UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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 26, 2019

SAVARA INC.
(Exact name of registrant as specified in its charter)

Delaware	001-32157	84-1318182
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6836 Bee Cave Road, Building III, Suite 200
Austin, TX 78746
(Address of principal executive offices, including zip code)

(Registrant's telephone number, including area code) (512) 961-1891

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 (see General Instruction A.2. below):

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 1.01. Entry into a Material Definitive Agreement.

On April 26, 2019, Savara Inc. (the "**Company**"), through its wholly-owned subsidiary, Savara ApS, and GEMABIOTECH SAU, a corporation organized under the laws of Argentina ("**GEMA**"), entered into a Manufacture and Supply Agreement (the "**Agreement**") pursuant to which GEMA will supply the active pharmaceutical ingredient for the Company's Molgradex product (the "**API**"). The Agreement supersedes the Supply and License Agreement between Savara ApS (as assignee of Serendex ApS) and GEMA dated December 10, 2012, as amended on February 22, 2016 and September 20, 2017.

Under the Agreement, GEMA shall manufacture and supply the API exclusively for the Company for commercial sale and continue to supply the API to the Company for clinical studies and research and development activities. Pursuant to the terms of the Agreement, GEMA agreed to undertake the actions required to comply with the requirements of the U.S. Food & Drug Administration (the "**FDA**") and other similar regulatory authorities and obtain the approvals necessary to manufacture and supply the API to the Company for commercial sale. Additionally, GEMA transferred and assigned to the Company all right, title and interest in and to the master cell bank and working cell bank necessary to produce the API.

As consideration for the rights granted by GEMA, the Company is required to pay GEMA an agreed upon price per vial of 1 gram of the API. Additionally, the Company is obligated to make milestone payments to GEMA upon (i) the effective date of the Agreement, (ii) completion of certain developmental activities, (iii) successful completion of an audit by the FDA, and (iv) marketing approval of a product containing the API. If the Company successfully commercializes a product containing the API in a country, it must pay GEMA a single digit percentage royalty on annual net sales. The Company is obligated to make such royalty payments until the earlier of (i) 10 years after the first receipt of marketing approval for the product in that country or (ii) the date a biosimilar of such product is first sold in that country.

The term of the Agreement continues until the twentieth anniversary of the date of receipt of marketing approval for a product containing the API in any country and may be extended for additional twelve-month terms by the agreement of both parties. The Company may terminate the Agreement immediately if (i) products containing the API will not be sold or will be withdrawn from the market, (ii) the FDA or other regulatory authority withdraws marketing approval for or fails to approve products incorporating the API, (iii) three or more batches of API supplied in any six month period fail to conform to specifications, (iv) GEMA receives notice of deficiencies in its manufacturing and fails to adequately respond, or (v) GEMA fails to achieve compliance with the requirements of the FDA and other regulatory authorities necessary to manufacture and supply the API to the Company for commercial sale.

The Agreement also contains customary representations, warranties, mutual indemnities, limitations of liability and confidentiality provisions.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, which the Company plans to file with its Form 10-Q for the quarter ended March 31, 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.

Date: April 30, 2019

SAVARA INC.
a Delaware corporation

By: /s/ Dave Lowrance
Dave Lowrance
Chief Financial Officer