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 10, 2022

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 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 o

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. o

Item 2.02. Results of Operations and Financial Condition.

On March 10, 2022, Selecta Biosciences, Inc. announced its financial results for the quarter and year ended December 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued on March 10, 2022
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: March 10, 2022

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

Exhibit 99.1

Selecta Biosciences Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

- *U.S. Food and Drug Administration ("FDA") removed clinical hold on SEL-302 for the treatment of patients with methylmalonic acidemia ("MMA")*
- *Observed the synergy of ImmTOR in combination with engineered Treg-selective IL-2 to expand antigen-specific Tregs and improve durability of immune tolerance (ImmTOR-IL)*
- *Further validated and expanded the ImmTOR precision immune tolerance platform through numerous strategic collaborations*
- *Completed enrollment in DISSOLVE I the first of two studies in the Phase 3 program evaluating SEL-212 for chronic refractory gout*
- *Presented topline data for SEL-399 human proof-of-concept data in healthy volunteers where ImmTOR was observed to inhibit the formation of neutralizing antibodies to empty AAV capsids, an important step toward enabling re-dosing of life saving gene therapies*
- *As of December 31, 2021, Selecta had approximately $129.4 million in cash, cash equivalents, restricted cash and marketable securities which is expected to provide runway into the third quarter of 2023*
- *Selecta to host conference call today at 8:30 AM ET*

WATERTOWN, Mass., March 10, 2022 -- 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 quarter and full year ended December 31, 2021 and provided a business update.

"I am pleased to announce that on March 9th the FDA lifted the clinical hold on our SEL-302 gene therapy program to treat methylmalonic acidemia. We look forward to starting our phase 1 clinical trial expeditiously and to bring hope to those patients and families seeking a potentially durable and lifelong treatment for this terrible disease." said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. Dr. Brunn continued, "2021 was a transformative year for Selecta. We continued to grow our pipeline and achieved many significant development milestones. We also further validated and expanded our precision immune tolerance platform by entering into five important collaborations over the prior 12 months. Additionally, In January, we released preclinical data demonstrating the synergistic effects of ImmTOR in combination with a Treg selective IL-2. This potentially transformative combination, which we call ImmTOR-IL™, represents an evolution of our ImmTOR platform to enhance the induction and durability of antigen-specific regulatory T cells. By comparison, Treg-selective IL-2 molecules currently in development non-specifically expand total Tregs. We believe ImmTOR-IL has the potential to be a first-in-class antigen-specific therapeutic."

Dr. Brunn continued, "With our recently presented topline data from the empty AAV8 capsid study of SEL-399 in healthy volunteers and our partnership with Genovis for Xork, Genovis' highly differentiated IgG protease, we aim to unlock the full potential of AAV-mediated gene therapies. First, in the human volunteer clinical trial conducted with our partner AskBio, we evaluated a single dose of ImmTOR combined with an AAV8 empty capsid and observed the ability of ImmTOR to inhibit neutralizing antibodies to AAV8 empty capsids out to 30 days. Our preclinical data in mice and nonhuman primates indicate that an additional two monthly doses of ImmTOR has the potential to durably inhibit anti-AAV antibody formation, which is an important step toward enabling re-dosing and transforming gene

therapies from a treatment into a cure. Secondly, by developing the Xork IgG protease with the goal of enabling treatment of those 20-50% of the population who are ineligible for gene therapy due to preexisting antibodies to AAV vectors, we aim to bring hope to those suffering from rare monogenic disease who would otherwise benefit from gene therapy treatment. Finally, we continued to prosecute our clinical pipeline, and in Q4 of 2021 we both announced completion of enrollment for DISSOLVE I, the first of two clinical studies of the Phase 3 DISSOLVE development program of SEL-212 for chronic refractory gout, and filed our IND for SEL-302, a wholly owned gene therapy program for the treatment of methylmalonic acidemia. We are incredibly excited about our future, and we are focused on continuing to prosecute our growing wholly owned pipeline, continuing to advance our technologies to enable AAV gene therapies, supporting our numerous collaboration partners and rapidly advancing our next generation ImmTOR-IL into the clinic."

Recent Highlights and Anticipated Upcoming Milestones:

Recent Strategic Collaborations:

- Autoimmune:
  - ***Cyrus Biotechnology, Inc. ("Cyrus")***: Protein engineering collaboration combining Selecta's ImmTOR platform with Cyrus' ability to radically redesign protein therapeutics. The lead program in the collaboration is a proprietary interleukin-2 (IL-2) receptor agonist designed to selectively promote expansion of regulatory T cells (Treg) for the treatment of patients with autoimmune diseases and other deleterious immune conditions. Selecta believes the combination of ImmTOR with a Treg-selective IL-2 agonist (ImmTOR-IL) has the potential to be a first-in-class therapeutic profile with antigen specific Treg expansion.
- Gene Therapies:
  - ***Genovis AB (publ.) ("Genovis")***: Exclusive license agreement to advance a next-generation IgG protease. This partnership leverages Genovis' proprietary and differentiated immunoglobulin G (IgG) protease, IdeXork (Xork), and Selecta's ImmTOR platform to enable the dosing of transformative gene therapies in patients with pre-existing adeno-associated virus (AAV) immunity and treat certain IgG-mediated autoimmune diseases. In contrast to other IgG proteases, Xork has been observed to have low cross-reactivity to pre-existing antibodies in human sera. The combination of Xork with ImmTOR has the potential to address two of the biggest immunological challenges to gene therapy – expanding access to gene therapies by overcoming pre-existing antibodies to AAV and enabling vector re-dosing.
  - ***Ginkgo Bioworks, Inc. ("Ginkgo")***: Collaboration agreement to design novel AAV capsids with potentially improved transduction, enhanced tissue tropism and reduced immunogenicity. This partnership leverages Ginkgo's high throughput screening and cell engineering capabilities and Selecta's ImmTOR platform to advance gene therapy delivery with the goal of improving gene therapies through best in class and fit for purpose capsid design. Ginkgo plans to design and engineer the capsids and Selecta will conduct all pre-clinical and clinical studies thereafter.
  - ***Takeda Pharmaceutical Company Limited ("Takeda")***: Strategic license agreement to develop next-generation gene therapies in two lysosomal storage disorders. The collaboration leverages Selecta's ImmTOR platform to enable the redosing of transformative gene therapies.
- Biologic Therapies:
  - ***Ginkgo***: Partnership to design novel enzymes and proteins with transformative therapeutic potential to advance treatments for all IgA mediated diseases including IgA nephropathy. This partnership leverages Ginkgo's cell programing platform and high throughput screening capabilities and Selecta's ImmTOR platform with the goal of creating transformative biologic and enzymatic therapies.

Pipeline and Development Updates:

Tolerogenic Therapies for Autoimmune Disease:

- ***ImmTOR with proprietary IL-2 protein agonist (ImmTOR-IL)****:* ImmTOR may have profound synergistic activity with engineered IL-2 molecules that are selective for Tregs. Selecta has observed, when ImmTOR-IL was co-administered with an antigen of interest in a preclinical study, synergistic effects in further expanding antigen-specific Tregs when compared to ImmTOR alone, positioning it to be a potential first-in-class antigen-specific therapy for the treatment of autoimmune diseases.

- ***Primary biliary cholangitis (PBC)***: Selecta continues IND-enabling work on an ImmTOR-based approach to treating PBC.

Gene Therapies:

- ***SEL-399 human proof-of-concept***: On November 8, 2021, in collaboration with AskBio, Selecta reported topline data for 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 key objective was to determine the dose regimen of ImmTOR to effectively mitigate the formation of antibodies to AAV8 capsids used in gene therapies.
- ***SEL-302 for methylmalonic acidemia (MMA)***: On March 9, 2022, the U.S. Food and Drug Administration ("FDA") removed the clinical hold on SEL-302 for the treatment of patients with methylmalonic acidemia ("MMA"). Selecta expects to start the phase 1 clinical trial in the second half of 2022.
- ***SEL-313 for ornithine transcarbamylase deficiency (OTC deficiency):*** Selecta has decided to temporarily pause development in order to prioritize resources on the MMA program.
- ***SEL-018 IgG Protease (Xork)***: On October 21, 2021, Selecta and Genovis entered into an exclusive license agreement to advance Xork, a next-generation IgG protease. The novel combination of Xork and ImmTOR has the potential to simultaneously address two of the key hurdles in gene therapy today: pre-existing immunity and the inability to re-dose AAV gene therapies.
    - IND-enabling studies are expected to commence in 2022.

Biologic Therapies:

- ***SEL-212 for chronic refractory gout***: On December 1, 2021, Selecta announced complete enrollment for DISSOLVE I, the first of two studies in our Phase 3 development program of SEL-212 (which has been licensed to Swedish Orphan Biovitrum AB (publ.) ("Sobi")) and is currently being run in the United States.
    - The currently enrolling DISSOLVE II trial has sites in the United States and 4 Eastern European countries (including Russia and Ukraine). We have temporarily closed screening and randomization in both Russia and Ukraine to preserve in country study supplies. We have proactively activated additional enrollment sites in the United States to offset and speed enrollment in DISSOLVE II with 9 sites having already been activated and 2 pending initiation and activation.

- ***ImmTOR with IgA1 protease for IgA nephropathy***:
    - Selecta continues with IND-enabling studies in IgA nephropathy.

Fourth Quarter and Full Year 2021 Financial Results:

Cash Position: Selecta had $129.4 million in cash, cash equivalents, marketable securities, and restricted cash as of December 31, 2021, as compared to cash, cash equivalents, marketable securities, and restricted cash of $140.1 million as of December 31, 2020. Selecta believes its available cash, cash equivalents, restricted cash, and marketable securities will be sufficient to meet its operating requirements into the third quarter of 2023. Net cash used in operating activities was $60.4 million for the year ended December 31, 2021, as compared to $34.9 million of cash provided by operating activities for the same period in 2020.

Collaboration and License Revenue: Revenue for the fourth quarter and full year 2021 was $29.9 million and $85.1 million, respectively, as compared to $12.0 million and $16.6 million for the same periods in 2020. Revenue was primarily driven by 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. Additionally, during 2021, Selecta recognized $1.0 million for shipments of clinical supply under the license agreement with Takeda and $0.4 million for shipments under the license agreement with Sarepta Therapeutics, Inc.

Research and Development Expenses: Research and development expenses for the fourth quarter and full year 2021 were $20.3 million and $68.7 million, respectively, as compared to $15.1 million and $54.5 million for the same periods in 2020. The quarterly and annual increases were primarily driven by expenses incurred for preclinical programs, payroll costs and AskBio collaboration costs.

General and Administrative Expenses: General and administrative expenses for the fourth quarter and full year 2021 were $5.5 million and $20.9 million, respectively, as compared to $4.8 million and $18.9 million for the same periods in 2020. The quarterly and annual increases were primarily driven by increases in stock compensation expenses and consulting fees, offset by a reduction in professional fees.

Net Income (loss): For the fourth quarter and full year 2021, Selecta reported net income of $12.2 million, or basic net income per share of $0.10, and a net loss of $(25.7) million, or basic net loss per share of $(0.22), respectively. For the fourth quarter and full year 2020, Selecta reported net losses of $(15.4) million, or $(0.14) per share, and $(68.9) million, or $(0.68) per share, respectively.

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 fourth quarter and full year 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 10157869. 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 Company's cash runway, 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 potential of ImmTOR and the Company's product pipeline to treat chronic refractory gout, MMA, IgAN, other autoimmune diseases, lysosomal storage disorders, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's and its partners' ability to conduct its and their clinical trials and preclinical 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 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 technology 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 subjects, 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, substantial fluctuation in the price of its common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K 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.

Financial Tables

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

(Amounts in thousands, except share data and par value)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 114,057	$ 138,685
Marketable securities	13,998	—
Accounts receivable	9,914	7,224
Prepaid expenses and other current assets	6,474	5,434
Total current assets	144,443	151,343
Non-current assets:		
Property and equipment, net	2,142	1,395
Right-of-use asset, net	9,829	10,948
Long-term restricted cash	1,379	1,379
Investments	2,000	—
Other assets	90	370
Total assets	$ 159,883	$ 165,435
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 224	$ 443
Accrued expenses	10,533	8,146
Loan payable	5,961	—
Lease liability	1,049	908
Income taxes payable	601	—
Deferred revenue	53,883	72,050
Total current liabilities	72,251	81,547
Non-current liabilities:		
Loan payable, net of current portion	19,673	24,793
Lease liability, net of current portion	8,598	9,647
Deferred revenue	11,417	38,746
Warrant liabilities	25,423	28,708
Total liabilities	137,362	183,441
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 123,622,965 and 108,071,249 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	12	11
Additional paid-in capital	457,391	391,175
Accumulated deficit	(430,316)	(404,629)
Accumulated other comprehensive loss	(4,566)	(4,563)
Total stockholders' equity (deficit)	22,521	(18,006)
Total liabilities and stockholders' equity (deficit)	$ 159,883	$ 165,435

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,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Collaboration and license revenue	$ 29,937	$ 11,951	$ 85,077	$ 16,597
Operating expenses:				
Research and development	20,318	15,091	68,736	54,505
General and administrative	5,541	4,758	20,938	18,913
Total operating expenses	25,859	19,849	89,674	73,418
Operating income (loss)	4,078	(7,898)	(4,597)	(56,821)
Investment income	9	3	44	260
Loss on extinguishment of debt	—	—	—	(461)
Foreign currency transaction gain (loss), net	5	(27)	—	56
Interest expense	(711)	(713)	(2,844)	(1,556)
Change in fair value of warrant liabilities	8,996	(6,837)	(2,339)	(10,443)
Other income, net	—	26	15	89
Income (loss) before income taxes	12,377	(15,446)	(9,721)	(68,876)
Income tax expense	(138)	—	(15,966)	—
Net income (loss)	12,239	(15,446)	(25,687)	(68,876)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(7)	21	(2)	(40)
Unrealized loss on marketable securities	—	—	(1)	—
Total comprehensive income (loss)	$ 12,232	$ (15,425)	$ (25,690)	$ (68,916)
Net income (loss) per share:				
Basic	$ 0.10	$ (0.14)	$ (0.22)	$ (0.68)
Diluted	$ 0.03	$ (0.14)	$ (0.22)	$ (0.68)
Weighted average common shares outstanding:				
Basic	117,792,406	107,855,065	114,328,798	101,202,176
Diluted	124,058,955	107,855,065	114,328,798	101,202,176

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