, we believe that SEL-212 has been licensed (except as to Greater China) to Sobi, pursuant to our license and development agreement dated June 11, 2020 with Sobi, or the Sobi License.

We and Sobi commenced the Phase 3 DISSOLVE clinical program of SEL-212 in September 2020. The Phase 3 clinical program consists of two double blinded, placebo-controlled trials of SEL-212, DISSOLVE I and DISSOLVE II. Each trial is expected to enroll 105 patients, with 35 patients receiving 0.1 mg/kg of ImmTOR and 0.2 mg/kg of pegadricase, 35 patients receiving 0.15 mg/kg of ImmTOR and 0.2 mg/kg of pegadricase, and 35 patients receiving placebo. DISSOLVE I and DISSOLVE II both have a six-month primary endpoint with a six-month safety extension for DISSOLVE I. The primary endpoint of the DISSOLVE program is the maintenance of SUA levels below 6 mg/dL at six months. Secondary endpoints include tender and swollen joint counts, tophus burden, patient reported outcomes of activity limitation and quality of life and gout flare incidence. Topline data from the Phase 3 DISSOLVE clinical program is expected in the second half of 2022. The Phase 3 DISSOLVE clinical program is being conducted by Selecta and funded by Sobi.

### Amplifying the Efficacy of Biologics: Enzyme therapy – IgA Nephropathy

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

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

We expect to file an Investigational New Drug, or IND, application, for this program in 2022.

### Amplifying the Efficacy of Biologics: Gene Therapies

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

ImmTOR into a gene therapy protocol has the potential to provide a first dose benefit by enhancing liver-directed transgene expression and durability, as well as the potential for enabling re-dosing.

Our lead therapeutic gene therapy program is in methylmalonic acidemia, or MMA, an inherited disorder in which the body is unable to process certain proteins and fats (lipids) properly. This program was previously being conducted under our collaboration with AskBio. In 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. The previously disclosed MMA-101 manufacturing issue was resolved. Manufacturing of a new lot has been completed and is currently undergoing final release testing. We expect to file an IND for this product candidate, SEL-302, 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 October and November 2020, we and AskBio received rare pediatric disease designation and orphan drug designation, respectively, from the FDA for MMA-101, for the treatment of MMA due to methylmalonyl-CoA mutase, or MMUT gene mutations.

Our proprietary gene therapy product candidate, SEL-313, is being developed to treat ornithine transcarbamylase, or OTC deficiency, and is currently in preclinical development. OTC deficiency is a rare genetic disorder that causes ammonia to accumulate in the blood due to mutations in the OTC gene, which is critical for proper function of the urea cycle. The most severe form of the disorder presents within the first few days of life. Severe symptoms include inability to control body temperature and breathing rate, seizures, coma, developmental delays and intellectual disability. Less severe forms of the disorder are characterized by delirium, erratic behavior, aversion to high protein foods, vomiting and seizures. We expect to file an IND and/or Clinical Trial Application for SEL-313 in 2022.

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

#### Restoring Self-tolerance in Autoimmune Diseases

Our lead autoimmune diseases indication is PBC, a T-cell driven autoimmune disease that causes progressive destruction of the bile ducts. Patients with PBC are in need of a highly targeted, liver-directed approach to treating the root cause of the disorder. We believe PBC has a well-defined target antigen, significant unmet medical need, and is well suited to the application of our ImmTOR immune tolerance platform, as preclinical data suggest that ImmTOR has the potential to enhance the tolerogenic environment in the liver and provide a hepatoprotective benefit. We expect to file an IND for our PBC program in the second half of 2022.

#### Licenses and Collaborations

### Swedish Orphan Biovitrum

In June 2020, we announced that we had entered into the Sobi License, pursuant to which we agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize SEL-212, which is currently in development for the treatment of chronic refractory gout. In September 2020, pursuant to the Sobi License, Sobi paid us a one-time, up-front payment of \$75 million. Sobi has also agreed to make milestone payments totaling up to \$630 million to us upon the achievement of various development and regulatory milestones and sales thresholds for annual net sales of SEL-212, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier.

Additionally, Sobi purchased an aggregate of 5,416,390 shares of our common stock at \$4.6156 for aggregate gross proceeds of \$25 million, which we refer to as the Sobi Private Placement. The closing of the Sobi Private Placement occurred on July 31, 2020.

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

### IGAN Biosciences

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



### Sarepta Therapeutics

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

### AskBio

In August 2019, we entered into the AskBio Collaboration Agreement. The initial proof-of-concept study being conducted under this collaboration is in SEL-399, which combines an empty AAV capsid (EMC-101), an AAV capsid containing no transgene, with ImmTOR, and is being conducted in partnership with AskBio. Building on the preclinical data we have generated showing ImmTOR's effect on mitigating or reducing the formation of neutralizing antibodies to AAV gene therapies, we have commenced a clinical trial of SEL-399 in healthy adult volunteers in Belgium. The goal of the SEL-399 clinical trial is to demonstrate the appropriate dose of ImmTOR in humans to mitigate the formation of antibodies to AAV capsids used in gene therapies, which currently precludes re-dosing. An initial control cohort of healthy volunteers received a single dose of EMC-101 in December 2020 and dose escalating cohorts of EMC-101 plus ImmTOR were initiated in February 2021. Topline results are expected in the fourth quarter of 2021.

Previously, we and AskBio were developing a gene therapy for MMA, which can cause severe developmental defects and premature death as a result of an accumulation of toxic metabolites. We conducted preclinical studies for this product candidate and will leverage that 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 and we intend to continue to develop SEL-302 through clinical development.

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

#### Spark Therapeutics

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

#### Impact of COVID-19

We are closely monitoring how COVID-19 is affecting our employees, business, preclinical studies and clinical trials. In response to the spread of COVID-19, we have continued to have our administrative employees work outside of our offices and limited the number of staff in any given research and development laboratory. Disruptions caused by the COVID-19 pandemic may result in difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials, and the incurrence of unforeseen costs as a result of preclinical study or clinical trial delays.

While the COVID-19 pandemic has not had a material impact on our clinical programs as of the date of this Quarterly Report, it could have an impact on our ability to complete the Phase 3 DISSOLVE clinical program of SEL-212, our ability to commence preclinical and clinical studies of our IgA nephropathy, gene therapy, and autoimmune disease programs, and our ability to obtain supply of both active drug substances and finished drug product as well as efficient execution of the overall supply chain for SEL-212 and our other programs. We have been proactively working with our CRO, clinical sites, and principal investigators to provide patients with more convenient locations to have their SUA measured for the primary endpoint of the study, such as at local laboratories or their homes, as well as alternative sites to receive infusions of study drug. We are also working with our primary and back-up suppliers for SEL-037 (pegadricase) and SEL-110 (ImmTOR) to ensure that we have adequate supply of our materials for both our clinical and preclinical programs. We believe we will have adequate supply of all material necessary to conduct our Phase 3 DISSOLVE clinical program of SEL-212 in chronic refractory gout and to complete our clinical trial for SEL-399 in gene therapy under our collaboration with AskBio.

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

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

### **Financial Operations**

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

Since inception, we have incurred significant operating losses. We incurred net losses of \$20.0 million and \$43.7 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$424.7 million. We expect to continue to incur significant expenses and operating losses for at least the next several years as we:

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

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

We believe that our existing cash, cash equivalents, marketable securities, and restricted cash as of June 30, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

### **Collaboration and grant revenue**

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

### **Research and development**

Our research and development expenses consist of external research and development costs, which we track on a program-by-program basis and primarily include CMO-related costs, fees paid to CROs and internal research and development costs, which are primarily compensation expenses for our research and development employees, lab supplies, analytical testing,



allocated overhead costs and other related expenses. Our internal research and development costs are often devoted to expanding our programs and are not necessarily allocable to a specific target.

We have incurred a total of \$322.8 million in research and development expenses from inception through June 30, 2021, with a majority of the expenses being spent on the development of SEL-212 and a prior nicotine vaccine candidate, and the remainder being spent on our various discovery and preclinical stage product candidate programs and the general expansion of our technology.

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

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

	Three Months	June 30,	Six Months Ended June 30,				
	 2021		2020		2021		2020
Research and development expenses (key projects and initiatives):							
SEL-212	\$ 5,956	\$	5,969	\$	12,680	\$	14,933
AskBio collaboration	364		598		1,177		1,574
Discovery and preclinical stage product candidate programs, collectively	2,821		195		3,392		480
Other internal research and development expenses	5,322		3,968		10,218		8,467
Total research and development expenses	\$ 14,463	\$	10,730	\$	27,467	\$	25,454

On June 11, 2020, we and Sobi entered into the Sobi License. Pursuant to the Sobi License, clinical trial costs incurred to complete development of SEL-212, including but not limited to costs incurred while conducting and completing the Phase 3 DISSOLVE trials, will be reimbursed by Sobi. These costs, when reimbursed, will be recognized as revenue consistent with the revenue recognition methodology disclosed in 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.

### General and administrative

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

### **Investment income**

Investment income consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

### Interest expense

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

### Other income (expense)

Other income was de minimis during the three and six months ended June 30, 2021 and 2020.

### Change in fair value of warrant liabilities

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

#### Foreign currency transaction gain (loss)

The functional currency of our Russian subsidiary is the Russian ruble. In addition to holding cash denominated in Russian rubles, our Russian bank accounts also hold cash balances denominated in U.S. dollars to facilitate payments to be settled in U.S. dollars or other currencies. As of June 30, 2021 and December 31, 2020, we maintained cash of \$0.3 million in Russian



banks, all of which was denominated in U.S. dollars. The amounts denominated in U.S. dollars and used in transacting the day-to-day operations of our Russian subsidiary are subject to transaction gains and losses, which are reported as incurred.

### **Results of Operations**

### Comparison of the Three Months Ended June 30, 2021 and 2020

#### Revenue

The following is a comparison of revenue for the three months ended June 30, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended June 30,					Increase		
		2021		2020		(decrease)		
Collaboration revenue	\$	19,663	\$	_	\$	19,663 —		

During the three months ended June 30, 2021, collaboration revenue was \$19.7 million, compared to no revenue recognition in 2020. During the three months ended June 30, 2021 we recognized \$19.5 million under the license agreement with Sobi which began in July 2020 resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program. Additionally, during the second quarter, we recognized less than \$0.1 million for shipments under the license agreement with Sarepta and \$0.1 million resulting from the expiration of the contractual audit term under the Skolkovo Foundation grant.

### **Research and development**

The following is a comparison of research and development expenses for the three months ended June 30, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended June 30,				Increase			
	2021 2020			2020				
Research and development	\$	14,463	\$	10,730	\$	3,733	35 %	

During the three months ended June 30, 2021, our research and development expenses increased by \$3.7 million, or 35%, as compared to 2020. The increase in cost was primarily the result of expenses incurred for consulting, salaries, and the discovery and preclinical programs, offset by a decrease of AskBio collaboration costs.

### General and administrative

The following is a comparison of general and administrative expenses for the three months ended June 30, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended June 30,				Increase		
	202	1		2020		(decrease)	
General and administrative	\$	4,748	\$	5,637	\$	(889)	(16 %)

During the three months ended June 30, 2021, our general and administrative expenses decreased by \$0.9 million, or 16%, as compared to 2020. The decrease in costs was primarily the result of reduced expense for salaries, professional fees and patent expense, offset by increased consulting and stock compensation expenses.

#### Investment income

Investment income was de minimis for each of the three months ended June 30, 2021 and 2020, respectively.

#### Foreign currency transaction gain (loss)

We recognized minimal foreign currency fluctuations during each of the three months ended June 30, 2021 and 2020, respectively.

### Interest expense

Interest expense was \$0.7 million and \$0.2 million for the three months ended June 30, 2021 and 2020, 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, 2021, we recognized a \$4.8 million change in the fair value of warrant liabilities utilizing the Black-Scholes valuation methodology. The decrease in value was primarily driven by a decrease in the Company's share price (see Note 5). For the three months ended June 30, 2020, we recognized \$7.5 million as a change in the fair value of warrant liabilities primarily driven by an increase in the Company's share price and volatility, offset by a decreased discount rate this quarter.

### Other income (expense)

Other income was de minimis for each of the three months ended June 30, 2021 and 2020.

### Net income (loss)

Net income for the three months ended June 30, 2021 was \$4.6 million compared to a net loss of \$24.1 million for the three months ended June 30, 2020.

### Comparison of the Six Months Ended June 30, 2021 and 2020

### Revenue

The following is a comparison of revenue for the six months ended June 30, 2021 and 2020 (in thousands, except percentages):

	Six Months Ended June 30,			Increase		
	2021	2020		(decrease)		
Collaboration revenue	\$ 30,713	\$	— \$	30,713	— %	

During the six months ended June 30, 2021, we recognized \$30.6 million under the license agreement with Sobi which began in July 2020 resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program, less than \$0.1 million for shipments under the license agreement with Sarepta, and \$0.1 million resulting from the expiration of the contractual audit term under the Skolkovo Foundation grant. During the six months ended June 30, 2020, we did not recognize revenue.

### **Research and development**

The following is a comparison of research and development expenses for the six months ended June 30, 2021 and 2020 (in thousands, except percentages):

	Six Months Ended June 30,				Increase		
		2021		2020		(decrease)	
at	\$	27,467	\$	25,454	\$	2,013	8 %

During the six months ended June 30, 2021, our research and development expenses increased by \$2.0 million, or 8%, as compared to 2020. The increase in cost was primarily the result of expenses incurred for the discovery and preclinical programs, offset by a decrease of clinical supply expense for the SEL-212 clinical programs and AskBio collaboration costs.

### General and administrative

The following is a comparison of general and administrative expenses for the six months ended June 30, 2021 and 2020 (in thousands, except percentages):

	Six Months Ended June 30,				Increase		
		2021		2020		(decrease)	
General and administrative	\$	9,952	\$	9,735	\$	217	2 %

During the six months ended June 30, 2021, our general and administrative expenses increased by \$0.2 million, or 2%, as compared to 2020. The increase in costs was the result of expenses incurred for consulting fees offset by decreased patent costs, reduced expense for salaries and less travel expense.

### **Investment income**

Investment income was less than \$0.1 million and \$0.3 million, respectively during the six months ended June 30, 2021 as compared to 2020. The decrease reflects reduced interest rates.

### Foreign currency transaction gain (loss)

We recognized minimal foreign currency fluctuations during each of the six months ended June 30, 2021 and 2020, respectively.

### **Interest expense**

Interest expense was \$1.4 million and \$0.5 million for the six months ended June 30, 2021 and 2020, 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, 2021, we recognized a \$11.9 million charge for the increase in the fair value of warrant liabilities utilizing a Black-Scholes valuation methodology. The increase in value was primarily driven by an increase in the Company's share price and a small increase in the discount rate this quarter (see Note 5). For the six months ended June 30, 2020, we recognized \$8.4 million as a change in the fair value of warrant liabilities primarily driven by an increase in the Company's share price and volatility, offset by a decreased discount rate this quarter.

### Other income (expense)

Other income was de minimis for each of the six months ended June 30, 2021 and 2020.

#### Net loss

Net loss for the six months ended June 30, 2021 was \$20.0 million compared to \$43.7 million for the six months ended June 30, 2020.

#### Liquidity and Capital Resources

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

From our inception through June 30, 2021, we have raised an aggregate of \$596.8 million to fund our operations, which includes \$118.5 million from the sale of preferred stock, \$11.1 million in government grant funding, \$36.7 million from borrowings under our credit facility, \$184.1 million from our collaborations and license agreements, \$64.5 million in combined net proceeds from our initial public offering, \$149.3 million in combined net proceeds from private placements and follow-on offerings of our common stock, and \$32.6 million in aggregate net proceeds from "at-the-market" offerings of our common stock.

As of June 30, 2021, our cash, cash equivalents, restricted cash, and marketable securities were \$151.5 million, of which \$1.4 million was restricted cash related to lease commitments and \$0.3 million was held by our Russian subsidiary designated solely for use in its operations. Our Russian subsidiary cash is consolidated for financial reporting purposes.

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

#### Indebtedness

On August 31, 2020, we entered into a term loan of up to \$35.0 million, consisting of term loans in an aggregate amount of \$25.0 million, or the Term A Loan, and term loans in an aggregate amount of \$10.0 million, or the Term B Loan, governed by a loan and security agreement among us and Oxford Finance LLC, or Oxford, as collateral agent and a lender, and Silicon Valley Bank, or SVB, as a lender. The Term A Loan was funded in full on August 31, 2020, the proceeds of which were used to repay our previously existing 2017 Term Loan and for general corporate and working capital purposes. The Term B Loan will be available, subject to the collateral agent's discretion and customary terms and conditions, during the period commencing on the date we have delivered to Oxford and SVB evidence: (i) we or one of the our collaboration partners has enrolled its first patient for a Phase 1 clinical trial evaluating the treatment of MMA, and (ii) we have enrolled the first patient in each of two Phase 3 pivotal trials evaluating SEL-212, or the Second Draw Period Milestone, and ending on the earliest of (i) the date which is 30 days following the date the Second Draw Period Milestone is achieved, (ii) September 30, 2021 (iii) and the occurrence of an event of default, other than an event of default that has been waived in writing by Oxford and SVB in their sole discretion.

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

The 2020 Term Loan contains customary covenants and representations, including but not limited to financial reporting obligations and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. The 2020 Term Loan also contains other customary provisions, such as expense reimbursement, non-disclosure obligations as well as indemnification rights.

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

For a further description of the 2020 Term Loan, see Note 9 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report.

#### Plan of operations and future funding requirements

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

As of June 30, 2021, we had an accumulated deficit of \$424.7 million. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of our product candidates, conducting preclinical studies and clinical trials, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital.

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

We believe that our existing cash, cash equivalents, marketable securities and restricted cash as of June 30, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2023. Additionally, while the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital as and when needed. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

- the number of product candidates that we pursue;
- our collaboration agreements remaining in effect, our entering into additional collaboration agreements and our ability to achieve milestones under these agreements;
- the cost of manufacturing clinical supplies of our product candidates;
- our headcount growth and associated costs;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;



- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- · the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

As noted above, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity future funding requirements is uncertain as of the filing date of this Quarterly Report as this continues to evolve globally.

#### **Summary of Cash Flows**

		Six Months Ended June 30,		
thousands)	-	2021	2020	
ih (used in) and provided by:	-			
Operating activities	\$	(18,136)	(23,506)	
Investing activities		(25,060)	(289)	
Financing activities		30,291	(6,327)	
ect of exchange rate changes on cash		9	(42)	
change in cash, cash equivalents, and restricted cash	\$	(12,9 <b>3</b> 6)	(30,164)	

#### **Operating activities**

Cash used in operations of \$18.2 million for the six months ended June 30, 2021 included approximately \$2.9 million of net losses, adjusted for noncash items, and uses of cash of approximately \$15.3 million for changes in operating assets and liabilities.

Cash used in operations of \$23.5 million for the six months ended June 30, 2020 included \$31.3 million of net losses, adjusted for non-cash items, partially offset by cash generated from changes in operating assets and liabilities of \$7.8 million, principally related to changes in accounts receivable and deferred revenue.

#### Investing activities

Net cash used in investing activities for the six months ended June 30, 2021 was \$25.1 million compared to net cash used in investing activities of \$0.3 million in the same period in 2020. The net cash used in investing activities in 2021 was to purchase marketable securities. The net cash used in investing activities in 2020 was to purchase property and equipment.

### Financing activities

Net cash provided by financing activities for the six months ended June 30, 2021 was \$30.3 million compared to net cash used in financing activities of \$6.3 million in the same period in 2020. The net cash provided by financing activities in 2021 was primarily the result of net proceeds from "at-the-market" offerings and from the exercise of stock options.

The net cash used in financing activities in 2020 was the result of \$4.4 million of issuance costs paid for December 2019 financing, \$4.2 million principal payment on outstanding debt, offset by \$2.1 million net proceeds from "at-the-market" offerings.

#### **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, 2021, 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 U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. During the three and six months ended June 30, 2021, 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, 2020.

### **Emerging Growth Company Status**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We will remain an emerging growth company until December 31, 2021, the last day of the fiscal year following the fifth anniversary of the closing of the initial public offering of our common stock. However, if certain events occur prior to December 31, 2021, including if we become a "large accelerated filer," our annual gross revenues exceed \$1.07 billion or we issue more than \$1.07 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to December 31, 2021.

### **Smaller Reporting Company**

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

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

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of June 30, 2021 and December 31, 2020, we had cash, cash equivalents, restricted cash and marketable securities of \$151.5 million and \$140.1 million, respectively, consisting of non-interest and interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term and the low risk profile of our money market accounts and marketable securities, and our current plan to hold marketable securities to maturity, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents or short-term marketable securities.

In addition, we are subject to currency risk for balances held in Russian rubles in our foreign subsidiary. We hold portions of our funds in both U.S. dollars and Russian rubles. The exchange rate between the U.S. dollar and Russian ruble changes from period to period. As of June 30, 2021, we held cash and cash equivalents totaling \$0.3 million in Russian banks to support our Russian subsidiary, all of which were denominated in U.S. dollars. We do not hedge against foreign currency risks. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

#### **Item 4. Controls and Procedures**

#### Limitations on effectiveness of controls and procedures

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

### Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Vice President, Finance and Corporate Controller, 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 Vice President, Finance and Corporate Controller concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2021.

### 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### PART II. OTHER INFORMATION

### **Item 1. Legal Proceedings**

On August 4, 2020, a putative stockholder of Selecta filed a stockholder derivative action, purportedly on behalf of Selecta and against certain current and former members of the Company's Board of Directors, as well as one affiliated company owned by a current board member, in the Court of Chancery of the State of Delaware, namely Franchi v. Barabe, et al. The complaint alleges that the individual defendants breached their fiduciary duties and committed corporate waste when they authorized a private placement transaction, announced on December 19, 2019, at a price allegedly below fair value. The complaint further alleges that the four defendant directors who participated in the private placement were unjustly enriched in connection with the transaction. On September 25, 2020, the defendants filed a motion to dismiss the lawsuit. On November 6, 2020, the plaintiff filed an amended complaint, and the defendants filed a second motion to dismiss on January 8, 2021. On December 31, 2020, we received a litigation demand letter from two other putative stockholders relating to the same private placement transaction. On April 12, 2021, the Court of Chancery in the State of Delaware granted a motion to stay the litigation pending a review by a Special Committee appointed by the Company's Board of Directors.

### Item 1A. Risk Factors

Our risk factors are disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no material changes from the risk factors previously disclosed in such filing.

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

None.

### Item 3. Defaults Upon Senior Securities

None.

#### Item 4. Mine Safety Disclosures

None.

### **Item 5. Other Information**

None.



### Item 6. Exhibits

# EXHIBIT INDEX

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	
<u>3.1</u>	Restated Certificate of Incorporation of Selecta Biosciences, Inc.	8-K	001-37798	3.1	6/29/2016	
<u>3.2</u>	Amended and Restated By-laws of Selecta Biosciences, Inc.	8-K	001-37798	3.2	6/29/2016	
<u>10.1#</u>	Promotion Letter dated May 11, 2021, between Selecta Biosciences, Inc. and Ann K. Donohue	-	-	-	Filed herewith	
<u>31.1</u>	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer	-	-	-	Filed herewith	
<u>31.2</u>	<u>Rule 13a-14(a) / 15d-14(a) Certification of Principal Financial and</u> <u>Accounting Officer</u>	-	-	-	Filed herewith	
<u>32.1</u>	Section 1350 Certification of Chief Executive Officer	-	-	-	Furnished herewith	
<u>32.2</u>	Section 1350 Certification of Principal Financial and Accounting Officer	-	-	-	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	

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## SIGNATURES

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

# SELECTA BIOSCIENCES, INC.

Date: August 12, 2021

/s/ Carsten Brunn, Ph.D.

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

Date: August 12, 2021

By:

By:

/s/ Ann K. Donohue, CPA

Ann K. Donohue, CPA VP, Finance and Corporate Controller (Principal Financial and Accounting Officer)

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May 11, 2020

Dear Annie,

I am pleased to congratulate you on your promotion to Vice President Finance & Corporate Controller effective May 17, 2021, with a new annual salary of \$225,000 and 30% bonus target.

This promotion recognizes the contributions you have made to Selecta as well as the additional responsibilities you have taken on within your position. The Company appreciates your diligence and commitment to our short- and long-term strategies and all you do to help move the

Company forward.

Congratulations!

Sincerely,

/s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D. President and CEO

65 Grove Street, Watertown, MA 02472 617.923.1400 selectabio.com

# 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 12, 2021

/s/ Carsten Brunn, Ph.D.

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

# CERTIFICATIONS

I, Ann K. Donohue, 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 12, 2021

/s/ Ann K. Donohue, CPA

Ann K. Donohue, CPA VP, Finance and Corporate Controller (Principal Financial and Accounting Officer)

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

I, Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta Biosciences, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- 1. The Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2021 (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 12, 2021

/s/ Carsten Brunn, Ph.D.

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

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

I, Ann K. Donohue, Chief Financial Officer of Selecta Biosciences, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- 1. The Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2021 (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 12, 2021

/s/ Ann K. Donohue, CPA

Ann K. Donohue, CPA VP, Finance and Corporate Controller (Principal Financial and Accounting Officer)