

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 11, 2017

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 11, 2017, Selecta Biosciences, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 2017. 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 information contained in Item 2.02 of this Form 8-K (including Exhibit 99.1 related thereto) 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 August 11, 2017

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 11, 2017

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

Werner Cautreels, Ph.D.

President and Chief Executive Officer

EXHIBIT INDEX

**Exhibit
No.**

Description

99.1

Press Release issued on August 11, 2017



Selecta Biosciences Announces Second Quarter 2017 Financial Results and Provides Corporate Update

- *Positive Data from Ongoing Phase 2 Study of SEL-212 Reported at Clinical Meetings in June 2017*
- *Further Preclinical Data Confirm Immune Tolerance Platform's Broad Potential*
- *Recent Financing Extends Cash Runway Into 2019*
- *Company to Host Conference Call Today at 8:30 a.m. ET*

Watertown, Mass., August 11, 2017 - [Selecta Biosciences, Inc.](#) (NASDAQ: SELB), a clinical-stage biopharmaceutical company focused on unlocking the full potential of biologic therapies by avoiding unwanted immune responses, today reported financial results for the second quarter ended June 30, 2017 and provided a corporate update.

“The second quarter of 2017 was a time of significant accomplishment for the Selecta team as we advanced our pipeline of candidates that utilize our proprietary immune tolerance agent, SVP-Rapamycin,” said Werner Cautreels, Ph.D., CEO and Chairman of Selecta. “We in-licensed a new clinical-stage oncology product candidate, presented additional gene therapy data and strengthened our balance sheet by raising \$50 million in additional financing.

“Most importantly, we presented positive clinical data from our ongoing Phase 2 trial for our lead product candidate, SEL-212, indicating that we have identified a minimum effective dose that mitigates the formation of anti-drug antibodies (ADAs), allowing for a significant lowering and durable control of serum uric acid for gout patients over multiple monthly doses,” Dr. Cautreels continued. “We believe such a treatment would enable the resolution of crystallized uric acid deposits, or tophi, that are increasingly being cited as sources of morbidity and mortality in chronic severe gout patients. The clinical data also suggest that the incidence of gout flares in patients treated with SEL-212 was reduced as compared to the control cohorts.”

Recent Business Highlights and Activities

- **Presented SEL-212 Phase 2 Trial Data:** In June 2017, Selecta presented clinical data from its ongoing open-label, multiple ascending dose Phase 2 trial of SEL-212 (SVP-Rapamycin in combination with pegsiticase) at the Annual European Congress of Rheumatology (EULAR 2017) and the Federation of Clinical Immunology Societies (FOCIS 2017). As of August 1, 2017, a total of 63 patients had been dosed in eight cohorts. No additional serious adverse events or new notable safety trends have been observed in the trial since the presentations in June. The company plans to report further data from this trial at a medical meeting in late 2017 and to initiate its Phase 3 program in 2018.
- **Added a Clinical-Stage Oncology Asset:** In May 2017, Selecta announced that it had licensed LMB-100, a clinical-stage, next-generation recombinant immunotoxin, from the Center for Cancer Research at the National Cancer Institute (NCI), part of National Institutes of Health. LMB-100 contains a potent toxin that is derived from *Pseudomonas* exotoxin A fused to an antibody fragment targeting mesothelin, which is overexpressed in virtually all mesotheliomas and pancreatic adenocarcinomas and a high percentage of other malignancies, including ovarian, lung and breast cancers. A precursor to LMB-100 was shown to induce marked tumor reduction and prolonged survival in mesothelioma patients in which an ADA response was inhibited by immunosuppressants; however, ADAs limited the number of cycles that could be administered in the vast majority of patients. Additionally, a July 2017 publication entitled “Combining Local Immunotoxins Targeting Mesothelin with CTLA-4 Blockade Synergistically Eradicates Murine Cancer by Promoting Anti-Cancer Immunity” (Leshem Y et al) in *Cancer Immunology Research* described a preclinical study showing that a combination of LMB-100 and a checkpoint inhibitor induced complete mesothelioma regression in most mice. NCI is currently conducting two Phase 1 trials of LMB-100 in mesothelioma and pancreatic cancer, and Selecta and NCI are currently planning a Phase 1b clinical trial to evaluate multiple cycles of a combination treatment consisting of LMB-100 and SVP-Rapamycin.

- **Announced New Gene Therapy Data:** Additional preclinical data regarding non-immunogenic gene therapies were presented at the American Society of Gene & Cell Therapy (ASGCT) 2017 Annual Meeting in Washington, D.C. in May 2017. Selecta's collaborators at the National Human Genome Research Institute and Massachusetts Eye and Ear presented preclinical proof-of-concept data showing the efficacy of the company's methylmalonic acidemia (MMA) gene therapy candidate and SVP-Rapamycin's ability to mitigate immune responses to an Anc80 capsid. A team led by Federico Mingozzi, Ph.D., Head of Immunology and Liver Gene Therapy at Genethon, also presented preclinical data in mice and non-human primates indicating that co-administration of SVP-Rapamycin completely blocked anti-AAV immune responses and allowed for vector re-administration and gene therapy dose titration.
- **Published Preclinical Data in Pompe Disease:** *Molecular Genetics and Metabolism Reports* published a paper in July 2017 from collaborators at Duke University led by Dr. Priya Kishnani entitled "A pilot study on using rapamycin-carrying synthetic vaccine particles (SVP) in conjunction with enzyme replacement therapy to induce immune tolerance in Pompe disease." These investigators utilized a mouse model of Pompe disease to show that the co-administration of SVP-Rapamycin with the enzyme replacement therapy alglucosidase alfa (marketed as Myozyme® and Lumizyme®) inhibited the formation of ADAs, reduced glycogen storage, and improved weight and motor skills compared to co-administration of the enzyme with the immunosuppressive methotrexate.
- **Added a New Board Member:** At Selecta's 2017 Annual Meeting of Stockholders in June 2017, Patrick J. Zenner was elected to the company's Board of Directors. Mr. Zenner previously served as President and Chief Executive Officer of Hoffmann-La Roche Inc., North America, the prescription drug unit of Roche.
- **Raised \$50 Million in Financing:** Selecta completed a private placement with new and existing investors during the second quarter that resulted in gross proceeds to the company of \$50 million, before deducting placement agent and other offering expenses.

Second Quarter Financial Results:

- **Revenue:** For the second quarter of 2017, the company's total revenue was less than \$0.1 million, which compares with \$2.0 million for the second quarter of 2016. The decline is primarily the result of reduced revenue recognized from the company's nicotine vaccine candidate grant award from the National Institute on Drug Abuse, which is now winding down, as well as the previously announced termination of its collaboration with Sanofi.
- **Research and Development Expenses:** Research and development expenses for the second quarter of 2017 were \$11.0 million, which compares with \$6.0 million for the second quarter of 2016. The increase is primarily the result of clinical costs related to the company's Phase 2 program for SEL-212, incremental headcount, and consulting, licensing, supplies and testing activities related to the company's other pipeline programs.
- **General and Administrative Expenses:** General and administrative expenses for the second quarter of 2017 were \$4.9 million, which compares with \$2.4 million for the second quarter of 2016. The increase is primarily the result of greater expenses related to patents as well as general expenses and incremental salaries from increased headcount to support a clinical-stage public company.
- **Net Loss:** For the second quarter of 2017, Selecta reported a net loss attributable to common stockholders of \$(16.0) million, or \$(0.85) per share, compared to a net loss of \$(9.1) million, or \$(2.75) per share, for the same period in 2016. The decrease in net loss per share in the most recent quarter is primarily the result of shares of common stock that were issued in the company's June 2016 initial public offering (IPO) and conversion of Selecta's redeemable preferred stock into common stock in connection with the IPO, partially offset by an increase in net loss for the period.
- **Cash Position:** Selecta had \$113.0 million in cash, cash equivalents, short-term deposits, investments and restricted cash as of June 30, 2017, which compares with a balance of \$68.9 million at March 31, 2017. The increase is primarily the result of net proceeds from the company's aforementioned private placement as well as cash payments associated with the company's license and stock purchase agreements with Spark Therapeutics. Selecta expects 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 2019.

Conference Call 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 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 10111055.

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 avoiding unwanted immune responses. Selecta plans to combine its tolerogenic Synthetic Vaccine Particles (SVP™) to 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 clinical oncology candidate, LMB-100, is in a Phase 1 program targeting pancreatic cancer and mesothelioma. Its two 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 potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, whether the Phase 3 trial will be initiated in 2018, the company's ability to unlock the full potential of biologic therapies, 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, whether Selecta and NCI initiate a Phase 1b clinical trial of the LMB-100 and SVP-Rapamycin combination, the potential of the company's two gene therapy product candidates to enable repeat administration, the sufficiency of the company's cash, cash equivalents, investments, and restricted cash 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 11, 2017, 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, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 82,630	\$ 58,656
Short-term deposits and investments	30,025	25,485
Restricted cash	74	78
Accounts receivable	1	215
Prepaid expenses and other current assets	1,848	2,382
Total current assets	114,578	86,816
Property and equipment, net	2,131	2,047
Restricted cash and other deposits	316	316
Other assets	—	122
Total assets	\$ 117,025	\$ 89,301
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,280	\$ 3,882
Accrued expenses	8,595	3,921
Loans payable, current portion	4,612	4,067
Deferred revenue, current portion	2,566	1,836
Total current liabilities	20,053	13,706
Non-current liabilities:		
Deferred rent and lease incentive	189	222
Loans payable, net of current portion	5,732	7,977
Deferred revenue, net of current portion	11,619	12,439
Other long-term liabilities	1,250	—
Total liabilities	38,843	34,344
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively.	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 22,056,147 and 18,438,742 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively.	1	1
Additional paid-in capital	265,297	211,125
Receivable from stock option exercises	(26)	(75)
Accumulated deficit	(182,677)	(151,576)
Accumulated other comprehensive loss	(4,413)	(4,518)
Total stockholders' equity	78,182	54,957
Total liabilities and stockholders' equity	\$ 117,025	\$ 89,301

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Grant and collaboration revenue	\$ 26	\$ 2,017	\$ 163	\$ 4,105
Operating expenses:				
Research and development	10,994	6,000	22,038	12,648
General and administrative	4,903	2,418	8,778	4,799
Total operating expenses	15,897	8,418	30,816	17,447
Loss from operations	(15,871)	(6,401)	(30,653)	(13,342)
Investment income	101	10	214	23
Foreign currency transaction gain (loss), net	82	(158)	(83)	(378)
Interest expense	(279)	(310)	(579)	(620)
Other expense, net	—	(64)	—	(82)
Net loss	(15,967)	(6,923)	(31,101)	(14,399)
Other comprehensive loss:				
Foreign currency translation adjustment	(43)	170	80	401
Unrealized gain (loss) on securities	10	—	25	—
Comprehensive loss	\$ (16,000)	\$ (6,753)	\$ (30,996)	\$ (13,998)
Net loss	(15,967)	(6,923)	(31,101)	(14,399)
Accretion of redeemable convertible preferred stock	—	(2,210)	—	(4,566)
Net loss attributable to common stockholders	\$ (15,967)	\$ (9,133)	\$ (31,101)	\$ (18,965)
Net loss per share attributable to common stockholders				
Basic and diluted	\$ (0.85)	\$ (2.75)	\$ (1.67)	\$ (6.90)
Weighted average common shares outstanding				
Basic and diluted	18,814,570	3,322,546	18,645,339	2,749,105

Contact Information:

Jason Fredette
Selecta Biosciences, Inc.
617-231-8078
jfredette@selectabio.com