# **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, 2019

# 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.)

480 Arsenal Way

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:

0	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
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o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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,	SELB	Nasdaq Global Market
\$0.0001 par value per share		

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  $\boxtimes$ 

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 1.01. Entry into a Material Definitive Agreement.

On August 6, 2019, Selecta Biosciences, Inc. (the "Company") and Asklepios BioPharmaceutical, Inc., a Delaware corporation ("AskBio"), entered into a Feasibility Study and License Agreement (the "Agreement"). Pursuant to the Agreement the Company and AskBio agree to license intellectual property rights to each other as part of a collaboration to research, develop, and commercialize certain adeno-associated virus ("AAV") gene therapy products utilizing the Company's synthetic vaccine particle(s) encapsulating the immunomodulator rapamycin ("ImmTOR") to enable re-dosing of such AAV gene therapy products to treat serious rare and orphan genetic diseases for which there is a significant unmet medical need.

Pursuant to the Agreement, the Company and AskBio will conduct proof of concept studies to validate the use of ImmTOR in conjunction with AAV for the treatment of Methylmalonic Acidemia (MMA) based on the Company's product candidate SEL-302 to mitigate the formation of neutralizing anti-AAV capsid antibodies (the "POC Studies"). If the POC Studies are successful, or the parties otherwise elect to do so, the parties will proceed with a collaboration to pursue the development and commercialization of AAV gene therapy products utilizing ImmTOR for the treatment of certain agreed serious rare and orphan genetic diseases. If the POC Studies fail to demonstrate a proof of concept, and the parties do not mutually agree in writing to proceed with the collaboration, the Agreement will expire.

The Company and AskBio will share responsibility for the research, development and commercialization of products developed under this collaboration. The parties will also share research, development and commercialization costs equally for all collaboration products, but with a right of either party to opt out of certain products, and thereby no longer be required to share costs for such products. Each party will receive a percentage of net profits for each product sold under the collaboration equal to the percentage of shared costs borne by such party in the development of such product. Pursuant to the Agreement, AskBio is responsible for manufacturing the AAV capsids and AAV vectors and the Company is responsible for manufacturing ImmTOR.

The above description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the text of the Agreement. A copy of the Agreement will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019.

#### Item 8.01 Other Events.

On August 7, 2019, the Company issued a press release announcing the execution of the Agreement, a copy of which is attached hereto as Exhibit 99.1.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description		
99.1	Press release issued by Selecta Biosciences, Inc. on August 7, 2019		

## 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 7, 2019

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

Carsten Brunn, Ph.D. President and Chief Executive Officer

Exhibit	
Number	

## Description

<u>99.1</u>

Press release issued by Selecta Biosciences, Inc. on August 7, 2019





## Selecta Biosciences Combines ImmTOR<sup>™</sup> Platform with AskBio's Industry-Leading Gene Therapy Platform in Strategic Partnership

Development pipeline and human trials planned for repeat dosing of AAV-based gene therapies to address the unmet medical need for patients with rare and orphan genetic diseases.

**Watertown, Mass., and Research Triangle Park, N.C., August 7, 2019** - <u>Selecta Biosciences, Inc.</u> (NASDAQ: SELB) and <u>Asklepios</u> <u>BioPharmaceutical, Inc. (AskBio</u>), today announced a strategic partnership to jointly develop, manufacture and commercialize targeted therapeutics for life-changing, next-generation adeno-associated virus (AAV) gene therapies in areas of high medical need. This partnership will leverage the unique proprietary technology platforms of both companies with a human proof of concept trial to validate the potential for redosing in patients with genetic diseases.

Selecta is the first company with preclinical evidence to support the potential for re-dosing patients receiving gene therapy. When used in combination with AAV gene therapy vectors, Selecta's ImmTOR<sup>TM</sup> inhibits the immune response to the vector (*Nature Communications*, October 2018). Currently the ability to re-administer systemic AAV gene therapy is limited by the development of neutralizing antibodies. The ability to safely re-dose AAV should help achieve therapeutic benefit in patients who are under-dosed; it should also help restore transgene expression in patients, particularly growing pediatric patients, who may lose expression over time. In addition, integrating ImmTOR into a gene therapy protocol provides a first dose benefit by enhancing liver-directed transgene expression in preclinical models.

"We are very excited to partner with AskBio, as they are proven leaders in next-generation gene therapy development and scaled manufacturing," said Carsten Brunn, PhD, Chief Executive Officer of Selecta. "We expect that Selecta's ImmTOR technology, in combination with AskBio's AAV technology and clinical leadership, will allow us to rapidly advance a portfolio of new combination therapies through proof of concept and into the clinic. We look forward to working together as we aim to bring targeted therapeutics into clinical development that can offer patients a new treatment paradigm in areas of high unmet need."

AskBio was founded in 2001 as one of the first gene therapy companies and now owns over 500 patents and applications for AAV technology and processes. AskBio's gene therapy platform includes a robust pipeline of potentially curative gene therapies, an extensive capsid library, groundbreaking manufacturing process and several advanced AAV initiatives under development, including Doggybone DNA. The AskBio platform also was used to develop the only two FDA-approved gene therapies available today (Zolgensma<sup>®</sup> and Luxterna<sup>™</sup>). Several of AskBio's founders have been influential in the field. Dr. Jude Samulski was the first to clone AAV and discovered how AAV could be safely used to deliver corrected genes to cells with genetic defects. Dr. Xiao Xiao, was the first to create a mini-dystrophin gene that opened the door for the development of potential Duchenne Muscular Dystrophy therapies. Dr. Josh Grieger, Askbio's Chief Technology Officer, pioneered a production technology, the Pro10 cell line, that is paving the way to ensure these important gene therapeutics can reach all patients.

"We only seek to collaborate with companies that share our mission and core values, which are focused on one goal, finding the answers that will cure patients suffering from life-threatening genetic diseases," said Sheila Mikhail, CEO and cofounder of AskBio. "Selecta is a leading example of that kind of company, and we're enthusiastic to have this opportunity to work with them on behalf of patients and their families."

According to Dr. Jude Samulski, "We look forward to this opportunity to deploy our collective platforms to overcome one of the key obstacles to providing long-term treatment from AAV based therapeutics to all patients."

#### About AskBio

Asklepios BioPharmaceutical, Inc. (AskBio) is a privately held, clinical stage gene therapy platform company dedicated to improving the lives of children and adults with rare genetic disorders. AskBio's gene therapy platform includes an industry-leading proprietary cell line manufacturing process known as Pro10<sup>™</sup> and an extensive AAV capsid library. The company has generated hundreds of proprietary third-generation gene vectors, several of which have entered clinical testing. AskBio maintains a portfolio of clinical programs across a range of indications, including Pompe, Limb Girdle Muscular Dystrophy, Cystic Fibrosis, Myotonic Muscular Dystrophy, Huntington's, Hemophilia (Chatham Therapeutic/Takeda) and Duchenne Muscular Dystrophy (Bamboo Therapeutics/Pfizer). For more information, visit www.askbio.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, Mass. For more information, please visit <a href="http://selectabio.com">http://selectabio.com</a>.

## **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 gene therapy products using ImmTOR and AskBio's technology, the novelty of treatment paradigms that the Company is able to develop, 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 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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