# 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 5, 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.) |

**65 Grove Street, 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 (Par Value $0.0001) | SELB | The 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 5, 2020, Selecta Biosciences, Inc. announced its financial results for the three and nine months ended September 30, 2020. 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

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release issued on November 5, 2020 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**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 5, 2020

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

Carsten Brunn, Ph.D.

President and Chief Executive Officer

**Exhibit 99.1**

**Selecta Biosciences Reports Third Quarter 2020 Financial Results and Provides Corporate Updates**

- *Phase 3 DISSOLVE clinical program with Sobi ongoing to evaluate SEL-212; topline data expected in the second half of 2022*
- *IND filing for gene therapy expected in Q1 2021; preliminary Phase 1 data expected by end of 2021*
- *IgA nephropathy program underway with IND expected by end of 2021*
- *Ended quarter with cash position of $147.6 million with runway into the first quarter of 2023*
- *Company to host conference call today at 8:30 a.m. ET*

**WATERTOWN, Mass., Nov. 5, 2020** -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its clinically validated ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses, today announced financial results for the third quarter ended September 30, 2020 and provided corporate updates.

“This past quarter has been productive for our team as we have continued to progress our clinical programs,” said Carsten Brunn, Ph.D., President and CEO of Selecta. “We reported topline data from the Phase 2 COMPARE trial of SEL-212 which demonstrated the potential of our ImmTOR platform when combined with a highly immunogenic enzyme, and we commenced the Phase 3 DISSOLVE program in partnership with Sobi. We look forward to continuing to build our pipeline with our gene therapy programs in MMA and OTC deficiency, and our second enzyme program in IgA nephropathy. Our strategy is focused on leveraging ImmTOR to amplify the efficacy of biologic therapies and restore self-tolerance in autoimmune diseases.”

**Recent Highlights and Anticipated Upcoming Milestones:**

- **Two Key Clinical Milestones for SEL-212:** In September, Selecta and Sobi commenced the Phase 3 clinical program, known as DISSOLVE, with Selecta running the program and Sobi reimbursing Selecta for costs associated with the program. The DISSOLVE clinical program consists of two double-blind, placebo-controlled trials of SEL-212 (NCT04513366) in which SEL-212 will be evaluated at two doses of ImmTOR (0.1 mg/kg and 0.15 mg/kg), and one dose of pegadricase (0.2 mg/kg) in both studies. Each trial will aim to enroll 105 patients (35 at each dose level and 35 on placebo). In DISSOLVE I, safety and efficacy will be evaluated at six months and will have a six-month extension. DISSOLVE II will assess safety and efficacy at only the six-month time point, with no extension. The primary endpoint in both studies is serum uric acid levels (SUA) less than 6 mg/dL at six months, a well-validated measure of disease severity in chronic refractory gout. Topline data from the DISSOLVE program is expected in the second half of 2022. Also in September, the Company reported topline results from the Phase 2 COMPARE clinical trial in which a once-monthly dose of SEL-212 (ImmTOR + pegadricase) was compared to biweekly doses of pegloticase. Sobi has in-licensed SEL-212 and assumes responsibility for all development (excluding DISSOLVE, which is run by Selecta and funded by Sobi), regulatory, and commercial activities, and expenses in all markets outside China. Selecta is eligible to receive potential development, regulatory, and commercial milestone payments of up to $630 million, and tiered double-digit royalties on net sales.

- **Granted Rare Pediatric Disease Designation with AskBio for Gene Therapy for Methylmalonic Acidemia:** Selecta and AskBio have received Rare Pediatric Disease Designation from the U.S. Food and Drug Administration (FDA) to develop MMA-101 in combination with ImmTOR for the treatment of isolated methylmalonic acidemia (MMA) due to

methylmalonyl-CoA mutase (MMUT) gene mutations. Selecta and AskBio expect to commence a Phase 1 clinical trial in this program in the first half of 2021, with preliminary data expected by the end of 2021.

- **Entered into Research License and Option Agreement with IGAN Biosciences for the Use of ImmTOR in IgA Nephropathy:** In October, Selecta and IGAN Biosciences reached an agreement which provides Selecta with the option to an exclusive license for the rights to develop and commercialize the ImmTOR platform in combination with IGAN's immunoglobulin A (IgA) protease for the treatment of IgA nephropathy (IgAN). Selecta intends to submit its Investigational New Drug Application (IND) for IgA nephropathy by the end of 2021. IgA nephropathy is characterized by deposition of galactose-deficient IgA1 immunoglobulin in the glomerular mesangium and is a leading contributor to development of chronic kidney disease and renal failure. There are no approved therapies for the treatment of IgAN.

**Third Quarter 2020 Financial Results:**

- **Cash Position:** Selecta had $147.6 million in cash, cash equivalents, and restricted cash as of September 30, 2020, which compares to cash, cash equivalents, and restricted cash of $91.6 million as of December 31, 2019. Selecta believes its available cash, cash equivalents, and restricted cash as of September 30, 2020 will enable Selecta to fund operating expenses and capital expenditure requirements into the first quarter of 2023.

    - Net cash provided by operating activities was $42.1 million for the nine months ended September 30, 2020, as compared to $38.6 million used for the same period in 2019.

- **Revenue:** Revenue recognition for the third quarter 2020 was $4.6 million. During the three months ended September 30, 2020, we recognized $4.3 million under the license agreement with Sobi resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program and $0.3 million for shipments under the collaboration agreement with Sarepta. During the three months ended September 30, 2019, Selecta did not recognize revenue.

- **Research and Development Expenses:** Research and development expenses for the third quarter 2020 were $14.0 million, which compares with $8.1 million for the same period in 2019. The increase in cost was primarily the result of the initiation of the Phase 3 DISSOLVE clinical program. These costs are subject to the cost reimbursement arrangement under the license agreement with Sobi. The increase in expense was also the result of the completion of its Phase 2 COMPARE trial for SEL-212, and for the AskBio Collaboration.

- **General and Administrative Expenses:** General and administrative expenses for the third quarter 2020 were $4.4 million, which compares with $3.7 million for the same period in 2019. The increase in costs was the result of expenses incurred for facilities, legal and professional fees offset by decreased travel expense.

- **Net Loss:** For the third quarter 2020, Selecta reported a net loss of $9.7 million, or $0.09 per share, compared to a net loss of $12.0 million, or $0.26 per share, for the same period in 2019.

**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 third quarter 2020 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 10138608. Investors and the public can access the live and archived webcast of this call via the Investors & Media section of the company's website, www.selectabio.com.

**About Selecta Biosciences, Inc.**
Selecta Biosciences Inc. (NASDAQ: SELB) is leveraging its clinically validated ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses. With an observed ability to induce tolerance to highly immunogenic proteins, ImmTOR has the potential to amplify the efficacy of biologic therapies, including redosing of life-saving gene therapies, as well as restore the body's natural self-tolerance in autoimmune diseases. The company's first program aimed at addressing immunogenicity to AAV gene therapies is expected to enter clinical trials in early 2021 in collaboration with AskBio for the treatment of methylmalonic acidemia (MMA), a rare metabolic disorder. A wholly-owned program focused on addressing IgA nephropathy driven by ImmTOR and a therapeutic enzyme is also in development among additional product candidates. Selecta recently licensed its Phase 3 clinical product candidate, SEL-212, in chronic refractory gout to Sobi. For more information, please visit www.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 potential, safety and efficacy of the company's product candidates, the design, progress, timing, and availability of results from the company's clinical trials, including with respect to the Phase 3 DISSOLVE clinical program and planned clinical trial for MMA-101, planned regulatory filings or submissions and timing thereof, the potential of the company's ImmTOR technology platform generally or the technology platforms of its collaboration partners, and the sufficiency of the company's cash, cash equivalents, and restricted cash to fund operating expenses and capital expenditure requirements, 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 proof of concept trials, including the 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 effect of the COVID-19 pandemic on the company, specifically on its clinical trials, manufacturing, and operations, 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, 2020 (Unaudited) | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 146,261 | $ 89,893 |
| Restricted cash | — | 279 |
| Accounts receivable | 12,626 | 5,000 |
| Prepaid expenses and other current assets | 7,615 | 1,495 |
| Total current assets | 166,502 | 96,667 |
| Property and equipment, net | 1,363 | 1,222 |
| Right-of-use asset, net | 11,216 | 301 |
| Long-term restricted cash | 1,379 | 1,379 |
| Other assets | 536 | — |
| Total assets | $ 180,996 | $ 99,569 |
| **Liabilities and stockholders' (deficit) equity** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 471 | $ 500 |
| Accrued expenses | 11,285 | 13,492 |
| Loan payable | — | 18,905 |
| Lease liability | 875 | 372 |
| Deferred revenue | 64,373 | 1,674 |
| Total current liabilities | 77,004 | 34,943 |
| **Non-current liabilities:** | | |
| Loan payable, net of current portion | 24,589 | — |
| Lease liability | 9,886 | — |
| Deferred revenue | 51,466 | 14,680 |
| Warrant liabilities | 25,433 | 41,549 |
| Total liabilities | 188,378 | 91,172 |
| **Stockholders' (deficit) equity :** | | |
| Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively | — | — |
| Common stock, $0.0001 par value; 200,000,000 shares authorized; 107,235,976 and 86,325,547 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively | 11 | 9 |
| Additional paid-in capital | 386,374 | 348,664 |
| Accumulated deficit | (389,183) | (335,753) |
| Accumulated other comprehensive loss | (4,584) | (4,523) |
| Total stockholders' (deficit) equity | (7,382) | 8,397 |
| Total liabilities and stockholders' (deficit) equity | $ 180,996 | $ 99,569 |

**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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | | | (Unaudited) | |
| Grant and collaboration revenue | $ 4,646 | $ — | $ 4,646 | $ 23 |
| Operating expenses: | | | | |
| Research and development | 13,960 | 8,104 | 39,414 | 27,591 |
| General and administrative | 4,420 | 3,690 | 14,155 | 12,317 |
| Total operating expenses | 18,380 | 11,794 | 53,569 | 39,908 |
| Loss from operations | (13,734) | (11,794) | (48,923) | (39,885) |
| Investment income | 4 | 184 | 257 | 707 |
| Loss on extinguishment of debt | (461) | — | (461) | — |
| Foreign currency transaction (loss), net | 43 | 7 | 83 | (33) |
| Interest expense | (365) | (388) | (843) | (1,184) |
| Change in fair value of warrant liabilities | 4,779 | — | (3,606) | — |
| Other income (expense), net | 5 | (3) | 63 | (67) |
| Net loss | (9,729) | (11,994) | (53,430) | (40,462) |
| Other comprehensive loss: | | | | |
| Foreign currency translation adjustment | (32) | (5) | (61) | 24 |
| Unrealized gain on securities | — | (3) | — | — |
| Total comprehensive loss | $ (9,761) | $ (12,002) | $ (53,491) | $ (40,438) |
| | | | | |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.09) | $ (0.26) | $ (0.54) | $ (0.94) |
| Weighted average common shares outstanding: | | | | |
| Basic and diluted | 105,325,788 | 46,407,846 | 98,968,359 | 43,265,909 |

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