

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): March 15, 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 March 15, 2018, Selecta Biosciences, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 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 "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 March 15, 2018



Selecta Biosciences Announces Fourth Quarter and Year End 2017 Financial Results and Provides Corporate Update

- *SEL-212 Severe Gout Program on Track; Additional Phase 2 Data for Higher Dose Cohorts to be Presented on April 9th or 10th, 2018 at PANLAR Congress*
- *Phase I Clinical Trial of SEL-403 for Mesothelioma Initiated*
- *Company Reports Year-End 2017 Cash of \$97 Million and Reiterates Runway Through Mid-2019*
- *Company to Host Conference Call Today at 8:30 a.m. ET*

Watertown, Mass., March 15, 2018 - [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 fourth quarter and full year ended December 31, 2017 and provided a corporate update.

“Several important achievements have been made over the course of the past several months, and we are excited to be in a strong position to execute on our 2018 milestones,” said Werner Cautreels, Ph.D., President and CEO of Selecta. “We remain on track with the development of SEL-212 for chronic severe gout, with higher dose data from our Phase 2 trial to be presented in April and plans underway to initiate our Phase 3 program in 2018. We also recently announced that our next clinical candidate, SEL-403, has entered the clinic for the treatment of patients with mesothelioma at the National Cancer Institute. This also provides us with the opportunity to demonstrate for a second time the translation of our technology in the clinic. When coupled with the Board and management enhancements that were made over the course of the past year, we believe we have positioned Selecta for a momentous year in 2018.”

Recent Business Highlights and Activities

- **Cohorts Added to SEL-212 Phase 2 Trial with Initial Data to be Reported in April 2018:** As of March 9, 2018, a total of 111 patients had been dosed in Selecta’s ongoing Phase 2 trial of SEL-212 (SVP-Rapamycin in combination with pegsiticase) for the treatment of chronic severe gout. Selecta has now fully enrolled cohorts that are receiving three monthly doses of either 0.125 or 0.15 milligrams (mg) per kilogram (kg) of SVP-Rapamycin in combination with either 0.2 or 0.4 mg/kg of pegsiticase followed by two monthly doses of pegsiticase alone. The company plans to report further data from this ongoing trial at the upcoming Pan American League of Associations for Rheumatology (PANLAR) Congress on April 9th or 10th, 2018 and will host a conference call at 8:30 a.m. ET on the day of the presentation.
- **Initiated Dosing of SEL-212 Cohort Expected to Receive Five Combination Doses:** In February 2018, Selecta began enrolling patients in the current Phase 2 trial who are expected to receive five monthly doses of SVP-Rapamycin in combination with pegsiticase. The patients will

be 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 a medical meeting in Q3 2018.

- **SEL-212 End of Phase 2 (EOP2) Meeting Planned for Mid-2018 and Plans for Phase 3 Program Initiation in 2018:** The Selecta team is currently compiling the data package for an EOP2 meeting with the FDA, targeted for mid-2018, which will define the company's design for the Phase 3 program. The team has also begun preparations for the Phase 3 program which the company plans to initiate in 2018.
- **SEL-403 Phase 1 Trial Initiated:** On March 8, 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, anti-drug antibody (ADA) levels, as well as an objective response rate assessment.
- **Published SEL-403 Preclinical Data in January 2018:** *Proceedings of the National Academies of Sciences* (PNAS) published a paper in January 2018 co-authored by the company and researchers from the NCI. The paper, entitled "Tolerogenic nanoparticles restore the anti-tumor activity of recombinant immunotoxins by mitigating immunogenicity," focuses on SEL-403 preclinical work conducted by Selecta and Dr. Ira Pastan's lab at the NCI. Dr. Pastan is Senior Investigator, Head, Molecular Biology Section, at NCI's Center for Cancer Research and a Fellow of the National Academy of Sciences.
- **Enhanced Leadership of the Company:** Selecta announced the addition of two management team members in the fourth quarter of 2017: Chief Financial Officer and Head of Corporate Strategy John Leaman, M.D., and Chief Commercial Officer Stephen Smolinski. Dr. Leaman most recently served as Head of Corporate Development at InfaCare Pharmaceutical Corp., a specialty pharmaceutical company that was acquired by Mallinckrodt plc. Mr. Smolinski most recently served as Vice President and Head of Sanofi/Genzyme's North American Rheumatology Business Unit. In early January, the company announced that Dr. Omid Farokhzad, a member of Selecta's Board and a cofounder of the company, was appointed Chairman of the Board effective December 31, 2017.
- **Received Payment from Spark Therapeutics:** In the fourth quarter of 2017, Selecta received a cash payment of \$2.5 million under a license agreement, and proceeds from share purchases under a stock purchase agreement in the amount of \$5.0 million (\$7.5 million in the aggregate), bringing the total amount of proceeds received by Selecta from Spark Therapeutics to \$30.0 million. These payments are associated with the December 2016 license and stock purchase agreements that provided Spark Therapeutics with exclusive worldwide rights to SVP-Rapamycin for co-administration with Spark's gene therapy vectors for Hemophilia A and up to four additional pre-specified and undisclosed indications.

Fourth Quarter Financial Results:

- **Revenue:** For the fourth quarter of 2017, the company's total revenue was less than \$0.1 million, which compares with \$2.9 million for the fourth quarter of 2016. The decline is primarily the result of the termination of the company's collaboration with Sanofi, and reduced revenue recognized from the company's nicotine vaccine candidate grant award from the National Institute on Drug Abuse.
- **Research and Development Expenses:** Research and development expenses for the fourth quarter of 2017 were \$13.6 million, which compares with \$11.0 million for the fourth quarter of 2016. The increase is primarily the result of greater clinical costs related to the company's Phase 2 trial of SEL-212, planning for the SEL-212 Phase 3 program and incremental headcount-related expenses.
- **General and Administrative Expenses:** General and administrative expenses for the fourth quarter of 2017 were \$5.7 million, which compares with \$5.8 million for the fourth quarter of 2016. The decrease is primarily the result of greater headcount and related salaries needed to support a clinical-stage public company offset by a reduction in sublicensing payments made to the Massachusetts Institute of Technology resulting from the agreement with Spark Therapeutics.
- **Net Loss:** For the fourth quarter of 2017, Selecta reported a net loss attributable to common stockholders of \$(19.5) million, or \$(0.88) per share, compared to a net loss of \$(14.1) million, or \$(0.77) per share, for the same period in 2016.
- **Cash Position:** Selecta had \$97.0 million in cash, cash equivalents, short-term deposits, investments and restricted cash as of December 31, 2017, which compares with a balance of \$104.8 million at September 30, 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 provide a corporate update and review the company's fourth 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 10116990.

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™) 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 1/2 clinical program of SEL-212, the potential of SEL-212 to treat chronic severe gout patients and resolve their debilitating symptoms, the company’s plans to present data concerning higher dose cohorts in the Phase 2 of SEL-212 in April 2018, whether the Phase 3 trial for SEL-212 will be initiated in 2018 or at all, the company’s ability to execute on its 2018 milestones, 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, whether the company will meet with the FDA for an End of Phase 2 meeting in mid-2018 or 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 translation of the company’s SVP technology in the clinic, 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, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on November 7, 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)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 70,622	\$ 58,656
Short-term deposits and investments	25,940	25,485
Restricted cash	76	78
Accounts receivable	63	215
Prepaid expenses and other current assets	1,979	2,382
Total current assets	98,680	86,816
Property and equipment, net	2,091	2,047
Restricted cash and other deposits	329	316
Other assets	—	122
Total assets	\$ 101,100	\$ 89,301
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,606	\$ 3,882
Accrued expenses	8,580	3,921
Loans payable, current portion	—	4,067
Deferred revenue, current portion	787	1,836
Total current liabilities	10,973	13,706
Non-current liabilities:		
Deferred rent and lease incentive	151	222
Loans payable, net of current portion	21,042	7,977
Deferred revenue, net of current portion	15,919	12,439
Other long-term liabilities	1,201	—
Total liabilities	49,286	34,344
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 22,343,254 and 18,438,742 shares issued and outstanding as of December 31, 2017 and December 31, 2016, respectively	3	1
Additional paid-in capital	273,128	211,125
Receivable from stock option exercises	—	(75)
Accumulated deficit	(216,897)	(151,576)
Accumulated other comprehensive loss	(4,420)	(4,518)
Total stockholders' equity	51,814	54,957
Total liabilities and stockholders' equity	\$ 101,100	\$ 89,301

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Grant and collaboration revenue	\$ 17	\$ 2,930	\$ 207	\$ 8,083
Operating expenses:				
Research and development	13,623	11,033	45,165	29,702
General and administrative	5,671	5,757	18,826	13,051
Total operating expenses	<u>19,294</u>	<u>16,790</u>	<u>63,991</u>	<u>42,753</u>
Loss from operations	(19,277)	(13,860)	(63,784)	(34,670)
Investment income	238	113	617	234
Loss on extinguishment of debt	—	—	(673)	—
Foreign currency transaction gain (loss), net	(10)	(96)	(123)	(525)
Interest expense	(359)	(322)	(1,206)	(1,253)
Other income (expense), net	(136)	82	(152)	4
Net loss	<u>(19,544)</u>	<u>(14,083)</u>	<u>(65,321)</u>	<u>(36,210)</u>
Other comprehensive loss:				
Foreign currency translation adjustment	(1)	88	78	504
Unrealized gain (loss) on securities	(10)	(52)	20	(36)
Total comprehensive loss	<u>\$ (19,555)</u>	<u>\$ (14,047)</u>	<u>\$ (65,223)</u>	<u>\$ (35,742)</u>
Net loss	\$ (19,544)	\$ (14,083)	\$ (65,321)	\$ (36,210)
Accretion of redeemable convertible preferred stock	—	—	—	(4,566)
Net loss attributable to common stockholders	<u>\$ (19,544)</u>	<u>\$ (14,083)</u>	<u>\$ (65,321)</u>	<u>\$ (40,776)</u>
Net loss per share attributable to common stockholders:				
Basic and diluted	<u>\$ (0.88)</u>	<u>\$ (0.77)</u>	<u>\$ (3.20)</u>	<u>\$ (3.89)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>22,269,282</u>	<u>18,265,771</u>	<u>20,425,050</u>	<u>10,493,939</u>

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