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): June 13, 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 7.01 Regulation FD Disclosure.

On June 13, 2022, Selecta Biosciences, Inc. (the "Company") issued a press release announcing certain information relating to its business. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information in this Item 7.01, 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 into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth 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 June 13, 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: June 13, 2022

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

Exhibit 99.1

Selecta Biosciences Announces Partnership Advancements and Clinical Trial Updates

- *Sarepta extends Research License and Option Agreement for ImmTOR® in Duchenne Muscular Dystrophy and certain Limb-Girdle Muscular Dystrophies-*
- *Selecta to receive a $2 million payment from Sarepta extending their option periods under the agreement to Q1 2023-*
- *Enrollment in DISSOLVE II, the Phase 3 study evaluating SEL-212 for chronic refractory gout, continues to advance with full enrollment anticipated by the end of Q2 2022. The achievement of this milestone would trigger a $10 million milestone payment obligation from Sobi-*
- *DISSOLVE I & II studies remain on track for completion in Q4 2022 with joint topline data in Q1 2023-*

WATERTOWN, Mass., June 13, 2022 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its clinically validated ImmTOR® platform to develop tolerogenic therapies for autoimmune diseases, enhance gene therapies and mitigate unwanted immune responses to biologics, today announced several pipeline advancements and partnership updates.

Extension of Sarepta's Research License and Option Agreement

Sarepta Therapeutics (NASDAQ: SRPT) has extended the options under the Research License and Option Agreement to license the rights to develop and commercialize Selecta's immune tolerance platform, ImmTOR®, for use in Duchenne Muscular Dystrophy (DMD) and certain Limb-Girdle Muscular Dystrophies (LGMD). Selecta will receive a $2 million payment for the nine-month extension to both options. Additionally, Selecta is eligible to receive an additional $4 million payment upon the achievement of certain near-term preclinical milestones by Sarepta. If Sarepta exercises its option to enter a commercial license agreement for DMD or LGMD Selecta will be eligible for additional development, regulatory, and commercial milestone payments, as well as tiered royalties on net product sales.

Clinical Pipeline Updates

DISSOLVE II, the second of two Phase 3 clinical studies evaluating SEL-212 for chronic refractory gout, continues to progress. SEL-212 is a combination of Selecta's ImmTOR® immune tolerance platform and a therapeutic uricase enzyme (pegadricase).

"As a result of Selecta's proactive addition of 11 trial sites in the United States and the commitment of our clinical team, investigators and study participants around the world, DISSOLVE II is on track to successfully enroll approximately 140 study participants by the end of Q2 2022" said Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta. "We expect to complete the study in Q4 2022 and announce joint topline data from DISSOLVE I and II in Q1 2023. The upcoming completion of enrollment for DISSOLVE II brings us one step closer to our ultimate goal of providing a differentiated and more convenient treatment option for patients suffering from chronic refractory gout.
Swedish Orphan Biovitrum AB, (Sobi) has in-licensed SEL-212 from Selecta and is responsible for development, regulatory and commercial activities in all markets outside of China. The Phase 3 program for SEL-212 is being run by Selecta and funded by Sobi. The completion of enrollment in DISSOLVE I & II will result in a $10 million milestone payment obligation from Sobi to Selecta.

Additionally, Selecta continues to progress its wholly owned gene therapy program, SEL-302 for the treatment of patients with methylmalonic acidemia (MMA), toward the clinic. Selecta expects to start a Phase 1 clinical trial in Q4 2022.

DISSOLVE clinical program

The DISSOLVE Phase 3 clinical program consists of two double-blind, placebo-controlled studies of SEL-212, titled "A Randomized Double-Blind, Placebo-Controlled Study of SEL-212 in Patients with Gout Refractory to Conventional Therapy," 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. In DISSOLVE I, safety and efficacy will be evaluated in 112 patients at six months and will have a six-month extension to evaluate safety. DISSOLVE II will assess safety and efficacy in approximately 140 patients at only the six-month time point, with no extension. The primary endpoint in both studies is serum uric acid (SUA) control during month six, a well-validated measure of disease severity in chronic refractory gout. Secondary endpoints include tender and swollen joint counts, tophus burden, patient-reported outcomes of activity limitation and quality of life and gout flare incidence. For more details about the study, visit clinicaltrials.gov (NCT04513366).

SEL-212

SEL-212 is a novel combination medicine designed to sustain SUA levels in people with chronic refractory gout, potentially reducing harmful tissue urate deposits which when left untreated can lead to debilitating gout flares and joint deformity.[1] SEL-212 consists of pegadricase, Selecta's proprietary pegylated uricase, co-administered with ImmTOR, designed to mitigate the formation of anti-drug antibodies (ADAs). ADAs develop due to unwanted immune responses to biologic medicines, reducing their efficacy and tolerability, which remains an issue across multiple therapeutic modalities and disease states including chronic refractory gout.

Chronic refractory gout

Gout is the most common form of inflammatory arthritis with more than 8.3 million people in the United States having been diagnosed with gout, which is caused by high levels of uric acid in the body that accumulate around the joints and other tissues and can result in flares that cause intense pain. Approximately 160,000 people in the United States suffer from chronic gout refractory to conventional medicines, a painful and debilitating condition in which people SUA levels below 6 mg/dL and therefore have several flares per year and can develop nodular masses of uric acid crystals known as tophi.[1] Elevated SUA levels have been associated with diseases of the heart, vascular system, metabolism, kidney and joints.[2]

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

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding 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 enrollment in the Company's clinical trials. 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 and in other filings that the Company makes with the Securities and Exchange Commission All information in this press release is as of the date of the release, and Selecta undertakes no duty to update this information unless required by law.

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