# **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): July 19, 2021 (July 14, 2021)

# XERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation)

Emerging growth company  $\boxtimes$ 

001-38536

(Commission File Number)

20-3352427 (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 tl             | ne appropriate box below if the Form 8-K filing is intended to s   | imultaneously satisfy the filing obligat | ion of the registrant under any of the following provisions: |  |
| $\boxtimes$          | 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))                   |  |  |  |
| Securitie            | es 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<br>12b-2 of | by check mark whether the registrant is an emerging growth the Securities Exchange Act of 1934 (§ 240.12b-2 of this chap | company as defined in Rule 405 of th     | e Securities Act of 1933 (§ 230.405 of this chapter) or Rule |  |

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.  $\Box$ 

#### Item 8.01. Other Events.

On July 14, 2021, Xeris Pharmaceuticals, Inc. ("Xeris US"), Xeris Pharmaceuticals Ireland Limited ("Xeris Ireland" and, together with Xeris US, "Xeris"), a wholly-owned subsidiary of Xeris US, and Tetris Pharma Limited ("Tetris") entered into an exclusive agreement for the purpose of allowing Tetris to commercialize Xeris' Ogluo® glucagon product (the "Product") in the member countries of the European Economic Area, the United Kingdom and Switzerland (collectively, the "Territory") for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

Xeris will be responsible for product supply and Tetris will be responsible for the commercialization of Ogluo in the Territory. Subject to the terms and conditions set forth in the agreements, Xeris will receive up to \$71 million in payments tied to the first commercial sale and other time-, launch- and sales-related milestones and collect a royalty on net sales. The company expects the first commercial launch to be in Q4 2021 in the United Kingdom.

## **Forward-Looking Statements**

Any statements in this Form 8-K about future expectations, plans and prospects for Xeris Pharmaceuticals, Inc., including statements regarding the market and therapeutic potential of its products and product candidates, the potential or likelihood of future payments under the agreements, the timing or likelihood of expansion into additional markets, including, the United Kingdom in Q4 2021, future performance of Tetris under the agreements and anticipated results and potential benefits of the commercialization partnership, 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 impact of COVID-19 on its business operations, its reliance on third-party suppliers for Gvoke® and Ogluo®, 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 Form 8-K 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.

#### No Offer or Solicitation

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote or approval in any jurisdiction pursuant to the Proposed Transaction (as defined below), the merger or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made in the United States absent registration under the Securities Act or pursuant to an exemption from, or in a transaction not subject to, such registration requirements. The Proposed Transaction will be made solely by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

## IMPORTANT ADDITIONAL INFORMATION WILL BE FILED WITH THE SEC

Xeris Biopharma Holdings, Inc. ("Xeris Biopharma Holdings") has filed with the United States Securities and Exchange Commission (the "SEC") a registration statement on Form S-4 that includes the preliminary joint proxy statement of Strongbridge and Xeris and that also constitutes a preliminary prospectus with respect to the shares of Xeris Biopharma Holdings to be issued pursuant to the proposed acquisition by Xeris and Xeris Biopharma Holdings of the entire issued and to be issued ordinary share capital of Strongbridge Biopharma plc ("Strongbridge") pursuant to a scheme of arrangement under Chapter 1 of Part 9 of the Irish Companies Act 2014 and a capital reduction under Sections 84 to 86 of the Act (such acquisition, the "Proposed Transaction"). The joint proxy statement also contains the transaction agreement describing the terms and conditions of the Proposed Transaction, as well as further information relating to the implementation of the Proposed Transaction, notices of the Xeris shareholder meeting and the Strongbridge shareholder meetings and information on the Xeris Biopharma Holdings shares. Xeris and Strongbridge have filed and may also file other documents with the SEC regarding the Proposed Transaction. This communication is not a substitute for the preliminary joint proxy statement or any other document which Xeris, Xeris Biopharma Holdings or Strongbridge has filed or may file with the SEC.

The preliminary joint proxy statement, as well as Xeris' and Strongbridge's other public filings with the SEC, may be obtained without charge at the SEC's website at www.sec.gov and, in the case of Xeris' filings, at Xeris' website at www.xerispharma.com.

INVESTORS, XERIS SHAREHOLDERS AND STRONGBRIDGE SHAREHOLDERS ARE URGED TO READ THE PRELIMINARY JOINT PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS THAT ARE FILED OR WILL BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS,

# CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE ACQUISITION AND RELATED MATTERS.

Any decision in respect of the resolutions to be proposed at the Xeris shareholder meeting or any decision in respect of, or other response to, the Proposed Transaction, should be made only on the basis of the information contained in the preliminary joint proxy statement.

# PARTICIPANTS IN THE SOLICITATION

Xeris, Xeris Biopharma Holdings, Strongbridge and their respective directors and executive officers and employees may be deemed to be participants in the solicitation of proxies from their respective shareholders in connection with the Proposed Transaction. Information regarding the persons who may, under the rules of the SEC, be deemed to be participants in the solicitation of shareholders in connection with the Proposed Transaction, including a description of their direct or indirect interests in the Proposed Transaction, which may be different from those of Xeris shareholders or Strongbridge shareholders generally, by security holdings or otherwise, will be set forth in the joint proxy statement (which will contain the Scheme Document) and any other relevant documents that are filed or will be filed with the SEC relating to the Proposed Transaction. Information about Xeris' directors and executive officers is contained in Xeris' Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 9, 2021, and its Proxy Statement on Schedule 14A, dated and filed with the SEC on April 29, 2021. Information regarding Strongbridge's directors and executive officers is contained in Strongbridge's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 3, 2021, and its Proxy Statement on Schedule 14A, dated and filed with the SEC on April 14, 2021.

#### **Item 9.01 Financial Statements and Exhibits**

(d) Exhibits:

| <b>Exhibit Number</b> | Description   |  |
|-----------------------|---|--|
| 99.1                  | Press release issued by Xeris Pharmaceuticals, Inc. dated July 19, 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.

Date: July 19, 2021 Xeris Pharmaceuticals, Inc.

By: /s/ Barry M. Deutsch

Barry M. Deutsch Chief Financial Officer



# XERIS PHARMACEUTICALS ENTERS INTO AN EXCLUSIVE LICENSE AND SUPPLY AGREEMENT WITH TETRIS PHARMA LIMITED TO COMMERCIALIZE OGLUO® IN EUROPE

Up to \$71 million in time- and milestone-based payments, plus royalties on sales

Agreement covers 32 countries

First launch expected in Q4 2021 in UK

Chicago, IL – July 19, 2021 -- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel formulation technology platforms to develop and commercialize ready-to-use injectable drug formulations, today announced an exclusive agreement with Tetris Pharma Limited ("Tetris") for the commercialization of Ogluo® in the European Economic Area, United Kingdom, and Switzerland (the "Territory") for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

Under the terms of the applicable agreements, Xeris will be responsible for product supply and Tetris will be responsible for the commercialization of Ogluo in the Territory. Subject to the terms and conditions set forth in the agreements, Xeris will receive up to \$71 million in payments tied to the first commercial sale and other time-, launch- and sales-related milestones and collect a royalty on net sales.

"We were seeking and found, in Tetris, a partner for whom success with Ogluo would be absolutely critical to their European expansion and to their future as a company. We also are excited by their entrepreneurial approach and understanding of the importance of ready-to-use glucagon and specifically, how Ogluo can impact the lives of patients and caregivers," said Paul R. Edick, Chairman and CEO of Xeris. "Like in the US, very few diabetes patients on insulin in the EU and UK have glucagon on hand in case of a severe hypoglycaemia event. The Tetris team is dedicated to getting Ogluo in the hands of patients on insulin."

"We are delighted to have acquired the pan-European license for Ogluo, a ready-to-use auto-injector of glucagon to help rescue patients from the debilitating and potentially life-threatening consequences of severe hypoglycaemia. As the incidence and prevalence of diabetes continues to rise globally, we are committed to bringing this important and ready-to-use product to patients at risk of suffering from severe low blood sugar levels," said Shafiq Choudhary, PhD, CEO of Tetris Pharma. Dr. Choudhary continued, "Tetris was founded by a leadership team of complementary highly experienced individuals from the UK and international pharmaceutical industry with a shared vision to bring effective treatments to patients in areas of unmet clinical need. We expect to launch Ogluo in the UK by the end of this year and at least seven additional countries by mid-2022, enabling us to accelerate our footprint throughout Europe and pave the way for future successes."

Xeris estimates there are more than five million patients on insulin and at risk of severe hypoglycaemia in the Territory, with only an estimated 10-20% having a prescription for glucagon.

## ABOUT Gvoke® (US) /Ogluo® (EU)

Gvoke® PFS and Gvoke HypoPen® (glucagon injection), the first prescription, ready-to-use, pre-mixed, pre-measured glucagon injection, were approved by the FDA in September 2019 for use in the United States. Gvoke is indicated for the treatment of severe hypoglycaemia in paediatric and adult patients with diabetes ages 2 years and above. Ogluo received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in December 2020 and the European Commission (EC) granted the marketing authorisation on 11 February 2021. The United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) approved Ogluo® (glucagon) injection on April 29, 2021. Ogluo is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

## INDICATION AND IMPORTANT SAFETY INFORMATION FOR GVOKE

Gvoke is indicated for the treatment of severe hypoglycaemia in adult and paediatric patients with diabetes ages 2 years and above.

#### IMPORTANT SAFETY INFORMATION

#### Contraindications

Gvoke is contraindicated in patients with pheochromocytoma, insulinoma, and known hypersensitivity to glucagon or to any of the excipients in Gvoke. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.

## **Warnings and Precautions**

Gvoke is contraindicated in patients with pheochromocytoma because glucagon may stimulate the release of catecholamines from the tumour. If the patient develops a dramatic increase in blood pressure and a previously undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate, administered intravenously, has been shown to be effective in lowering blood pressure.

In patients with insulinoma, administration of glucagon may produce an initial increase in blood glucose; however, Gvoke administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycaemia. Gvoke is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycaemia after a dose of Gvoke, give glucose orally or intravenously.

Allergic reactions have been reported with glucagon. These include generalized rash, and in some cases, anaphylactic shock with breathing difficulties and hypotension. Gvoke is contraindicated in patients with a prior hypersensitivity reaction.

Gvoke is effective in treating hypoglycaemia only if sufficient hepatic glycogen is present. Patients in states of starvation, with adrenal insufficiency or chronic hypoglycaemia, may not have adequate levels of hepatic glycogen for Gvoke administration to be effective. Patients with these conditions should be treated with glucose.

Necrolytic migratory erythema (NME), a skin rash commonly associated with glucagonomas, has been reported post-marketing following continuous glucagon infusion and resolved with discontinuation of the glucagon. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks. Glucagon administered to patients with glucagonoma may cause secondary hypoglycaemia.

#### **Adverse Reactions**

Most common (≥5%) adverse reactions associated with Gvoke are nausea, vomiting, injection site edema (raised 1 mm or greater), and hypoglycaemia.

## **Drug Interactions**

Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given Ogluo. In patients taking indomethacin, Gvoke may lose its ability to raise blood glucose or may even produce hypoglycaemia. Gvoke may increase the anticoagulant effect of warfarin.

Please see full Prescribing Information for Gvoke on <a href="www.xerispharma.com">www.xerispharma.com</a>. Manufactured for Xeris Pharmaceuticals, Inc. by Pyramid Laboratories Inc., Costa Mesa, CA 92626.

# **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 (hypoglycaemia), is also prevalent in this population due to dysregulated glucagon secretion. Severe hypoglycaemia 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 hypoglycaemia. According to the American Diabetes Association, glucagon should be prescribed for all individuals at increased risk of clinically significant hypoglycaemia, defined as blood glucose <54 mg/dL (3.0 mmol/L). Leveraging XeriSol™, one of Xeris' two proprietary formulation technology platforms, Xeris was able to develop the first ready-to-use, room-temperature stable liquid glucagon for use by people with diabetes and other conditions to prevent or manage various forms of hypoglycaemia and improve glucose control.

# **About Severe Hypoglycaemia**

Hypoglycemic events of any severity are a daily concern for people with diabetes. Mild or moderate hypoglycaemia can occur multiple times a month. Severe hypoglycaemia is characterized by severe cognitive impairment, requiring external assistance for recovery, and can be extremely frightening for patients and caregivers. Severe hypoglycaemia can result in cardiovascular disease, seizure, coma, and, if left untreated, death. These severe hypoglycemic events can occur multiple times a year. Such events require emergency assistance from another person or caregiver such as a family member, friend, or co-worker.

# About Xeris Pharmaceuticals, Inc.

Xeris (Nasdaq: XERS) is a specialty pharmaceutical company delivering innovative solutions to simplify the experience of administering important therapies that people rely on every day around the world. With novel technology platforms that enable ready-to-use, room-temperature stable formulations of injectable and infusible therapies, the company is advancing a portfolio of solutions in various therapeutic categories, including its first U.S. commercial product, Gvoke®. Its proprietary XeriSol™ and XeriJect™ formulation technologies have the potential to offer distinct advantages over conventional product formulations, including eliminating the need for reconstitution, enabling long-term, room-temperature stability, significantly reducing injection volume, and eliminating the requirement for intravenous (IV) infusion. With Xeris' technology, new product formulations are intended to be easier to use by patients, caregivers, and health practitioners and help reduce costs for payers and the healthcare system.

Xeris is headquartered in Chicago, IL. For more information, visit <u>www.xerispharma.com</u>, or follow us on <u>Twitter</u>, <u>LinkedIn</u> or <u>Instagram</u>.

#### **About Tetris Pharma**

Tetris Pharma is a UK-based 'niche speciality' pharmaceutical company with extensive experience of launching products, not only in the UK, but across Europe. Our vision is to build a pan-European pharmaceutical company that specialises in marketing a range of prescription products in areas of unmet clinical need. Tetris has a team of highly experienced and complementary individuals, with international expertise across a range of therapeutic areas and in-depth understanding of the complexities of the EU environment allowing them to maximise sales potential.

## **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Xeris Pharmaceuticals, Inc., including statements regarding the market and therapeutic potential of its products and product candidates, the potential or likelihood of future payments under the agreements, the timing or likelihood of expansion into additional markets, including, the United Kingdom in Q4 2021 and additional countries within the Territory by mid-2022, future performance of Tetris under the agreements and anticipated results and potential benefits of the commercialization partnership, 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 impact of COVID-19 on its business operations, its reliance on third-party suppliers for Gvoke® and Ogluo®, 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.

#### No Offer or Solicitation

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote or approval in any jurisdiction pursuant to the Proposed Transaction (as defined below), the merger or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made in the United States absent registration under the Securities Act or pursuant to an exemption from, or in a transaction not subject to, such registration requirements. The Proposed Transaction will be made solely by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

# IMPORTANT ADDITIONAL INFORMATION WILL BE FILED WITH THE SEC

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notices of the Xeris shareholder meeting and the Strongbridge shareholder meetings and information on the Xeris Biopharma Holdings shares. Xeris and Strongbridge have filed and may also file other documents with the SEC regarding the Proposed Transaction. This communication is not a substitute for the preliminary joint proxy statement or any other document which Xeris, Xeris Biopharma Holdings or Strongbridge has filed or may file with the SEC.

The preliminary joint proxy statement, as well as Xeris' and Strongbridge's other public filings with the SEC, may be obtained without charge at the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a> and, in the case of Xeris' filings, at Xeris' website at <a href="https://www.serispharma.com">www.sec.gov</a> and, in the case of Xeris' filings, at Xeris' website at <a href="https://www.serispharma.com">www.serispharma.com</a>.

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# **Xeris Investor Contact**

Allison Wey Senior Vice President, Investor Relations and Corporate Communications awey@xerispharma.com 312-736-1237