

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): **November 9, 2016**

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))

Item 1.02. Termination of a Material Definitive Agreement.

On November 9, 2016, Selecta Biosciences, Inc., or the Company, received written notice from Sanofi that Sanofi has elected to terminate in its entirety the License and Research Collaboration Agreement by and between the Company and Sanofi dated as of November 27, 2012, or the Sanofi Agreement. The termination of the Sanofi Agreement will be effective on May 8, 2017, or the Termination Date, which is six months from the date of the notice.

Under the terms of the Sanofi Agreement, the Company granted Sanofi an exclusive, worldwide license to certain intellectual property rights and technologies owned by or licensed exclusively to the Company for the research, development and commercialization of one or more treatments for food allergies. The Sanofi Agreement contains an option to extend the license grant for two additional indications, including celiac disease but excluding house dust mite allergies. The Company received an upfront payment of \$2,000,000 for the initial indication in November 2012 and an additional payment of \$3,000,000 in August 2013.

In November 2014, Sanofi exercised the option to include celiac disease as an additional indication, and in May 2015, the Sanofi Agreement was amended to add terms specific to the celiac disease indication and to terminate Sanofi's right to exercise its option for any additional indications. Sanofi paid the Company an additional \$2,000,000 upon the exercise of the option in May 2015 and an additional \$1,000,000 in July 2016 upon attaining the first milestone for the celiac disease indication related to formulations containing gluten epitopes with the Company's proprietary Synthetic Vaccine Particles (SVP) technology. To date, Sanofi has paid the Company \$8,000,000 in the aggregate under the Sanofi Agreement. The Company would have been eligible to receive additional development-based, regulatory-based and sales-based milestone payments and tiered royalties on net sales of any approved product generated by the collaboration had the Sanofi Agreement not been terminated.

Except as authorized by Sanofi or permitted under the Sanofi Agreement, during the term of the Sanofi Agreement, exclusivity obligations prevent the Company from researching, developing, or commercializing products in these indications or granting third party licenses under the intellectual property rights and technologies licensed to Sanofi for use in these indications. These exclusivity obligations expire on the Termination Date.

Effective on the Termination Date, all rights granted to Sanofi will terminate and revert to the Company, and Sanofi is required to grant to the Company a royalty bearing, exclusive license, with the right to grant sublicenses, under certain Sanofi intellectual property solely to the extent necessary to research, develop, make, have made, use, offer for sale, import, export and otherwise commercialize the vaccine candidates developed under the Sanofi Agreement.

The Company intends to exercise its right to acquire the development programs under the Sanofi Agreement. The Company will be solely responsible for performing and funding any development and clinical trial activities relating to further development of vaccine candidates that it chooses to undertake after the Termination Date.

The foregoing is only a summary of the material terms of the Sanofi Agreement, does not purport to be complete and is qualified in its entirety by reference to the full text of the Sanofi Agreement, which was filed as Exhibit 10.8(a) to the Company's Registration Statement on Form S-1, as amended (File No. 333-211555), filed with the Securities and Exchange Commission on May 24, 2016.

Item 2.02. Results of Operations and Financial Condition.

On November 10, 2016, the Company announced its financial results for the quarter ended September 30, 2016. 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 November 10, 2016

Forward-Looking Statements Disclaimer

This Current Report on Form 8-K (the “Current Report”) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding our expectations surrounding the Termination Date and our intent to exercise our right to acquire the development programs under the Sanofi Agreement. These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials; availability and timing of data from ongoing and future clinical trials and the results of such trials; whether preliminary results from a 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 our SVP technology; potential delays in enrollment of patients; undesirable side effects of our product candidates; our reliance on third parties to manufacture our product candidates and to conduct our clinical trials; our inability to maintain our existing or future collaborations or licenses; expectations for regulatory approvals; availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements; ability to attract and retain key executives; managing our growth could result in difficulties; substantial fluctuation in the price of our common stock; and a significant portion of our total outstanding shares are eligible to be sold into the market in the near future. These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on August 9, 2016, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management’s estimates as of the date of this Current Report. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Current Report.

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: November 10, 2016

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 November 10, 2016



Selecta Biosciences Announces Third Quarter 2016 Financial Results and Provides Corporate Update

- *Phase 2 Trial of SEL-212 for Treatment of Gout Initiated*
- *SEL-212 Phase 1 Clinical Data to be Presented December 7-8, 2016*
- *Preclinical Data Presented for SVP's Potential in Gene Therapy and Oncology*
- *Exclusive Rights Obtained to Peanut Allergy and Celiac Disease Programs*
- *\$79.9 million in Cash, Cash Equivalents, Investments and Restricted Cash as of September 30, 2016*

Watertown, Mass., November 10, 2016 - [Selecta Biosciences, Inc.](http://selectabio.com) (NASDAQ: SELB), a clinical-stage biopharmaceutical company developing a novel class of targeted antigen-specific immune therapies, today reported financial results for the third quarter ended September 30, 2016 and provided a corporate update.

“We have recently reported a series of scientific and clinical advances demonstrating the breadth of our Synthetic Vaccine Particles (SVP™) platform and culminating with the dosing of the first gout patients in our Phase 2 clinical trial of SEL-212,” said Werner Cautreels, Ph.D, President, CEO and Chairman of Selecta. “SEL-212 is designed to dramatically lower serum uric acid levels, allowing for the elimination of inflammatory uric acid crystal deposits that cause debilitating pain and often serious damage to joints and organs. SEL-212 has the potential to address the large unmet need of patients suffering from chronic refractory and chronic tophaceous gout. This program exemplifies Selecta’s focus on building a pipeline of product candidates that leverage the immune tolerance application of the SVP platform to prevent unwanted immunogenicity in biologics. We also have been emboldened by recent preclinical data demonstrating SVP’s potential benefit in gene therapy and oncology indications, where undesired antibody and cellular immune responses have restricted otherwise beneficial therapies.”

Recent Business Highlights

- **Initiated Phase 2 Trial of SEL-212 in Gout:** Selecta recently began dosing the first patients in its Phase 2 clinical trial of SEL-212 (SVP-Rapamycin in combination with pegsiticase). This Phase 2 trial is being conducted at 15 centers in the United States and is expected to enroll more than 36 symptomatic gout patients with elevated uric acid levels. The primary and secondary endpoints include safety and tolerability of multiple doses of SEL-212, reduction of serum uric acid levels and mitigation of anti-drug antibodies (ADAs) against the enzyme product. Exploratory endpoints include measurement of uric acid deposits by Dual Energy Computed Tomography (DECT) imaging. Multiple dose treatment with SEL-212 has the potential to significantly lower total uric acid crystal burden in joints and tissues, which cannot be effectively or rapidly achieved by oral gout therapy. The removal of the uric acid crystal deposits is expected to reduce overall inflammation and the frequency of debilitating gout flares. Initial results from this trial are expected in the first half of 2017.
- **SEL-212 Phase 1a/b Data to be Presented December 7/8:** Data from Selecta’s SEL-212 Phase 1 program, including its ongoing Phase 1b trial, will be presented on December 7, 2016 at the 11th Annual Immunization and Vaccine Summit (IMVACS) in Boston, MA. At 8:30 a.m. ET on Thursday, December 8, 2016, this data will be discussed on a conference call. 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) 309-6574 (domestic) or (484) 747-6923 (international)

and may access a teleconference replay for one week by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and using confirmation code 14490302.

- **Reported Gene Therapy Data:** Preclinical data were recently presented at the Annual Congress of the European Society of Gene and Cell Therapy in Florence, Italy that demonstrate the benefits of applying Selecta's immune tolerance SVP technology to an AAV8 gene therapy vector expressing Factor IX, a coagulation protein deficient in patients with Hemophilia B. These studies elucidate the mechanism by which SVP-Rapamycin demonstrated successful mitigation of both humoral (antibody) and cellular immune responses that are associated with gene therapy using adeno-associated viral (AAV) vectors. Cellular immune responses observed in clinical trials of gene therapies have been associated with an increase in liver enzymes and a loss of transgene expression in patients. Antibodies against AAV develop with the first dose of gene therapy and can prevent re-administration of therapy, which may be important in pediatric applications and diseases where sufficient protein expression cannot be achieved with a single dose. Selecta's technology has the potential to overcome these limitations and enable repeat administrations.
- **Announced Oncology Cancer Data:** Results from preclinical studies applying Selecta's immune tolerance SVP technology to LMB-100, an anti-cancer therapeutic, were recently presented at the Immunogenicity and Bioassay Summit 2016 in Baltimore, Maryland. LMB-100 is a targeted immunotoxin that is currently undergoing Phase 1 clinical trials in patients with mesothelioma and pancreatic cancer. In a collaboration between the National Cancer Institute and Selecta, SVP-Rapamycin prevented the formation of anti-LMB-100 antibodies in mice, allowing for a significant increase in the number of treatment cycles and restoring the beneficial effect of LMB-100 on controlling tumor growth.
- **Received Exclusive Rights to Peanut Allergy, Celiac Disease Programs:** Selecta announced today that it is receiving worldwide rights to intellectual property, data and materials generated through a discovery collaboration initiated and funded by Sanofi for the development of product candidates to treat peanut allergy and celiac disease. This follows Sanofi's strategic review of its R&D portfolio, which resulted in its decision to exit this collaboration with Selecta. The transition of these discovery programs is not expected to have a material impact on Selecta's cash runway. Selecta plans to evaluate strategic opportunities to continue advancing these non-core programs.

Unaudited Third Quarter Financial Results:

- **Revenue:** For the third quarter of 2016, the company's total revenue was \$1.0 million, which compares with \$1.6 million for the same period in the prior year. The decline is primarily the result of lower collaboration revenue.
- **Research and Development Expenses:** Research and development expenses for the third quarter of 2016 were \$6.0 million, which compares with \$5.5 million for the same period in the prior year. The increase is primarily the result of incremental headcount and consulting to support the development of SEL-212 as well as increased stock compensation and insurance expense.
- **General and Administrative Expenses:** General and administrative expenses for the third quarter of 2016 were \$2.5 million, which compares with \$2.2 million for the same period in the prior year. The increase is primarily the result of additional costs related to market research as well as increased consulting and insurance fees associated with being a public company.
- **Net Loss:** For the third quarter of 2016, Selecta reported a net loss attributable to common stockholders of \$(7.7) million, or \$(0.43) per share, compared to a net loss of \$(7.6) million, or \$(3.50) per share, for the same period in 2015.
- **Cash Position:** Selecta had \$79.9 million in cash, cash equivalents, investments and restricted cash as of September 30, 2016, which compared with a balance of \$85.3 million at June 30, 2016. The decline is primarily

a result of the company's operating expenditures, partially offset by cash received from collaborations and grants as well as the partial exercise by underwriters of the company's initial public offering (IPO) overallotment option.

- **Financial Guidance:** Based on the company's current operating plan, Selecta expects that its cash, cash equivalents, investments and restricted cash are sufficient to fund the company's operating expenses and capital expenditure requirements into the first quarter of 2018.

Conference Call Reminder

Selecta management will host a conference call at 8:30 am ET today to review the company's third quarter 2016 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) 309-6574 (domestic) or (484) 747-6923 (international) and may access a teleconference replay for one week by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and using confirmation code 2975242.

About Selecta Biosciences, Inc.

[Selecta Biosciences, Inc.](http://selectabio.com) is a clinical-stage biopharmaceutical company developing targeted therapies that use immunomodulators encapsulated in nanoparticles to induce antigen-specific immune responses to prevent and treat disease. Selecta's proprietary Synthetic Vaccine Particles (SVP) technology is a highly flexible nanoparticle platform, capable of incorporating a wide range of antigens and immunomodulators, allowing the SVP-based products to either induce antigen-specific tolerance or activate the immune system.

Selecta's focus and strategy is to leverage its SVP immune modulating platform to develop and commercialize highly differentiated life-sustaining biologic drugs that are uniquely capable of mitigating the formation of anti-drug antibodies (ADAs). Proprietary programs that use SVP-Rapamycin to enhance efficacy and safety of therapy include SEL-212, Selecta's lead Phase 2 clinical program in chronic refractory gout, and two gene therapies programs for genetic metabolic diseases. Tolerance-inducing SVP biological products also have potential applications in the treatment of allergies and autoimmune diseases.

Selecta is also developing SVP product candidates that activate the immune system to prevent and treat cancer, infections and other diseases.

Selecta is based in Watertown, Massachusetts, USA. 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 impact of the company’s initial public offering on its financial position and the development of its pipeline, the progress of the Phase 1/2 clinical program of SEL-212 including the number of centers in the Phase 2 clinical trial of SEL-212 and the announcement of data, conference presentations, the ability of the company’s SVP platform, including SVP-Rapamycin, to mitigate immune response and create better therapeutic outcomes, the potential treatment applications for products utilizing the SVP platform, any future development of the company’s discovery programs in peanut allergy and celiac disease, 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 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, a significant portion of the company’s total outstanding shares are eligible to be sold into the market in the near future, 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 August 9, 2016, 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 this release 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)

	September 30, 2016	December 31, 2015
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,488	\$ 32,337
Short term deposits and investments	19,788	4,125
Restricted cash	335	133
Accounts receivable	483	824
Prepaid expenses and other current assets	3,303	1,494
Total current assets	83,397	38,913
Property and equipment, net	2,066	2,029
Restricted cash and other deposits	316	316
Other assets	—	1,566
Total assets	\$ 85,779	\$ 42,824
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,040	\$ 2,179
Accrued expenses	2,434	3,378
Loans payable, current portion	2,913	—
Deferred revenue, current portion	1,041	1,313
Contingently repayable grant funding	262	420
Total current liabilities	7,690	7,290
Non-current liabilities:		
Deferred rent and lease incentive	234	105
Loans payable, net of current portion	9,064	11,855
Deferred revenue, net of current portion	3,348	2,295
Other long-term liabilities	—	290
Total liabilities	20,336	21,835
Commitments and contingencies (Notes 8 and 13)		
Redeemable Convertible Preferred Stock:		
Series A redeemable convertible preferred stock, \$0.0001 par value; 0 and 2,589,868 shares authorized; 0 and 2,589,868 shares issued and outstanding; as of September 30, 2016 and December 31, 2015 respectively.	—	3,644
Series B redeemable convertible preferred stock, \$0.0001 par value; 0 and 7,437,325 shares authorized; 0 and 7,437,325 shares issued and outstanding; as of September 30, 2016 and December 31, 2015 respectively.	—	21,448
Series C redeemable convertible preferred stock, \$0.0001 par value; 0 and 5,000,002 shares authorized; 0 and 5,000,002 shares issued and outstanding; as of September 30, 2016 and December 31, 2015 respectively.	—	20,178
Series D redeemable convertible preferred stock, \$0.0001 par value; 0 and 8,166,662 shares authorized; 0 and 8,099,994 shares issued and outstanding; as of September 30, 2016 and December 31, 2015 respectively.	—	42,902
Series SRN redeemable convertible preferred stock, \$0.0001 par value; 0 and 5,611,112 shares authorized; 0 and 2,111,109 shares issued and outstanding; as of September 30, 2016 and December 31, 2015 respectively.	—	12,082
Series E redeemable convertible preferred stock, \$0.0001 par value; 0 and 9,030,654 shares authorized; 0 and 8,888,888 shares issued and outstanding; as of September 30, 2016 and December 31, 2015 respectively.	—	37,228
Total redeemable convertible preferred stock	—	137,482
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000,000 and 0 shares authorized; 0 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively.	—	—
Common stock, \$0.0001 par value; 200,000,000 and 62,164,377 shares authorized at September 30, 2016 and December 31, 2015 respectively; 18,190,180 and 2,180,976 shares issued, 18,188,313 and 2,173,399 shares outstanding as of September 30, 2016 and December 31, 2015, respectively.	1	—
Additional paid-in capital	207,489	1
Accumulated deficit	(137,493)	(111,508)
Accumulated other comprehensive loss	(4,554)	(4,986)
Total stockholders' equity (deficit)	65,443	(116,493)
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 85,779	\$ 42,824

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Grant and collaboration revenue	\$ 1,048	\$ 1,607	\$ 5,153	\$ 3,877
Operating expenses:				
Research and development	6,021	5,483	18,669	15,769
General and administrative	2,495	2,195	7,294	6,305
Total operating expenses	8,516	7,678	25,963	22,074
Loss from operations	(7,468)	(6,071)	(20,810)	(18,197)
Investment income	98	25	121	149
Foreign currency transaction gain (loss), net	(51)	668	(429)	616
Interest expense	(311)	(334)	(931)	(843)
Other expense, net	4	(13)	(78)	(50)
Net loss	(7,728)	(5,725)	(22,127)	(18,325)
Other comprehensive loss:				
Foreign currency translation adjustment	15	(800)	416	(763)
Unrealized gain (loss) on securities	16	—	16	—
Comprehensive loss	\$ (7,697)	\$ (6,525)	\$ (21,695)	\$ (19,088)
Net loss	(7,728)	(5,725)	(22,127)	(18,325)
Accretion of redeemable convertible preferred stock	—	(1,836)	(4,566)	(4,959)
Net loss attributable to common stockholders	\$ (7,728)	\$ (7,561)	\$ (26,693)	\$ (23,284)
Net loss per share attributable to common stockholders				
Basic and diluted	\$ (0.43)	\$ (3.50)	\$ (3.39)	\$ (10.86)
Weighted average common shares outstanding				
Basic and diluted	18,108,014	2,159,658	7,881,625	2,144,731

Contact Information:

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