

**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): August 8, 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))

**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,<br>\$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.

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**Item 2.02. Results of Operations and Financial Condition.**

On August 8, 2019, Selecta Biosciences, Inc. announced its financial results for the quarter ended June 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:

| <b>Exhibit<br/>No.</b> | <b>Description</b>                                     |
|------------------------|--|
| <a href="#">99.1</a>   | <a href="#">Press Release issued on August 8, 2019</a> |

**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: August 8, 2019

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

Carsten Brunn, Ph.D.

President and Chief Executive Officer



## Selecta Biosciences Reports Second Quarter 2019 Financial Results and Provides Corporate Update

- *New strategic partnership with gene therapy leader, AskBio, to jointly develop next-generation AAV-based gene therapies to address the unmet medical need for repeat dosing in patients with rare and orphan genetic diseases*
- *Patient enrollment ongoing in COMPARE trial evaluating efficacy and safety of SEL-212 vs. KRYSTEXXA® in patients with chronic refractory gout; interim data expected in 4Q19*
- *Company to host conference call today at 8:30 a.m. ET*

**Watertown, Mass., August 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 second quarter ended June 30, 2019 and provided a corporate update.

“Our gene therapy program has gained a lot of momentum, most notably with our new strategic partnership with AskBio, which will combine our ImmTOR platform technology with AskBio’s AAV technology and know-how. We believe this partnership will allow us to develop a robust pipeline of products that can potentially be re-dosed and offer patients a new treatment paradigm in areas of high unmet need,” said Carsten Brunn, Ph.D., President and CEO of Selecta. “We are also pleased that the COMPARE trial continues to actively enroll patients, and we look forward to differentiating SEL-212 compared to the current FDA-approved uricase therapy in adult patients with chronic refractory gout. We believe the clinical profile of SEL-212, along with its more convenient monthly dosing, makes it a compelling product for patients and their providers and represents a very large market opportunity of over \$1.0 billion.”

### Recent Highlights and Anticipated Upcoming Milestones

#### **Chronic Refractory Gout Program:**

- **COMPARE Clinical Trial of SEL-212 vs. Krystexxa Enrolling Patients:** In March 2019, Selecta initiated a six-month head-to-head clinical trial (COMPARE) designed to evaluate the superiority of its lead product candidate, SEL-212 (ImmTOR + Pegadricase), compared to Krystexxa, the current U.S. Food and Drug Administration (FDA)-approved uricase therapy, in adult patients with chronic refractory gout. The COMPARE trial, which is currently enrolling patients, is expected to enroll 150 patients, and the primary endpoint is the maintenance of serum uric acid (sUA) levels of <6mg/dL at six months. An interim data analysis is expected in the fourth quarter of 2019 with a full statistical superiority analysis expected in the second quarter of 2020.

## AAV Gene Therapy Program:

- **New 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 adeno-associated virus (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.
- **Advancing Collaboration with CureCN Consortium:** Under a collaboration with the European consortium, CureCN, for an ImmTOR+AAV gene therapy combination product candidate in Crigler-Najjar Syndrome, Selecta expects CureCN to obtain scientific advice from the German drug regulatory authority in the second half of 2019.

## Corporate Updates:

- **Strengthened Management Team:** Selecta announced the appointment of Alison Schecter, M.D., as Chief Medical Officer in July 2019. Dr. Schecter has over 20 years of combined drug development, strategic management and practical clinical experience in academia and industry and joins Selecta from Sanofi, where she was the Global Project Head, Rare Diseases, and was responsible for leading the Niemann-Pick Disease (ASMD) project.
- **Expanded Board of Directors:** Selecta announced the addition of Scott D. Myers to its Board of Directors, in June 2019. Mr. Myers has more than 20 years of leadership experience in the biopharmaceutical industry and currently serves as Chief Executive Officer and Chairman of the Board of Rainier Therapeutics.

## Second Quarter 2019 Financial Results:

- **Revenue:** For the second quarter ended June 30, 2019, the company recognized less than \$0.1 million of revenue under its collaboration agreement with Spark.
- **Research and Development Expenses:** Research and development expenses for the second quarter ended June 30, 2019 were \$12.1 million, which compares with \$14.4 million for the second quarter of 2018. Research and development expenses decreased by \$2.3 million, or 16%, as compared to the same period in 2018. The decrease reflects the reduced salaries and benefits as a result of the company's headcount reduction at the beginning of fiscal 2019. There were further cost reductions related to discontinued programs. These cost reductions were offset by the timing of costs incurred for both the company's Phase 2 and Phase 3 clinical programs for SEL-212.
- **General and Administrative Expenses:** General and administrative expenses for the second quarter ended June 30, 2019 were \$4.1 million, which compares with \$4.4 million for the second quarter of 2018. General and administrative expenses decreased by \$0.3 million, or 6%, as compared to the same period in 2018. The reduction in costs was primarily the result of reduced legal fees, offset by an increase in professional fees.
- **Net Loss:** For the second quarter ended June 30, 2019, Selecta reported a net loss of \$16.4 million, or \$0.37 per share, compared to a net loss of \$18.8 million, or \$0.84 per share, for the same period in 2018.

- **Cash Position:** Selecta had \$42.0 million in cash, cash equivalents, restricted cash and short-term investments as of June 30, 2019, which compares to cash, cash equivalents, restricted cash and short-term investments of \$48.7 million as of March 31, 2019.

## **Financial Outlook:**

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

## **Conference Call and Webcast 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 second 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 10127459.

## **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 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 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 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)

|  | June 30, 2019 | December 31, 2018 |
|--|---------------|-------------------|
|  | (Unaudited)   |                   |
| <b>Assets</b>  |               |                   |
| <b>Current assets:</b>   |               |                   |
| Cash, cash equivalents, and restricted cash  | \$ 30,479     | \$ 37,403         |
| Short-term deposits and investments  | 11,480        | —                 |
| Prepaid expenses and other current assets  | 2,490         | 4,673             |
| Total current assets   | 44,449        | 42,076            |
| Property and equipment, net  | 1,620         | 2,127             |
| Right of Use Asset, net  | 878           | —                 |
| Restricted cash and other assets   | —             | 279               |
| Total assets   | \$ 46,947     | \$ 44,482         |
| <b>Liabilities and stockholders' equity</b>  |               |                   |
| <b>Current liabilities:</b>  |               |                   |
| Accounts payable   | \$ 2,463      | \$ 1,100          |
| Accrued expenses   | 5,789         | 11,700            |
| Loan payable, current portion  | 21,548        | 21,385            |
| Lease Liability, current portion   | 1,085         | —                 |
| Deferred revenue, current portion  | 1,023         | 959               |
| Total current liabilities  | 31,908        | 35,144            |
| <b>Non-current liabilities:</b>  |               |                   |
| Deferred rent and lease incentive  | —             | 34                |
| Deferred revenue, net of current portion   | 14,983        | 13,818            |
| Other long-term liabilities  | —             | 904               |
| Total liabilities  | 46,891        | 49,900            |
| <b>Stockholders' equity (deficit):</b>   |               |                   |
| Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively                         | —             | —                 |
| Common stock, \$0.0001 par value; 200,000,000 shares authorized; 44,952,951 and 22,471,776 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively | 5             | 3                 |
| Additional paid-in capital   | 313,447       | 279,539           |
| Accumulated deficit  | (308,871)     | (280,403)         |
| Accumulated other comprehensive loss   | (4,525)       | (4,557)           |
| Total stockholders' equity (deficit)   | 56            | (5,418)           |
| Total liabilities and stockholders' equity (deficit)   | \$ 46,947     | \$ 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 June 30, |                    | Six Months Ended June 30, |                    |
|---|-----------------------------|--------------------|---------------------------|--------------------|
|   | 2019                        | 2018               | 2019                      | 2018               |
|   | <b>(Unaudited)</b>          |                    |                           |                    |
| Grant and collaboration revenue             | \$ 13                       | \$ —               | \$ 23                     | \$ —               |
| Operating expenses:                         |                             |                    |                           |                    |
| Research and development                    | 12,134                      | 14,407             | 19,487                    | 25,546             |
| General and administrative                  | 4,114                       | 4,362              | 8,627                     | 9,036              |
| Total operating expenses                    | <u>16,248</u>               | <u>18,769</u>      | <u>28,114</u>             | <u>34,582</u>      |
| Loss from operations                        | <u>(16,235)</u>             | <u>(18,769)</u>    | <u>(28,091)</u>           | <u>(34,582)</u>    |
| Investment income                           | 246                         | 246                | 523                       | 534                |
| Foreign currency transaction (loss), net    | (10)                        | 84                 | (40)                      | 71                 |
| Interest expense                            | (400)                       | (365)              | (796)                     | (715)              |
| Other (expense), net                        | 5                           | 8                  | (64)                      | 8                  |
| Net loss                                    | <u>(16,394)</u>             | <u>(18,796)</u>    | <u>(28,468)</u>           | <u>(34,684)</u>    |
| Other comprehensive loss:                   |                             |                    |                           |                    |
| Foreign currency translation adjustment     | 7                           | (90)               | 29                        | (71)               |
| Unrealized gain on securities               | 1                           | 12                 | 3                         | 15                 |
| Total comprehensive loss                    | <u>\$ (16,386)</u>          | <u>\$ (18,874)</u> | <u>\$ (28,436)</u>        | <u>\$ (34,740)</u> |
| Net loss per share:                         |                             |                    |                           |                    |
| Basic and diluted                           | <u>\$ (0.37)</u>            | <u>\$ (0.84)</u>   | <u>\$ (0.68)</u>          | <u>\$ (1.55)</u>   |
| Weighted average common shares outstanding: |                             |                    |                           |                    |
| Basic and diluted                           | <u>44,855,083</u>           | <u>22,355,603</u>  | <u>41,668,902</u>         | <u>22,350,591</u>  |

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**For Media:**

Leticia Diaz  
Spectrum Science Communications, Inc.  
+1-202-587-2517  
ldiaz@spectrumsience.com

**For Investors:**

Sarah McCabe  
Stern Investor Relations, Inc.  
+1-212-362-1200  
sarah@sternir.com