

**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): December 14, 2022

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 7.01 Regulation FD Disclosure.

On December 14, 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
99.1 104	Press Release Issued on December 14, 2022 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: December 14, 2022

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



Selecta Biosciences Announces Next Generation IgA Protease Clinical Candidate Selection for IgA Nephropathy Program

– *IgA protease candidate in combination with ImmTOR further enhances pipeline* –

– *Novel mechanism of action of IgA protease has the potential to address the underlying kidney pathophysiology of IgA nephropathy* –

WATERTOWN, Mass. December 14, 2022 -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its clinically validated ImmTOR™ platform to develop tolerogenic therapies for autoimmune diseases and gene therapies, today announced the selection of a next generation Immunoglobulin A (IgA) protease from IGAN Biosciences for its IgA nephropathy (IgAN) program.

IgAN is an autoimmune disease that is a leading cause of chronic kidney disease and renal failure. IgAN is a disease with significant unmet medical need characterized by the deposition of the protein IgA inside the filters (glomeruli) in the kidney which may lead to blood (hematuria) and protein (proteinuria) being present in urine, inflammatory tissue damage and progressive renal failure.

“In preclinical studies, IgA protease has been observed to remove injurious IgA from the kidney and improve markers of renal dysfunction, hallmarks of IgAN,” said Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta. “However, development of enzymes derived from common human pathogens have been stifled by immunogenicity that results in the formation of anti-drug antibodies (ADAs). To address this major hurdle, we worked closely with IGAN Biosciences to identify a new class of IgA protease from a commensal bacteria with a lower level of baseline ADAs. By combining ImmTOR with this next generation IgA protease candidate, we believe our novel approach has the potential to mitigate the formation of new ADAs and address the underlying pathophysiology of the disease. We believe the results observed in clinical trials of our Phase 3 product candidate, SEL-212, provide proof-of-concept for this approach, and we look forward to building on our learnings to expand the potential use of ImmTOR for the treatment of autoimmune diseases.”

The selection of the IgA protease candidate triggers the payment of \$1.6 million to IGAN Biosciences.

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 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 anticipated timing or outcome of selection of developmental product candidates, 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 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 and 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 the Company's 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 subsequent Quarterly Reports 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, except as required by law.

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