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, 2019

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 November 8, 2019, Selecta Biosciences, Inc. announced its financial results for the quarter ended September 30, 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 November 8, 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: November 8, 2019

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

Selecta Biosciences Reports Third Quarter 2019 Financial Results and Provides Corporate Update

- *Compelling preclinical data presented at the European Society of Gene and Cell Therapy Annual Congress demonstrates the potential for redosing in AAV-mediated gene therapy; announced strategic partnership with AskBio and expect to enter the clinic in 2020*
- *COMPARE head-to-head trial of SEL-212 in chronic refractory gout expected to be fully enrolled by the end of 2019; confirmed FDA meeting in January 2020 regarding Phase 3 clinical development plan*
- *Raised $5.7 million in net proceeds in a private placement with participation from the management team and board of directors*
- *Strengthened management team with appointments of Alison D. Schecter, M.D. as Chief Medical Officer and Brad Dahms as Chief Financial Officer*
- *Company to host conference call today at 8:30 AM ET*

Watertown, Mass., Nov. 8, 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™, today reported financial results for the third quarter ended September 30, 2019 and provided a corporate update.

“We have made significant strides this quarter to advance the ImmTOR platform across its potential indications. Preclinical data from our gene therapy program presented at ESGCT demonstrates that ImmTOR prevents the formation of adenoviral vector-induced neutralizing antibodies and has the potential to enable re-administration of therapeutic AAV vectors,” said Carsten Brunn, Ph.D., President and CEO of Selecta. “This quarter, we partnered with AskBio, proven leaders in next-generation gene therapy development and scalable manufacturing, to accelerate the innovation of gene therapy medicines. Our chronic refractory gout program continues to advance, and we expect to complete enrollment in our head-to-head COMPARE trial by the end of 2019. We have also strengthened our management team with two recent C-suite additions.”

Recent Highlights and Anticipated Upcoming Milestones:

- **Compelling Preclinical Gene Therapy Data Presented at the European Society of Gene and Cell Therapy (ESGCT):** Data from four preclinical studies were presented at the ESGCT Annual Congress in Barcelona, Spain. These studies highlight the ability of ImmTOR to address key challenges in gene therapy, specifically, the re-dosing limitations which stem from adaptive immune responses against the adeno-associated virus (AAV) capsid. These data demonstrate that ImmTOR enables repeat dosing and enhances first dose transgene expression up to four-fold compared to gene therapy with AAV vector alone. These conclusions support the advancement of the Company’s gene therapy pipeline, and Selecta looks forward to the clinical development of its

lead gene therapy programs in Methylmalonic Acidemia (MMA) and Ornithine Transcarbamylase (OTC) deficiency.

- **Announced Strategic Partnership with Gene Therapy Leader AskBio:** In August 2019, Selecta announced a strategic partnership with Asklepios BioPharmaceutical, Inc. (AskBio), to jointly develop, manufacture, and commercialize a broad portfolio of life-changing, 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. Selecta and AskBio anticipate entering the clinic in 2020.

- **New SEL-212 Data to be Presented at the American College of Rheumatology Annual Meeting:** On November 11, three abstracts of additional data from the Phase 2 dose-ranging study of SEL-212 will be presented at the American College of Rheumatology annual meeting. A press release detailing the results of these studies will be issued following the meeting's embargo lift.

- **COMPARE Clinical Trial Expected to be Fully Enrolled by End of 2019:** The head-to-head COMPARE study of Selecta's lead product candidate SEL-212 (ImmTOR + pegadricase) vs. pegloticase (KRYSTEXXA®) continues to enroll patients. The trial is evaluating a once-monthly dose of SEL-212 compared to pegloticase, with the primary endpoint of the maintenance of serum uric acid (SUA) levels of <6mg/dL at six months. The COMPARE trial is built upon the Phase 2 dose-ranging study which showed that in the five monthly dose cohorts, SEL-212 maintained SUA levels below 6mg/dL in 66% of evaluable patients, and that only 35% of patients in these cohorts experienced flares in the first month. Selecta expects to report interim data from the COMPARE trial in the first quarter of 2020, with top-line statistical superiority data expected by mid-2020.

- **Key Regulatory Update for SEL-212:** The U.S. Food and Drug Administration (FDA) has granted Selecta a meeting to be held in January 2020, which is expected to inform the design of the Phase 3 clinical trial, and outline requirements for the Biologic License Application (BLA) filing for SEL-212.

- **Bolstered Balance Sheet with Private Equity Offering:** In August 2019, Selecta announced it had raised net proceeds of approximately $5.7 million in a private equity offering to primarily the management team and members of the board of directors of the Company.

- **Strengthened Management Team:** In the third quarter of 2019, Selecta announced the appointments of Dr. Alison D. Schecter as Chief Medical Officer and Brad Dahms as Chief Financial Officer. Dr. Schecter brings more than 20 years of combined drug development, strategic management, and clinical experience in academia and industry. Mr. Dahms brings deep financial and strategic expertise from his experience as an investment banker for life sciences companies.

Third Quarter 2019 Financial Results:

- **Cash Position:** Selecta had $35.9 million in cash, cash equivalents, and restricted cash as of September 30, 2019, which compares to cash, cash equivalents, restricted cash and short-term investments of $42.0 million as of June 30, 2019.

- **Research and Development Expenses:** Research and development expenses for the third quarter ended September 30, 2019 were $8.1 million, which compares with $11.9 million for the third quarter of 2018, a 32% decrease compared to the same period in 2018. The decrease reflects the timing of expenses recognized for Selecta's head-to-head COMPARE study, in addition to reduced salaries and benefits resulting from the headcount reduction in early 2019 and the completion of work on prior programs.

- **General and Administrative Expenses:** General and administrative expenses for the third quarter ended September 30, 2019 were $3.7 million, which compares with $4.1 million for the third quarter of 2018, a 9% decrease compared to the same period in 2018. The reduction in costs was primarily the result of reduced legal fees and professional fees.

- **Net Loss:** For the third quarter ended September 30, 2019, Selecta reported a net loss of $12.0 million, or $0.26 per share, compared to a net loss of $16.0 million, or $0.71 per share, for the same period in 2018.

Financial Outlook:

Selecta believes its available cash, cash equivalents, and restricted cash will be sufficient to meet its operating requirements through the first quarter of 2020.

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 third quarter 2019 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 10127460.

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 and the anticipated timing of preclinical toxicology studies in collaboration with CureCN and initiation of a clinical trial related thereto, CureCN's abilities and timeliness in obtaining advice from the German drug regulatory authority, 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, 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 Quarterly Report on Form 10-Q, 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)

	September 30, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	$ 34,513	$ 37,403
Prepaid expenses and other current assets	1,606	4,673
Total current assets	36,119	42,076
Property and equipment, net	1,452	2,127
Right of Use Asset, net	594	—
Long-term restricted cash	1,379	279
Total assets	$ 39,544	$ 44,482
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,478	$ 1,100
Accrued expenses	5,316	11,700
Loan payable, current portion	20,927	21,385
Lease liability, current portion	734	—
Deferred revenue, current portion	1,023	959
Total current liabilities	29,478	35,144
Non-current liabilities:		
Deferred rent and lease incentive	—	34
Deferred revenue, net of current portion	14,981	13,818
Other long-term liabilities	—	904
Total liabilities	44,459	49,900
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 48,196,387 and 22,471,776 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	5	3
Additional paid-in capital	320,478	279,539
Accumulated deficit	(320,865)	(280,403)
Accumulated other comprehensive loss	(4,533)	(4,557)
Total stockholders' equity (deficit)	(4,915)	(5,418)
Total liabilities and stockholders' equity (deficit)	$ 39,544	$ 44,482

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,	
	2019	2018	2019	2018
			(Unaudited)	
Grant and collaboration revenue	$ —	$ —	$ 23	$ —
Operating expenses:				
Research and development	8,104	11,885	27,591	37,431
General and administrative	3,690	4,056	12,317	13,092
Total operating expenses	11,794	15,941	39,908	50,523
Loss from operations	(11,794)	(15,941)	(39,885)	(50,523)
Investment income	184	295	707	829
Foreign currency transaction (loss), net	7	26	(33)	97
Interest expense	(388)	(384)	(1,184)	(1,099)
Other (expense), net	(3)	3	(67)	11
Net loss	(11,994)	(16,001)	(40,462)	(50,685)
Other comprehensive loss:				
Foreign currency translation adjustment	(5)	(42)	24	(113)
Unrealized gain on securities	(3)	1	—	16
Total comprehensive loss	$ (12,002)	$ (16,042)	$ (40,438)	$ (50,782)
Net loss per share:				
Basic and diluted	$ (0.26)	$ (0.71)	$ (0.94)	$ (2.27)
Weighted average common shares outstanding:				
Basic and diluted	46,407,846	22,403,954	43,265,909	22,368,574

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