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): August 17, 2023

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 ☐

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 August 17, 2023, Selecta Biosciences, Inc. announced its financial results for the quarter ended June 30, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report 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 August 17, 2023
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: August 17, 2023

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

Selecta Biosciences Reports Second Quarter 2023 Financial Results and Updates on Strategic Initiative Designed to Maximize Stockholder Value Associated with SEL-212 Economics

– Company to continue focusing on advancement of SEL-212, a potential treatment for chronic refractory gout; Biologics License Application (BLA) filing on track for 1H 2024 –

– Company to suspend further investment in majority of pipeline; evaluating potential licensing and corporate development initiatives for pipeline assets –

– Cash, cash equivalents, restricted cash, and marketable securities of $115.0 million as of June 30, 2023 expected to fund operations into 2027 –

– Selecta to host conference call today at 8:30 AM ET –

WATERTOWN, Mass., August 17, 2023 (GLOBE NEWSWIRE) – 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 reported financial results for the second quarter ended June 30, 2023 and provided a business update.

The Company also provided an update on its ongoing strategic initiative to maximize stockholder value related to its economic interests in SEL-212, which is being developed for the treatment of chronic refractory gout, which Selecta will continue to support. In order to preserve capital, the Company plans to suspend further investment in its pipeline assets, including ImmTOR-IL, and instead focus on maximizing the value of its pipeline through potential licensing and corporate development activities. These initiatives are expected to extend its cash runway into 2027.

“At Selecta, we remain committed to SEL-212, a potentially unique and differentiated once monthly uricase based treatment option for patients with chronic refractory gout, which we believe has the potential to exceed $700 million in peak sales in the U.S.,” said Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta. “Our actions today will allow us to preserve capital and maintain our stockholders’ interest in this asset without the dilution that would have been required to support the development of our pipeline assets over the long term. While we believe that our pipeline programs represent great potential, we intend to pursue partnership opportunities to advance the balance of our portfolio and maximize their value.”

Strategic Initiative Overview:

Following a comprehensive review of its portfolio and capital resources, Selecta, in consultation with the Company’s Board of Directors, plans to halt further investments in its pipeline programs outside of SEL-212 and stop or discontinue non-essential activities. As part of this initiative, the Company plans to:

Continue to Advance SEL-212 in Patients with Chronic Refractory Gout in Partnership with Sobi. Selecta plans to continue working with Swedish Orphan Biovitrum AB (publ.) (Sobi), its SEL-212 development

partner, to advance SEL-212 for the treatment of patients with chronic refractory gout. A BLA submission remains on track for the first half of 2024. Under the 2020 agreement with Sobi, Selecta is eligible to receive up to $615.0 million in remaining regulatory and commercial milestone payments and tiered double-digit royalties on net sales of SEL-212. In May 2023, Selecta presented positive data from the Phase 3 DISSOLVE program of SEL-212 in patients with chronic refractory gout at the European Alliance of Associations of Rheumatology (EULAR) 2023 European Congress of Rheumatology.

Advance the Combination of ImmTOR and Company's Proprietary Treg-Selective IL-2 (ImmTOR-IL) Through Potential Partnerships. Selecta will pause further investments in, and development of, its combination ImmTOR-IL program, including the Investigational New Drug-enabling studies that were anticipated later this year. The Company is currently assessing ways to support the development of this program through potential partnerships.

Continue the Development of SEL-018 IgG Protease (Xork) for LOPD in Connection with its Partnership with Astellas Gene Therapies. Selecta will continue the development activities of IdeXork (Xork) under its January 2023 licensing and development agreement with Astellas Gene Therapies (Astellas). Xork is a next-generation immunoglobulin G (IgG) protease being developed for use with AT845, Astellas' investigational adeno-associated virus (AAV)-based treatment for Late-Onset Pompe disease (LOPD) in adults. Xork is designed to be differentiated by its low-cross reactivity to pre-existing antibodies in human serum, which the Company believes has the potential to expand access to life-changing gene therapies for more patients.

Maximizing Potential of Additional Pipeline Assets. The Company is also assessing ways to maximize value and support further development of its other pipeline programs through potential partnerships. This includes SEL-302, an AAV gene therapy combined with ImmTOR for the treatment of methylmalonic acidemia; ImmTOR, which can be combined with a variety of therapeutic approaches to reduce immunogenicity across a range of indications; Xork, its proprietary IgG protease, for the mitigation of pre-existing anti-AAV antibodies; and the next generation Immunoglobulin A (IgA) protease for IgA nephropathy.

Second Quarter 2023 Financial Results:

Cash Position: Selecta had $115.0 million in cash, cash equivalents, restricted cash, and marketable securities as of June 30, 2023, as compared to cash, cash equivalents, restricted cash, and marketable securities of $136.2 million as of December 31, 2022. Selecta believes that following the capital efficiencies expected to be realized through its strategic reprioritization and following receipt of the next anticipated milestone payment related to SEL-212 development activities, its available cash, cash equivalents, restricted cash, and marketable securities will be sufficient to meet its operating requirements into 2027.

Collaboration and License Revenue: Collaboration and license revenue for the second quarter of 2023 was $5.2 million, as compared to $39.3 million for the same period in 2022. Collaboration and license revenue was primarily driven by the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program under the license agreement with Sobi.

Research and Development Expenses: Research and development expenses for the second quarter of 2023 were $17.8 million, as compared to $19.2 million for the same period in 2022. The decrease was primarily the result of the capital prioritization initiative that was enacted in the second quarter of 2023.

General and Administrative Expenses: General and administrative expenses for the second quarter of 2023 were $6.1 million, as compared to $6.2 million for the same period in 2022. The decrease was primarily the result of a reduction in expenses incurred for stock compensation.

Net (Loss) Income: For the second quarter of 2023, Selecta reported net loss of $11.4 million, or basic net loss per share of $(0.07). For the second quarter of 2022, Selecta reported net income of $8.6 million, or basic net income per share of $0.06 per share.

Conference Call and Webcast

Selecta's management will host a conference call at 8:30 AM ET today to provide a corporate update and review the Company's second quarter 2023 financial results and strategic updates. Individuals may participate in the live call via telephone by dialing 1-844-845-4170 (domestic) or 1-412-717-9621 (international) and may access a teleconference replay for one week by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using confirmation code 8863115. The live and archived webcast of this call can also be accessed 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 expected cash runway, the Company's strategic prioritization of SEL-212 and its collaborations with Sobi and Astellas, the Company's plans to maximize the value of its pipeline through potential licensing and corporate development activities, the unique proprietary technology platform of the Company and its partners, the potential of ImmTOR to enable re-dosing of therapies and to mitigate immunogenicity, the potential of ImmTOR and the Company's product pipeline to treat chronic refractory gout, MMA, liver

diseases, other autoimmune diseases, 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 ability of the Company to consummate any expected agreements and licenses, 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, 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 ImmTOR technology platform generally, the Company's ability to grow and maintain 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 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 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.

For Investors and Media:

Blaine Davis
Chief Financial Officer
bdavis@selectabio.com

Financial Tables

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

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

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 112,027	$ 106,438
Marketable securities	—	28,164
Accounts receivable	5,385	6,596
Unbilled receivables	1,055	3,162
Prepaid expenses and other current assets	4,258	3,778
Total current assets	122,725	148,138
Non-current assets:		
Property and equipment, net	2,593	2,794
Right-of-use asset, net	10,775	11,617
Long-term restricted cash	1,377	1,311
Investments	2,000	2,000
Other assets	36	26
Total assets	$ 139,506	$ 165,886
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 267	$ 316
Accrued expenses	12,902	14,084
Loan payable	10,235	8,476
Lease liability	1,729	1,608
Deferred revenue	4,234	593
Total current liabilities	29,367	25,077
Non-current liabilities:		
Loan payable, net of current portion	13,787	17,786
Lease liability, net of current portion	9,163	10,055
Deferred revenue	4,863	—
Warrant liabilities	16,878	19,140
Total liabilities	74,058	72,058
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 153,427,571 and 153,042,435 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	15	15
Additional paid-in capital	498,016	493,308
Accumulated deficit	(427,987)	(394,937)
Accumulated other comprehensive loss	(4,596)	(4,558)
Total stockholders' equity	65,448	93,828
Total liabilities and stockholders' equity	$ 139,506	$ 165,886

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Income (Loss)

(Amounts in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited)			
Collaboration and license revenue	$ 5,249	$ 39,273	$ 11,187	$ 73,272
Operating expenses:				
Research and development	17,782	19,182	36,406	36,871
General and administrative	6,105	6,231	11,800	11,768
Total operating expenses	23,887	25,413	48,206	48,639
Operating (loss) income	(18,638)	13,860	(37,019)	24,633
Investment income	1,394	207	2,725	222
Foreign currency transaction, net	23	(104)	42	(76)
Interest expense	(752)	(715)	(1,560)	(1,422)
Change in fair value of warrant liabilities	6,341	(4,647)	2,262	13,868
Other income, net	245	—	500	154
Net (loss) income	$ (11,387)	$ 8,601	$ (33,050)	$ 37,379
Other comprehensive income (loss):				
Foreign currency translation adjustment	(27)	118	(49)	86
Unrealized gain on marketable securities	—	—	11	—
Total comprehensive income (loss)	$ (11,414)	$ 8,719	$ (33,088)	$ 37,465
Net (loss) income per share:				
Basic	$ (0.07)	$ 0.06	$ (0.22)	$ 0.27
Diluted	$ (0.07)	$ 0.06	$ (0.22)	$ 0.17
Weighted average common shares outstanding:				
Basic	153,442,413	148,505,729	153,396,380	136,436,316
Diluted	153,442,413	148,505,729	153,396,380	136,966,312