

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, 2018

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-37798
(Commission
File Number)

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

480 Arsenal Way
Watertown, MA 02472
(Address of principal executive offices) (Zip Code)

(617) 923-1400
(Registrant's telephone number, include 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.

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2018, Selecta Biosciences, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2018. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report").

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 (the "Securities Act"), 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, 2018

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, 2018

By: /s/ Werner Cautreels, Ph.D.

Werner Cautreels, Ph.D.

President and Chief Executive Officer



Selecta Biosciences Announces First Quarter 2018 Financial Results and Provides Corporate Update

- *3-month Phase 2 data presented at PANLAR 2018 indicate SEL-212 (SVP-Rapamycin + pegsiticase) product profile may provide better and more sustained serum uric acid control, fewer flares, and less frequent dosing compared with recent data reported for current FDA-approved uricase therapy*
- *Expansion data from PANLAR cohorts to be presented at EULAR on June 15th, 2018 and data from patients receiving five doses of SEL-212 expected at Q3 medical conference*
- *Phase 1 clinical trial for second product candidate, SEL-403, for mesothelioma actively enrolling patients*
- *Company reports Q1 2018 cash balance of \$83 million and reiterates runway through mid-2019*
- *Company to Host Conference Call Today at 8:30 a.m. ET*

Watertown, Mass., May 9, 2018 - [Selecta Biosciences, Inc.](#) (NASDAQ: SELB), a clinical-stage biopharmaceutical company focused on unlocking the full potential of biologic therapies by mitigating unwanted immune responses, today reported financial results for the first quarter ended March 31, 2018 and provided a corporate update.

“We are very pleased by the clinical activity seen in the SEL-212 phase 2 data presented recently at PANLAR, not only in SEL-212’s ability to control serum uric acid levels with convenient monthly doses, but also in the reduced incidence of gout flares compared to the current FDA-approved uricase. We have two more anticipated data readouts from this trial at EULAR and a medical conference in the third quarter and we are also planning to initiate the Phase 3 program later this year,” said Werner Cautreels, Ph.D., President and CEO of Selecta. “And now that our next program, SEL-403, has entered the clinic for the treatment of patients with mesothelioma at the National Cancer Institute, we have demonstrated the versatility of our tolerance SVP platform in an additional therapeutic area of high unmet need. SEL-403 is the first non-immunogenic immunotoxin that targets mesothelin on cancer cells providing the possibility of improving efficacy and safety for a broad group of cancer patients.”

Recent Business Highlights and Activities

- **Presented Positive New Data from Ongoing Phase 2 Trial of SEL-212 at PANLAR 2018 Congress in April:** In April 2018, Selecta presented new data from patients receiving SEL-212 for the treatment of chronic severe gout at the Pan American League of Associations for Rheumatology (PANLAR) 2018 Congress in Buenos Aires, Argentina. The data was generated from patients that received three monthly doses of SEL-212, up to 0.15 mg/kg of SVP-Rapamycin in combination with 0.2 or 0.4 mg/kg of pegsiticase, followed by two monthly doses

of pegsiticase alone. Approximately 75% of evaluable patients maintained serum uric acid level control below 6 mg/dl during the initial three months of therapy with concurrent mitigation of anti-drug antibodies (ADAs) against the pegsiticase enzyme. Furthermore, 91% of patients dosed with pegsiticase alone in month four after the initial three monthly doses of SEL-212 maintained serum uric acid control. The company plans to present an expanded data set of the PANLAR cohorts at the EULAR conference on June 15th and will host a conference call to discuss the data on June 15th at 8.30 am.

- **Data from Cohorts Receiving Five Combination Doses in Phase 2 Trial of SEL-212 to be Presented in the Third Quarter at a Medical Meeting:** In February 2018, Selecta began enrolling new cohorts of patients in the current Phase 2 trial who are expected to receive five monthly doses of SVP-Rapamycin in combination with pegsiticase. These patients are receiving SVP-Rapamycin doses ranging from 0.1mg/kg-0.15mg/kg in combination with 0.2mg/kg of pegsiticase. The company expects to present data from these patients at an upcoming medical meeting in the third quarter of 2018.
- **SEL-212 to Enter Phase 3 in 2018 Following Comprehensive Dose Selection Trial:** Selecta is actively engaged in preparations for an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), which will define the company's design for the Phase 3 program. The company plans to initiate its Phase 3 program in 2018.
- **Patient Enrollment Ongoing for SEL-403 Phase 1 Trial for Mesothelioma:** In March 2018, the first patient was dosed in a Phase 1 clinical trial of SEL-403, Selecta's combination product candidate consisting of SVP-Rapamycin and LMB-100, for the treatment of patients with malignant pleural or peritoneal mesothelioma who have undergone at least one regimen of chemotherapy. LMB-100, which was in-licensed by Selecta in 2017, is a recombinant immunotoxin that targets mesothelin, a protein expressed in nearly all mesotheliomas and pancreatic adenocarcinomas, and a high percentage of other malignancies, including lung, breast and ovarian cancers. This open-label dose-escalation Phase 1 trial is being conducted under a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes of Health, and is expected to enroll at least 18 patients. The trial will evaluate the safety and tolerability of this treatment and provide data on pharmacokinetics, ADA levels, as well as an objective response rate assessment.

First Quarter Financial Results:

- **Revenue:** For the first quarter of 2018, the company recognized no revenue, which compares with \$0.1 million for the first quarter of 2017. The decline is the result of reduced revenue recognized from the company's grants and collaborations.
- **Research and Development Expenses:** Research and development expenses for the first quarter of 2018 were \$11.1million, relatively unchanged from the \$11.0 million for the first quarter of 2017.
- **General and Administrative Expenses:** General and administrative expenses for the first quarter of 2018 were \$4.7 million, which compares with \$3.9 million for the first quarter of 2017. The increase is primarily the result of greater headcount and related salaries needed to support a maturing clinical-stage public company.

- **Net Loss:** For the first quarter of 2018, Selecta reported a net loss attributable to common stockholders of \$(15.9) million, or \$(0.71) per share, compared to a net loss of \$(15.1) million, or \$(0.82) per share, for the same period in 2017.
- **Cash Position:** Selecta had \$83.5 million in cash, cash equivalents, short-term deposits, investments and restricted cash as of March 31, 2018, which compares with a balance of \$97.0 million at December 31, 2017. Selecta continues to expect that its cash, cash equivalents, short-term deposits, investments and restricted cash will be sufficient to fund the company's operating expenses and capital expenditure requirements into mid-2019.

Conference Call Reminder

Selecta management will host a conference call at 8:30 a.m. ET today to announce the company's first quarter financial results and provide a corporate update. 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 10118841.

About Selecta Biosciences, Inc.

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company that is focused on unlocking the full potential of biologic therapies by mitigating unwanted immune responses. Selecta plans to combine its tolerogenic Synthetic Vaccine Particles (SVP™) with a range of biologics for rare and serious diseases that require new treatment options. The company's current proprietary pipeline includes SVP-enabled enzyme, oncology and gene therapies. SEL-212, the company's lead product candidate in Phase 2, is being developed to treat severe gout patients and resolve their debilitating symptoms, including flares and gouty arthritis. A Phase 1 trial is ongoing for a combination therapy consisting of SVP-Rapamycin and LMB-100 (Selecta's SEL-403 product candidate) for the treatment of patients with malignant pleural or peritoneal mesothelioma. Selecta's proprietary gene therapy product candidates are being developed for rare inborn errors of metabolism and have the potential to enable repeat administration. The use of SVP is also being explored in the development of vaccines and treatments for allergies and autoimmune diseases. Selecta is based in Watertown, Massachusetts. For more information, please visit <http://selectabio.com> and follow @SelectaBio on Twitter.

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 Phase 1/2 clinical program of SEL-212, the ability of SEL-212 to provide better and more sustained serum uric acid control, fewer flares, and less frequent dosing compared with recent data reported with the current FDA-approved uricase therapy, the potential of SEL-212 to treat chronic severe gout patients and resolve their debilitating symptoms, the company's plans to present expansion data concerning higher dose cohorts in the Phase 2 of SEL-212 in June 2018, whether the Phase 3 trial for SEL-212 will be initiated in 2018 or at all, the company's plans to dose patients with five monthly combination doses of SEL-212, the company's plans to present data on cohorts receiving five combination doses of SEL-212 in Q3 2018, when the company will meet with the FDA for an End of Phase 2 meeting if at all, the company's ability to define its design for the Phase 3 program with the FDA at its End of Phase 2 meeting or at all, statements regarding the progress of the Phase 1 trial for SEL-403, the company's ability to locate and enroll a sufficient number of eligible patients to participate in in the Phase I trial for SEL-403, the potential of the

trial for SEL-403 to demonstrate the ability of the company's SVP technology to unlock the full potential of an existing biologic therapy and mitigate unwanted immunogenicity, statements regarding the ability of SEL-403 to allow patients to safely receive multiple treatment cycles and benefit fully from LMB-100, statements regarding the sufficiency of our capital resources to fund our operating expenses and capital expenditure requirements into mid-2019, the company's ability to unlock the full potential of biologic therapies by mitigating unwanted immunogenicity, the company's plan to apply its SVP platform to a range of biologics for rare and serious diseases, the potential applications for products utilizing the SVP platform in areas such as enzyme therapy, gene therapy, oncology therapy, vaccines and treatments for allergies and autoimmune diseases, the potential of the company's two gene therapy product candidates to enable repeat administration 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 unproven approach of the company's SVP 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, 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, substantial fluctuation in the price of its common stock, a significant portion of the company's total outstanding shares have recently become eligible to be sold into the market, and other important factors discussed in the "Risk Factors" section of the company's Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 15, 2018, and in other filings that the company makes with the SEC. 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
(In thousands, except for shares and par value)

	March 31, 2018	December 31,
	(Unaudited)	2017
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	\$ 58,304	\$ 70,698
Short-term deposits and investments	24,839	25,940
Accounts receivable	52	63
Prepaid expenses and other current assets	1,789	1,979
Total current assets	84,984	98,680
Property and equipment, net	2,257	2,091
Restricted cash and other assets	2,696	329
Total assets	\$ 89,937	\$ 101,100
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,789	\$ 1,606
Accrued expenses	9,062	8,580
Deferred revenue, current portion	959	787
Total current liabilities	11,810	10,973
Non-current liabilities:		
Deferred rent and lease incentive	129	151
Loans payable, net of current portion	21,127	21,042
Deferred revenue, net of current portion	13,917	15,919
Other long-term liabilities	1,372	1,201
Total liabilities	48,355	49,286
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 22,349,840 and 22,343,254 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	3	3
Additional paid-in capital	274,334	273,128
Accumulated deficit	(228,357)	(216,897)
Accumulated other comprehensive loss	(4,398)	(4,420)
Total stockholders' equity	41,582	51,814
Total liabilities and stockholders' equity	\$ 89,937	\$ 101,100

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

	Three Months Ended March 31,	
	2018	2017
	(Unaudited)	
Grant and collaboration revenue	\$ —	\$ 137
Operating expenses:		
Research and development	11,139	11,044
General and administrative	4,674	3,875
Total operating expenses	15,813	14,919
Loss from operations	(15,813)	(14,782)
Investment income	288	113
Foreign currency transaction gain (loss), net	(13)	(165)
Interest expense	(350)	(300)
Net loss	(15,888)	(15,134)
Other comprehensive loss:		
Foreign currency translation adjustment	19	123
Unrealized gain on securities	3	15
Total comprehensive loss	\$ (15,866)	\$ (14,996)
Net loss attributable to common stockholders	\$ (15,888)	\$ (15,134)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.71)	\$ (0.82)
Weighted average common shares outstanding:		
Basic and diluted	22,345,523	18,474,227

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