

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): May 10, 2021

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.)

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 Stock Market LLC

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 May 13, 2021, Selecta Biosciences, Inc. announced its financial results for the quarter ended March 31, 2021. 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On May 10, 2021, Bradford D. Dahms notified Selecta Biosciences, Inc. (the “Company”) of his intention to resign as the Company’s Chief Financial Officer, effective May 21, 2021, to pursue other career opportunities.

Ann K. Donohue, the Company’s Vice President Finance, will serve as the Company’s principal accounting officer and principal financial officer, as appointed by the Board of Directors, on an interim basis while the Company’s search for a new Chief Financial Officer is ongoing. Ms. Donohue, age 40, has served as the Company’s Vice President Finance since May 2021. Ms. Donohue served as the Company’s Controller from December 2017 until May 2021, and as the Company’s SEC Reporting Manager from September 2016 to December 2017. From September 2009 to August 2016, she served as Corporate Reporting Manager at Orchard Brands, a direct marketing retailer. Ms. Donohue received a B.S. in accounting from the Carroll School of Management at Boston College, and a Master’s Degree in accounting from the Carroll Graduate School of Management at Boston College, and is a Certified Public Accountant (CPA).

Additionally, on April 1, 2021, the Company appointed Kristen Baldwin as Chief People Officer. She brings 20 years of Human Resources and Consulting experience to the Company. Most recently Ms. Baldwin served in dual capacity as the Chief People Officer for the LIVEKINDLY Collective, a high growth plant-based foods company, and as a Senior Partner at CEO.works. Ms. Baldwin has also held senior HR roles at Bayer and Otsuka Pharmaceuticals.

On May 10, 2021, the Company appointed Satish Tripathi, Ph.D., as Vice President of Global Regulatory Affairs. Dr. Tripathi has over 25 years of combined R&D, business, and global regulatory strategy experience. Dr. Tripathi most recently served as VP of Global Regulatory Affairs for AveXis which became Novartis Gene Therapies, where he led the regulatory strategy and implementation for the gene therapy product AVXS-101 for Spinal Muscular Atrophy. AVXS-101 is recognized as only one of the 3 drugs in the world to receive Breakthrough (US FDA), PRIME (EMA) and Sakigake (MHLW/PMDA) designations. Dr. Tripathi led the simultaneous submission of AVXS-101 in 2018 for global registration, which has been approved as Zolgensma for SMA in US, Europe, Japan, Canada, and Brazil.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on May 13, 2021
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: May 13, 2021

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



Selecta Biosciences Reports First Quarter 2021 Financial Results and Provides Business Update

- *SEL-399 (empty AAV8 capsid with ImmTOR) study on track with topline data expected in the fourth quarter of 2021*
- *SEL-212 enrollment on track with topline data from DISSOLVE phase 3 program expected in second half of 2022*
- *IND filing for IgA nephropathy program expected by the end of 2021*
- *IND filing for wholly-owned gene therapy program in MMA expected by the end of 2021; IND in OTC deficiency gene therapy program expected in 2022*
- *As of March 31, 2021, Selecta had approximately \$149.2 million in cash, cash equivalents, and marketable securities which is expected to provide runway into the second quarter of 2023*

WATERTOWN, Mass., May 13, 2021 (GLOBE NEWSWIRE) -- 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 reported financial results for the first quarter ended March 31, 2021 and provided a business update.

“We are very pleased about the continued progress across all aspects of the company,” said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. “We regained exclusive rights to our MMA program and now have two proprietary gene therapy programs to rapidly follow our ongoing empty capsid study. Additionally, we continue to progress our enzyme program, with an expected IND filing by the end of 2021 in IgA nephropathy, and topline data from the Phase 3 DISSOLVE program for SEL-212 anticipated in the second half of 2022.”

Recent Highlights and Anticipated Upcoming Milestones:

Enzyme Therapies:

- *SEL-212 for chronic refractory gout:* Enrollment for the Phase 3 DISSOLVE clinical program for SEL-212 for the treatment of chronic refractory gout, which was licensed to Sobi, is progressing as planned with topline data expected in the second half of 2022.
- Leveraging the success of SEL-212, Selecta expects to file an Investigational New Drug, or IND, application by the end of 2021 for a novel therapeutic approach that combines ImmTOR with an enzyme, IgA1 protease for the treatment of IgA nephropathy.

Gene Therapies:

- *First-in-human trial of SEL-399:* In collaboration with AskBio, Selecta initiated the first-in-human, dose-escalation trial of SEL-399, an adeno-associated viral serotype 8 (AAV8) empty vector capsid (EMC-101) containing no DNA combined with ImmTOR. The trial aims to determine the optimal dose of ImmTOR to mitigate the formation of antibodies to AAV8 capsids used in gene therapies. Selecta and AskBio expect to report topline data in the fourth quarter of 2021.
- *MMA-101 for methylmalonic acidemia (MMA):* Selecta regained exclusive rights to its lead gene therapy program in MMA from AskBio and expects to file an IND in MMA-101, in combination with ImmTOR, by the end of 2021. The phase 1/2 MMA-101 program, which is expected to commence in 2022, will evaluate biomarkers of efficacy, neutralizing antibodies and safety and tolerability.
- *SEL-313 for ornithine transcarbamylase deficiency (OTC deficiency):* Selecta’s proprietary gene therapy product candidate, SEL-313, is being developed to treat OTC deficiency, a rare genetic urea cycle disorder that causes ammonia to accumulate in the blood due to mutations in the OTC gene. SEL-313 is currently in preclinical development and a clinical trial application, or CTA and/or IND filing are expected in 2022.

A Pediatric Investigation Plan (PIP) for SEL-313 was submitted to the European Medicines Agency (EMA) pediatric committee in February 2021.

- *Sarepta Therapeutics program in Duchenne Muscular Dystrophy (DMD) and certain Limb-Girdle Muscular Dystrophies (LGMD) subtypes*: Selecta has achieved a \$3 million milestone payment related to the completion of a preclinical study under the Research License and Option Agreement.

Restoring Self-Tolerance in Autoimmune Diseases:

- Selecta continues IND-enabling work on an ImmTOR-based approach to treating primary biliary cholangitis (PBC), a chronic, progressive autoimmune liver disorder that leads to inflammation, damage and scarring of the small bile ducts. Selecta expects to file an IND in PBC in the second half of 2022.

Corporate Updates:

- Kristen Baldwin was appointed Chief People Officer. She brings 20 years of Human Resources and Consulting experience to the company. Most recently Ms. Baldwin served in dual capacity as the Chief People Officer for the LIVEKINDLY Collective, a high growth plant-based foods company, and as a Senior Partner at CEO.works. Ms. Baldwin has also held senior HR roles at Bayer and Otsuka Pharmaceuticals.
- Satish Tripathi, Ph.D., was appointed Vice President of Global Regulatory Affairs. Dr. Tripathi has over 25 years of combined R&D, business, and global regulatory strategy experience. Dr. Tripathi most recently served as VP of Global Regulatory Affairs for AveXis which became Novartis Gene Therapies, where he led the regulatory strategy and implementation for the gene therapy product AVXS-101 for Spinal Muscular Atrophy. AVXS-101 is recognized as only one of the 3 drugs in the world to receive Breakthrough (US FDA), PRIME (EMA) and Sakigake (MHLW/PMDA) designations. Dr. Tripathi led the simultaneous submission of AVXS-101 in 2018 for global registration, which has been approved as Zolgensma for SMA in US, Europe, Japan, Canada, and Brazil.
- Brad Dahms will be stepping down as Chief Financial Officer effective May 21st, 2021 to pursue another opportunity. Mr. Dahms' departure is not related to Selecta's operations, financial reporting, or controls. A search is currently underway for a successor.
- Ann Donohue will be promoted to Vice President Finance, effective immediately, after having served as Controller of Selecta since December 2017.

First Quarter 2021 Financial Results:

Cash Position: Selecta had \$149.2 million in cash, cash equivalents, marketable securities, and restricted cash as of March 31, 2021, which compares to cash, cash equivalents, and restricted cash of \$140.1 million as of December 31, 2020. Selecta believes its available cash, cash equivalents, marketable securities, and restricted cash will be sufficient to meet its operating requirements into the second quarter of 2023.

- Net cash used in operating activities was \$12.1 million for the first quarter of 2021, as compared to \$11.7 million for the same period in 2020.

Revenue: Revenue recognition for the first quarter of 2021 was \$11.1 million, compared to no revenue recognition for the same period in 2020. Revenue was recognized under the license agreement with Sobi which began in July 2020 resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program.

Research and Development Expenses: Research and development expenses for the first quarter 2021 were \$13.0 million, which compares with \$14.7 million for the same period in 2020. During the quarter ended March 31, 2021, there was a reduction in expenses for the SEL-212 clinical program and for the AskBio Collaboration, offset by an increase of expense for discovery and preclinical programs.

General and Administrative Expenses: General and administrative expenses for the first quarter 2021 were \$5.2 million, which compares with \$4.1 million for the same period in 2020. The quarterly increase in expense was the result of expenses for consulting and professional fees and salaries offset by reduced travel expenses.

Net Loss: For the first quarter 2021, Selecta reported a net loss of \$24.6 million, or \$0.22 per share, compared to a net loss of \$19.6 million, or \$0.21 per share for the same period in 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 first quarter 2021 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 10147801. 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. (NASDAQ: SELB) is a clinical stage biotechnology company leveraging its ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses. With a proven 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. Selecta has several proprietary and partnered programs in its pipeline focused on enzyme therapies, gene therapies, and autoimmune diseases. Selecta Biosciences is headquartered in the Greater Boston area. For more information, please visit www.selectabio.com.

Selecta 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 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 to mitigate immunogenicity, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the Company's ability to conduct those clinical trials and studies, the timing or making of any regulatory filings, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, gout and autoimmune disease, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human primate study subjects will translate to studies performed with human beings, the potential of any therapies developed by the Company to fulfill unmet medical needs, the Company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the potential of the Company's intellectual property to enable repeat administration in gene therapy product candidates and products, the ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, the potential of the ImmTOR technology platform generally and the Company's ability to grow its strategic partnerships, 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 ability to predict results of studies performed on human beings based on results of studies performed on non-human primates, 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 to be filed after this release, 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)

	March 31, 2021	December 31, 2020
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 125,407	\$ 138,685
Marketable securities	22,405	—
Accounts receivable	8,342	7,224
Prepaid expenses and other current assets	6,971	5,434
Total current assets	<u>163,125</u>	<u>151,343</u>
Property and equipment, net	1,301	1,395
Right-of-use asset, net	10,676	10,948
Long-term restricted cash	1,379	1,379
Other assets	265	370
Total assets	<u>\$ 176,746</u>	<u>\$ 165,435</u>
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 594	\$ 443
Accrued expenses	6,847	8,146
Loan payable	460	—
Lease liability	942	908
Deferred revenue	75,764	72,050
Total current liabilities	<u>84,607</u>	<u>81,547</u>
Non-current liabilities:		
Loan payable, net of current portion	24,551	24,793
Lease liability	9,403	9,647
Deferred revenue	32,301	38,746
Warrant liabilities	45,455	28,708
Total liabilities	<u>196,317</u>	<u>183,441</u>
Stockholders' (deficit) equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 112,977,004 and 108,071,249 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	11	11
Additional paid-in capital	414,214	391,175
Accumulated deficit	(429,226)	(404,629)
Accumulated other comprehensive loss	(4,570)	(4,563)
Total stockholders' (deficit) equity	<u>(19,571)</u>	<u>(18,006)</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 176,746</u>	<u>\$ 165,435</u>

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 March 31,	
	2021	2020
	(Unaudited)	
Grant and collaboration revenue	\$ 11,050	\$ —
Operating expenses:		
Research and development	13,004	14,724
General and administrative	5,204	4,098
Total operating expenses	18,208	18,822
Loss from operations	(7,158)	(18,822)
Investment income	12	240
Foreign currency transaction gain, net	7	82
Interest expense	(711)	(273)
Change in fair value of warrant liabilities	(16,747)	(846)
Other income (expense), net	—	(1)
Net loss	(24,597)	(19,620)
Other comprehensive loss:		
Foreign currency translation adjustment	(6)	(60)
Unrealized (losses) on marketable securities	(1)	—
Total comprehensive loss	\$ (24,604)	\$ (19,680)
Net loss per share:		
Basic and diluted	\$ (0.22)	\$ (0.21)
Weighted average common shares outstanding:		
Basic and diluted	110,742,150	94,723,513

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For Investors:

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