
**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): June 10, 2019

EVOLUS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38381
(Commission File Number)

46-1385614
(I.R.S. Employer
Identification No.)

**520 Newport Center Drive, Suite 1200
Newport Beach, California 92660**
(Address of principal executive offices) (Zip Code)

(949) 284-4555
(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))

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.

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.00001 per share	EOLS	Nasdaq Global Market

Item 8.01 Other Events.

On June 10, 2019, Evolus, Inc. (the “Company”) announced that the European Medicines Agency (“EMA”) Committee for Medicinal Products for Human Use (“CHMP”) had informed the Company that the European Commission (“EC”) has requested supplementary information from the EMA and CHMP as part of its administrative decision making process related to the Company’s Marketing Authorization Application (“MAA”) for Nuceiva™, an injectable 900 kilodalton botulinum toxin type A complex. The request for supplemental information may result in the EC extending its final decision on approval beyond the 90 days previously stated by the Company

On June 10, 2019, the Company issued a press release announcing the information set forth above. A copy of the Company’s press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Evolus, Inc., dated June 10, 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.

EVOLUS, INC.

Dated: June 10, 2019

By: /s/ David Moatizedi

David Moatizedi
President and Chief Executive Officer



Evolus Provides Update on Nuceiva™ Marketing Authorization Application in Europe

NEWPORT BEACH, Calif., June 10, 2019 – Evolus, Inc. (NASDAQ: EOLS) today provided an update on the marketing authorization application (MAA) for Nuceiva™ in Europe that may result in the European Commission (EC) extending its final decision on approval beyond the 90 days previously stated by the company.

On April 26, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion on the MAA for Nuceiva™. Following a positive opinion from the CHMP, the EC undergoes an administrative decision-making process before issuing a final decision on an MAA.

Evolus was informed by the EMA that the EC has requested supplementary information from the EMA/CHMP as part of their review of the Nuceiva™ MAA. The EC has the ability to delay its standard timeline if additional information is requested of the EMA/CHMP during its decision-making process.

“We remain confident in the merits of the Nuceiva™ MAA. The CHMP conducted a thorough review prior to granting us a positive opinion,” said Rui Avelar, MD, Chief Medical Officer and Head of Research and Development. “We look forward to the timely resolution of this final step with the European regulators and plan to confirm our timeline for approval upon receipt of clarification from the European Commission.”

About Nuceiva™

Nuceiva™ (prabotulinumtoxinA-xvfs) is a proprietary 900 kDa purified botulinum toxin type A formulation. Nuceiva™ is produced under strict quality and safety standards in a state-of-the-art facility, specifically built to manufacture Nuceiva™. The safety and efficacy of Nuceiva™ has been evaluated in clinical studies with over 2,100 patients enrolled. Nuceiva™ is being evaluated by the EMA for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines), when the severity of the above facial lines has an important psychological impact in adults below 65 years of age.

About Evolus, Inc.

Evolus is a performance beauty company with a customer-centric approach focused on delivering breakthrough products. In 2019, the U.S. Food and Drug Administration approved Jeuveau™ (prabotulinumtoxinA-xvfs), the first and only neurotoxin dedicated exclusively to aesthetics and manufactured in a state-of-the-art facility using Hi-Pure™ technology. Jeuveau™ is powered by Evolus' unique technology platform and is designed to transform the aesthetic market by eliminating the friction points existing for customers today. Visit us at: www.evolus.com.

Forward-Looking Statements

Statements made in this release that relate to the status of regulatory processes, future plans, events, prospects or performance are forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, are statements that

could be deemed forward-looking statements, including statements containing the words “planned,” “expect,” “believes,” “strategy,” “opportunity,” “anticipates,” “outlook,” “designed,” and similar words. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from the expectations expressed in this release, including the risks and uncertainties disclosed in Evolus’ periodic filings with the Securities and Exchange Commission, including factors described in the section entitled “Risk Factors” in its Annual Report on Form 10-K for the year ended December 31, 2018 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 as filed with the Securities and Exchange Commission on March 20, 2019 and May 1, 2019, respectively, all of which are available online at www.sec.gov. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Evolus undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

Jeuveau™ and Nuceiva™ are trademarks of Evolus, Inc.

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