

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 15, 2019

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37798
(Commission
File Number)

26-1622110
(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:

- 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 2.02. Results of Operations and Financial Condition.

On March 15, 2019, Selecta Biosciences, Inc. (the “Company”) announced its financial results for the quarter and year ended December 31, 2018. 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 “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, 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 15, 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: March 15, 2019

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

Carsten Brunn, Ph.D.

President and Chief Executive Officer



Selecta Biosciences Announces Fourth Quarter and Year End 2018 Financial Results and Provides Corporate Update

- *Phase 2 head-to-head (COMPARE) clinical trial of SEL-212 vs. KRYSTEXXA® to begin in 1Q19, interim six-month data expected in 4Q19*
- *Collaboration with CureCN projected to dose first patient with combination of ImmTOR + AAV gene therapy candidate in 2H19*
- *Company raises \$33M in gross offering proceeds and \$31.3M in net proceeds in 1Q19, cash runway into 1Q20*
- *Company to host conference call today at 8:30 a.m. ET*

Watertown, Mass., March 15, 2019 - [Selecta Biosciences, Inc.](http://www.selectabiosciences.com) (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 fourth quarter and full year ended December 31, 2018 and provided a corporate update.

“During 2018 we laid a strong groundwork for a year of execution in 2019. We kicked off the year by streamlining the company through a corporate restructuring, which is projected to cut our cash burn rate by 19%. We then completed an equity fundraise of approximately \$33 million in gross proceeds and \$31.3 million in net proceeds, and anticipate reporting key milestones for both our chronic refractory gout and gene therapy programs. We continue to believe that our lead program, SEL-212, has the potential to address several unmet needs in chronic refractory gout patients, including sustained serum uric acid reduction, reduced painful flares and once monthly dosing, and we look forward to initiating the planned six-month head-to-head (COMPARE) clinical trial against Krystexxa this month,” said Carsten Brunn, Ph.D., President and CEO of Selecta. “We also look forward to further advancing our ImmTOR + AAV gene therapy combination product candidate in Crigler-Najjar Syndrome in collaboration with CureCN in the second half of the year and identifying other ways to advance our ImmTOR platform and grow our strategic partnerships.”

2018 and Recent Highlights and Anticipated Upcoming Milestones

SEL-212 (ImmTOR+Pegadricase) for the Treatment of Chronic Refractory Gout:

- **Six-Month Head-to-Head (COMPARE) Clinical Trial of SEL-212 vs. Krystexxa Expected to Begin in 1Q19:** Selecta expects to initiate a Phase 2 head-to-head (COMPARE) clinical trial of SEL-212, 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 data analysis expected in the first quarter of 2020. The results of the COMPARE 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.

- **Reported Phase 2 Data:** Selecta has reported data from its Phase 2 trial showing that 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.

AAV Gene Therapy Program:

- **Collaboration with CureCN Consortium Projected to Dose First Patient in 2H19:** In September 2018, Selecta announced a collaboration with CureCN, a European consortium, for an ImmTOR+AAV gene therapy combination product candidate in Crigler-Najjar Syndrome, building upon preclinical work that was published together with Genethon in Nature Communications in October 2018. 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 2019.

Corporate Updates:

- **Corporate Restructuring Completed in January 2019:** Selecta completed a corporate restructuring that reduced the company's workforce by 36 percent 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 percent.
- **Successfully Completed a \$33.3 Million Public Offering; Providing Cash Runway into 1Q20:** In January 2019, Selecta completed an underwritten public offering of 22,188,706 shares of its common stock, at a price to public of \$1.50 per share, resulting in net proceeds to Selecta of \$31.3 million, after deducting underwriting discounts and commissions.
- **Strengthened Management Team:** 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 Region and member of the Global Pharmaceutical Executive Committee at Bayer.

Fourth Quarter 2018 Financial Results:

- **Revenue:** For the fourth quarter of 2018, the company recognized \$0.9 million of revenue, which compares to less than \$0.1 million for the fourth quarter of 2017. The increase resulted from an increase in grant revenue and was the sole result of the conclusion of the company's grant with NIDA.
- **Research and Development Expenses:** Research and development expenses for the fourth quarter of 2018 were \$10.3 million, which compares with \$13.6 million for the fourth quarter of 2017. The decrease was driven by reduced expenditures for our preclinical product candidates combined with the winding down of the Phase 2 clinical trial of SEL-212 in the second half of 2018.

- **General and Administrative Expenses:** General and administrative expenses for the fourth quarter of 2018 were \$5.1 million, which compares with \$5.7 million for the fourth quarter of 2017. The reduction in costs was primarily the result of reduced consulting fees.
- **Net Loss:** For the fourth quarter of 2018, Selecta reported a net loss of \$(14.7) million, or \$(0.65) per share, compared to a net loss of \$(19.5) million, or \$(0.88) per share, for the same period in 2017.
- **Cash Position:** Selecta had \$37.7 million in cash, cash equivalents and restricted cash as of December 31, 2018, which compares to cash, cash equivalents and short-term investments of \$50.5 million at September 30, 2018. The company currently has a cash runway into the first quarter of 2020, which includes proceeds net of underwriting discounts and commissions of \$31.3 million from the company's recent follow-on offering in January 2019.

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 fourth quarter and year end 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 10127200.

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 Phase 2 clinical trial of SEL-212, the anticipated timing of the planned Phase 2 head-to-head (COMPARE) clinical trial comparing SEL-212 and Krystexxa, related data readouts and expectations surrounding 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 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, 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 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 potential of the ImmTOR technology platform generally and the company's ability to grow its strategic partnerships, 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, 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 Annual Report on Form 10-K for the year ended December 31, 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)

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	\$ 37,403	\$ 70,698
Short-term deposits and investments	—	25,940
Prepaid expenses and other current assets	4,673	2,042
Total current assets	<u>42,076</u>	<u>98,680</u>
Property and equipment, net	2,127	2,091
Restricted cash and other assets	279	329
Total assets	<u>\$ 44,482</u>	<u>\$ 101,100</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,100	\$ 1,606
Accrued expenses	11,700	8,580
Loan payable, current portion	21,385	—
Deferred revenue, current portion	959	787
Total current liabilities	<u>35,144</u>	<u>10,973</u>
Non-current liabilities:		
Deferred rent and lease incentive	34	151
Loan payable, net of current portion	—	21,042
Deferred revenue, net of current portion	13,818	15,919
Other long-term liabilities	904	1,201
Total liabilities	<u>49,900</u>	<u>49,286</u>
Stockholders' (deficit) equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 22,471,776 and 22,343,254 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	3	3
Additional paid-in capital	279,539	273,128
Accumulated deficit	(280,403)	(216,897)
Accumulated other comprehensive loss	(4,557)	(4,420)
Total stockholders' (deficit) equity	<u>(5,418)</u>	<u>51,814</u>
Total liabilities and stockholders' equity	<u>\$ 44,482</u>	<u>\$ 101,100</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Grant and collaboration revenue	\$ 903	\$ 17	\$ 903	\$ 207
Operating expenses:				
Research and development	10,256	13,623	47,687	45,165
General and administrative	5,146	5,671	18,238	18,826
Total operating expenses	15,402	19,294	65,925	63,991
Loss from operations	(14,499)	(19,277)	(65,022)	(63,784)
Investment income	221	238	1,050	617
Loss on extinguishment of debt	—	—	—	(673)
Foreign currency transaction gain (loss), net	23	(10)	120	(123)
Interest expense	(395)	(359)	(1,494)	(1,206)
Other income (expense), net	(1)	(136)	10	(152)
Net loss	(14,651)	(19,544)	(65,336)	(65,321)
Other comprehensive loss:				
Foreign currency translation adjustment	(40)	(1)	(153)	78
Unrealized gain (loss) on securities	—	(10)	16	20
Total comprehensive loss	\$ (14,691)	\$ (19,555)	\$ (65,473)	\$ (65,223)
Net loss per share:				
Basic and diluted	\$ (0.65)	\$ (0.88)	\$ (2.92)	\$ (3.20)
Weighted average common shares outstanding:				
Basic and diluted	22,450,828	22,269,282	22,389,286	20,425,050
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Contact Information:

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