

**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): April 29, 2021

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 8.01. Other Events.

On April 29, 2021, Selecta Biosciences, Inc. (the “Company”) and Asklepios BioPharmaceutical, Inc. (“AskBio”) issued a press release relating to their methylmalonic acidemia program. A copy of the above-referenced press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company and AskBio dated April 29, 2021
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: April 29, 2021

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



Selecta Biosciences and AskBio Announce Updates to Methylmalonic Acidemia (MMA-101) Program

– Methylmalonic Acidemia (MMA) program to become wholly-owned by Selecta –

– Selecta to postpone IND submission until at least the fourth quarter of 2021 –

– Empty capsid (SEL-399) study remains on track –

WATERTOWN, Mass., and Research Triangle Park, N.C., April. 29, 2021 — Selecta Biosciences, Inc. (NASDAQ: SELB) and Asklepios BioPharmaceutical, Inc. (AskBio), today announced an update to the companies' collaboration to evaluate gene therapy candidate MMA-101 and ImmTOR™ for the treatment of methylmalonic acidemia (MMA). Selecta will assume all rights to the MMA program and will continue to progress the MMA-101 and ImmTOR combination through clinical development. AskBio's decision to give all rights to Selecta is based on an internal strategic review and prioritization of its portfolio.

"Obtaining exclusive rights to the MMA program further strengthens Selecta's wholly-owned gene therapy portfolio," said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. "We are grateful to the AskBio team for their partnership in progressing MMA-101 through IND-enabling studies and look forward to taking advantage of this opportunity to independently advance the program through clinical development. Additionally, we are pleased with the progress made to date in our first-in-human trial of ImmTOR for gene therapy with the empty capsid study, which remains a collaborative effort with AskBio."

Due to a manufacturing issue we believe is related to a component sourced from a third-party, Selecta now expects that submission of the IND for MMA-101 and ImmTOR will be delayed until at least the fourth quarter of 2021. A detailed assessment of the manufacturing process is currently being conducted, and the Company expects to provide an update on program timelines as they are clarified. ImmTOR manufacturing continues to proceed smoothly, and there is no impact to any of Selecta's ImmTOR programs.

The dose-escalation trial of SEL-399, an adeno-associated viral serotype 8 (AAV8) empty vector capsid (EMC-101) containing no DNA combined with ImmTOR, is currently underway and progressing as expected. The study, being conducted in healthy volunteers at the SGS Life Sciences Clinical Pharmacology Unit in Antwerp, Belgium, is designed to evaluate the safety and preliminary efficacy of ImmTOR in gene therapy. Selecta and AskBio intend to provide topline data in the fourth quarter of this year.

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.

About AskBio

Asklepios BioPharmaceutical, Inc. (AskBio), a wholly owned and independently operated subsidiary of Bayer AG acquired in 2020, is a fully integrated AAV gene therapy company dedicated to developing life-saving medicines that cure genetic diseases. The company maintains a portfolio of clinical programs across a range of neuromuscular, central nervous system, cardiovascular and metabolic disease indications with a clinical-stage pipeline that includes therapeutics for Pompe disease, Parkinson's disease and congestive heart failure, as well as out-licensed clinical indications for hemophilia and Duchenne muscular dystrophy. AskBio's gene therapy platform includes Pro10™, an industry-leading proprietary cell line manufacturing process, and an extensive AAV capsid and promoter library. With global headquarters in Research Triangle Park, North Carolina, and European headquarters in Edinburgh, UK, the company has generated hundreds of proprietary third-generation AAV capsids and promoters, several of which have entered clinical testing. Founded in 2001 and an early innovator in the gene therapy field, the company holds more than 500 patents in areas such as AAV production and chimeric and self-complementary capsids. Learn more at www.askbio.com or follow us on [LinkedIn](#).

AskBio Forward-Looking Statements

This press release contains "forward-looking statements." Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include without limitation statements regarding AskBio's pipeline of development candidates; AskBio's collaboration with Selecta and AskBio's clinical trials, including the SEL-399 trial, and manufacturing technology and process. These forward-looking statements involve risks and uncertainties, many of which are beyond AskBio's control. Known risks include, among others: AskBio may not be able to execute on its business plans and goals, including meeting its expected or planned regulatory milestones and timelines, its reliance on third-parties, clinical development plans, manufacturing processes and plans, and bringing its product candidates to market, due to a variety of reasons, including the ongoing COVID-19 pandemic, possible limitations of company financial and other resources, manufacturing limitations that may not be anticipated or resolved in a timely manner, potential disagreements or other issues with our third-party collaborators and partners, and regulatory, court or agency feedback or decisions, such as feedback and decisions from the United States Food and Drug Administration or the United States Patent and Trademark Office. Any of the foregoing risks could materially and adversely affect AskBio's business and results of operations. You should not place undue reliance on the forward-looking statements contained in this press release. AskBio does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

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 the unique proprietary platform of its partners, the potential of ImmTOR to enable re-dosing of AAV gene therapy, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, the ability of the Company and AskBio to develop and manufacture gene therapy products using ImmTOR and AskBio's

technology, the rights of the Company and AskBio in the MMA program, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human primate study subjects will translate to studies performed with human beings, the potential of any therapies developed by the company and AskBio 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 intellectual property 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 primates, 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 from operations raise substantial doubt regarding its ability to continue as a going concern, substantial fluctuation in the price of its common stock, 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.

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