



Xeris Pharmaceuticals Announces Fourth Quarter and Full Year 2018 Financial Results and Highlights Pipeline Progress

March 6, 2019

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

Advancing pipeline of preclinical and clinical development-stage products

Cash position of \$112.6 million at year-end 2018; February 2019 public offering raised additional \$55.6 million to support commercial launch of Gvoke HypoPen and advance the pipeline

CHICAGO, March 06, 2019 (GLOBE NEWSWIRE) -- 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, today announced financial results for the fourth quarter and full year 2018, as well as pipeline and corporate highlights.

"2018 was an important year for Xeris in which we completed a successful IPO, submitted an NDA to the FDA for our lead product candidate, Gvoke HypoPen, for the treatment of severe hypoglycemia, advanced the development of ready-to-use liquid stable glucagon in several additional indications and progressed other drug candidates through preclinical and clinical development," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "During 2019, we look forward to delivering on our important milestones, including potential FDA approval of our Gvoke HypoPen, as well as the build-out of our organization to support our development pipeline and the eventual commercialization of those products once approved. To that end, proceeds from our February 2019 public equity offering significantly strengthened our financial position and allow us to focus all of our efforts on execution."

Full Year 2018 and Recent Business Highlights

- **Strengthened the balance sheet:** In addition to the net proceeds of \$88.9 million from the IPO, Xeris raised an additional \$55.6 million in net proceeds in February 2019 to support the commercial launch of Gvoke HypoPen, continued advancement of the pipeline, and other general corporate purposes.
- **Gvoke HypoPen PDUFA goal June 10, 2019:** As previously announced, the U.S. Food and Drug Administration (FDA) accepted for review the NDA of Xeris' lead product candidate, Gvoke HypoPen, for the treatment of severe hypoglycemia in people with diabetes. The FDA has assigned a PDUFA goal date of June 10, 2019.
- **Strengthened commercial organization and operations:** Xeris has hired key commercial leadership personnel in areas of U.S. Marketing and Sales, Global Commercialization and Business Development to begin market preparation, launch readiness, ex-U.S. commercial plans and partnering.
- **Additional Phase 3 clinical trial data released on Company's ready-to-use glucagon:** In November 2018, the Company presented positive efficacy and usability data at the 18th Annual Diabetes Technology Meeting demonstrating the potential of the Xeris investigational glucagon pen as an alternative to currently marketed rescue systems, which require complex, multi-step preparation and administration processes.
- **Initiated Phase 2 study of ready-to-use glucagon for post-bariatric hypoglycemia (PBH) (NCT03770637):** The Company commenced a randomized, placebo-controlled, double-blind, two-treatment, 2-period, crossover study in-patient phase to be followed by a placebo-controlled, double-blind, parallel two-treatment outpatient phase. Xeris expects top-line data in the first half of 2019 from the in-patient portion of the study. The results from this trial are expected to help enable the evaluation of ready-to-use glucagon in a future Phase 3 clinical trial using a vial/syringe in an outpatient setting. *(PBH can begin to occur one to eight years after gastric bypass surgery. These severe hypoglycemic episodes are characterized by extreme low blood sugar levels that occur two to three hours after a meal. The etiology appears to be excessive insulin secretion in response to the meal.)*
- **EMA grants Orphan Drug Designation for investigational ready-to-use glucagon for the treatment of non-insulinoma pancreatogenous hypoglycaemia syndrome (NIPHS):** NIPHS is a spectrum of metabolic conditions, which includes post-bariatric hypoglycemia (PBH). The EU orphan designation is associated with a 10-year commercial exclusivity for this indication.
- **Completed Phase 2 clinical trial in congenital hyperinsulinism (CHI) (NCT02937558):** In this Phase 2 trial, continuous subcutaneous glucagon infusion (CSI Glucagon) within the tested dose range was observed to directly reduce glucose infusion rates to a large and clinically meaningful extent when used as a sole therapy. Xeris expects results from this trial to support its efforts to evaluate CSI Glucagon in the context of a Phase 3 outpatient study, which the Company anticipates initiating in the first half of 2019. *(CHI is a very rare disease that causes severe, persistent hypoglycemia in newborn babies and children. Common symptoms include irritability, sleepiness, lethargy, excessive hunger, and rapid heart rate. More severe symptoms such as seizures and coma can occur with a prolonged or extremely low blood sugar level.)*
- **Xeris room-temperature liquid stable glucagon used in dual-hormone closed-loop system:** In August 2018, Xeris

announced that OHSU School of Medicine and OHSU Harold Schnitzer Diabetes Health Center in Portland, Oregon are conducting a clinical trial with a dual-hormone artificial pancreas using Xeris' ready-to-use liquid glucagon to evaluate a new closed-loop algorithm before and after exercise. OHSU is expected to report top-line results from this trial in the first half of 2019. Based on these results, the Company expects to move forward with a clinical program for a bi-hormonal artificial pancreas closed-loop system. *(The artificial pancreas is a technology in development to help people with diabetes automatically control their blood glucose level by providing the substitute endocrine functionality of a healthy pancreas.)*

■ **Xeris featured as one of the top diabetes companies for 2018 by *MedTech Outlook* magazine**

Upcoming Events

- Xeris' senior management will be participating in the following upcoming investor conferences:
 - Needham & Co. Annual Healthcare Conference on April 9-10, 2019 in New York City
 - 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

Fourth Quarter and Full Year 2018 Financial Highlights

Cash position: As of December 31, 2018, Xeris reported total cash, cash equivalents, and short-term investments (collectively, "cash and investments") of \$112.6 million, compared to \$42.0 million at December 31, 2017. The Company's cash and investments at December 31, 2018 included \$88.9 million in net proceeds from the Company's IPO completed in June 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, commissions and offering expenses.

Research and development (R&D) expenses: R&D expenses for the fourth quarter and full year 2018 were \$12.4 million and \$40.7 million, respectively, compared to \$6.6 million and \$20.2 million for the same periods in 2017. The increases for both the three-month and twelve-month periods were primarily due to increased product development expenses in support of the Gvoke HypoPen NDA filing and additional pipeline programs, as well as increased personnel expenses. Additionally, the increase for the twelve-month period was due to increased expenses associated with clinical programs and trials.

Selling, general and administrative (SG&A) expenses: SG&A expenses for the fourth quarter and full year 2018 were \$8.7 million and \$21.1 million, respectively, compared to \$3.1 million and \$8.0 million for the same periods in 2017. The increases were due to additional headcount and other employee-related costs, as well as increased marketing and market research expenses.

Net loss: For the fourth quarter and full year 2018, Xeris reported a net loss of \$20.4 million, or \$0.98 per share, and \$60.1 million, or \$4.99 per share, respectively, compared to a net loss of \$9.1 million, or \$4.47 per share, and \$26.6 million, or \$13.09 per share, for the same periods in 2017.

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 Gvoke HypoPen™, 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.

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(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Grant income	\$ 754	\$ 467	\$ 2,365	\$ 1,540
Service revenue	47	-	100	16
Cost of revenue	-	-	42	4
Gross profit	801	467	2,423	1,552
Operating expenses:				
Research and development	12,390	6,578	40,654	20,166
Selling, general and administrative	8,725	3,098	21,113	8,015
Expense from operations	21,115	9,676	61,767	28,181
Loss from operations	(20,314)	(9,209)	(59,344)	(26,629)
Other income (expense):				
Interest income	817	79	1,613	124
Interest expense	(1,055)	(1)	(2,545)	(2)
Change in fair value of warrants	133	(14)	196	(46)
Other expense	-	(1)	-	(1)
Total other income (expense)	(105)	63	(736)	75
Net loss	\$ (20,419)	\$ (9,146)	\$ (60,080)	\$ (26,554)
Net loss per common share - basic and diluted	\$ (0.98)	\$ (4.47)	\$ (4.99)	\$ (13.09)
Weighted average common shares outstanding, basic and diluted	20,774,604	2,048,187	12,045,999	2,028,224

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 45,716	\$ 42,045
Short-term investments	66,917	-
Accounts receivable, net	2,869	1,199
Prepaid expenses and other current assets	2,397	809
Total current assets	117,899	44,053
Property and equipment, net	2,034	788
Other assets	95	157
Total assets	\$ 120,028	\$ 44,998

Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)

Current liabilities:

Accounts payable	\$	866	\$	1,976
Accrued expenses		8,214		2,557
Warrant liabilities		860		93
Deferred grant awards		232		234
Total current liabilities		10,172		4,860
Long-term debt, net of unamortized deferred costs		31,890		-
Other long-term liabilities		2,560		90
Total liabilities		44,622		4,950
Total convertible preferred stock		-		97,878
Total stockholders' equity (deficit)		75,406		(57,830)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$	120,028	\$	44,998



Source: Xeris Pharmaceuticals, Inc.