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 12, 2020

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37798**	**26-1622110**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

480 Arsenal Way
Watertown, MA 02472
(Address of principal executive offices) (Zip Code)

(617) 923-1400
Registrant's telephone number, including 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	SELB	Nasdaq Global Market

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 12, 2020, Selecta Biosciences, Inc. announced its financial results for the quarter and year ended December 31, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report and on Form 8-K.

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, 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 12, 2020

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: March 12, 2020

By: /s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.

President and Chief Executive Officer

Exhibit 99.1

Selecta Biosciences Reports Fourth Quarter 2019 and Year-End Financial Results

- *Topline results from head-to-head COMPARE trial of SEL-212 in chronic refractory gout expected in Q3 2020*
- *Received guidance from the FDA on SEL-212 Phase 3 clinical trial design; study to commence in 2H 2020*
- *Gene therapy program expected to enter the clinic by the end of 2020*
- *Company to host conference call today at 8:30 AM ET*

Watertown, Mass., Mar. 12, 2020 - 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, ImmTOR™, today reported financial results for the fourth quarter and year ended December 31, 2019.

"2019 was a pivotal year for Selecta. We made substantial clinical advancements, as we completed enrollment in the head-to-head COMPARE trial for our lead product candidate, SEL-212, in chronic refractory gout, and advanced our gene therapy program through strategic partnerships with AskBio. We also strengthened our organization with the addition of several key members to the executive team and welcomed a new Chairman of our Board of Directors, and completed a $70 million financing," said Carsten Brunn, Ph.D., President and CEO of Selecta. "In the coming year, we look forward to reporting topline data from the COMPARE study, commencing the Phase 3 clinical program of SEL-212, and advancing our gene therapy program into the clinic in partnership with AskBio."

Recent Highlights and Anticipated Upcoming Milestones:

- **Topline Results from COMPARE Clinical Trial Expected in the Third Quarter of 2020:** In December 2019, we announced the completion of enrollment in the head-to-head COMPARE study of Selecta's lead product candidate, SEL-212 (ImmTOR + pegadricase), vs. pegloticase. Topline data from this trial is expected in the third quarter of 2020. The trial is evaluating a once-monthly dose of SEL-212 compared to biweekly doses of pegloticase, with the primary endpoint of the maintenance of serum uric acid (SUA) levels of <6mg/dL at three and six months.

- **Meeting with FDA Provides Clarity on Phase 3 Clinical Program of SEL-212:** Selecta held a meeting with the U.S. Food and Drug Administration (FDA) in January 2020 to inform the design of the planned Phase 3 clinical program. Selecta plans to commence its Phase 3 clinical program of SEL-212 against placebo in the second half of 2020.

- **Gene Therapy Program in the Clinic by the End of 2020:** In August 2019, Selecta announced a strategic partnership with Asklepios BioPharmaceutical, Inc. (AskBio), to jointly develop, manufacture, and commercialize a broad portfolio of next-generation AAV gene therapies. This

partnership will leverage the unique proprietary technology platforms of both companies with a human proof of concept trial to validate this portfolio of products and their potential for re-dosing in patients, which could represent a significant advancement in the gene therapy field. Selecta and AskBio anticipate entering the clinic by the end of 2020. Additionally, the Company intends to advance its proprietary program in ornithine transcarbamylase (OTC) deficiency.

- **Broadened Strategic Partnership with AskBio:** In December 2019, Selecta and AskBio jointly announced that the companies entered into a license agreement under which AskBio exercised its option to exclusively license rights to develop and commercialize Selecta's immune tolerance platform, ImmTOR, for use in adeno-associated virus (AAV) gene therapy for the treatment of Pompe disease. Affecting 5,000-10,000 people worldwide, Pompe disease is a rare, genetic, lysosomal storage disease characterized by the abnormal buildup of a sugar molecule called glycogen inside cells. Under the terms of the agreement, Selecta received upfront payments of $7 million and is eligible to receive milestone payments of $237 million plus royalties on product sales.

- **Raised $70 Million in a Private Placement:** In December 2019, Selecta announced the closing of a transaction to sell securities in a private placement with institutional investors and certain members of the Company's Board of Directors, resulting in gross proceeds of approximately $70 million.

- **Strengthened Board of Directors:** In November 2019, Selecta announced the appointment of Carrie S. Cox to the position of Chairman of the Board of Directors. A renowned industry leader and successful biopharmaceutical executive, Ms. Cox has served on multiple Boards, and has held the position of Chair, for several biopharmaceutical companies.

Fourth Quarter and Full Year 2019 Financial Results:

- **Cash Position:** Selecta had $91.6 million in cash, cash equivalents, and restricted cash as of December 31, 2019, which compares to cash, cash equivalents, restricted cash, and short-term investments of $35.9 million as of September 30, 2019. Selecta believes its available cash, cash equivalents, and restricted cash will be sufficient to meet its operating requirements into the first quarter of 2021.

    - Net cash used in operating activities was $12.9 million and $51.4 million for the fourth quarter and fiscal year 2019, respectively, as compared to $12.7 million and $59.2 million for the same periods in 2018.

- **Research and Development Expenses:** Research and development expenses for the fourth quarter and fiscal year 2019 were $15.2 million and $42.7 million, respectively, which compares with $10.3 million and $47.7 million for the same periods in 2018. The quarterly increase reflects additional costs incurred specific to our Phase 2 head-to-head (COMPARE) clinical trial of SEL-212, for which we completed enrollment in December 2019. The decrease year over year reflects reduced costs in 2019 due to the completion of prior programs in 2018, combined with reduced salaries and benefits resulting from the headcount reduction in early 2019. The cost reductions were offset by an overall increase in costs incurred on our lead product candidate, SEL-212.

- **General and Administrative Expenses:** General and administrative expenses for the fourth quarter and fiscal year 2019 were $4.1 million and $16.4 million, respectively, which compares with $5.1 million and $18.2 million for the same periods in 2018. The decrease is the result of lower salaries and stock compensation expense resulting from reduced headcount at the end of 2018, combined with reduced patent and professional fees.

- **Net Loss:** For the fourth quarter and fiscal year 2019, Selecta reported a net loss of $14.9 million, or $0.28 per share and $55.4 million, or $1.22 per share, compared to a net loss of $14.7 million, or $0.65 per share, and $65.3 million, or $2.92 per share, for the same periods in 2018.

Conference Call and Webcast Reminder:

Selecta management will host a conference call at 8:30 AM ET today to provide a corporate update and review the company's fourth quarter 2019 financial results. Individuals may 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 10138603. Investors and the public can access the live and archived webcast of this call and a copy of the presentation via the Investors & Media section of the company's website, www.selectabio.com.

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.

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, expectations surrounding the enrollment and design of the Phase 2 head-to-head (COMPARE) clinical trial comparing SEL-212 and Krystexxa, timing of related data readouts and the ability of the COMPARE results to inform the planned Phase 3 clinical trial of SEL-212, the anticipated timing of the planned Phase 3 clinical trial, whether the head-to-head trial with Krystexxa will demonstrate superiority, the unique proprietary technology platform of the company and the unique proprietary platform of its partners, the potential of ImmTOR to enable re-dosing of AAV gene therapy, the potential of SEL-212 to fulfill unmet needs in chronic refractory gout patients including sustained SUA reduction, reduced flares, and once monthly dosing, the company's commercial plans, the ability of the company's ImmTOR platform, including SEL-212, 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 product candidates utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy, the ability of the ImmTOR platform to enhance transgene expression, the ability of the Company and AskBio to develop gene therapy products using ImmTOR and

AskBio's core technology, the novelty of treatment paradigms that the Company and AskBio are able to develop, the potential of any therapies developed by the Company and AskBio to fulfill unmet medical needs, AskBio's ability to make milestone payments, AskBio's ability to develop and commercialize a drug product containing ImmTOR for the treatment of Pompe disease, the company's plan to apply its ImmTOR technology 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 Company's ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential of the ImmTOR technology platform generally and the company's ability to grow its strategic partnerships, the Company's plans to present at the American College of Rheumatology Annual Meeting, the sufficiency of the company's cash, cash equivalents and short-term investments, 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, management's ability to perform as expected, 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 most recent Annual Report on Form 10-K, 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 intention 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)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 89,893	$ 37,403
Restricted cash	279	—
Accounts receivable	5,000	—
Prepaid expenses and other current assets	1,495	4,673
Total current assets	96,667	42,076
Property and equipment, net	1,222	2,127
Right-of-use asset, net	301	—
Long-term restricted cash	1,379	279
Total assets	$ 99,569	$ 44,482
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 500	$ 1,100
Accrued expenses	13,492	11,700
Loan payable	18,905	21,385
Lease liability	372	—
Deferred revenue	1,674	959
Total current liabilities	34,943	35,144
Non-current liabilities:		
Deferred revenue	14,680	13,818
Warrant liabilities	41,549	—
Other long-term liabilities	—	938
Total liabilities	91,172	49,900
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 86,325,547 and 22,471,776 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	9	3
Additional paid-in capital	348,664	279,539
Accumulated deficit	(335,753)	(280,403)
Accumulated other comprehensive loss	(4,523)	(4,557)
Total stockholders' equity (deficit)	8,397	(5,418)
Total liabilities and stockholders' equity (deficit)	$ 99,569	$ 44,482

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Grant and collaboration revenue	$ 6,654	$ 903	$ 6,677	$ 903
Operating expenses:				
Research and development	15,152	10,256	42,743	47,687
General and administrative	4,072	5,146	16,389	18,238
Total operating expenses	19,224	15,402	59,132	65,925
Loss from operations	(12,570)	(14,499)	(52,455)	(65,022)
Investment income	127	221	834	1,050
Foreign currency transaction (loss), net	(14)	23	(47)	120
Interest expense	(335)	(395)	(1,519)	(1,494)
Change in fair value of warrant liabilities	(857)	—	(857)	—
Other (expense), net	(1,239)	(1)	(1,306)	10
Net loss	(14,888)	(14,651)	(55,350)	(65,336)
Other comprehensive loss:				
Foreign currency translation adjustment	10	(40)	34	(153)
Unrealized gain on securities	—	—	—	16
Total comprehensive loss	$ (14,878)	$ (14,691)	$ (55,316)	$ (65,473)
Net loss per share:				
Basic and diluted	$ (0.28)	$ (0.65)	$ (1.22)	$ (2.92)
Weighted average common shares outstanding:				
Basic and diluted	52,321,884	22,450,828	45,548,511	22,389,286

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