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 6, 2019 (June 5, 2019)

XERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38536**	**20-3352427**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

180 N. LaSalle Street, Suite 1600
Chicago, Illinois 60601

(Address of principal executive offices, including zip code)

(844) 445-5704

(Registrant's telephone number, including area code)

Not Applicable

(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 per share	XERS	The Nasdaq Global Select 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 8.01 Other Events

On June 6, 2019, Xeris Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) extended from June 10, 2019 until September 10, 2019 the initial Prescription Drug User Fee Act (PDUFA) action goal date for the Company's new drug application (NDA) seeking marketing approval of Gvoke™ (ready-to-use glucagon injection). The Company received a notification letter from the FDA on June 5, 2019, which states that the Company's recent submission in response to an information request from the FDA constitutes a major amendment to the NDA, and the FDA therefore is extending the goal date by three months to provide time for a full review of the submission.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

99.1	Press release issued by Xeris Pharmaceuticals, Inc. on June 6, 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: June 6, 2019

Xeris Pharmaceuticals, Inc.

By: /s/ Barry M. Deutsch

Name: Barry M. Deutsch

Title: *Chief Financial Officer*

Exhibit 99.1

XERIS PHARMACEUTICALS RECEIVES NOTIFICATION OF PDUFA DATE EXTENSION FOR GVOKE™

Conference call and webcast today at 5:00 pm ET

CHICAGO, IL; June 6, 2019 - Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel technology platforms to develop and commercialize ready-to-use injectable and infusible drug formulations, announced today that the U.S. Food and Drug Administration (FDA) has extended the initial Prescription Drug User Fee Act (PDUFA) goal date for its review of the Company's New Drug Application (NDA) seeking marketing approval of Gvoke™ (ready-to-use glucagon injection) by three months. The new PDUFA goal date is September 10, 2019.

The Company received a notification letter from the FDA on June 5, 2019, which states that the Company's recent submission in response to an information request from the FDA constitutes a major amendment to the NDA, and therefore, the FDA is extending the goal date by three months to provide time for a full review of the submission. According to FDA's current PDUFA Performance Goals, an FDA decision to extend the review period typically is limited to situations where review of the new information could address an outstanding issue(s) and lead to approval in the current review cycle. The FDA has not requested additional clinical data in connection with the Gvoke NDA, and the Company has provided all additional information that FDA has requested to date.

"We believe that we have sufficiently responded to FDA's requests for information throughout the review, and we look forward to working with the FDA to answer any additional questions the agency may have as it completes its review of the Gvoke NDA," commented Paul R. Edick, Chairman and Chief Executive Officer of Xeris. "Our commercial team remains focused on preparing for the potential launch of Gvoke in the fourth quarter."

Xeris Pharmaceuticals will host a conference call and webcast today, Thursday, June 6, 2019 at 5:00 pm Eastern Time. The conference call can be accessed by dialing 866-951-8137 for domestic callers and 270-215-9500 for international callers. Please provide the operator with the conference ID 5391267 to join the conference call. The conference call will be available via webcast under the Investors section of Xeris' website at www.xerispharma.com. An archive of today's webcast will be available on Xeris' website for 60 days following the call.

About Glucagon

Glucagon is a metabolic hormone secreted by the pancreas that raises blood glucose levels by causing the liver to rapidly convert glycogen (the stored form of glucose) into glucose, which is then released into the bloodstream. Glucagon and insulin are two critical hormones in a glycemic control system that keep blood glucose at the right level in healthy individuals. In people with diabetes who are dependent on insulin, this control system is disrupted, and insulin must be injected to avoid high levels of blood glucose (hyperglycemia). The opposite effect, or low blood glucose (hypoglycemia), is also prevalent in this population due to dysregulated glucagon secretion. Severe hypoglycemia is a serious condition and can lead to seizures, coma, potential brain injury and, if untreated, death.

Glucagon is the standard of care for treating severe hypoglycemia. According to the American Diabetes Association, glucagon should be prescribed for all individuals at increased risk of clinically significant hypoglycemia, defined as blood glucose <54 mg/dL (3.0 mmol/L). Leveraging XeriSol™, one of Xeris' two proprietary formulation technology platforms, Xeris has the potential to provide the first ready-to-use, room-temperature stable liquid glucagon for use by people with diabetes and other indications to prevent or manage various forms of hypoglycemia and improve glucose control.

About Xeris Pharmaceuticals, Inc.

Xeris is a specialty pharmaceutical company leveraging its novel technology platforms to develop and commercialize ready-to-use, room-temperature stable injectable and infusible drug formulations. The Company's proprietary XeriSol™ and XeriJect™ formulation technologies are being evaluated for the subcutaneous (SC) and intramuscular (IM) delivery of highly-concentrated, non-aqueous, ready-to-use formulations of peptides, small molecules, proteins, and antibodies using commercially available syringes, auto-injectors, multi-dose pens, and infusion pumps. XeriSol™ and XeriJect™ have the potential to offer distinct advantages over existing formulations of marketed and development-stage products, including eliminating the need for reconstitution, enabling long-term, room-temperature stability, significantly reducing injection volume, and eliminating the requirement for intravenous (IV) infusion. These attributes may lead to products that are easier to use by patients, caregivers, and health practitioners and reduce costs for payers and the healthcare system. Further information about Xeris can be found at www.xerispharma.com.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Xeris Pharmaceuticals, Inc., including statements concerning the timing or likelihood of approval by the FDA of its NDA for its glucagon pen, the market and therapeutic potential of its product candidates, the timing or likelihood of commercialization of our product candidates, the potential utility of its formulation platforms and other statements containing the words "will," "would," "continue," 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, without limitation, the regulatory approval of its product candidates, its ability to market and sell its products, if approved, and other factors discussed in the "Risk Factors" section of the most recently filed Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Xeris' subsequent filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Xeris expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

The Company intends to use the investor relations portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

Investor Contact

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