

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 9, 2019

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.)

480 Arsenal Way
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))

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.

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	Nasdaq Global Market

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2019, Selecta Biosciences, Inc. announced its financial results for the quarter ended March 31, 2019. 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 9, 2019

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 9, 2019

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

Carsten Brunn, Ph.D.

President and Chief Executive Officer



Selecta Biosciences Reports First Quarter 2019 Financial Results and Provides Corporate Update

- *Patient enrollment ongoing in COMPARE trial evaluating efficacy and safety of SEL-212 vs. KRYSTEXXA® in patients with chronic refractory gout; interim data expected in 4Q19*
- *Preclinical data showing potential for re-dosing of AAV-based vectors when administered in combination with ImmTOR™ (SVP-Rapamycin) presented at ASGCT 22nd Annual Meeting*
- *Company to host conference call today at 8:30 a.m. ET*

Watertown, Mass., May 9, 2019 - [Selecta Biosciences, Inc.](http://www.selectabiosciences.com) (Nasdaq: SELB), a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance platform technology, ImmTOR, today reported financial results for the first quarter ended March 31, 2019 and provided a corporate update.

“We are excited to be enrolling patients in the COMPARE trial and look forward to the opportunity to differentiate SEL-212 compared to the current FDA-approved uricase therapy in adult patients with chronic refractory gout,” said Carsten Brunn, Ph.D., President and CEO of Selecta. “As we continue to develop our ImmTOR platform for rare and serious diseases, we are pleased by the advancements in our gene therapy program, most recently with the presentation of new preclinical data at ASGCT highlighting how the co-administration of our technology with AAV-based vectors suppressed the immune response to the vector, potentially enabling re-dosing to provide sustained therapeutic efficacy over time.”

Recent Highlights and Anticipated Upcoming Milestones

SEL-212 (ImmTOR+Pegadricase) for the Treatment of Chronic Refractory Gout:

- **Initiated 6-Month COMPARE Clinical Trial of SEL-212 vs. Krystexxa:** In March 2019, Selecta initiated a six-month head-to-head clinical trial (COMPARE) designed to evaluate the superiority of its lead product candidate, SEL-212 (ImmTOR + Pegadricase), compared to Krystexxa, the current U.S. Food and Drug Administration (FDA)-approved uricase therapy, in adult patients with chronic refractory gout. The COMPARE trial is expected to enroll 150 patients, and the primary endpoint is the maintenance of serum uric acid (sUA) levels of <6mg/dL at six months. An interim six-month data readout is projected in the fourth quarter of 2019 with a full statistical superiority data analysis readout expected in the first quarter of 2020.
- **Initiation of Phase 3 Clinical Trial of SEL-212 Anticipated in Q4 19:** The interim results of the COMPARE trial, which are anticipated in the fourth quarter of 2019, are expected to inform the design of the Phase 3 clinical trial of SEL-212, which the company plans to initiate in the fourth quarter of 2019.

ImmTOR + AAV Gene Therapy Program:

- **Presented New Preclinical Data at the American Society of Gene & Cell Therapy (ASGCT) 22nd Annual Meeting:** In April 2019, Selecta scientists and collaborators from the National Institutes of Health (NIH) and the International Centre for Genetic Engineering and Biotechnology (ICGEB) gave five presentations of new preclinical data demonstrating the potential for the re-dosing of adeno-associated virus (AAV)-based gene therapy vectors when administered in combination with its ImmTOR (SVP-Rapamycin) at the ASGCT Annual Meeting in Washington, DC.
- **Advancing Collaboration with CureCN Consortium:** Our collaboration with the European consortium, CureCN, for an ImmTOR+AAV gene therapy combination product candidate in Crigler-Najjar Syndrome continues to progress.

Corporate Updates:

- **Strengthened Management and Clinical Teams:** In March 2019, Selecta appointed Elona Kogan, J.D. as General Counsel and Secretary. She was most recently General Counsel and head of Government Relations at ARIAD Pharmaceuticals, Inc., a rare disease oncology company, where she was a key executive through the acquisition of the company by Takeda Pharmaceuticals Company Limited. Also, in March, Selecta appointed Horacio Plotkin, MD, FAAP as the new Head of Clinical Development. He brings 20 years of clinical pediatric experience and 12 years in biotech and was most recently Head of Clinical Development, Rare Diseases at Moderna Therapeutics.

First Quarter 2019 Financial Results:

- **Revenue:** For the first quarter of 2019, the company recognized less than \$0.1 million of revenue for a shipment under its collaboration agreement with Spark, which compares to zero revenue recognized for the first quarter of 2018.
- **Research and Development Expenses:** Research and development expenses for the first quarter of 2019 were \$7.4 million, which compares with \$11.1 million for the first quarter of 2018. The decrease was driven by reduced salaries and benefits as a result of the company's headcount reduction at the beginning of the first quarter of 2019 combined with expenses incurred for both the Phase 2 and Phase 3 clinical programs for SEL-212.
- **General and Administrative Expenses:** General and administrative expenses for the first quarter of 2019 were \$4.5 million, which compares with \$4.7 million for the first quarter of 2018. The reduction in costs was primarily the result of reduced consulting fees.
- **Net Loss:** For the first quarter of 2019, Selecta reported a net loss of \$12.1 million, or \$0.31 per share, compared to a net loss of \$15.9 million, or \$0.71 per share, for the same period in 2018.
- **Cash Position:** Selecta had \$48.7 million in cash, cash equivalents, restricted cash and short-term investments as of March 31, 2019, which compares to cash, cash equivalents and restricted cash of \$37.7 million at December 31, 2018.

Financial Outlook:

Selecta believes its available cash, cash equivalents and restricted cash will be sufficient to meet its operating requirements into the first quarter of 2020.

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 2019 financial results. Investors and the public can access a live and archived webcast of this call via the Investors & Media section of the company's website, <http://selectabio.com>. Individuals may also 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 10127202.

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 <http://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, statements regarding the progress of the clinical development of SEL-212, expectations surrounding the enrollment and design of the Phase 2 head-to-head (COMPARE) clinical trial comparing SEL-212 and Krystexxa, timing of related data readouts and the ability of the COMPARE results to inform the planned Phase 3 clinical trial of SEL-212, the anticipated timing of the planned Phase 3 clinical trial, whether the head-to-head trial with Krystexxa will demonstrate superiority, the potential of ImmTOR to enable re-dosing of AAV gene therapy and the anticipated timing of preclinical toxicology studies in collaboration with CureCN and initiation of a clinical trial related thereto, the potential of SEL-212 to fulfill unmet needs in chronic refractory gout patients including sustained sUA reduction, reduced flares, and once monthly dosing, 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 of SEL-212 to treat chronic refractory gout patients and resolve their debilitating symptoms, the potential treatment applications for product candidates utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy, the company's plan to apply its ImmTOR technology platform to a range of biologics for rare and serious diseases, the potential of the company's two gene therapy product candidates to enable repeat administration, the Company's ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, 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 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, potential delays in enrollment of patients, 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, 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, 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, and other important factors discussed in the "Risk Factors" section of the company's Annual Report on Form 10-Q for the quarter ended March 31, 2019, 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 obligation 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, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	\$ 32,452	\$ 37,403
Short-term deposits and investments	16,244	—
Prepaid expenses and other current assets	10,832	4,673
Total current assets	59,528	42,076
Property and equipment, net	1,799	2,127
Right of Use Asset, net	1,155	—
Restricted cash and other assets	—	279
Total assets	\$ 62,482	\$ 44,482
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 693	\$ 1,100
Accrued expenses	8,500	11,700
Loan payable, current portion	21,466	21,385
Lease Liability, current portion	1,428	—
Deferred revenue, current portion	959	959
Total current liabilities	33,046	35,144
Non-current liabilities:		
Deferred rent and lease incentive	—	34
Deferred revenue, net of current portion	13,816	13,818
Other long-term liabilities	801	904
Total liabilities	47,663	49,900
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 44,788,025 and 22,471,776 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	5	3
Additional paid-in capital	311,824	279,539
Accumulated deficit	(292,477)	(280,403)
Accumulated other comprehensive loss	(4,533)	(4,557)
Total stockholders' equity (deficit)	14,819	(5,418)
Total liabilities and stockholders' equity	\$ 62,482	\$ 44,482

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

	Three Months Ended March 31,	
	2019	2018
	(Unaudited)	
Grant and collaboration revenue	\$ 10	\$ —
Operating expenses:		
Research and development	7,353	11,139
General and administrative	4,513	4,674
Total operating expenses	11,866	15,813
Loss from operations	(11,856)	(15,813)
Investment income	277	288
Foreign currency transaction (loss), net	(30)	(13)
Interest expense	(396)	(350)
Other (expense), net	(69)	—
Net loss	(12,074)	(15,888)
Other comprehensive loss:		
Foreign currency translation adjustment	22	19
Unrealized gain on securities	2	3
Total comprehensive loss	\$ (12,050)	\$ (15,866)
Net loss per share:		
Basic and diluted	\$ (0.31)	\$ (0.71)
Weighted average common shares outstanding:		
Basic and diluted	38,447,319	22,345,523

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For Investors:
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