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): January 3, 2019

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

☐ 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 2.05. Costs Associated with Exit or Disposal Activities.

On December 21, 2018, the Board of Directors (the "Board") of Selecta Biosciences, Inc. ("Selecta" or the "Company") approved a plan to reduce Selecta's headcount by approximately 36% (the "Workforce Reduction") following a strategic review of the Company's business. The Workforce Reduction aims to align Selecta's workforce with the Company's newly announced strategy to focus on the development of the Company's lead product candidate, SEL-212, for the treatment of chronic refractory gout, and advancement of the Company's ImmTOR™ technology (SVP-Rapamycin) in the area of gene therapy, specifically ImmTOR in combination with AAV gene therapy for the treatment of Crigler-Najjar Syndrome ("CN"), as well as the deprioritization of the Company's oncology development program. While the Workforce Reduction generally affects employees in all areas of Selecta, primarily affected are those working in research and related general and accounting functions. The Workforce Reduction resulted in the termination of approximately 17 employment positions effective January 3, 2019, and the affected employees were notified on the same date. Following the Workforce Reduction, Selecta expects to have approximately 45 full-time employment positions and to be appropriately resourced to continue executing on its current strategy. Selecta estimates that it will incur aggregate charges in connection with the Workforce Reduction of approximately $488,000 for employee severance and termination benefit costs, all of which are expected to be cash expenditures.

Selecta expects to substantially complete the Workforce Reduction during the first quarter of 2019.

Item 7.01. Regulation FD Disclosure.

On January 3, 2019, the Company announced new interim data from its ongoing Phase 2 Company-sponsored trial of SEL-212, for the treatment of chronic refractory gout, which is assessing single ascending dose safety, pharmacokinetics and pharmacodynamics of SEL-212 in patients with elevated uric acid levels. 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 furnished under this Item 7.01, 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On January 3, 2019, the Company announced new interim data from five patients in its Phase 2 trial of SEL-212 receiving five monthly combination doses of SEL-212, consisting of up to 0.15 mg/kg of ImmTOR in combination with 0.2 or 0.4 mg/kg of pegadricase. In these cohorts, approximately 66% of the evaluable patients maintained serum uric acid level control below 6 mg/dL throughout five months of therapy. Furthermore, reduced total urate burden and lowered flare rates and severity were observed in the Phase 2 clinical trial, and SEL-212 continued to be generally well tolerated.

In addition, the Company announced plans to initiate a head-to-head superiority trial of SEL-212, utilizing revised stopping rules, compared to the current FDA-approved uricase therapy, Krystexxa, in the first quarter of 2019. An interim six-month

data readout is projected for the fourth quarter of 2019 with a full statistical superiority data analysis expected in the first quarter of 2020. The Company plans to initiate a Phase 3 clinical trial of SEL-212 in the fourth quarter of 2019.

In September 2018, the Company announced a collaboration with the European consortium, CureCN, for an ImmTOR+AAV gene therapy combination product candidate in CN. The Company expects CureCN to initiate preclinical toxicology studies in the first half of 2019 and for the combination product candidate to enter the clinic in the second half of 2019.

In March 2018, the Company initiated a Phase 1 trial of SEL-403 in patients with malignant pleural or peritoneal mesothelioma who have undergone at least one regimen of chemotherapy under a Cooperative Research and Development Agreement at the National Cancer Institute, part of the National Institutes of Health. On January 3, 2019, the Company announced that it plans to deprioritize the SEL-403 Phase 1 oncology development program, which was placed on clinical hold by the FDA.

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 business strategy and operations, the size, timing and impact of the Workforce Reduction and related activities, the expected size and sufficiency of our workforce following such reduction, the estimated charges and costs expected to be incurred in connection with such reduction, and the amount of such charges expected to result in cash expenditures, the anticipated timing of the head-to-head trial comparing SEL-212 and Krystexxa and related data readouts, expectations surrounding the initiation of a Phase 3 clinical trial of SEL-212 and timing thereof, the potential of ImmTOR to enable re-dosing of AAV gene therapy and the anticipated timing of preclinical toxicology studies and initiation of a clinical trial related thereto, and plans to deprioritize the SEL-403 program. 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: our strategy may change, and we may not be able to effectively implement our current strategic plan; the size of our workforce following the reduction in force may not be sufficient, and we may not be able to effectively attract or retain new employees; risks associated with our reduction in workforce, such as employee claims and the risk that the actual financial and other impacts of the reduction could vary materially from the outcomes anticipated; the uncertainties inherent in the initiation, completion and cost of clinical trials including their uncertain outcomes; the unproven approach of our ImmTOR technology; 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; our inability to protect our proprietary technology and intellectual property; potential delays in regulatory approvals; our dependence on our ability to retain key executives and to attract, retain and motivate qualified personnel; and availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements. 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 November 8, 2018, 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on January 3, 2019

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: January 3, 2019

By: /s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President and Chief Executive Officer

Selecta Biosciences Expands Potential for ImmTOR™ Platform and Streamlined Structure Under Leadership of New CEO, Carsten Brunn, Ph.D.

- *Reported completion of SEL-212 Phase 2 study with positive efficacy and tolerability results observed in the clinical trial, in addition to monthly dosing, indicating potential to serve unmet need for patients with chronic refractory gout*
- *Held end of Phase 2 meeting for SEL-212 with FDA*
- *Head-to-head superiority trial for SEL-212 vs. KRYSTEXXA® expected to begin in Q1 2019; results anticipated to inform Phase 3 design*
- *Projected to dose first patient with combination of ImmTOR (SVP-Rapamycin) + AAV gene therapy in 2H 2019 in collaboration with CureCN consortium*

Watertown, Mass., January 3, 2019 - Selecta Biosciences, Inc. (Nasdaq: SELB), a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance platform technology, ImmTOR (SVP Rapamycin), today provided updates on its platform priorities and streamlined structure under the leadership of its new President and CEO, Carsten Brunn, Ph.D.

"We believe 2019 will be a transformative year for Selecta with key milestones anticipated for both our chronic refractory gout and gene therapy programs. We intend to focus on executing our strategic priorities, advancing our ImmTOR platform, and growing our strategic partnerships. With this renewed focus, we plan to deprioritize our oncology pipeline and undergo a restructuring to better align with our new priorities. The restructuring was a difficult decision and I want to personally thank all those who are affected for all their contributions to Selecta," said Dr. Brunn.

Selecta strongly committed to chronic refractory gout:
The company remains committed to the development of its lead product candidate, SEL-212, (ImmTOR+pegadricase) in chronic refractory gout. Based on interim data from the recently completed Phase 2 study, inclusive of the five outstanding patients who had not previously completed their course of therapy as of October 9th, 2018, 66% of evaluable patients (21/32), maintained serum uric acid (sUA) levels of <6mg/dL after five once-monthly treatments of SEL-212 at doses of 0.1 or 0.15 mg/kg of ImmTOR in combination with 0.2mg/kg of pegadricase. Furthermore, reduced total urate burden and lowered flare rates and severity were observed in the Phase 2 clinical trial, and SEL-212 continued to be generally well tolerated.

Following a December 2018 U.S. Food and Drug Administration (FDA) meeting, the company plans to initiate a head-to-head superiority trial of SEL-212, utilizing revised stopping rules,compared to the current FDA-approved uricase therapy, Krystexxa, in the first quarter of 2019. An interim six-month data readout is projected for the fourth quarter of 2019 with a full statistical superiority data analysis expected in the first quarter of 2020. The results of the planned head-to-head superiority trial are expected to inform the design of the planned Phase 3 clinical trial of SEL-212, which the company plans to initiate in the fourth quarter of 2019.

Selecta plans to explore the potential of re-dosing AAV gene therapy:
In September 2018, Selecta announced a collaboration with the European consortium, CureCN, for an ImmTOR+AAV gene therapy combination product candidate in Crigler-Najjar Syndrome. Selecta expects CureCN to initiate preclinical toxicology studies in the first half of 2019 and for the combination product candidate to enter the clinic in the second half of the year.

In addition to this renewed focus on AAV gene therapy applications, Selecta plans to deprioritize its SEL-403 Phase 1 oncology program. The trial, which was placed on clinical hold by the FDA, was being conducted by the National Cancer Institute, part of the National Institutes of Health.

Selecta's new CEO, Dr. Brunn, announces a streamlined structure:
Effective December 1, 2018, Carsten Brunn, Ph.D., assumed the role of President and CEO of Selecta, following his previous position as President of Pharmaceuticals for the Americas and member of the Global Pharmaceutical

Executive Committee at Bayer. He has also held senior executive positions at Eli Lilly, Novartis, Basilea, and Bausch and Lomb in Europe, Asia and the United States.

The company is restructuring to reduce the current workforce by 36% as of January 3, 2019. This reduction, coupled with a reprioritization of the company's pipeline programs, is projected to reduce the yearly cash burn by 19% going forward.

About Selecta Biosciences, Inc.
Selecta Biosciences, Inc. is a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance technology (ImmTOR) platform. Selecta plans to combine ImmTOR with a range of biologic therapies for rare and serious diseases that require new treatment options due to high immunogenicity. The company's current proprietary pipeline includes ImmTOR-powered therapeutic enzyme and gene therapy product candidates. SEL-212, the company's lead product candidate, is being developed to treat chronic refractory gout patients and resolve their debilitating symptoms, including flares and gouty arthritis. Selecta's proprietary gene therapy product candidates are in preclinical development for certain rare inborn errors of metabolism and incorporate ImmTOR with the goal of addressing barriers to repeat administration. 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 clinical development 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 or provide guidance for the design of the Phase 3 trial for SEL-212, the potential of ImmTOR to enable re-dosing of AAV gene therapy and the anticipated timing of preclinical toxicology studies and initiation of a clinical trial related thereto, the potential of SEL-212 to serve unmet needs in chronic refractory 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, anticipated achievement of key milestones for the company's chronic refractory gout and gene therapy programs, the company's ability to execute on its strategic priorities, advance its ImmTOR platform, and grow its strategic partnerships, the impact of the restructuring on the company's ability to achieve its new priorities, the company's ability to reduce its annual cash burn rate in connection with the restructuring, the company's plans to deprioritize the SEL-403 program, the ability of the company's ImmTOR platform to unlock the full potential of biologic therapies, the potential of SEL-212 to treat chronic refractory gout patients and resolve their debilitating symptoms, the potential treatment applications for products utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy, the company's plan to apply its ImmTOR platform to a range of biologic therapies for rare and serious diseases, the potential of the company's gene therapy product candidates to enable repeat administration, the potential of the ImmTOR 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 ImmTOR 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, the company's strategy may change, and the company may not be able to effectively implement its current strategic plan, the size of the company's workforce following the restructuring may not be sufficient, and the company may not be able to effectively attract or retain new employees, risks associated with the restructuring, such as employee claims and the risk that the actual financial and other impacts of the reduction could vary materially from the outcomes anticipated, 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 8, 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.

# # #

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