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): October 17, 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

☐ 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 8.01. Other Events.

As previously reported, Selecta Biosciences, Inc. (the "Company") has provided SVP-Rapamycin to the Center for Cancer Research at the National Cancer Institute (the "NCI"), part of the National Institutes of Health, to use in an NCI-sponsored Phase 1 clinical trial of the combination product candidate consisting of SVP-Rapamycin and LMB-100, an investigational immunotoxin targeting mesothelin, which is expressed on mesothelioma, pancreatic and other solid tumors. In this combination product candidate (referred to as SEL-403), SVP-Rapamycin may reduce the immunogenicity of LMB-100 potentially enhancing its efficacy and enabling repeat dosing through the mitigation of anti-drug antibody formation. The Company licensed LMB-100 from the NCI and the Phase 1 clinical trial of SEL-403 is being conducted under a Cooperative Research and Development Agreement (CRADA) between the NCI and the Company.

To date four patients have been dosed in this trial. The NCI informed the Company of a Grade 5 Serious Adverse Event (patient death) in this clinical trial related to pneumonitis, which was deemed by the trial investigator to be probably related to SVP-Rapamycin and possibly related to the patient's pleural mesothelioma condition. This patient had received previous therapies, including two courses of radiation therapy and three different immune checkpoint inhibitors, which can be associated with pneumonitis[1,2]; however, the possible relationship to SVP-Rapamycin cannot be excluded. Pneumonitis has been reported in patients receiving mTOR therapies, including daily oral rapamycin[3].

In addition, a Serious Adverse Event (pericardial effusion) was seen in one of the other three patients dosed in the SEL-403 clinical trial. Pericardial effusion can be a side effect of immunotoxin therapies targeting mesothelin[4].

There are currently no patients active in the SEL-403 clinical trial nor are new patients being enrolled at this time. The Company is working with the NCI investigators to fully understand the data from the trial in order to define the future development of SEL-403 in mesothelioma, pancreatic cancer and other oncology indications.

SVP-Rapamycin is also being investigated as a component of SEL-212 (combination of SVP-Rapamycin and pegsiticase) in an ongoing Phase 2 clinical trial in patients with symptomatic gout. In the Phase 2 trial to date, over 150 patients have received multiple (up to 5) doses of SEL-212 and no cases of pneumonitis have been reported.

The Company continues to dose patients in the SEL-212 Phase 2 trial and plans to report data from the trial at the 2018 American College of Rheumatology (ACR)/Association for Rheumatology Health Professionals (ARHP) Annual Meeting on October 23, 2018.

[1] Keytruda Label Section 5.1 (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125514s004s006lbl.pdf)
[2] Bledsoe TJ, Nath S2, Decker RH. Radiation Pneumonitis. Clin Chest Med. 2017 38(2):201-208
[3] Rapamune Label Section 5.11 (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021110s058lbl.pdf)
[4] Hassan R, et al., Phase I study of SS1P, a recombinant anti-mesothelin immunotoxin given as a bolus I.V. infusion to patients with mesothelin-expressing mesothelioma, ovarian, and pancreatic cancers. Clin Cancer Res. 2007 13(17):5144-9.

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 the ability of SVP-Rapamycin to reduce the immunogenicity of LMB-100, enhance its efficacy and enable repeat dosing, the potential relationship between SVP-Rapamycin and pneumonitis, ongoing discussions with NCI investigators and the future development of SEL-403, and the continued dosing and anticipated timing for reporting further data from the Phase 2 trial of SEL-212. 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 including their uncertain outcomes; the unproven approach of our SVP technology; undesirable side effects of our product candidates, including potential drug-related patient deaths; 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 August 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.

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: October 17, 2018

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

Werner Cautreels, Ph.D.
President and Chief Executive Officer