

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): August 8, 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 August 8, 2018, Selecta Biosciences, Inc. (the "Company") announced its financial results for the quarter ended June 30, 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 August 8, 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: August 8, 2018

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

Werner Cautreels, Ph.D.

President and Chief Executive Officer



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

- *Expanded three-month Phase 2 data presented at EULAR 2018 continue to indicate that SEL-212 product profile may provide better and more sustained serum uric acid control, fewer flares and less frequent dosing compared with data reported for current FDA-approved uricase therapy*
- *Data from patients receiving five monthly doses of SEL-212 expected to be presented at the American College of Rheumatology (ACR) Annual Meeting in October 2018*
- *SEL-212 Phase 3 pivotal program expected to begin in Q4 2018 with a planned head-to-head trial against Krystexxa conducted in parallel*
- *Enrollment ongoing for SEL-403 Phase 1 trial for mesothelioma, company working with NCI to potentially expand clinical studies for treatment in pancreatic cancer*
- *Company to host conference call today at 8:30 a.m. ET*

Watertown, Mass., Aug. 8, 2018 - [Selecta Biosciences, Inc.](http://www.selectabiosciences.com) (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 second quarter ended June 30, 2018 and provided a corporate update.

“The continued improvement in clinical activity observed in the expanded patient data set recently presented at the EULAR conference in June further demonstrates the benefit SEL-212 may provide to chronic severe gout patients and its potential ability to change the current treatment paradigm in these patients with high medical need,” said Werner Cautreels, Ph.D., President and CEO of Selecta. “We look forward to presenting data from patients receiving five monthly doses of SEL-212 at the upcoming ACR meeting in October and expect to initiate the Phase 3 program for SEL-212 in the fourth quarter of this year. In addition, we plan to conduct a head-to-head clinical trial against Krystexxa in parallel with our Phase 3 program.”

Recent Highlights and Anticipated Upcoming Milestones

- **Presented New Expansion Data from Ongoing Phase 2 Trial of SEL-212 at the European League Against Rheumatism (EULAR) 2018 in June:** In June 2018, Selecta presented new expansion data from patients receiving SEL-212 for the treatment of chronic severe gout at EULAR 2018 in Amsterdam, the Netherlands. The data was from patients receiving 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 80% of evaluable patients (n=27) had serum uric acid control below 6 mg/dl at week 12. In a separately conducted and designed study of the only FDA-approved uricase therapy, 44% of evaluable

patients had serum uric acid control below 6 mg/dl at week 16. 33% of the patient population represented by our EULAR data, and only 27% of all current patients in the SEL-212 Phase 2 trial, experienced gout flares during the first month after treatment with continued reduction of gout flare rates over months two to five. This reduced rate of gout flares appears to be substantially lower than the incidence of gout flares reported in clinical trials involving the current FDA-approved uricase and other uric acid lowering therapies.

- **Data from Cohorts Receiving Five Combination Doses in Ongoing Phase 2 Trial of SEL-212 to be Presented at the ACR Annual Meeting scheduled for October 19-24, 2018:** The company expects to present data from new cohorts of patients in the ongoing Phase 2 trial who are receiving five monthly doses of SVP-Rapamycin in combination with pegsiticase at the upcoming ACR meeting scheduled for October 19-24, 2018. These patients are receiving SVP-Rapamycin doses ranging from 0.10 - 0.15mg/kg in combination with 0.2mg/kg of pegsiticase.
- **Active Preparations Underway for SEL-212 Phase 3 Clinical Program and Expected Initiation of Patient Enrollment in Fourth Quarter of 2018:** Selecta is actively preparing for the start of a pivotal Phase 3 program for SEL-212, and plans to initiate patient enrollment in the fourth quarter of 2018 in a couple of clinical trial sites. The company expects to evaluate maintenance of serum uric acid control below 6 mg/dl at month three and month six as the primary clinical endpoint in two placebo-controlled clinical trials. The company's end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) will define the company's design for the Phase 3 program.
- **Active Preparations Underway for Head-to-Head Trial of SEL-212 Versus the Current FDA-Approved Uricase Therapy, Krystexxa:** The company is actively preparing to start a head-to-head clinical trial of SEL-212 compared to the current FDA-approved uricase therapy, Krystexxa, which will be designed to have the potential to demonstrate superiority. Selecta plans to initiate this trial in parallel with the Phase 3 program and expects to report clinical data at both the three month and six month time points in 2019.
- **Patient Enrollment Ongoing for SEL-403 Phase 1 Trial for Mesothelioma:** The company is actively dosing patients in an open-label dose-finding 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. The trial is being conducted in cooperation with the National Cancer Institute (NCI), part of the National Institutes of Health, and will evaluate the safety and tolerability of this treatment and provide data on pharmacokinetics, anti-drug antibody levels, as well as an objective response rate assessment. The company is also working with investigators at the NCI to potentially conduct a Phase 1 study of SEL-403 in patients with pancreatic cancer, and is further exploring additional studies in other cancers.
- **Preclinical Work Continues in Gene Therapy:** Previously presented data from the 2017 annual meetings of the American Society of Gene & Cell Therapy and the European Society of Gene and Cell Therapy have provided evidence for the potential of SVP-Rapamycin to unlock the full potential of this novel modality. The company continues to engage in preclinical work focused on its proprietary product candidate for the treatment of methylmalonic acidemia, as well as in support of its collaboration with Spark Therapeutics.

Second Quarter 2018 Financial Results:

- **Revenue:** For the second quarter of 2018, the company recognized no revenue, which compares to less than \$0.1 million for the second 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 second quarter of 2018 were \$14.4 million, which compares to \$11.0 million for the second quarter of 2017. The increase is primarily the result of higher clinical costs related to the company's Phase 2 trial of SEL-212, preparation for the start of the SEL-212 Phase 3 program and incremental headcount-related expenses.
- **General and Administrative Expenses:** General and administrative expenses for the second quarter of 2018 were \$4.4 million, which compares with \$4.9 million for the second quarter of 2017. The reduction in costs is primarily the result of reduced patent related costs and contract license fees associated with collaborations.
- **Net Loss:** For the second quarter of 2018, Selecta reported a net loss of \$(18.8) million, or \$(0.84) per share, compared to a net loss of \$(16.0) million, or \$(0.85) per share, for the same period in 2017.
- **Cash Position:** Selecta had \$66.2 million in cash, cash equivalents, short-term deposits and investments as of June 30, 2018, which compares with a balance of \$83.1 million at March 31, 2018. Selecta expects that its cash, cash equivalents, short-term deposits and investments will be sufficient to fund the company's operating expenses and capital expenditure requirements through the end of the third quarter of 2019. The current operating plan accounts for funding in preparation for the planned Phase 3 clinical trial for SEL-212 and initial patient enrollment into a couple of Phase 3 clinical trial sites, but the company will require an additional equity offering or other external sources of capital to expand enrollment in the Phase 3 trial and to conduct the planned head-to-head trial against Krystexxa.

Conference Call Reminder

Selecta management will host a conference call at 8:30 a.m. ET today to review the company's second quarter 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 10122287.

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 candidate in Phase 2, is being developed to treat severe gout patients and resolve their debilitating symptoms, including flares and gouty arthritis. Selecta's SEL-403 product candidate, a combination therapy consisting of SVP-Rapamycin and LMB-100, recently entered a Phase 1 trial in 2018 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 also holds potential 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 2 clinical trial of SEL-212, the anticipated timing for reporting further data from the Phase 2 trial, conducting an End-of-Phase 2 meeting (if at all) and advancing into Phase 3 (if at all), the potential for patient data from the SEL-212 Phase 2 trial to continue to show improved clinical activity, 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 design and potential significance of a head-to-head trial of SEL-212 and Krystexxa and the company’s expectations surrounding the timing of initiating and reporting data from the head-to-head trial (if at all), statements regarding the progress and enrollment of the Phase 1 trial for SEL-403 in mesothelioma, the potential Phase 1 study of SEL-403 in patients with pancreatic cancer in cooperation with NCI, and the potential of SEL-403 to treat other cancers, statements regarding the company’s proprietary product candidate for the treatment of methylmalonic acidemia, statements regarding the company’s ability to unlock the full potential of biologic therapies by mitigating unwanted immune responses, the ability of the company’s SVP platform, including SVP-Rapamycin, to enable new therapies or to improve the efficacy or safety of existing biologics by mitigating immune response, the potential of SEL-212 to treat severe gout patients, resolve their debilitating symptoms, and to change the chronic severe gout treatment paradigm, the potential of SEL-403 to treat mesothelioma, the potential treatment 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 company’s plan to apply its SVP 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 potential of the SVP-Rapamycin platform to unlock the full potential of gene therapy as a treatment modality, the sufficiency of the company’s capital resources to fund its operating expenses and capital expenditure requirements through the third quarter of 2019, 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 SVP 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 or licenses, 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, and other important factors discussed in the “Risk Factors” section of the company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 9, 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)

	June 30, 2018	December 31, 2017
	(Unaudited)	
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	\$ 60,237	\$ 70,698
Short-term deposits and investments	5,991	25,940
Prepaid expenses and other current assets	2,607	2,042
Total current assets	68,835	98,680
Property and equipment, net	2,137	2,091
Restricted cash and other assets	2,465	329
Total assets	\$ 73,437	\$ 101,100
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,789	\$ 1,606
Accrued expenses	10,184	8,580
Deferred revenue, current portion	1,918	787
Total current liabilities	13,891	10,973
Non-current liabilities:		
Deferred rent and lease incentive	98	151
Loan payable	21,212	21,042
Deferred revenue, net of current portion	12,870	15,919
Other long-term liabilities	1,104	1,201
Total liabilities	49,175	49,286
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 22,396,183 and 22,343,254 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	3	3
Additional paid-in capital	275,888	273,128
Accumulated deficit	(247,153)	(216,897)
Accumulated other comprehensive loss	(4,476)	(4,420)
Total stockholders' equity	24,262	51,814
Total liabilities and stockholders' equity	\$ 73,437	\$ 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(Unaudited)			
Grant and collaboration revenue	\$ —	\$ 26	\$ —	\$ 163
Operating expenses:				
Research and development	14,407	10,994	25,546	22,038
General and administrative	4,362	4,903	9,036	8,778
Total operating expenses	<u>18,769</u>	<u>15,897</u>	<u>34,582</u>	<u>30,816</u>
Loss from operations	<u>(18,769)</u>	<u>(15,871)</u>	<u>(34,582)</u>	<u>(30,653)</u>
Investment income	246	101	534	214
Foreign currency transaction gain (loss), net	84	82	71	(83)
Interest expense	(365)	(279)	(715)	(579)
Other income (expense), net	8	—	8	—
Net loss	<u>(18,796)</u>	<u>(15,967)</u>	<u>(34,684)</u>	<u>(31,101)</u>
Other comprehensive loss:				
Foreign currency translation adjustment	(90)	(43)	(71)	80
Unrealized gain on securities	12	10	15	25
Total comprehensive loss	<u>\$ (18,874)</u>	<u>\$ (16,000)</u>	<u>\$ (34,740)</u>	<u>\$ (30,996)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.84)</u>	<u>\$ (0.85)</u>	<u>\$ (1.55)</u>	<u>\$ (1.67)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>22,355,603</u>	<u>18,814,570</u>	<u>22,350,591</u>	<u>18,645,339</u>

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