

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): May 7, 2020

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37798
(Commission
File Number)

26-1622110
(IRS Employer
Identification No.)

65 Grove Street, Watertown, MA 02472
(Address of principal executive offices)(Zip Code)

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 (Par Value \$0.0001)	SELB	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

On May 7, 2020, Selecta Biosciences, Inc. announced its financial results for the quarter ended March 31, 2020. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report and on Form 8-K.

The information contained in Item 2.02 of this Form 8-K (including Exhibit 99.1 attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on May 7, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SELECTA BIOSCIENCES, INC.

Date: May 7, 2020

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

Carsten Brunn, Ph.D.

President and Chief Executive Officer



Selecta Biosciences Reports First Quarter 2020 Financial Results

- *Topline data announcement from the ongoing head-to-head COMPARE trial of SEL-212 remains on schedule for Q3 2020*
- *Phase 3 clinical program of SEL-212 to commence in 2H 2020*
- *Ongoing COVID-19 pandemic has not materially impacted COMPARE trial progress; continual ongoing assessment and coordination with CRO and clinical sites taking place*
- *Gene therapy program in collaboration with AskBio remains on track to enter the clinic by Q4 2020*
- *Company to host conference call today at 8:30 a.m. ET*

Watertown, Mass., May 7, 2020 - Selecta Biosciences, Inc. (NASDAQ: SELB), a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance platform, ImmTOR™, today reported financial results for the first quarter ended March 31, 2020.

“To date, Selecta has been able to navigate many of the challenges presented by the COVID-19 pandemic, and as such, the ongoing COMPARE clinical trial of SEL-212 in chronic, refractory gout is still on schedule, and we continue to expect to announce topline data in the third quarter of this year. However, we continue to recognize the inherent unpredictability of this ongoing situation. During this time, we have made the health and safety of our patients and healthcare providers the top priority, and we continue to work with our CRO and clinical sites to ensure that any risk posed to a patient or provider coming in for visits is properly mitigated,” said Carsten Brunn, Ph.D., President and CEO of Selecta. “We have also continued to advance our operations in other critical areas, including preparations for the commencement of the Phase 3 trial of SEL-212, and collaborating with AskBio to advance our gene therapy program. We remain on track to enter the clinic under this collaboration by the end of the year.”

Recent Highlights and Anticipated Upcoming Milestones:

- **Topline Results from COMPARE Clinical Trial Expected in the Third Quarter of 2020:** The head-to-head COMPARE study of Selecta’s lead product candidate, SEL-212 (ImmTOR + pegadricase), vs. pegloticase is expected to readout on schedule, as the Company continues to work closely with the CRO and clinical sites to monitor patient follow-up in light of the COVID-19 pandemic. The trial is evaluating a once-monthly dose of SEL-212 compared to biweekly doses of pegloticase, with the primary endpoint of the maintenance of serum uric acid (SUA) levels of <6mg/dL at three and six months. The trial completed enrollment in December 2019, and as of April 2020, half of the patients had completed the study and all patients had reached three months of treatment.

- **Gene Therapy Program Expected to Enter the Clinic by the End of 2020:** Selecta and its partner AskBio are jointly developing a broad portfolio of next-generation AAV gene therapies. This partnership will leverage the unique proprietary technology platforms of both companies with a human proof of concept trial to validate this portfolio of products and their potential for re-dosing in patients, which could represent a significant advancement in the gene therapy field. Selecta and AskBio anticipate entering the clinic by the end of 2020. Additionally, Selecta intends to advance its proprietary program in Ornithine Transcarbamylase (OTC) deficiency.

First Quarter 2020 Financial Results:

- **Cash Position:** Selecta had \$74.3 million in cash, cash equivalents, and restricted cash as of March 31, 2020, which compares to cash, cash equivalents, and restricted cash of \$91.6 million as of December 31, 2019. Selecta believes its available cash, cash equivalents, and restricted cash will be sufficient to meet its operating requirements into the first quarter of 2021.
 - Net cash used in operating activities was \$11.7 million for the first quarter of 2020, as compared to \$20.2 million for the same period in 2019.
- **Research and Development Expenses:** Research and development expenses for the first quarter 2020 were \$14.7 million, which compares with \$7.4 million for the same period in 2019. The increase in costs was primarily the result of expenses incurred for our Phase 2 COMPARE trial for SEL-212 and for our gene therapy program in collaboration with AskBio.
- **General and Administrative Expenses:** General and administrative expenses for the first quarter 2020 were \$4.1 million, which compares with \$4.5 million for the same period in 2019. The reduction in costs was the result of reduced salaries, consulting and professional fees offset by increased stock compensation expense.
- **Net Loss:** For the first quarter 2020, Selecta reported a net loss of \$19.6 million, or \$0.21 per share, compared to a net loss of \$12.1 million, or \$0.31 per share, for the same period in 2019.

Conference Call and Webcast Reminder:

Selecta management will host a conference call at 8:30 a.m. ET today to provide a corporate update and review the company's first quarter 2020 financial results. Individuals may participate in the live call via telephone by dialing (844) 845-4170 (domestic) or (412) 717-9621 (international) and may access a teleconference replay for one week by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and using confirmation code 10138607. Investors and the public can access the live and archived webcast of this call via the Investors & Media section of the company's website, www.selectabio.com.

About Selecta Biosciences, Inc.

Selecta Biosciences, Inc. is a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance technology (ImmTOR) platform. Selecta plans to combine ImmTOR with a range of biologic therapies for rare and serious diseases that require new treatment options due to high immunogenicity. The company's current proprietary pipeline includes ImmTOR-powered therapeutic enzyme and gene therapy product candidates. SEL-212, the company's lead product candidate, is being developed to treat chronic refractory gout patients and resolve their debilitating symptoms, including flares and gouty arthritis. Selecta's

proprietary gene therapy product candidates are in preclinical development for certain rare inborn errors of metabolism and incorporate ImmTOR with the goal of addressing barriers to repeat administration. Selecta is based in Watertown, Massachusetts. For more information, please visit www.selectabio.com.

Forward-Looking Statements

Any statements in this press release about the future expectations, plans and prospects of Selecta Biosciences, Inc. (“the company”), including without limitation, the company’s actions regarding the monitoring and assessment of COVID-19 on the company’s operations, clinical trials and manufacturing, statements regarding the progress of the clinical development of SEL-212, timing of related data readouts from the head-to-head (COMPARE) clinical trial comparing SEL-212 and pegloticase, the anticipated timing and commencement of the planned Phase 3 clinical trial, the unique proprietary technology platform of the company and the unique proprietary platform of its partners, the potential of ImmTOR to enable re-dosing of AAV gene therapy, the potential of SEL-212 to fulfill unmet needs in chronic refractory gout patients including sustained SUA reduction, reduced flares, and once monthly dosing, and to resolve their debilitating symptoms, the company’s commercial plans, the ability of the company’s ImmTOR platform, including SEL-212, to unlock the full potential of biologic therapies, the potential treatment applications for product candidates utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy, plans to advance the company’s gene therapy program with AskBio and the timing of entering the clinic under this collaboration, including a human proof of concept trial, the ability of the Company and AskBio to develop gene therapy products using ImmTOR and AskBio’s core technology, the novelty of treatment paradigms that the Company and AskBio are able to develop, the potential of any therapies developed by the Company and AskBio to fulfill unmet medical needs, the company’s plans to advance its gene therapy program to treat Ornithine Transcarbamylase deficiency, the company’s plan to apply its ImmTOR technology platform to a range of biologics for rare and serious diseases, the potential of the ImmTOR technology platform generally and the company’s ability to grow its strategic partnerships, the sufficiency of the company’s cash, cash equivalents and short-term investments, and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “hypothesize,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including their uncertain outcomes, the effect of the COVID-19 outbreak on any of the company’s planned or ongoing clinical trials, manufacturing activities, supply chain and operations, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, the unproven approach of the company’s ImmTOR technology, undesirable side effects of the company’s product candidates, its reliance on third parties to manufacture its product candidates and to conduct its clinical trials as well as the impact of the COVID-19 outbreak on those third parties and their ability to continue their operations, the company’s inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, management’s ability to perform as expected, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the company’s recurring losses from operations and negative cash flows from operations raise substantial doubt regarding its ability to continue as a going concern, substantial fluctuation in the price of its common stock including stock market fluctuations that occur as a result of the COVID-19 outbreak, and other important factors discussed in the “Risk Factors” section of the

company's most recent Annual Report on Form 10-K, and in other filings that the company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent the company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The company specifically disclaims any intention to update any forward-looking statements included in this press release.

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

	March 31, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 72,606	\$ 89,893
Restricted cash	279	279
Accounts receivable	—	5,000
Prepaid expenses and other current assets	1,555	1,495
Total current assets	74,440	96,667
Property and equipment, net	1,134	1,222
Right-of-use asset, net	11,847	301
Long-term restricted cash	1,379	1,379
Total assets	<u>\$ 88,800</u>	<u>\$ 99,569</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,330	\$ 500
Accrued expenses	8,775	13,492
Loan payable	16,868	18,905
Lease liability	1,425	372
Deferred revenue	1,674	1,674
Total current liabilities	30,072	34,943
Non-current liabilities:		
Lease liability	10,440	—
Deferred revenue	14,656	14,680
Warrant liabilities	42,395	41,549
Total liabilities	97,563	91,172
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 87,019,172 and 86,325,547 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	9	9
Additional paid-in capital	351,184	348,664
Accumulated deficit	(355,373)	(335,753)
Accumulated other comprehensive loss	(4,583)	(4,523)
Total stockholders' equity (deficit)	(8,763)	8,397
Total liabilities and stockholders' equity (deficit)	<u>\$ 88,800</u>	<u>\$ 99,569</u>

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

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Grant and collaboration revenue	\$ —	\$ 10
Operating expenses:		
Research and development	14,724	7,353
General and administrative	4,098	4,513
Total operating expenses	18,822	11,866
Loss from operations	(18,822)	(11,856)
Investment income	240	277
Foreign currency transaction (loss), net	82	(30)
Interest expense	(273)	(396)
Change in fair value of warrant liabilities	(846)	—
Other (expense), net	(1)	(69)
Net loss	(19,620)	(12,074)
Other comprehensive loss:		
Foreign currency translation adjustment	(60)	22
Unrealized gain on securities	—	2
Total comprehensive loss	\$ (19,680)	\$ (12,050)
Net loss per share:		
Basic and diluted	\$ (0.21)	\$ (0.31)
Weighted average common shares outstanding:		
Basic and diluted	94,723,513	38,447,319

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