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 6, 2020

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 Global Market

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 6, 2020, Selecta Biosciences, Inc. announced its financial results for the three and six months ended June 30, 2020. 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 August 6, 2020
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 6, 2020

By: /s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.

President and Chief Executive Officer

Selecta Biosciences Reports Second Quarter 2020 Financial Results and Provides Corporate Updates

- *Closed strategic licensing agreement with Sobi for SEL-212 for $100 million in initial payments and up to $630 million in potential milestones, and tiered double-digit royalties*
- *Entered into research license and option agreement with Sarepta for the use of the ImmTOR™ immune tolerance platform in Sarepta's gene therapy programs in certain neuromuscular diseases*
- *Gene therapy program in MMA in collaboration with AskBio on track to enter the clinic in the first half of 2021; preliminary data expected in the second half of 2021*
- *Phase 3 clinical program of SEL-212 to commence with Sobi in Q3 2020; on track to report topline data from ongoing head-to-head COMPARE trial in Q3 2020*
- *Cash runway into the first quarter of 2023*
- *Company to host conference call today at 8:30 a.m. ET*

Watertown, Mass., August 6, 2020 - Selecta Biosciences, Inc. (NASDAQ: SELB), a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance platform, ImmTOR, today reported financial results for the second quarter ended June 30, 2020 and provided corporate updates.

"This is a transformational time for Selecta, as we reinforce our position as a leader in immune tolerance. The strategic licensing agreement with Sobi puts us in a financial position that allows us to maximize efforts to unlock the full potential of the ImmTOR immune tolerance platform, by optimizing the efficacy and safety of biologics, enabling re-dosing of life saving gene therapies, and creating novel immunotherapies for autoimmune diseases," said Carsten Brunn, Ph.D., President and CEO of Selecta. "We remain committed to the development of SEL-212, and look forward to the initiation of the Phase 3 clinical program with Sobi in the third quarter of this year and the topline data readout from the Phase 2 COMPARE trial, also in the third quarter. We also look forward to advancing our gene therapy program in MMA to the clinic in the first half of 2021, and for the submission of an IND for our autoimmune diseases program, also in 2021."

Recent Highlights and Anticipated Upcoming Milestones:

- **Closed Strategic Licensing Agreement with Sobi for SEL-212, the Company's Phase 3-ready Novel Treatment for Chronic Refractory Gout:** The Company announced the closing of a strategic licensing agreement with Sobi for SEL-212, the Company's lead product candidate

leveraging the ImmTOR immune tolerance platform. Sobi assumes responsibility for all development, regulatory, and commercial activities, and expenses in all markets outside China, while Selecta will run the Phase 3 study on behalf of Sobi, at Sobi's expense. Selecta will also maintain manufacturing of ImmTOR, for which Sobi will reimburse Selecta for activities relating to SEL-212. The initial payments to Selecta total $100 million. Sobi must pay $75 million in cash as an upfront license fee within 45 days of the effective date and has paid $25 million in cash in a private placement of Selecta common stock at $4.62 per share. Selecta is also eligible to receive potential development, regulatory, and commercial milestone payments of up to $630 million, and tiered double-digit royalties on net sales.

- **Entered into Research License and Option Agreement with Sarepta for the Use of ImmTOR in Certain Neuromuscular Diseases:** Selecta and Sarepta reached an agreement which provides Sarepta with the option to license the rights to develop and commercialize the ImmTOR platform for use in select neuromuscular diseases; Duchenne muscular dystrophy (DMD) and certain limb-girdle muscular dystrophies (LGMDs). Sarepta will evaluate its investigational gene therapies in combination with ImmTOR to mitigate the formation of neutralizing antibodies. Sarepta has made an initial payment to Selecta, and Selecta is eligible to receive certain pre-clinical milestone fees.

- **Two Key Clinical Milestones for SEL-212:** Selecta and Sobi anticipate initiating the Phase 3 clinical program in the third quarter of 2020. Selecta will take the lead running the Phase 3 program, at Sobi's expense. The Phase 3 clinical program will consist of two double blinded, placebo-controlled trials of SEL-212. Each trial is expected to enroll 105 patients and have 35 patients receiving 0.1 mg/kg of ImmTOR and 0.2 mg/kg of pegadricase, 35 patients receiving 0.15 mg/kg of ImmTOR and 0.2 mg/kg of pegadricase, and 35 patients receiving placebo. The primary endpoint of the Phase 3 clinical trials is the maintenance of serum uric acid (SUA) levels of <6mg/dL at six months. One of the trials will have a six-month extension. In addition, the Company expects topline results from the Phase 2 COMPARE clinical trial in Q3 2020. This head-to-head study of a once-monthly dose of SEL-212 (ImmTOR + pegadricase) compared to biweekly doses of pegloticase is expected to read out on schedule. The primary endpoint of the COMPARE trial is the maintenance of serum uric acid (SUA) levels of <6mg/dL at three and six months.

- **Timeline for Gene Therapy and Autoimmune Diseases Programs Confirmed:** The Company's gene therapy program in methylmalonic acidemia, or MMA, in collaboration with AskBio, is expected to enter the clinic in the first half of 2021, with preliminary data expected in 2H 2021. In addition, Selecta intends to submit its Investigational New Drug Application (IND) for its autoimmune disease program in 2021. The first indication will be IgA nephropathy, a kidney disease that occurs when an antibody called immunoglobulin A (IgA) accumulates in the kidneys. The second indication is expected to be primary biliary cholangitis, or PBC, an autoimmune disease that causes progressive destruction of the bile ducts. Both diseases have well-defined target antigens, significant unmet medical need, and are well suited to the application of Selecta's ImmTOR immune tolerance platform.

- **Appointed Peter G. Traber, MD, to the Position of Chief Medical Officer:** Dr. Traber, who has been serving in the same position in an interim capacity, joined the Company full-time as of August 1, 2020. Dr. Traber has a broad range of experience in large pharma, biotech, and academia, and will oversee medical affairs, program management, and all aspects of clinical

development and strategy, as well as provide scientific and clinical guidance for potential business development initiatives.

Second Quarter 2020 Financial Results:

- **Cash Position:** Selecta had $61.4 million in cash, cash equivalents, and restricted cash as of June 30, 2020, which compares to cash, cash equivalents, and restricted cash of $91.6 million as of December 31, 2019. Selecta believes its available cash, cash equivalents, and restricted cash as of June 30, 2020, together with the $25 million payment received from Sobi under the Sobi Private Placement in July and the expected payment from Sobi of $75 million under the Sobi License, which is due 45 days after the effective date, will enable Selecta to fund operating expenses and capital expenditure requirements into the first quarter of 2023.

    - Net cash used in operating activities was $23.5 million for the six months ended June 30, 2020, as compared to $27.4 million for the same period in 2019.

- **Research and Development Expenses:** Research and development expenses for the second quarter 2020 were $10.7 million, which compares with $12.1 million for the same period in 2019. The decrease in costs was primarily the result of reduced expense for the Phase 2 COMPARE trial for SEL-212 offset by increases for the gene therapy program in collaboration with AskBio, and salaries and benefits.

- **General and Administrative Expenses:** General and administrative expenses for the second quarter 2020 were $5.6 million, which compares with $4.1 million for the same period in 2019. The increase in costs was the result of expenses incurred for salaries, legal and professional fees offset by decreased travel expense.

- **Net Loss:** For the second quarter 2020, Selecta reported a net loss of $24.1 million, or $0.25 per share, compared to a net loss of $16.4 million, or $0.37 per share, for the same period in 2019.

Conference Call and Webcast Reminder:
Selecta management will host a conference call at 8:30 a.m. ET today to provide a corporate update and review the company's second quarter 2020 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 10138605. Investors and the public can access the live and archived webcast of this call via the Investors & Media section of the company's website, www.selectabio.com.

About Selecta Biosciences, Inc.
Selecta Biosciences, Inc. is a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance technology (ImmTOR) platform. Selecta plans to combine ImmTOR with a range of biologic therapies for rare and serious diseases that require new treatment options due to high immunogenicity. The company's current proprietary pipeline includes ImmTOR-powered therapeutic enzyme and gene therapy product candidates. SEL-212, the company's lead product candidate, is being developed to treat chronic refractory gout patients and resolve their debilitating symptoms, including flares and gouty arthritis. Selecta's proprietary gene therapy product candidates are in preclinical development for certain rare inborn errors of metabolism and incorporate ImmTOR with the goal of addressing barriers to repeat

administration. Selecta is based in Watertown, Massachusetts. For more information, please visit www.selectabio.com.

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, the company's actions regarding the monitoring and assessment of COVID-19 on the company's operations, clinical trials and manufacturing, Sarepta's plans to evaluate its gene therapies in combination with the company's ImmTOR technology, the possibility of Sarepta exercising an option to enter into a commercial license agreement, Sarepta's achievement of any milestones that would trigger payment(s) to Selecta, 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, the ability of the company's ImmTOR platform to unlock the full potential of biologic therapies, the potential treatment applications for product candidates utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy, the novelty of treatment paradigms that Sarepta is able to develop in combination with the company's ImmTOR technology, the potential of any therapies developed by Sarepta in combination with the company's ImmTOR technology to fulfill unmet medical needs, the company's plan to apply its ImmTOR technology platform to a range of biologics for rare and serious diseases, the clinical development, commercialization, and regulatory activities related to SEL-212 by either the company or Sobi, including with respect to anticipated geographic markets, the anticipated timing of the planned Phase 3 clinical trial, the potential market opportunity for SEL-212, the potential of SEL-212 to fulfill unmet needs in chronic refractory gout patients including sustained SUA reduction, reduced flares, and repeated once monthly dosing, as well as the ability to dose longer than the current standard of care, the company's and Sobi's commercial plans, the expected upfront, milestone, and royalty-based payments to the company under the strategic licensing agreement with Sobi, the company's development of a product candidate to treat an autoimmune indication, including for IgA nephropathy, the timing and execution of company's plans to file an IND for such product candidate,, the potential of the ImmTOR technology platform generally and the company's ability to grow its strategic partnerships, the sufficiency of the company's cash, cash equivalents and short-term investments, 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 their uncertain outcomes, the effect of the COVID-19 outbreak on any of the company's planned or ongoing clinical trials, manufacturing activities, supply chain and operations, 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 unproven approach of the company's ImmTOR technology, Sarepta's ability to research and develop therapeutic candidates using the company's ImmTOR technology, 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 as well as the impact of the COVID-19 outbreak on those third parties and their ability to continue their operations, 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, management's ability to perform as expected, potential delays in regulatory approvals, Sobi and/or Sarepta's ability to make up-front and milestone payments, the company's business development strategy, 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 including stock market fluctuations that occur as a result of the COVID-19 outbreak, and other important factors discussed in the "Risk Factors" section of the company's most recent Quarterly Report 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.

Selecta Biosciences, Inc. and Subsidiaries
Consolidated Balance Sheets
(Amounts in thousands, except share data and par value)

	June 30, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 59,730	$ 89,893
Restricted cash	278	279
Accounts receivable	—	5,000
Prepaid expenses and other current assets	1,044	1,495
Total current assets	61,052	96,667
Property and equipment, net	1,301	1,222
Right-of-use asset, net	11,474	301
Long-term restricted cash	1,379	1,379
Total assets	$ 75,206	$ 99,569
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,242	$ 500
Accrued expenses	9,308	13,492
Loan payable	8,384	18,905
Lease liability	1,648	372
Deferred revenue	1,928	1,674
Total current liabilities	22,510	34,943
Non-current liabilities:		
Loan payable, net of current portion	6,449	—
Lease liability	10,120	—
Deferred revenue	16,412	14,680
Warrant liabilities	32,767	41,549
Total liabilities	88,258	91,172
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 100,847,810 and 86,325,547 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	10	9
Additional paid-in capital	370,944	348,664
Accumulated deficit	(379,454)	(335,753)
Accumulated other comprehensive loss	(4,552)	(4,523)
Total stockholders' equity (deficit)	(13,052)	8,397
Total liabilities and stockholders' equity (deficit)	$ 75,206	$ 99,569

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
			(Unaudited)	
Grant and collaboration revenue	$ —	$ 13	$ —	$ 23
Operating expenses:				
Research and development	10,730	12,134	25,454	19,487
General and administrative	5,637	4,114	9,735	8,627
Total operating expenses	16,367	16,248	35,189	28,114
Loss from operations	(16,367)	(16,235)	(35,189)	(28,091)
Investment income	13	246	253	523
Foreign currency transaction (loss), net	(42)	(10)	40	(40)
Interest expense	(205)	(400)	(478)	(796)
Change in fair value of warrant liabilities	(7,539)	—	(8,385)	—
Other (expense), net	59	5	58	(64)
Net loss	(24,081)	(16,394)	(43,701)	(28,468)
Other comprehensive loss:				
Foreign currency translation adjustment	31	7	(29)	29
Unrealized gain on securities	—	1	—	3
Total comprehensive loss	$ (24,050)	$ (16,386)	$ (43,730)	$ (28,436)
Net loss per share:				
Basic and diluted	$ (0.25)	$ (0.37)	$ (0.46)	$ (0.68)
Weighted average common shares outstanding:				
Basic and diluted	96,785,915	44,855,083	95,754,714	41,668,902

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For Media:
Joshua R. Mansbach
Solebury Trout
+1-646-378-2964
jmansbach@soleburytrout.com

For Investors:
Lee M. Stern
Solebury Trout
+1-646-378-2922
lstern@soleburytrout.com