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 8, 2018

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37798**	**26-1622110**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 November 8, 2018, Selecta Biosciences, Inc. (the “Company”) announced its financial results for the quarter ended September 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 November 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: November 8, 2018

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

Werner Cautreels, Ph.D.

President and Chief Executive Officer

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

- *Prioritized head-to-head superiority clinical trial of SEL-212 compared to Krystexxa, expected to begin in the first quarter of 2019 as part of overall planned Phase 3 clinical development program and commercialization strategy*
- *Potential for re-dosing of AAV gene therapy with SVP-Rapamycin platform to be explored in anticipated new clinical trial to start in 2H 2019*
- *Newly appointed President and Chief Executive Officer, Carsten Brunn, Ph.D., to start December 1, 2018*
- *Company to host conference call today at 8:30 a.m. ET*

Watertown, Mass., Nov. 8, 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 third quarter ended September 30, 2018 and provided a corporate update.

“We believe that our lead program, SEL-212, has the potential to fulfill several unmet needs in chronic severe gout patients including sustained serum uric acid reduction, reduced painful flares and once monthly dosing. We have recently presented interim data from our Phase 2 trial at ACR showing sustained SUA control over a five-month combination period. Based on these data, we are planning the initiation of a six-month head-to-head superiority clinical trial against Krystexxa with interim data readouts expected in 2019 and full data presentation anticipated in first quarter of 2020,” said Werner Cautreels, Ph.D., President and CEO of Selecta. “We believe our SVP technology has the potential to induce antigen specific tolerance allowing for the full benefit of biologics, including the possible re-dosing of AAV gene therapy programs. As Selecta enters the next stage of its growth, we look forward to the portfolio development strategy under the leadership of new CEO, Carsten Brunn, Ph.D.”

Recent Highlights and Anticipated Upcoming Milestones

- **SEL-212 6-Month Head-to-Head Trial vs. Krystexxa Expected to Begin in 1Q 2019:** Selecta plans to start a head-to-head superiority trial of SEL-212 compared to the current FDA-approved uricase therapy, Krystexxa, in the first quarter of 2019. Selecta expects to report interim data at the 3-month and 6-month timepoints in 2019 with full data anticipated in the first quarter of 2020.
- **Presented New Interim Phase 2 Clinical Data from Patients Receiving 5-Monthly Doses of SEL-212 at ACR 2018:** At the 2018 American College of Rheumatology (ACR)/Association for Rheumatology Health Professionals (ARHP) Annual Meeting in Chicago, Selecta presented interim data from new cohorts of patients that received five monthly doses of SEL-212 for the

treatment of chronic severe gout. These interim data continue to show that SEL-212 is generally well-tolerated at clinically active doses following repeated administrations in the trial and the serum uric acid (SUA) control rates observed for patients who completed the 5-month treatment period support the 6-month dosing strategy the company plans to pursue in the head-to-head trial and Phase 3 clinical program.

- **Announced Collaboration with CureCN for the Exploration of Clinical Use of SVP-Rapamycin in Combination with AAV Gene Therapy for Treatment of Crigler-Najjar Syndrome (CN):** The company announced its exploration of a new collaboration with CureCN, a European consortium, for the use of Selecta's SVP-Rapamycin technology in combination with an AAV gene therapy in CN, a rare genetic disorder characterized by an inability to properly convert and clear bilirubin from the body. Preclinical toxicology studies will need to be completed and then the combination product candidate is projected to enter the clinic in the second half of 2019 with the goal of potentially re-dosing gene therapy. This opportunity builds upon preclinical work that was published together with Genethon in Nature Communications in October 2018.

- **Appointed Carsten Brunn, Ph.D. as President and Chief Executive Officer:** In September 2018, the company announced that Carsten Brunn, Ph.D., had been appointed President and Chief Executive Officer of Selecta Biosciences, effective December 1, 2018. He will also serve on the company's Board of Directors. Current President and CEO, Werner Cautreels, Ph.D., will continue to lead the company until December, will assist Dr. Brunn during the transition and will remain a member of the Board through December 31, 2018. Dr. Cautreels is expected to serve as an advisor to the company following his retirement. Dr. Brunn joins Selecta from Bayer, where he was most recently the President of Pharmaceuticals for the Americas Region and a member of the Global Pharmaceutical Executive Committee.

Third Quarter 2018 Financial Results:

- Revenue: For the third quarter of 2018, the company recognized no revenue, which compares to less than $0.1 million for the third 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 third quarter of 2018 were $11.9 million, which compares to $9.5 million for the third 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 planned SEL-212 Phase 3 program and head-to-head clinical trial, and incremental headcount-related expenses.

- General and Administrative Expenses: General and administrative expenses for the third quarter of 2018 were $4.1 million, which compares with $4.4 million for the third quarter of 2017. The reduction in costs is primarily the result of reduced employee salaries and benefits and patent related costs.

- Net Loss: For the third quarter of 2018, Selecta reported a net loss of $(16.0) million, or $(0.71) per share, compared to a net loss of $(14.7) million, or $(0.66) per share, for the same period in 2017.

- Cash Position: Selecta had $50.5 million in cash and cash equivalents as of September 30, 2018, which compares to cash, cash equivalents and short-term investments of $66.2 million at June 30, 2018. The current operating plan accounts for funding in preparation for the planned Phase 3 clinical

program for SEL-212. However, prior to beginning the Phase 3 clinical program, the company expects to conduct the planned head-to-head trial against Krystexxa. The company will require an additional equity offering or other external sources of capital 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 provide a corporate update and review the company's third quarter 2018 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 10124090.

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™) 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 therapeutic candidates. 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. A Phase 1 trial was initiated for a combination therapeutic candidate 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. We believe 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 of the head-to-head trial comparing SEL-212 and Krystexxa and related data readouts, whether the head-to-head trial with Krystexxa will demonstrate superiority, the potential of SVP-Rapamycin to enable re-dosing of AAV gene therapy and the anticipated timing of preclinical toxicology studies and initiation of a clinical trial related thereto, whether the company's SVP technology has the potential to induce antigen specific tolerance and allow for the full benefit of biologics, the potential of SEL-212 to fulfill unmet needs in severe gout patients including sustained SUA reduction, reduced flares, and once monthly dosing, whether interim data related to the SEL-212 clinical program will be predictive of future data, the anticipated timing for advancing into Phase 3 (if at all), whether current evaluable SEL-212 patients will be predictive of future evaluable SEL-212 patients, whether patients receiving SEL-212 will be able to complete full therapy cycles over 6 months, whether SEL-212 will continue to be generally well-tolerated following repeat administrations, the company's ability to raise additional capital to fund the head-to-head trial against Krystexxa, the company's commercial plans, the ability of the company's SVP platform, including SVP-Rapamycin, to mitigate unwanted immunogenicity, unlock the full potential of biologic therapies, enable new therapies and improve the efficacy and safety of existing biologics, the potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, 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 generally, 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, 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, the company's recurring losses from operations and negative cash flows from operations raise substantial doubt regarding its ability to continue as a going concern, 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 for the quarter ended September 30, 2018, and in other filings that the company makes with the Securities and Exchange Commission. 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
(Amounts in thousands, except share data and par value)

	September 30, 2018	December 31, 2017
Assets	(Unaudited)	
Current assets:		
Cash, cash equivalents, and restricted cash	$ 50,485	$ 70,698
Short-term deposits and investments	—	25,940
Prepaid expenses and other current assets	5,083	2,042
Total current assets	55,568	98,680
Property and equipment, net	2,109	2,091
Restricted cash and other assets	2,646	329
Total assets	$ 60,323	$ 101,100
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,252	$ 1,606
Accrued expenses	10,218	8,580
Loan payable, current portion	21,299	—
Deferred revenue, current portion	1,863	787
Total current liabilities	34,632	10,973
Non-current liabilities:		
Deferred rent and lease incentive	67	151
Loan payable, net of current portion	—	21,042
Deferred revenue, net of current portion	13,824	15,919
Other long-term liabilities	1,800	1,201
Total liabilities	50,323	49,286
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 22,426,493 and 22,343,254 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	3	3
Additional paid-in capital	277,721	273,128
Receivable from stock option exercises	(53)	—
Accumulated deficit	(263,154)	(216,897)
Accumulated other comprehensive loss	(4,517)	(4,420)
Total stockholders' equity	10,000	51,814
Total liabilities and stockholders' equity	$ 60,323	$ 101,100

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited)			
Grant and collaboration revenue	$ —	$ 27	$ —	$ 190
Operating expenses:				
Research and development	11,885	9,504	37,431	31,542
General and administrative	4,056	4,377	13,092	13,155
Total operating expenses	15,941	13,881	50,523	44,697
Loss from operations	(15,941)	(13,854)	(50,523)	(44,507)
Investment income	295	165	829	379
Loss on extinguishment of debt	—	(673)	—	(673)
Foreign currency transaction gain (loss), net	26	(30)	97	(113)
Interest expense	(384)	(268)	(1,099)	(847)
Other income (expense), net	3	(16)	11	(16)
Net loss	(16,001)	(14,676)	(50,685)	(45,777)
Other comprehensive loss:				
Foreign currency translation adjustment	(42)	(1)	(113)	79
Unrealized gain on securities	1	5	16	30
Total comprehensive loss	$ (16,042)	$ (14,672)	$ (50,782)	$ (45,668)
Net loss per share:				
Basic and diluted	$ (0.71)	$ (0.66)	$ (2.27)	$ (2.31)
Weighted average common shares outstanding:				
Basic and diluted	22,403,954	22,082,207	22,368,574	19,803,551

Contact Information:

John Leaman, MD
Selecta Biosciences, Inc.
617-231-8081
jleaman@selectabio.com

Sarah McCabe
Stern Investor Relations, Inc.
+1-212-362-1200
sarah@sternir.com