



Xeris Pharmaceuticals Announces First Quarter 2019 Financial Results and Highlights Its Pipeline

May 9, 2019

Continuing to execute commercial build and launch readiness for Gvoke HypoPen™ and Gvoke PFS™

Dosed first patient in a Phase 2 study evaluating ready-to-use (RTU) glucagon in EIH

Advancing diazepam to Phase 2 based on recently reported favorable Phase 1 results

Strengthened the balance sheet with February equity offering

CHICAGO, May 09, 2019 (GLOBE NEWSWIRE) -- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel formulation technology platforms to develop and commercialize ready-to-use injectable and infusible drug formulations, today announced financial results for the first quarter ended March 31, 2019, as well as pipeline and corporate highlights.

"We have strong momentum already in 2019 with pipeline progress and infrastructure readily expanding in anticipation of our first commercial launch later this year. We remain focused on delivering on our near-term objectives, while training an eye toward our future," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "We are taking a thoughtful approach to building a strong and diverse portfolio of ready-to-use, liquid stable injectables, looking not only at the important applications using glucagon, but also in other areas where RTU and easier-to-use options may provide meaningful improvement in patients' lives. Starting with our recent first-in-man data in diazepam, the increasing breadth of our pipeline will reflect this growth strategy and demonstrate the broad utility of our technology platforms for patients, caregivers and the healthcare system."

First Quarter 2019 Corporate Highlight

- In February, Xeris raised an additional \$55.6 million in net proceeds to support the commercial launch of Gvoke HypoPen and Gvoke PFS, continue advancement of the pipeline, and for other general corporate purposes.

Pipeline Highlights

Ready-to-Use Glucagon for Hypoglycemia

■ Severe Hypoglycemia

- As previously announced, the FDA has assigned a PDUFA goal date of June 10, 2019 for the NDA of Xeris' lead product candidate, Gvoke HypoPen and Gvoke PFS, for the treatment of severe hypoglycemia in people with diabetes. The Company continues building out its commercial organization and readying commercial scale-up in anticipation of launching in the fourth quarter of 2019, if approved.

- Data from the Phase 3 European study to support Xeris' RTU glucagon Marketing Authorization Application (MAA) remain on track to be reported in the first half of 2019.

- In March, Xeris presented results of a Xeris budget impact model on the estimated potential reduction in costs associated with use of its RTU room-temperature stable liquid glucagon during a poster presentation at the Academy of Managed Care Pharmacy's (AMCP) Managed Care & Specialty Pharmacy Annual Meeting. Results of the analysis indicated that significant overall cost savings may be achieved with use of Xeris' glucagon.

■ Exercise-Induced Hypoglycemia (EIH)

- In March, Xeris dosed its first patient in a Phase 2 study of RTU glucagon to address EIH. This Phase 2 study will evaluate Xeris' ready-to-use glucagon as a pre-treatment to prevent EIH in 48 patients with Type 1 diabetes who receive daily insulin treatment via a subcutaneous infusion pump. In the two-period cross-over comparison study, patients will receive ready-to-use glucagon or placebo before at least 45 minutes of moderate or high intensity aerobic exercise in a clinical research center. Additional data will then be collected via a parallel comparison in an outpatient setting with a similar regimen involving at least 30 minutes of aerobic exercise performed by subjects 3-5 times per week for 12 weeks. Based on the current enrollment rate, Xeris expects to report top-line results from the in-clinic portion of study in the second half of 2019.

■ Post-Bariatric Hypoglycemia (PBH)*

- Xeris anticipates dosing its first patient in a Phase 2 study of RTU glucagon in patients who experience hypoglycemic episodes following bariatric surgery in the first half of 2019. This Phase 2, randomized, placebo-controlled, double-blind study will evaluate the efficacy, safety and tolerability of the Xeris RTU glucagon in treating symptomatic postprandial hypoglycemia among 12 patients with PBH initially during two in-patient clinical research center visits and then ongoing as part of a 12-week outpatient phase. Based on planned enrollment rates, Xeris anticipates reporting data from the in-clinic portion of the study in the second half of 2019.

■ **Congenital Hyperinsulinism (CHI)***

- During an oral presentation at ENDO 2019 in March, Xeris presented new Phase 2 data on RTU room-temperature stable glucagon for CHI showing patients treated with Xeris' RTU glucagon delivered continuously through an Omnipod® infusion pump had a positive clinical response compared to those receiving placebo and follow-up open-label treatment resulted in a clinically meaningful response in all evaluable patients. Xeris anticipates initiating a Phase 3 study mid-2019.

■ **Hypoglycemia Associated Autonomic Failure (HAAF)**

- Xeris is currently enrolling patients in its Phase 2 study of HAAF. This is a prospective, randomized, controlled, double-blind, parallel 4-group trial with the primary analysis after 4 weeks of treatment with continuous subcutaneous glucagon infusion (CSGI) or placebo. After a 1-week qualification on continuous glucose monitoring (CGM), subjects will have their baseline hypoglycemia counter-regulatory response hormones quantified using a step-wise hypoglycemia induction procedure. Subjects meeting eligibility requirements will be randomized to 1 of 4 treatment groups. Subjects will receive blinded study drug for 4 weeks, and they will be followed for an additional 26 weeks post-treatment. Subjects' counter-regulatory hormone response will be measured at baseline, the end of treatment (4 weeks), and 13 and 26 weeks after treatment ends. Based on the current enrollment rate, Xeris anticipates reporting the end-of-treatment results in the second half of 2019.

Ready-to-Use Products for Epilepsy and Diabetes

■ **Diazepam: Acute Repetitive Seizures* and Dravet syndrome***

- Xeris recently reported favorable Phase 1 data from a diazepam study comparing XeriSol™-formulated intramuscular (IM) and subcutaneous (SC) administration versus diazepam rectal gel (Diastat®). Based on the data from the Phase 1 study, the Company expects to initiate a Phase 2 open-label, single-arm, weight-based study in patients with seizure disorders in the second half of 2019 with its IM formulation.

■ **Pramlintide-insulin: Type 1 (T1D) and Type 2 (T2D) diabetes blood sugar control**

- In January, Xeris had a pre-IND meeting with the FDA and agreed upon a proposed study design. Xeris anticipates initiating a Phase 2 randomized, open-label, active-controlled, single-dose, three-treatment, three-period, three-way crossover, comparative pharmacodynamics (PD) and pharmacokinetics (PK) in-patient study in adults with T1D in the second half of 2019. The primary objective of this study is to evaluate the PD properties of a single dose of pramlintide-insulin compared to single doses of regular insulin and regular insulin plus pramlintide (co-administered as separate injections) in adults with T1D.

** orphan drug designation*

Upcoming Events

- Preclinical and clinical data will be presented at the upcoming scientific conferences:
 - Antiepileptic Drug and Device Trials Conference (AEDD) May 22-24, 2019 in Aventura, FL
 - Phase 1 data from diazepam study
 - American Diabetes Association's 79th Scientific Sessions (ADA) on June 7-11, 2019 in San Francisco
 - Preclinical data of XeriSol™ pramlintide-insulin co-formulation
 - Preclinical data of XeriSol™ formulation of two insulins: regular insulin and Lispro insulin
 - Clinical data summarizing combined safety and efficacy of Xeris' glucagon rescue pen
 - Clinical data using Xeris' RTU glucagon in a dual hormone, closed-loop system
- Xeris' senior management will be participating in the upcoming investor conferences:
 - RBC Capital Markets Global Healthcare Conference on May 21-22, 2019 in New York City
 - Jefferies 2019 Global Healthcare Conference on June 4-7, 2019 in New York City

First Quarter 2019 Financial Highlights

Cash position: As of March 31, 2019, Xeris reported total cash, cash equivalents, and short-term investments (collectively, "cash and investments") of \$147.7 million, compared to \$112.6 million at December 31, 2018. In February 2019, the Company sold an aggregate of 5,996,775 shares of common stock at a price of \$10.00 per share, which included the underwriters' partial exercise of their option to purchase additional common stock. Net proceeds from the offering were approximately \$55.6 million after deducting underwriting discounts and commissions, as well as other public offering expenses.

Research and development (R&D) expenses: R&D expenses for the three months ended March 31, 2019 were \$13.2 million, compared to \$8.7 million for the same period in 2018. The increase was primarily driven by manufacturing costs related to Gvoke HypoPen and Gvoke PFS prior to FDA approval and increased personnel expenses.

Selling, general and administrative (SG&A) expenses: SG&A expenses for the three months ended March 31, 2019 were \$12.5 million, compared to \$3.2 million for the same period in 2018. The increase was driven by increased marketing and selling expenses and increased personnel expenses due to additional headcount to support commercialization efforts of the Gvoke HypoPen and Gvoke PFS.

Net loss: For the three months ended March 31, 2019, Xeris reported a net loss of \$25.3 million, or \$1.07 per share, compared to a net loss of \$11.9 million, or \$5.49 per share, for the same period in 2018.

About Xeris Pharmaceuticals, Inc.

Xeris is a specialty pharmaceutical company leveraging its novel formulation 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 its 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 Annual Report on Form 10-K 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.

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XERIS PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data; unaudited)

	Three Months Ended March 31,	
	2019	2018
Grant income	\$ 215	\$ 210
Service revenue	33	53
Cost of revenue	-	42
Gross profit	248	221
Operating expenses:		
Research and development	13,167	8,712
Selling, general and administrative	12,518	3,239
Expense from operations	25,685	11,951
Loss from operations	(25,437)	(11,730)

Other income (expense):		
Interest income	671	96
Interest expense	(1,063)	(191)
Change in fair market value of warrants	552	(82)
Total other income (expense)	160	(177)
Net loss	<u>\$ (25,277)</u>	<u>\$ (11,907)</u>
Net loss per common share - basic and diluted	<u>\$ (1.07)</u>	<u>\$ (5.49)</u>
Weighted average common shares outstanding, basic and diluted	<u>23,561,193</u>	<u>2,169,576</u>

XERIS PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
(in thousands)

	<u>March 31, 2019</u> (unaudited)	<u>December 31, 2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 61,984	\$ 45,716
Short-term investments	85,687	66,917
Accounts receivable, net	3,628	2,869
Prepaid expenses and other current assets	2,146	2,397
Total current assets	<u>153,445</u>	<u>117,899</u>
Property and equipment, net	7,430	2,034
Other assets	95	95
Total assets	<u>\$ 160,970</u>	<u>\$ 120,028</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,408	\$ 866
Accrued expenses	11,482	8,214
Warrant liabilities	295	860
Deferred grant awards	221	232
Total current liabilities	<u>13,406</u>	<u>10,172</u>
Long-term debt, net of unamortized deferred costs	32,141	31,890
Other long-term liabilities	8,323	2,560
Total liabilities	<u>53,870</u>	<u>44,622</u>
Total stockholders' equity	<u>107,100</u>	<u>75,406</u>
Total liabilities and stockholders' equity	<u>\$ 160,970</u>	<u>\$ 120,028</u>



Source: Xeris Pharmaceuticals, Inc.